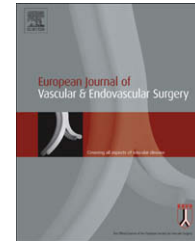




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# Long-term Outcomes after Angioplasty of Isolated, Below-the-knee Arteries in Diabetic Patients with Critical Limb Ischaemia

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## KEYWORDS

Below-the-knee arteries;  
Diabetic foot;  
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**Abstract** *Background:* It has been shown that concomitant percutaneous transluminal angioplasty (PTA) of above-the-knee (ATK) and below-the-knee (BTK) arteries is highly beneficial for limb salvage in patients with critical limb ischaemia (CLI), but few published studies have specifically investigated outcomes in diabetic patients with CLI associated with isolated small BTK-vessel disease. This study aimed to evaluate the long-term results of successful PTA for limb salvage in such patients.

*Materials and methods:* From among the 634 patients with CLI in our database, we retrospectively selected a consecutive series of 101 diabetics (16%) with 107 critically ischaemic limbs (33 Rutherford 5 and 74 Rutherford 6) and no critical ATK lesion, who underwent PTA on isolated BTK lesions.

*Results:* The limb salvage rate was 93% after a mean follow-up of  $1048 \pm 525$  days ( $2.9 \pm 1.4$  years). Transcutaneous oxygen tension significantly increased after 1 month ( $18.1 \pm 11.2$  vs.  $39.6 \pm 15.1$ ;  $p < 0.05$ ). After 1 year, target-vessel re-stenosis had occurred in 42% of the non-amputated limbs, nine patients (9%) had died because of medical conditions unrelated to PTA and three patients had undergone repeat PTA for recurrent CLI.

*Conclusions:* In our selected patient population with ischaemic diabetic foot and isolated BTK lesions, a successful endovascular procedure led to a high percentage of limb salvage at long-term follow-up.

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Peripheral percutaneous transluminal angioplasty (PTA) is a feasible method of treating critical limb ischaemia (CLI) whose outcomes are similar to those of bypass surgery.<sup>1,2</sup> However, studies of PTA in CLI have involved very

heterogeneous patient populations, and this limits our knowledge of the value of PTA in particular patient subsets. Many of the published studies included diabetic and non-diabetic patients, different stages of ischaemia (claudication, resting pain or tissue lesions) and PTA of above-the-knee (ATK) and below-the-knee (BTK) vessels performed in the same setting.<sup>3–9</sup> Furthermore, in many studies of BTK PTA, the most frequently treated vessels were the distal popliteal artery and the tibioperoneal trunk, whose diameters are more similar to those of ATK arteries than those of the smaller BTK arteries.<sup>5–10</sup>

It is well known that atherosclerotic involvement in diabetic patients with CLI mainly affects BTK arteries (leg and foot vessels),<sup>11</sup> but the therapeutic efficacy of PTA in such patients has not been clearly defined, especially given the high incidence of re-stenosis.<sup>12</sup> This study aimed to evaluate the long-term clinical outcomes and re-stenosis rate of PTA procedures performed for the purpose of limb salvage.

