Infrainguinal Percutaneous Transluminal Angioplasty in Limbs with Severe Lower Limb Ischaemia

BY

ANNE-MARIE LÖFBERG
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ABSTRACT


Infrainguinal bypass grafting is an established method in the treatment of patients with femoropopliteal and crural occlusive disease leading to critical lower limb ischaemia (CLI). However, complications related to surgical procedure are not negligible and percutaneous transluminal angioplasty (PTA) has emerged as an alternative. The present thesis covers some aspects of infrainguinal PTA in patients with chronic severe lower limb ischaemia.

The records of 217 patients undergoing 272 PTA procedures at various infrainguinal arterial segments were analysed. The indication for intervention was subcritical ischaemia in 76 limbs and critical ischaemia in 177 limbs. The role of duplex ultrasound examination in the selection of patients for PTA was retrospectively evaluated following a prospective validation of the method against angiography.

A technically successful PTA was achieved in 89%. The overall 30-day mortality was 2.7%. No patient underwent amputation directly related to failed PTA. The primary success rates at 12 and 60 months following femoropopliteal PTA were 40% and 27% compared, to 51% and 36% in limbs undergoing crural artery PTA. Primary success rate in limbs with SFA occlusion longer than 5 cm was only 12% after 5 years, compared to 32% if the occlusion was equal or less than 5 cm in length (p<0.01). In patients undergoing distal PTA through patent infrainguinal grafts, the primary and primary assisted patency rates at 3 years were 32% and 53%, respectively. The sensitivity of duplex scanning in the selection of lesions for PTA was less satisfactory in the popliteal and crural arteries compared to the superficial femoral arteries.

In conclusion, the results of infrainguinal PTA performed for treatment of subcritical or CLI seemed to be inferior to the results of surgical interventions reported in the literature. However, due to the fact that the PTA procedure does not preclude the performance of bypass grafting, it might be an alternative to surgical intervention in limbs with stenotic or short occlusive lesions.

Key words: infrainguinal, chronic ischaemia, percutaneous transluminal angioplasty, duplex, bypass grafts.

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ORIGINAL PAPERS

This thesis is based on the following papers, which are referred to in this text by the Roman numerals given below (I–V).


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CONTENTS

ABBREVIATIONS 6
INTRODUCTION 7
AIMS OF THE THESIS 9
MATERIAL AND METHODS 10
Data collection 10
Inclusion and exclusion criteria 10
Patient characteristics 12
Definitions of lower limb ischaemia 13
Guidelines for selection of treatment modalities 13
Duplex scanning 14
PTA Technique 15
Level of PTA 16
Follow-up 19
Analysis of data 20
Statistic analysis 20
RESULTS 21
Technical success 21
Early complications (within 30 days) 22
Results of femoropopliteal PTA 23
Results of crural artery PTA 27
Results of infrapopliteal PTA through infrainguinal grafts 28
Accuracy of infrapopliteal arterial duplex scanning 30
Selection of patients for infrainguinal PTA 31
DISCUSSION 33
Femoropopliteal PTA 33
Crural artery PTA 35
Infrapopliteal PTA through infrainguinal grafts 37
Accuracy of infrapopliteal duplex scanning 38
Selection of patients for infrainguinal PTA 39
CONCLUSIONS 41
ACKNOWLEDGEMENTS 42
REFERENCES 44
## ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABPI</td>
<td>Ankle brachial pressure index</td>
</tr>
<tr>
<td>CAD</td>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>CLI</td>
<td>Critical limb ischaemia</td>
</tr>
<tr>
<td>CTA</td>
<td>Computed tomography angiography</td>
</tr>
<tr>
<td>CVD</td>
<td>Cerebrovascular disease</td>
</tr>
<tr>
<td>DA</td>
<td>Distal anastomoses</td>
</tr>
<tr>
<td>HT</td>
<td>Hypertension</td>
</tr>
<tr>
<td>MRA</td>
<td>Magnetic resonance angiography</td>
</tr>
<tr>
<td>NA</td>
<td>None available</td>
</tr>
<tr>
<td>NPV</td>
<td>Negative predictive value</td>
</tr>
<tr>
<td>NS</td>
<td>Not significant</td>
</tr>
<tr>
<td>PPV</td>
<td>Positive predictive value</td>
</tr>
<tr>
<td>PSV</td>
<td>Peak systolic velocity</td>
</tr>
<tr>
<td>PTA</td>
<td>Percutaneous transluminal angioplasty</td>
</tr>
<tr>
<td>PTFE</td>
<td>Polytetrafluoroethylene</td>
</tr>
<tr>
<td>SFA</td>
<td>Superficial femoral artery</td>
</tr>
<tr>
<td>sub-CLI</td>
<td>Subcritical limb ischaemia</td>
</tr>
<tr>
<td>SVS</td>
<td>Society for Vascular Surgery</td>
</tr>
<tr>
<td>ISCVS</td>
<td>International Society for Cardiovascular Surgery</td>
</tr>
<tr>
<td>TASC</td>
<td>Trans Atlantic Inter-society Consensus</td>
</tr>
<tr>
<td>TP</td>
<td>Tibioperoneal</td>
</tr>
</tbody>
</table>
INTRODUCTION
The incidence of atherosclerotic disease affecting the lower leg arteries, determined by objective testing, ranges from 2.2% of a population aged 38 to 82 years to 17% of a population aged 55 to 74 years (Crigui 85, Fowkes 91). Chronic occlusive arterial disease in the femoropopliteal segment is three to five times more frequent than iliac disease. Occlusive lesions are more common than stenosis in the femoropopliteal arteries (Martin 92).

