

Infrapopliteal Percutaneous Transluminal Angioplasty: A Safe and Successful Procedure

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Aim: To review outcome of 40 consecutive infrapopliteal percutaneous transluminal angioplasty (PTA) procedures performed over a 65 month period.

Chief outcome measures: The indication for PTA was intermittent claudication in 20 (50%) cases and rest pain, ulceration or gangrene in the remainder.

Results: There was one technical failure; the remaining 39 limbs were all clinically improved by 24 h and this improvement was maintained at 3 months in 36 (90%). There were no deaths nor limb loss related to PTA and 2 embolic complications were successfully treated percutaneously. The primary and secondary symptomatic patencies at 24 months were 59 and 79% respectively. The actuarial limb salvage rate at 1 year for the 20 limbs presenting with critical ischaemia was 77%, and 10 of the 14 procedures performed for ulceration or gangrene resulted in healing with only minor surgical intervention.

Conclusions: With modern endovascular techniques, infrapopliteal PTA is a safe, worthwhile and durable procedure.

Key Words: Angioplasty; Infrapopliteal; Crural; Stenosis; Occlusion.

Introduction

Although percutaneous transluminal angioplasty (PTA) of the iliac, femoral and popliteal arteries is a well established therapeutic option in peripheral vascular disease,¹ experience with infrapopliteal PTA has been more limited and its role remains less well defined. This is because multiple lesions are a common finding in the infrapopliteal vessels and there has been the concern that failed PTA at this level could jeopardise subsequent bypass surgery.^{2,3}

Dotter and Judkins⁴ were the first to report dilatation of tibial artery stenoses with a series of concentric tapered catheters that were passed over each other. However, forward shearing forces caused vessel wall dissection and resulted in a high incidence of embolisation and reocclusion. Further experience of infrapopliteal PTA using tapered catheters led to a lower incidence of complications, but a poor long-term patency.⁵⁻⁷ The advent of coronary artery PTA triggered a number of technological advances that facilitated infrapopliteal angioplasty. These advances

included small strong low profile balloons, steerable hydrophilic guidewires, road mapping facilities and the use of vasodilators to overcome arterial spasm. Although a number of reports using these new techniques have appeared since 1988,^{2,3,8-14} only a few¹⁵⁻¹⁷ have provided data on long-term actuarial patency rates. The purpose of this study therefore was to review our experience of infrapopliteal PTA and document the intermediate-term cumulative patency.

Patients and Methods

Patients and PTA technique

All infrapopliteal PTA procedures performed by a single vascular radiologist (A.B.) during a 65-month period (November 1986 to April 1992) were reviewed. Details of the techniques used have previously been described.¹⁸ After diagnostic arteriography, the ipsilateral common femoral artery was cannulated antegradely and a size 5F (Van Andel type, Cook Ltd, Letchworth, U.K.) predilating catheter introduced. Prior to crossing an infrapopliteal lesion heparin (5000 Units) and 12.5 mg of tolazoline were injected into the

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artery. The lesions were crossed using steerable hydrophilic angled guide wires ranging in diameter from 0.05 to 0.09 cm (Terumo, Tokyo, Japan, or Schneider, Zurich, Switzerland). Having crossed the lesion, the Van Andel catheter was removed and replaced with a balloon angioplasty catheter (Schneider) that ranged in diameter 2 to 4 mm. Dilatation was achieved by inflation at 10 atmospheres for 15 s and if there was a residual stenosis of > 30%, then the dilatation was repeated. If spasm developed, 100 µg boluses of nitroglycerine were administered intraarterially. All patients were commenced on aspirin (150 mg) the morning of angioplasty and this was continued for a minimum of 3 months after successful recanalisation. Neither intravenous nor oral anti-coagulation were used after PTA.

In patients with critical ischaemia and a single calf vessel that was stenosed or occluded then PTA was attempted. However, in claudicants with a single calf vessel PTA was not attempted in case a complication converted a claudicant to a critical ischaemic.

Definitions of outcome and data analysis

Success, failure, complications and long-term patency were analysed according to the guidelines provided by the Society of Vascular Surgery and the International Society for Cardiovascular Surgery.¹⁹⁻²¹ Technical success was defined as recanalisation with 30% or less residual stenosis and antegrade flow at the conclusion of the procedure. Major complications were defined as those that altered the patient's clinical state, whereas minor complications did not. Patients were examined after the procedure at 24 h, 1, 3, 6, 9, 12 months and thereafter at 6-monthly intervals. Haemodynamic patency required that the ankle brachial pressure index (ABPI), measured in the angioplastied artery, rose by > 0.10 within 24 h and did not fall more than 0.15 from the post-procedure level or that the angioplastied segment was patent on repeat arteriography. Symptomatic patency required that claudication distance improved by at least 50%, the resolution of rest pain or healing of ulcers and minor amputations. Primary patency required that the affected limb had been treated at a single angioplasty session, secondary patency permitted further angioplasty procedures on the affected limb.