## Methods

### Study design

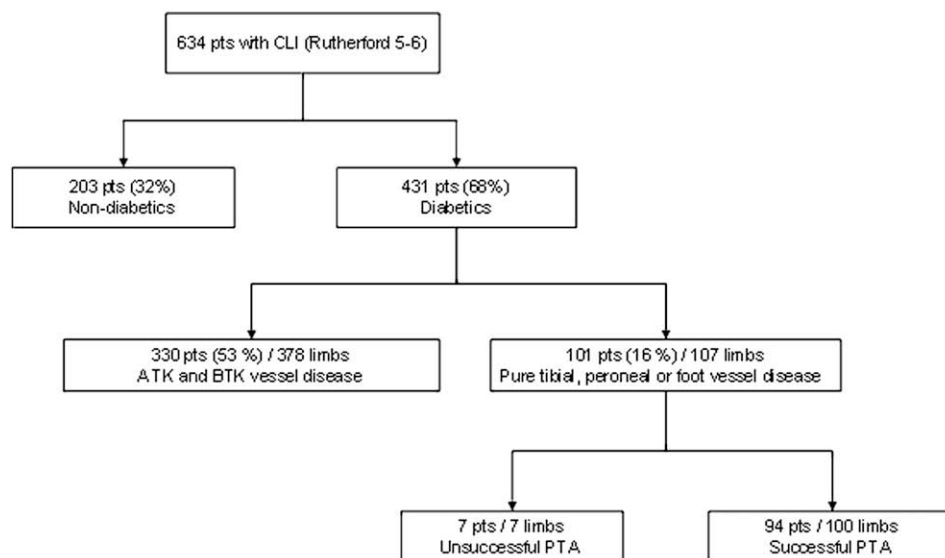
In the year 2000, we initiated a prospectively maintained database in which to record the clinical data of all of the patients treated in our catheterisation laboratory. We have now retrospectively reviewed this database in order to identify the patients with CLI (as defined by TASC II criteria) treated with PTA between March 2000 and December 2005 who satisfied the following parameters: (1) a history of diabetes mellitus diagnosed on the basis of the American Diabetes Association criteria<sup>13</sup>; (2) an ischaemic foot lesion (Fontaine stage 4; Rutherford category 5 and 6); (3) the absence of any critical lesion (>70% diameter stenosis or occlusion in the ATK arteries, the distal popliteal artery and the tibioperoneal trunk and (4) the presence of critical

small-BTK artery lesions, defined as >70% stenosis or occlusion involving either three leg vessels (anterior tibial, posterior tibial and peroneal arteries), with or without foot-vessel involvement (pedal or plantar arteries), or one or two leg vessels and at least one foot vessel (Figs. 1 and 2).

### Treatment protocol

All of the patients were treated in a specialised diabetic-foot clinic and underwent a three-step treatment protocol:

1. *Pre-PTA*: Surgical treatment to remove necrotic tissue and drain the abscess and phlegmon; broad-spectrum antibiotic therapy (piperacillin + tazobactam and metronidazole) until a more specific indication emerged from the microbiological specimens; glycaemic control; and double antiplatelet therapy with aspirin (100 mg per day) and clopidogrel (a 300-mg loading dose followed by 75 mg per day). A nephro-protection protocol was used in all patients with creatinine levels of  $>1.1 \text{ mg dl}^{-1}$ : a  $1.0 \text{ ml kg}^{-1} \text{ h}^{-1}$  saline infusion ( $0.5 \text{ ml kg}^{-1} \text{ h}^{-1}$  in patients with a history of heart failure) 12 h before and 24 h after the procedure and oral *N*-acetyl-cysteine 1200 mg twice daily on the day before and the day of the procedure.
2. *Angiography and PTA*: The procedures were performed under local anaesthesia by two operators at the same time. An antegrade puncture of the ipsilateral, common femoral artery was systematically used, even in obese patients, as was a 4/F introducer sheath. Optimal imaging of the vessel tree was obtained by using the non-ionic contrast medium iodixanol (Visipaque 320, GE Healthcare, USA), digital subtraction angiography, multiple oblique views and a lateral foot projection. A 0.014" wire (PT2, Boston Scientific, USA) was used to cross the lesions. Total occlusions were



**Figure 1** Study design: patient selection. CLI: critical limb ischaemia, ATK: above-the-knee; BTK: below-the-knee; PTA: percutaneous transluminal angioplasty and pts: patients.