Most of the patients with lower limb occlusive disease are asymptomatic. Clinical symptoms range from mild claudication to critical lower limb ischaemia (CLI). In most instances, an accurate history, physical examination and ankle pressure measurements by a hand-held Doppler instrument establish the diagnosis in patients with lower limb ischaemia. In limbs where there is clinical indication for surgical or endovascular intervention duplex scanning is the most common first choice of objective diagnostic modality. Duplex scanning which combines B-mode ultrasound imaging with pulsed-Doppler frequency spectral analysis allows direct visualisation of the arteries, together with measurement of the arterial flow velocities. The recent development of colour-flow imaging has facilitated the identification of the vascular anatomy and the localisation of the lesions. Measurement of the specific components of the flow-velocity waveforms by spectral Doppler analysis, such as peak systolic velocity (PSV), indicates the severity of atherosclerotic lesions (Legemate 91, Karacagil 94, 96).

Duplex scanning has been widely used for the selection of treatment modality in patients with lower limb arterial insufficiency (Jager 85, Edwards 91, Elsman 96, Levi 98, van der Zaag 98, Sarkar 98, Schneider 99, Ascher 99). It is also commonly used for surveillance after surgical or endovascular intervention (Moody 89, Lundell 95, Bergamini 95, Dougherty 98, Quinn 98). Magnetic resonance angiography (MRA), as another non-invasive modality, has been proved to have an even greater sensitivity than conventional angiography for detecting distal runoff vessels. It is not as operator dependent as duplex scanning and is less time consuming. (Levy 98, Cambria 97, Carpenter 92, Owen 92). Computed tomography angiography (CTA) for depicting infrainguinal vessels is still controversial and the amount of contrast agent needed still high (Kramer 98, Lawrence 95, Hayashi 99, Sugahara 98). During recent years more and more patients have been selected for endovascular or surgical interventions from the findings obtained solely
from duplex scanning or MRA (Carpenter 94, Elsman 95, 96, Schmiedl 96, Huber 97).

Despite recent advances in noninvasive methods for imaging the lower leg arteries, such as duplex scanning and MRA with or without contrast agents, conventional contrast angiography remains the ‘gold standard’ by which all other investigations are judged. In cases where noninvasive diagnosis reveals nondiagnostic findings or if the clinical findings are not in accordance with the noninvasive results, there is still a definite need for diagnostic angiography in planning interventions.

The documentation of lower limb arterial insufficiency is not an absolute indication for intervention. Only 5–7% of patients with claudication will come to amputation (Boyd 62, Imparato 75, Dormandy 91). After careful judgement of the symptoms and risk factor analysis, an individual treatment plan is decided in limbs with claudication, either conservative or invasive, endovascular or surgical. The incidence of CLI among all patients with symptomatic ischaemia of the leg is 1–3% (Dormandy 88, Varty 96). However, CLI constitutes a definite indication for arterial intervention (Bolin 88, Lepänto 96).

The prognosis of patients with CLI in terms of life expectancy is notoriously poor. Patients with CLI have a 50% survival rate after 5 years regardless of treatment (ICAI 97, Wolfe 97). Improved peripheral circulation cannot prolong survival but may save the legs. The decision between endovascular and surgical intervention is usually guided by anatomical factors such as the localisation, the extent of atherosclerosis and the status of the runoff vessels. During recent years, as the complications related to endovascular procedures have diminished with the introduction of modern catheters and balloons, the indications for angioplasty have increased (Johnston 92, Stanley 96). In some patients with CLI and associated severe risk factors, conventional surgical procedures might be contraindicated and endovascular intervention might be the only alternative to prevent amputation. Less durable procedures might be acceptable in these patients with limited life expectancy (Muluk 01, Källero 85, Sec Eur Cons 92).
AIMS OF THE THESIS