Patency was computed (Systat Survival package; Systat, London, U.K.) using the Kaplan-Meier method of life table analysis²² and compared with the Mantel-Haenzel log-rank test,²³ *p* rates of 0.05 or less were considered significant (confidence intervals are not

produced by the log rank test I have used). Standard error calculations were performed using the Greenwood formula.²⁴ Patency calculations were based on the number of procedures performed, not the number of patients. Patients who died were censored at their last follow-up visit, no patients were lost to follow-up during the study. The minimum follow up was 3 months, the maximum 60 months.

Results

Patient and procedure details

Thirty-eight patients underwent 40 infrapopliteal PTA procedures during the study period. The median (range) age was 74 (44-87) years, 30 patients were male. Risk factors for atherosclerosis included: smoking 11 (29%); diabetes 17 (45%); and hypertension 15 (40%). Associated symptomatic coronary artery disease was present in 15 (39%) patients and cerebrovascular disease in nine (24%) patients. The indication for PTA was intermittent claudication in 20 (50%), rest pain alone six (15%), ulceration four (10%), and gangrene 10 (25%). The median (range) ABPI at presentation was 0.55 (0.26-0.84).

Thirty-three (83%) of the 40 infrapopliteal procedures were for stenoses (Fig. 1) and seven (17%) were for occlusions (Fig. 2). The median (range) lesion length was 10 mm (2-80). Twenty-one procedures (52%) were to infrapopliteal vessels alone, 16 (40%) included one other arterial segment (one common femoral artery, 13 superficial femoral arteries and two



Fig. 1. Stenosis of the right proximal anterior tibial artery before (A) and after (B) successful PTA.



Fig. 2. Two centimetre occlusion of the left distal peroneal artery before (A) and after (B) successful PTA.

popliteal arteries), and three (8%) included two other arterial segments (one external iliac + superficial femoral artery and two superficial femoral + popliteal arteries). Seventeen (42%) procedures were to the anterior tibial artery alone, eight (20%) to the tibioperoneal trunk, seven (18%) to the peroneal artery, four (10%) to the posterior tibial artery, and four (10%) to multiple infrapopliteal vessels. In six cases, PTA was performed on the run-off artery distal to a patent bypass graft which was identified as failing on graft surveillance.

Technical success rate and complications

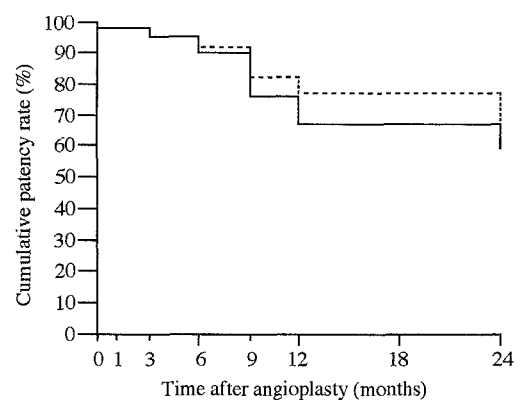
Technical success was achieved in 39/40 (98%) procedures. The one technical failure occurred in an anterior tibial artery with multiple stenoses and no other patent calf vessels. This patient presented with rest pain and ulceration and subsequently required a below-knee amputation. The 30-day mortality was zero and there were no limbs lost as a consequence of PTA. There were two major complications (5%), both

were distal embolisation. In each case the emboli were successfully retrieved by percutaneous aspiration and there were no adverse sequelae.

Outcome and patency

The median (range) post procedure ABPI was 0.84 (0.42–1.00), representing a median (range) increase of 0.26 (0.00–0.59). Thirty-eight (98%) limbs had improved clinically by 24 h and this improvement was maintained at 3 months in 36 (90%). Ten of the 14 procedures performed for ulceration or gangrene resulted in healing with only minor surgical intervention. The primary actuarial symptomatic and haemodynamic patencies for all procedures, including the technical failure, are shown in Fig. 3. Primary symptomatic patency at 2 years was 59% and the haemodynamic patency was 68%. There was not a significant difference in haemodynamic patency at 1 year between limbs that had undergone infrapopliteal angioplasty alone (63%, no. at risk = 6, S.E.M. = 11%) and those with angioplasty of additional arterial segments (75%, no. at risk = 10, S.E.M. = 9%), ($p = 0.39$, log rank test). The 1-year cumulative limb salvage rate in the 20 patients with rest pain, ulceration or gangrene was 77% (no. of limbs at risk at 1 year = 10, S.E.M. = 9.8%).