**Figure 2** A successful endovascular procedure, defined as the restoration of straight-line flow down to the foot circle in at least one crural artery with no significant residual stenosis (>30%). Outcome: salvaged limb.

preferably re-canalised through the true arterial lumen using dedicated 0.014" coronary wires such as Confianza (Asahi, Japan), but a sub-intimal approach<sup>14</sup> was used in some cases after the failure of the endoluminal approach. Small profile balloons (Bijou, Boston Scientific, USA; Submarine Plus and Amphirion Deep, Invatec, Italy) were inflated to 12–15 atm for 2 min. The balloon dimensions were chosen on the basis of the size of the artery and the length of the lesion. Stenting was only used in the case of a flow-limiting dissection that was not resolved by prolonged (5–10-min) balloon inflations. At the beginning of the PTA procedure, 5 000 IU of heparin were routinely administered intra-arterially, and additional heparin was given, if needed, to maintain an activated clotting time (ACT) of about 250 s. If vessel spasm occurred, 0.1–0.2 mg of nitroglycerine was infused as an intra-arterial bolus. At the end of the procedure, haemostasis was obtained by means of local compression.

3. **Post-PTA treatment:** Elective surgery was performed within 1 week with the aim of reconstructing a stump

suitable for proper walking. All of the patients received double antiplatelet therapy for a minimum of 1 month (aspirin 100 mg and clopidogrel 75 mg per day); the treatment was not interrupted when surgical procedures were undertaken. No patient received prostanoid therapy or underwent lumbar sympathectomy. After discharge, the patients were seen in our out-patient clinic every week for the first month, monthly for the next 5 months and then every 3 months. All of the patients received optimal medical treatment for vascular risk factors.

### Transcutaneous oxygen tension measurements

Transcutaneous partial oxygen tension (TcPO<sub>2</sub>) was measured at baseline (T0), the day after the procedure (T1) and 1 month later (T2). All of the measurements were made at the dorsum of the foot, in the peri-lesional site, using a TCM™ 3 Radiometer (GMBH, Copenhagen, Denmark).

### Colour duplex ultrasound

The patients who had not undergone a major amputation after 1 year were examined by a single operator using colour duplex ultrasonography (US). Peak systolic velocity (PSV) in the target-vessel was determined and compared with that in the preceding normal segment. A focal increase of at least 140% in the PSV (corresponding to a peak velocity ratio of >2.4) was considered indicative of >50% re-stenosis at that site.<sup>15,16</sup>

### End-points and definitions

The procedure was considered successful when it was possible to restore straight-line flow down to the foot circle in at least one crural artery with no significant residual stenosis (>30%).

In the case of isolated PTA of the peroneal artery, a successful procedure was defined as good distal collateralisation to the foot circle.

The primary end-point of the study was the rate of limb salvage at follow-up, defined as an ability to maintain plantar standing even if it required a minor (below-the-ankle) amputation.

The secondary end-points were: (1) the 1-month improvement in TcPO<sub>2</sub> from baseline; (2) the occurrence of all-cause death during the follow-up period; (3) the rate of US re-stenosis of the treated vessels after 1 year and (4) the incidence of new re-vascularisation interventions involving the same limb.

### Statistical analysis

The continuous data are given as mean values ± standard deviation. The TcPO<sub>2</sub> was compared between two groups (T0 vs. T1, T0 vs. T2 and T1 vs. T2) using the Student's *t*-test. A *p*-value of <0.05 was considered statistically significant. The rate of survival and limb salvage for successful and unsuccessful PTA has been estimated by the Kaplan–Meier approach with 95% confidence intervals.

## Results

### Population

Of the 634 patients with CLI in our database, 101 (16%) with 107 critically ischaemic limbs (33 Rutherford 5 and 74 Rutherford 6) met the selection criteria and were included in the study. The mean duration of diabetes mellitus was  $15.3 \pm 4.7$  years, and 55% of the patients were receiving insulin. Mean glycated haemoglobin (HbA1c) was  $7.6\% \pm 1.8\%$ . Fifty-one patients (50%) had arterial hypertension, and 28 (38%) a history of coronary artery disease. Table 1 summarises the patients' characteristics.

### Baseline angiographic patterns

Critical lesions were found in 406 BTK vessels: 103 anterior tibial, 104 posterior tibial, 74 peroneal, 51 pedal and 74 plantar arteries. The distribution of the diseased vessels is shown in Table 2.