The present thesis was designed to analyse the outcome following PTA in limbs with severe lower limb ischaemia and to study the role of duplex scanning in the selection of limbs for infrainguinal PTA. The first part of the thesis (studies I, II and III) covers the results of infrainguinal PTA. The outcome of infrainguinal PTA is dependent on symptoms, the extent and the localisation of atherosclerotic lesions. It is reasonable to speculate that the results might be easier to interpret if the outcomes of endovascular procedures are analysed in homogenous groups with less debatable indications, especially when the number of procedures is limited. This was the reason for the evaluation of only infrainguinal endovascular procedures in limbs with subcritical or CLI. In order to achieve more specific outcome analysis, the type or localisation of PTA was further divided into three groups: femoropopliteal, crural and infrapopliteal through patent infrainguinal bypass grafts.

In the second part of the thesis (studies IV and V), the accuracy of duplex scanning was validated against conventional angiography. Following this validation study, the role of duplex scanning in selection of patients for PTA was evaluated.

In summary, the specific aims were as follows:

1 – to evaluate the results of PTA of femoropopliteal arteries in patients with subcritical or CLI.

2 – to determine the efficacy, safety and long-term results of crural artery PTA in limbs with CLI.

3 – to evaluate the results of PTA performed through infrainguinal bypass grafts for stenotic or occlusive lesions at the distal anastomosis and/or in the runoff arteries.

4 – to study the accuracy of duplex scanning in the evaluation of the infrapopliteal arteries.

5 – to investigate the role of duplex scanning in the selection of patients with subcritical or CLI for infrainguinal PTA.
MATERIAL AND METHODS

Data collection
Written reports of all lower limb angiographies performed during the study periods and the medical files of these patients were retrospectively analysed in order to select those who were included in studies I, II and III. Following this selection, the angiographies of those who were included in the thesis were re-evaluated. Relevant data from medical and duplex scan files, together with information from the Swedish Population Registry were gathered for evaluation of outcome.

During the study period, 18,000 arterial duplex scans were performed in our vascular laboratory. Retrospective analysis of all these scans gave the opportunity of evaluating the noninvasive selection of patients for PTA. It also contributed to objective analysis of the results of PTA as all patients included in study III and 78% of those included in study I were followed by duplex scanning.

Inclusion and exclusion criteria
The study periods, design and localisation of PTA are summarised in Table I.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study period</th>
<th>Study design</th>
<th>Inclusion/PTA localisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>1992-1999</td>
<td>Retrospective</td>
<td>Limbs with subCLI/CLI PTA of femoropopliteal arteries</td>
</tr>
<tr>
<td>II</td>
<td>1989-1993</td>
<td>Retrospective</td>
<td>Limbs with CLI PTA of crural arteries</td>
</tr>
<tr>
<td>III</td>
<td>1992-2000</td>
<td>Retrospective</td>
<td>Limbs with infrainguinal bypass. PTA of distal anastomosis and/or runoff arteries</td>
</tr>
<tr>
<td>IV</td>
<td>1995</td>
<td>Prospective</td>
<td>Severe lower limb ischaemia Duplex prior to angiography</td>
</tr>
<tr>
<td>V</td>
<td>1995-1999</td>
<td>Retrospective</td>
<td>Limbs with subCLI/CLI Infrainguinal PTA</td>
</tr>
</tbody>
</table>
In study I, as the results of infrapopliteal PTA in limbs with severe lower limb ischaemia have been previously reported (study II), patients undergoing crural artery PTA alone or simultaneously with femoropopliteal dilatation were excluded, as were those infrainguinal endovascular procedures performed for claudication.

In study II, all patients undergoing crural artery PTA during the study period were included. Patients with infrainguinal bypass grafts undergoing crural artery PTA were excluded.

In study III, infrainguinal grafts with stenosis at the proximal anastomoses or in the graft without associated distal lesions undergoing PTA were excluded, as were those receiving intraarterial thrombolytic therapy for graft occlusion without additional PTA. Grafts with combined proximal and distal lesions as well as patients receiving thrombolysis followed by PTA at the distal anastomosis or in the runoff vessels were included. The reason for the above-mentioned criteria being used for inclusion in study III was to evaluate the results of PTA selectively at the distal anastomotic site and/or in the runoff arteries.

In study IV, all patients with severe lower limb ischaemia who underwent duplex scanning prior to angiography were included.