There were 12 symptomatic failures after the 39 technically successful procedures. Five of these failures occurred in claudicants, three of whom underwent further successful PTA, one had a vein graft and



No. at risk

Symptomatic	40	39	37	33	22	14	10	7
Haemodynamic	40	39	37	33	23	16	12	8

Fig. 3. Cumulative symptomatic (—) and haemodynamic (-----) patency rates after infrapopliteal PTA. The S.E.M. is < 10% at all time points for the two curves and the analysis includes the immediate technical failures.

one had no further procedure. Four of the symptomatic failures in the seven patients with rest pain, ulceration or gangrene were treated by further successful PTA, one limb required an above-knee amputation and the remaining two patients who presented with rest pain alone, were treated with analgesics. In total therefore, seven of the 12 symptomatic failures were treated by repeat angioplasty and this resulted in a 2-year secondary symptomatic patency of 79% (number of limbs at risk at 2 years = 10, S.E.M. = 10%).

Discussion

The high technical success rate and low incidence of complications in this study confirms the findings of previous reports of infrapopliteal PTA. The major complication rate calculated from the available literature^{2,3,7-17} in which a total of 781 procedures have been reported is 66 (8%). Urgent surgery was needed in only 15 (2%) cases and over half of these were for groin haematomas. There has been only one death and one limb loss reported that have resulted directly from infrapopliteal PTA. These data clearly demonstrate that lesions in the crural vessels can be reached, crossed and dilated successfully and safely with modern endovascular technology. Furthermore, there is little evidence in these figures to support the concern that these procedures may prejudice subsequent bypass surgery. In fact, in our series, infrapopliteal PTA was used in six cases to improve the outcome of bypass surgery when applied to the runoff of "at risk" grafts.

In the present study, 48% of infrapopliteal procedures also involved PTA of a proximal arterial segment. This is a common event^{8,11,12,15,16} and indeed in one series,¹⁷ 88% of infrapopliteal procedures were accompanied by a proximal PTA. Although the presence of a proximal PTA makes the separate effect of tibial PTA hard to analyse we have tried to overcome this by measuring the ABPI using the angioplastied tibial vessel. The advent of colour-coded Duplex should allow a more accurate, non-invasive assessment of tibial artery patency in future studies.

The low morbidity and mortality of infrapopliteal PTA makes it an ideal first line therapy for patients with critical ischaemia and a suitable lesion. The haemodynamic patency rate of 68% at 2 years in this study and of 65% at 3 years in the series reported by Horvath *et al.*¹⁵ demonstrate that the results are durable. Although it is not possible to make direct comparisons, these patency rates compare favourably

with those in a recent randomised multi-centre study of femorocrural vein bypass grafts which reported a secondary patency rate at 3 years of 68% for *in situ* grafts and 66% for reversed grafts.²⁵ The limb salvage rates; 77% at 2 years PTA, 78% *in situ* grafts at 3 years and 87% reversed grafts at 3 years are also comparable. However the distal bypass procedures were associated with an in-hospital mortality rate of 6%²⁶ compared with 0.1% for PTA.

Although the use of infrapopliteal PTA in patients with claudication is controversial, a number of authors have recommended this approach.^{12,15,16} We feel that the low morbidity reported in this series supports this policy. All of our claudicants are initially managed conservatively, being encouraged to exercise and stop smoking.²⁷ Only patients who deteriorate or remain significantly troubled by their claudication are referred for angiography. All of the patients in this study experienced claudication at less than 100 yards. The PTA procedure is usually performed at the same time as this diagnostic angiogram and the entire procedure rarely takes more than 60 min. This reduces the additional risk of repeat procedures for these patients whilst providing effective treatment of their symptoms.

Because of the relatively small numbers of patients in this and other studies of infrapopliteal PTA it is not possible to determine the influence of factors such as diabetes, multiple lesions and lesion length on outcome. Thus although the technical feasibility, safety and results of infrapopliteal PTA are becoming increasingly apparent there is now a need to investigate the factors influencing long-term patency so that rational decisions concerning patient selection can be made.

In conclusion, we have found infrapopliteal PTA to be a safe procedure with only two embolic complications in this series, both of which were aspirated percutaneously. The symptomatic patency rate of 59% at 2 years and limb salvage of 77% compare favourably with the results of bypass surgery and confirm the durability of this procedure.

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