### Angioplasty procedure

PTA was considered successful in 94 patients (100 limbs). The angiographic characteristics of the successfully treated vessels are shown in Table 3. The mean length of treated vessel per limb was  $21.3 \pm 15.2$  cm. Only four stents were implanted because of occlusive dissection.

The procedure was unsuccessful in seven patients (seven limbs), in whom all of the three leg vessels were totally occluded: the reasons for the failures were an inability to cross a highly calcified chronic total occlusion and/or an inability to dilate the lesions properly with the balloon. These patients were not suitable for surgical revascularisation.

There were two minor complications (two groin haematomas that did not require any special treatment), and therefore the overall complication rate was 1.9%.

### Primary end-point

The mean follow-up was  $1048 \pm 525$  days ( $2.9 \pm 1.4$  years); none of the patients was lost to follow-up. The major

**Table 2** Baseline angiographic patterns

Diseased vessels in 107 limbs	No.	%
Anterior tibial	103	96
Posterior tibial	104	97
Peroneal	74	69
Pedal artery	51	48
Plantar artery	74	69
0 leg vessel	—	—
1 leg vessel	4	4
2 leg vessels	32	30
3 leg vessels	71	66
0 foot vessel	28	26
1 foot vessel	33	31
2 foot vessels	46	43

amputation rate was 7% (eight out of 107 limbs: two of the thigh and six of the leg); the limb salvage rate was 93% (99 out of 107 limbs). The minor amputation rate was 64% (69 out of 107 limbs: four Lisfranc, 17 Chopart, 16 transmetatarsal, 21 rays and 11 toes). The major amputation rate was significantly lower in the patients who underwent a successful procedure than in those in whom the procedure was unsuccessful (5% vs. 43%;  $p = 0.003$ ). Fig. 3 shows the Kaplan–Meier curves (and 95% confidence bands) of limb salvage for successful and unsuccessful PTA.

### Secondary end-points

Baseline TcPO<sub>2</sub> was  $18.1 \pm 11.2$  mmHg, which increased to  $39.6 \pm 15.1$  mmHg on the day after the procedure ( $p < 0.001$ ) and to  $58.2 \pm 13.9$  mmHg after 1 month ( $p < 0.001$  vs. baseline;  $p < 0.05$  vs. post-procedural values).

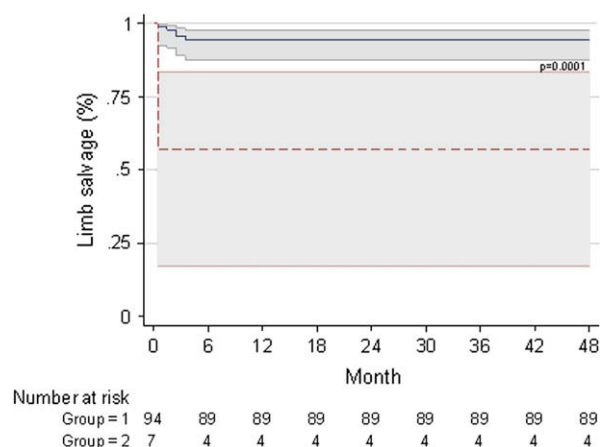
During the follow-up period, nine patients died (9%) because of medical conditions unrelated to PTA: cardiac disease (six), stroke (two) and malignancy (one). Mortality was significantly lower in the successful PTA group (five out of 94 patients, 5%) than in the unsuccessful PTA group (four out of seven patients, 57%) ( $p < 0.001$ ). Fig. 4 shows the

**Table 1** Demographic data of the 101 study patients

Variables		
Age (years)	$65.9 \pm 9.4$	
Females (No.)	16	16%
BMI	$26.65 \pm 4.01$	
Obese patients (BMI > 30)	18	18%
Insulin therapy (No.)	53	53%
Duration of diabetes (years)	$15.3 \pm 4.7$	
HbA1c (%)	$7.6 \pm 1.8$	
Dialysis (No.)	3	3%
Hypertension (No.)	51	50%
Coronary disease (No.)	28	28%
History of stroke (No.)	4	4%