In study V, patients having sub-CLI or CLI who underwent duplex scanning within 3 months prior to conventional diagnostic angiography and or infrainguinal PTA were included. Patients with significant iliac artery lesions and those with previous infrainguinal surgical reconstructions undergoing angiography or PTA of graft or distal lesions were excluded, as were those undergoing thrombolysis due to acute or subacute infrainguinal arterial occlusions. Patients with lower limb arterial insufficiency who underwent lower extremity conventional or MRA prior to duplex scanning were also excluded, as the findings of these investigations might have affected the interpretation of duplex scanning at the time of examination.
Patient characteristics
Patient demographics are summarised in Tables II and III.

Table II. The total number of patients, limbs, age and sex distribution

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of patients</th>
<th>No. of limbs</th>
<th>Age (years) Median</th>
<th>Sex male/female</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>94</td>
<td>121</td>
<td>75</td>
<td>52/42</td>
</tr>
<tr>
<td>II</td>
<td>82</td>
<td>86</td>
<td>72</td>
<td>42/40</td>
</tr>
<tr>
<td>III</td>
<td>41</td>
<td>57</td>
<td>70</td>
<td>22/19</td>
</tr>
<tr>
<td>IV</td>
<td>38</td>
<td>40</td>
<td>71</td>
<td>17/21</td>
</tr>
<tr>
<td>V</td>
<td>150</td>
<td>162</td>
<td>79</td>
<td>72/78</td>
</tr>
</tbody>
</table>

Table III. Patient characteristics (limbs)

| Study | Claudication Sub-CLI CLI Diabetes HT CAD CVD Smoking |
|-------|-----------------------------------------------------|--------------------------------------------------|
| I     | 0 30 91 52 (43%) 41 (34%) 38 (32%) 13 (11%) 32 (35%) |
| II    | 0 30 56 61 (74%) 30 (36%) 51 (62%) 6 (7%) 16 (20%)  |
| III   | 0 16 30 21 (46%) 24 (51%) 21 (46%) NA 28 (61%)  |
| IV**  | 6 12 20 17 (45%) 14 (37%) 20 (53%) NA 10 (26%)  |
| V***  | 0 NA NA NA NA NA NA NA |

*Indication at the time of by-pass grafting
**Number of patients
***Indication at the time of duplex-scanning
Definitions of lower limb ischaemia

CLI was defined according to SVS/ICSVS by either of the following two criteria: recurring ischemic rest pain that persists for more than 2 weeks and requires regular analgesics, with an ankle pressure of 40 mm Hg or less; ulceration or gangrene of the foot or toes, with ankle pressure 60 mm Hg or less (Rutherford 97). Limbs with rest pain or ulcer, having either falsely elevated ankle pressures or having an ankle brachial pressure index (ABPI) less than 0.5 and ankle pressure over 40 mm Hg were defined as having subcritical ischaemia (TASC 00).

Guidelines for selection of treatment modalities

Following clinical investigation and simple ankle pressure measurements, potential candidates for intervention underwent duplex scanning. In our department, PTA was generally the initial treatment of choice for occlusive lesions less than 10 cm in length in the femoropopliteal segment and less than 5 cm in length in crural arteries in limbs with subcritical or CLI. In 13 patients in study I, the length of occlusion in the SFA was equal or more than 10 cm in length. In patients with femoropopliteal and/or cruropedal atherosclerotic occlusive lesions, which are not amenable to PTA, reconstructive surgery is the treatment of choice if the symptoms justify intervention. When duplex scanning provided satisfactory visualisation and spectral Doppler evaluation in the inflow and outflow arteries, and if the lesions were not suitable for PTA according to the guidelines mentioned above, surgery without preoperative angiography was performed. The reason for performing angiography in some patients with diagnostic duplex scans prior to surgical intervention was mainly due to policy differences among vascular surgeons. No patients with claudication underwent crural artery PTA or femorodistal bypass grafting during the study period.

There were no strict guidelines for the selection of treatment modality in limbs with infrainguinal graft lesions. However, PTA was the treatment of choice for localised stenotic lesions (less than 2 cm in length) in the graft and/or at the distal anastomosis detected after the initial 3-month period following surgery. PTA was also the choice of initial treatment for stenosis or occlusions less than 5 cm in length in the runoff arteries. In cases where PTA was considered unsuitable due to extensive crural artery changes, femorodistal jump bypass grafting was the choice of treatment if technically feasible (i.e., if there was a patent distal vessel present).
In study III, the patients were selected for endovascular intervention using the findings obtained from duplex scanning. Peak systolic velocity (PSV) ratio more than 3 was the indication for intervention in grafts with stenosis (Olojuba 98, Bandyk 84, Levy 98). The following duplex criteria were used for definition of grafts at risk of occlusion in limbs with runoff lesions: PSV in the graft less than 45 cm/sec irrespective of symptoms and/or a decrease in ABPI measurements greater than 0.15 combined with rest pain or an ulcer (Dougherty 98, Taylor 92, Wilson 96, Moody 90).

**Duplex scanning**

Duplex scanning was performed using an Acuson model 128 XP or Sequoia fitted with 4-6 MHz linear, 2-4 MHz convex or vector array probes (Acuson, Mountainview, CA, USA). Duplex studies were performed with the patient in a supine position, starting from the infrarenal aorta. The popliteal and tibioperoneal segments were studied with the knee slightly flexed. Duplex scanning of the crural and foot arteries was not routinely performed, especially in those with a patent popliteal artery. Each arterial segment was examined over its entire length, searching for colour changes, which suggested the presence of an arterial lesion. PSV from these areas was compared with the normal segments immediately proximal to and rarely distal from the lesions. A PSV ratio (PSV-stenosis/PSV-normal segment) of equal to or more than 2.5 was considered as indicative of a 50% or greater stenosis when the Doppler angle was less than 60° (Fig.1) (Moneta 92). If the arterial segment was clearly visualised with B-mode images but giving no detectable Doppler signal, it was considered to be occluded. The investigations were interpreted as non-diagnostic if the artery in question could not be adequately visualised by B-mode images or if pulsed Doppler samples could not be obtained with an angle of insonation less than 60°.
During the initial phase of the study, similar criteria were used for diagnosis of more than 50% stenosis in the infrainguinal graft or at the anastomotic sites as in the native arteries. During the last, two-year period, a PSV ratio of equal to or more than 3 was used to define significant graft lesions that required intervention (Olojugba 98, Bandyk 89, Grigg 88, Mattos 93, Sladen 89, Belkin 94, 97).

**PTA Technique**
Antegrade puncture of the femoral artery was used in limbs when pre-PTA duplex scanning demonstrated patent aortoiliac segments. In patients with extreme obesity, or where duplex scanning was unavailable or inconclusive the crossover technique from the contra-lateral side was used for angiography.
and PTA. The crossover technique has been used more often during recent years even in cases with diagnostic iliac duplex scanning, in order to avoid compression of the ipsilateral femoral artery following PTA. Catheterisation was made through a 2.00-2.50 mm (6-8 French) introducer and with ‘road mapping’ of the arteries. Low profile balloons with a shaft size of 1.65-2.30 mm (5-7 French) (Schneider-Europe AG, Zurich, Switzerland) and a balloon diameter ranging from 2.5 to 6 mm were used. For recanalisation of total occlusions a low friction 0.89 mm (0.035 inch) diameter guide wire was used (Terumo Co, Japan). Immediate post-angioplasty angiograms were obtained for all patients. Technical success was defined as PTA resulting in less than 50% residual stenosis after dilatation. Intra-arterial heparin (5000 units) was injected during the procedure. The patients received low molecular heparin (Enoxaparin 40 mg sc) 4–6 hrs after the procedure and were on lifetime antiplatelet treatment (acetylsalicylic acid/ 160 mg daily).

**Level of PTA**

The level of PTA in each study is summarised in Table IV.

**Table IV. The level of PTA**

<table>
<thead>
<tr>
<th>Level of PTA</th>
<th>Study I</th>
<th>Study II</th>
<th>Study III</th>
<th>Study V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only SFA</td>
<td>68</td>
<td>0</td>
<td>0</td>
<td>22</td>
</tr>
<tr>
<td>Only popliteal</td>
<td>13</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Only crural</td>
<td>0</td>
<td>39</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Combined SFA -popliteal</td>
<td>40</td>
<td>0</td>
<td>0</td>
<td>22</td>
</tr>
<tr>
<td>Combined SFA/popliteal/crural</td>
<td>0</td>
<td>55</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>Distal anastomosis (DA)</td>
<td>0</td>
<td>0</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Runoff arteries</td>
<td>0</td>
<td>0</td>
<td>32</td>
<td>0</td>
</tr>
<tr>
<td>Combined DA-runoff arteries</td>
<td>0</td>
<td>0</td>
<td>12</td>
<td>0</td>
</tr>
</tbody>
</table>

Figures 2 through 5 demonstrate Pre- and post- PTA angiograms in some patients undergoing infrainguinal PTA at various arterial segments.
Fig. 3 Occlusion of AFS and tibioperoneal arteries (2 and 4 cm resp.) in 80-year-old woman with gangrene of the right foot. A-B before PTA. C-D after PTA. The ulcers healed after PTA but the patient died one year later of heart failure.