**Table 3** Characteristics of successfully treated vessels

Artery	No. (%)	Stenosis (n)	Mean length $\pm$ SD (mm)	Occlusions (n)	Mean length $\pm$ SD (mm)
Anterior tibial	57 (36)	30	$115 \pm 112$	27	$228 \pm 98$
Posterior tibial	35 (22)	17	$112 \pm 105$	18	$192 \pm 101$
Peroneal	44 (28)	32	$108 \pm 81$	12	$156 \pm 92$
Pedal artery	15 (9.5)	6	$50 \pm 23$	1	50
Plantar artery	7 (4.4)	15	$48 \pm 21$	0	0
Total	158 (100)	100	$98 \pm 91$	58	$199 \pm 101$



**Figure 3** Kaplan–Meier curves (and 95% confidence bands) of limb salvage for successful (group 1, solid line) and unsuccessful (group 2, dashed line) PTA.

Kaplan–Meier survival curves (and 95% confidence bands) for successful and unsuccessful PTA.

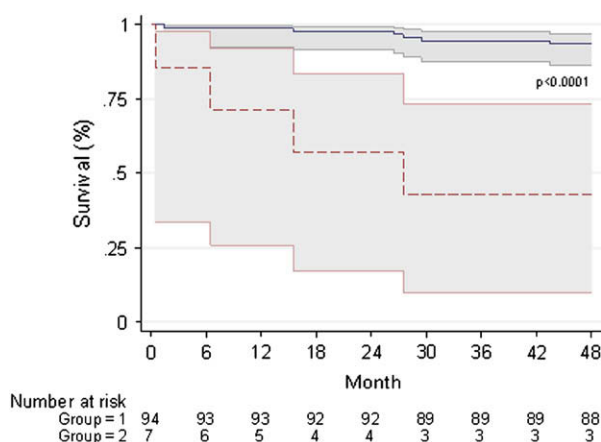
The 1-year target-vessel re-stenosis rate was 42% (66 out of 158 lesions): 35% (35 out of 100) in stenotic lesions and 53% (31 out of 58) in occlusive lesions.

Three patients underwent a second successful PTA procedure because of recurrent CLI in the same limb.

## Discussion

The main finding of our study is that a successful endovascular procedure saves a very high percentage of limbs at follow-up in a highly selected patient population with ischaemic diabetic foot and isolated tibial, peroneal or foot-artery disease; on the other hand, as observed by other authors,<sup>17</sup> the patients in whom re-vascularisation failed had a very poor prognosis.

Bypass surgery using outflow vessels in the distal ankle and foot should be considered the standard of care in patients with CLI due to BTK-vessel disease.<sup>18</sup> However, it



**Figure 4** Kaplan–Meier survival curves (and 95% confidence bands) for successful (group 1, solid line) and unsuccessful (group 2, dashed line) PTA.

needs a good vein conduit and at least one open foot artery and is associated with 0.9% perioperative mortality, 3.0% myocardial infarction or acute congestive heart failure and 6.6% early re-operation for graft thrombosis, postoperative bleeding or infection.<sup>19</sup> For these reasons, femoro-popliteal and infrapopliteal PTA is currently proposed as the primary treatment for CLI in patients with ischaemic diabetic foot<sup>2,3,7–9</sup> but, although many published papers have described interesting findings concerning the efficacy of the endovascular treatment of peripheral artery disease in such patients, there are discrepancies between the short- and long-term results because the studies have not involved carefully selected patient populations or appropriately stratified the vessels on the basis of the degree and localisation of atherosclerosis.