Fig. 2
6 cm long occlusion of SFA in a 60-year-old man. A- before PTA. B- after PTA. The leg was amputated in less than a year despite re-PTA and attempts with bypass operations.
Fig. 4
Short stenosis in AFS and 7 cm occlusion of the peroneal artery in a 65-year-old man with CLI. A-B and C before PTA, D-E and F after PTA. After PTA the ulcers healed and duplex scanning at 36 months, showed no signs of reocclusion.
Follow-up

Following infrainguinal PTA performed for treatment of sub-CLI or CLI, limbs undergo routine clinical examination and ABPI measurements at the following intervals in our department: before discharge, at 1, 6 and 12 months, and then on a yearly basis. During the last five years (1996–2001), the majority of patients were followed by duplex scanning at these intervals.

The following criteria were used for definition of clinical improvement: total or partial disappearance of rest pain (intermittent rest pain that did not require regular analgesics), healing of ulcers. In patients undergoing duplex scanning, special attention was paid to assessing the patency of the dilated segment. In limbs with clinical improvement following recanalisation of occluded segments, demonstration of an open dilated segment with less than 50% stenosis was considered as patent. PTA results were considered as successful in limbs with clinical and haemodynamic improvement. Recurrence of symptoms and/or haemodynamic deterioration and/or restenosis/occlusion verified by duplex scanning, were defined as failure.
Analysis of data
The technical details of PTA and follow-up data were not subjected to blind analysis but the angiographic data were registered before analysis of the outcome. The time difference between data collection from angiographies and patient files was at least 6 months. The findings obtained from duplex scanning and angiography, were subjected to blind analysis by two different investigators. The comparison between duplex scan findings and angiography was analysed by the third investigator.

Statistical analysis
Life tables for patency rates were constructed by the actuarial method according to SVS/ICSVS reporting standards and the differences between groups were analysed using the Log-rank test (Rutherford 97).

Accuracy, sensitivity, specificity, positive predictive and negative predictive values for duplex scanning in the selection of limbs for PTA were calculated from two-way contingency tables. The arterial segments with non-diagnostic duplex scan findings were interpreted as not suitable for PTA.
RESULTS

Technical success

In study I, the technical success rate was 88% (106/121) in limbs undergoing femoropopliteal PTA. Among 15 technical failures in 14 patients, 11 were at the superficial femoral level. All but two had occlusive lesions and the length of occlusion was longer than 5 cm in 10 cases. Two patients underwent acute infrainguinal bypass grafting following perforation and thrombosis of the SFA in one and thrombosis of the popliteal artery following successful PTA of the SFA in the other. In all other patients, technical failures did not worsen the status of the runoff vessels distal to the lesions. Six patients underwent elective infrainguinal bypass grafting following technical failure. In two cases elective major amputation was undertaken due to poor distal runoff. One patient died after six weeks and the remaining four managed with conservative treatment following failed PTA. There was no limb loss as a direct complication of the PTA procedure, such as distal embolisation or thrombosis of crural arteries precluding the performance of bypass grafting.

In study II, a technically successful PTA in at least one crural artery was achieved in 88% procedures (83/94 procedures). There was technical failure in a total of 27 segments, 26 of which were at the crural level. Among 11 procedures where no crural artery could be recanalised, one patient underwent acute distal reconstruction, three were amputated, three received elective bypass grafting, two died within 6 months and two were lost to follow-up during the first 3 months after PTA. In six instances among the initial 40 procedures, where PTA of the superficial femoral artery and/or popliteal artery preceded PTA of the crural artery, a peripheral embolisation was observed and in five cases it was possible to perform a successful transcatheter embolectomy. In one case with peripheral embolisation, successful lysis was achieved with local streptokinase infusion. Since we reversed the order of procedures, performing PTA of the crural arteries before that of the femoral artery, no embolisation has been noted.

In study III, a technically successful PTA was achieved in 91% (52/57) of distal PTA procedures performed through patent infrainguinal grafts. In two cases with acute femorodistal graft occlusion (both PTFE grafts with a distal vein cuff) following successful thrombolysis, the stenosis at the distal anastomosis could not be recanalised. Both patients underwent surgical
revision with vein patch angioplasty. One of these patients died 4 months after surgery with a patent graft and the other underwent amputation after graft occlusion at 3 months. In one patient with femoropopliteal vein graft and poor distal runoff, PTA of multiple short stenosis in the proximal anterior tibial and peroneal arteries failed. This patient underwent amputation with patent graft after one month. In the fourth patient with femoropopliteal vein bypass and poor distal runoff, the graft occluded following an attempt at PTA at the distal anastomosis. Following urgent graft thrombectomy and patch angioplasty, the graft occluded after 2 months and the patient underwent amputation after 28 months. In the fifth patient with femoropopliteal vein bypass, there was a residual stenosis greater than 50% after PTA at the distal anastomotic site. The graft was patent at 26 months with duplex verified distal stenosis and the patient had moderate claudication.