In particular, the use of PTA to treat BTK arteries is criticised because of the small diameter and length of the treated vessel – both of which tend to lead to a high re-stenosis rate; furthermore, it is not clear whether the clinical success of BTK-artery PTA is authentic or simply the result of improved outflow due to concomitant ATK procedures.<sup>20–23</sup>

In order to more precisely evaluate the clinical outcomes of PTA in patients with isolated BTK-vessel involvement, we excluded those with distal popliteal and tibioperoneal trunk disease because the diameters of these vessels are more similar to those of ATK arteries than those of the other smaller BTK arteries. This meant that the studied population consisted of a very homogeneous group of predominantly male patients with widespread small BTK-vessel involvement (66% had three diseased leg vessels and 43% two diseased foot vessels), a lesion length of >10 cm in most cases and an extraordinary length of treated vessel per procedure (up to 20 cm). However, despite the severity of the disease, the successful endovascular procedures led to optimal follow-up outcomes. Although this population only represents a minority of the patients referred for CLI treatment, they are technically challenging, and our results support the role of PTA as *the* therapeutic option for CLI patients with BTK-artery disease.

The limb salvage rate was 93% despite a US re-stenosis rate of 42%. This discrepancy probably reflects the fact that long-term complete patency of the treated vessel is less important in such patients than in those with coronary, carotid or renal arterial disease: the re-canalisation temporarily increases blood flow to the foot and has a positive effect in eradicating infection and healing ulcers and surgical wounds. As foot tissue healing reduces oxygen demand, less blood flow is generally required to maintain tissue integrity and keep the limb asymptomatic.<sup>4,24</sup> This is clearly demonstrated by the fact that only three of our 94 patients who underwent a total of 100 successful PTA procedures experienced recurrent CLI in the same limb during the follow-up period.

The effectiveness of PTA was demonstrated by the increase in TcPO<sub>2</sub> values 1 month after the procedure. This may explain the low rate of major amputations, as reported by Faglia et al.,<sup>25</sup> who looked specifically at the prognostic value of this index.

Finally, the incidence of follow-up mortality was only 8%, definitely lower than the annual 20% death rate for patients with CLI reported in the ‘TASC 2007’ document.<sup>26</sup>

This may have been due to various reasons: (1) our patients were younger, and the proportion with hypertension, coronary artery disease or a history of stroke or haemodialysis was lower than that observed in the patients enrolled in other studies<sup>2-10</sup>; (2) they closely adhered to our programme's very strict clinical follow-up schedule and (3) the exclusively BTK localisation of disease may identify a population with less extensive systemic atherosclerosis than patients with simultaneous ATK and BTK involvement. It is important to note that the majority of follow-up deaths occurred in those patients who had undergone unsuccessful PTA and showed diffuse and heavy calcification of the limb and foot arteries, a marker that has been previously identified as a strong predictor of a poor prognosis.<sup>27-29</sup>

### Study limitations

This is a retrospective case review and no independent angiographic or US core laboratories were involved; this may have led to a potential evaluation bias.

Our high rate of limb salvage at follow-up may have been due to our definition of 'successful' PTA because, as recently reported by Faglia et al.,<sup>25</sup> the restoration of straight-line flow down to the foot in at least one crural artery is of paramount importance for short- and long-term clinical success. Another explanation may be the combination of PTA and a good surgical approach to foot lesions (before and after the procedure), together with a strict clinical follow-up.

Follow-up re-stenosis in the surviving limbs was only ascertained by US. It is well known that angiography is the gold standard for evaluating infrapopliteal arteries, but US can be used to assess infrapopliteal artery patency if appropriate criteria are adopted.<sup>3,30,31</sup>

### Conclusions

In our study, pure isolated BTK-vessel disease seemed to identify a patient population characterised by a younger age and lower incidence of co-morbidities than those observed in patients with concomitant ATK- and BTK-vessel disease. In this selected population, successful angioplasty led to a very high rate of limb salvage and good long-term prognosis; although it must be borne in mind that complete patency of the treated vessel at follow-up seems to be less important than in other clinical situations. Further studies are needed to confirm the results of this study.

### Disclosures

None.

### Conflict of Interest/Funding

None.

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