Early complications (within 30 days)

In study I, four patients died within 30 days of PTA (4.3%). One patient died due to myocardial infarction on the same day after uncomplicated successful superficial femoral artery PTA. The other deaths were due to renal and cardiac insufficiency in one patient and myocardial infarction in three, occurring 1–2 weeks after PTA. Fifteen patients developed groin haematomas (12%), of whom only one received a blood transfusion and no patients underwent acute surgical intervention. Two patients had temporary creatinine elevation. No patient had an irreversible change in his or her creatinine.

In study II, of 82 patients undergoing 94 crural artery PTA, two patients died due to myocardial infarction (post-PTA mortality 2.4%). There was no limb loss as a complication of the PTA procedure. Fourteen patients developed groin haematomas (15%). Five received a blood transfusion and two underwent acute surgical intervention. One patient developed non fatal myocardial infarction during the first week after PTA. One patient had temporary creatinine elevation.

In study III, there was no mortality during the initial 30-day period following PTA procedures through infrainguinal grafts. In five cases, mild haematoma was observed at the puncture site that did not require surgical intervention or blood transfusion. In one patient the PTA attempt at distal anastomosis resulted in graft occlusion and this patient underwent urgent graft thrombectomy and patch angioplasty, as mentioned earlier.
Results of femoropopliteal PTA

Cumulative primary success rates at 6, 12, 36 and 60 months were 59%, 50%, 27% and 27%, respectively (Table V).

Table V. Cumulative life-table analysis for primary success rate (121 procedures)

<table>
<thead>
<tr>
<th>Interval (months)</th>
<th>No. of limbs at risk</th>
<th>No. failed PTA</th>
<th>No. Interval withdrawn*</th>
<th>Interval success</th>
<th>Cumulative success %</th>
<th>SE %</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>121</td>
<td>47</td>
<td>15</td>
<td>0.59</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>6-12</td>
<td>59</td>
<td>8</td>
<td>5</td>
<td>0.86</td>
<td>59</td>
<td>8.7</td>
</tr>
<tr>
<td>12-18</td>
<td>46</td>
<td>9</td>
<td>8</td>
<td>0.78</td>
<td>50</td>
<td>2.5</td>
</tr>
<tr>
<td>18-24</td>
<td>29</td>
<td>3</td>
<td>0</td>
<td>0.89</td>
<td>40</td>
<td>4</td>
</tr>
<tr>
<td>24-30</td>
<td>26</td>
<td>3</td>
<td>5</td>
<td>0.87</td>
<td>35</td>
<td>1.8</td>
</tr>
<tr>
<td>30-36</td>
<td>18</td>
<td>2</td>
<td>1</td>
<td>0.8</td>
<td>83</td>
<td>2.2</td>
</tr>
<tr>
<td>36-42</td>
<td>15</td>
<td>0</td>
<td>7</td>
<td>1</td>
<td>27</td>
<td>2</td>
</tr>
<tr>
<td>42-48</td>
<td>8</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>27</td>
<td>0</td>
</tr>
<tr>
<td>48-54</td>
<td>7</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>27</td>
<td>0</td>
</tr>
<tr>
<td>54-60</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>27</td>
<td>0</td>
</tr>
</tbody>
</table>

No. of patients withdrawn due to the short time since PTA, loss to follow-up, or death

The cumulative primary assisted success rate at 60 months was 34% (Fig. 6).

Fig. 6 Cumulative life-table analysis for primary assisted success rate
The primary assisted success rate in limbs with single SFA stenosis was 53% at 60 months, compared to 42% in limbs with multiple stenosis (p=NS) and 18% in those with occlusions (Table VI and Fig. 7).

The primary success rate in limbs with an SFA occlusion longer than 5 cm was only 12% after 5 years compared to 32% if the occlusion was 5 cm or less in length (p<0.01) (Table VII). Among 13 cases with SFA occlusions 10 cm or more in length, there were seven technical failures and five re-occlusions within 5 months.

The symptoms (subcritical, CLI), presence of diabetes, preoperative ABPI (ankle brachial pressure index) less than 0.2, combined femoral and popliteal PTA, the number of occluded crural arteries (one compared with two or three) and the occlusion of the foot arteries (dorsal pedal and plantar arteries) did not adversely affect the outcome. The occlusion of all three crural arteries was observed in 33%. Most limbs had only one patent crural vessel (49%). Dorsal pedal and/or plantar arteries were partially or totally occluded in 78%.

Twelve patients underwent amputation after failed PTA without any attempt at distal bypass grafting because of severe distal atherosclerotic involvement. Fifteen patients underwent infrainguinal bypass grafting (17 procedures) after failure of PTA. In these patients with restenosis or occlusion at the site of PTA, we did not observe worsening of the atherosclerotic process in the runoff arteries on preoperative or on-table postreconstruction angiograms. The cumulative limb salvage rate following endovascular and vascular interventions was 86% at 5 years (Fig. 8). The cumulative survival rate was 51% at 5 years (Fig. 9).
### Table VI. Cumulative life table success rates in various groups

<table>
<thead>
<tr>
<th>Various Groups</th>
<th>12 months % (at risk)</th>
<th>36 months % (at risk)</th>
<th>60 months % (at risk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Primary (all)</td>
<td>40 (46)</td>
<td>27 (15)</td>
<td>27 (6)</td>
</tr>
<tr>
<td>2-Primary assisted (all)</td>
<td>48 (53)</td>
<td>34 (18)</td>
<td>34 (7)</td>
</tr>
<tr>
<td>3-Secondary (all)</td>
<td>49 (54)</td>
<td>32 (19)</td>
<td>32 (7)</td>
</tr>
<tr>
<td>4-Primary (stenotic lesions)</td>
<td>50 (31)</td>
<td>39 (10)</td>
<td>39 (3)</td>
</tr>
<tr>
<td>5-Primary (occlusive lesions)</td>
<td>27 (15)</td>
<td>16 (5)</td>
<td>16 (3)</td>
</tr>
<tr>
<td>6-Primary (SFA- single stenosis)</td>
<td>72 (19)</td>
<td>49 (7)*</td>
<td>49 (2)*</td>
</tr>
<tr>
<td>7-Primary (SFA -multiple stenosis)</td>
<td>34 (12)</td>
<td>34 (5)</td>
<td>34 (3)</td>
</tr>
<tr>
<td>8-Primary (SFA -occlusions)</td>
<td>23 (9)</td>
<td>11 (3)</td>
<td>11 (1)</td>
</tr>
<tr>
<td>9-Primary (SFA -occlusions &lt;5 cm)</td>
<td>47 (35)</td>
<td>32 (12)</td>
<td>32 (3)</td>
</tr>
<tr>
<td>10-Primary (SFA -occlusions &gt;5 cm)</td>
<td>17 (3)</td>
<td>12 (2)</td>
<td>12 (2)</td>
</tr>
<tr>
<td>11-Primary assisted (SFA -single stenosis)</td>
<td>75 (21)</td>
<td>53 (7)*</td>
<td>53 (2)*</td>
</tr>
<tr>
<td>12-Primary assisted (SFA -multiple stenosis)</td>
<td>42 (14)*</td>
<td>42 (5)*</td>
<td>42 (3)*</td>
</tr>
<tr>
<td>13-Primary assisted (SFA-occlusions)</td>
<td>31 (12)</td>
<td>18 (5)</td>
<td>18 (2)</td>
</tr>
</tbody>
</table>

SFA = superficial femoral artery

*SE > 10

Comparisons: 4-5: p<0.01; 6-7:p=NS; 6-8:p<0.001;7-8=p=0.01; 9-10:p=0.001; 11-12:p=NS; 11-13:p<0.001; 12-13:p<0.01

**Fig. 7** Cumulative life-table analysis for primary assisted success rate in patients with SFA single stenosis (1); SFA multiple stenosis (2) and SFA occlusions (3)
Fig. 8 Cumulative life-table analysis for limb salvage rate

Fig. 9 Cumulative life-table analysis for survival rate
Results of crural artery PTA
Cumulative primary clinical success rates at 6, 12, 24 and 36 months were 55%, 51%, 36%, and 36%, respectively (Table VII). Cumulative secondary success and limb salvage rates at 36 months were 44% and 72%, respectively (Tables VIII and IX).

Table VII. Cumulative life-table analysis for primary success rate

<table>
<thead>
<tr>
<th>Interval (months)</th>
<th>No. of limbs at risk</th>
<th>No. failed PTA</th>
<th>No. with drawn*</th>
<th>Interval success</th>
<th>Cumulative success%</th>
<th>SE%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>86</td>
<td>35</td>
<td>14</td>
<td>0.55</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>6-12</td>
<td>37</td>
<td>2</td>
<td>9</td>
<td>0.93</td>
<td>55</td>
<td>6</td>
</tr>
<tr>
<td>12-14</td>
<td>26</td>
<td>6</td>
<td>11</td>
<td>0.70</td>
<td>51</td>
<td>7</td>
</tr>
<tr>
<td>24-36</td>
<td>9</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>36</td>
<td>9.7</td>
</tr>
</tbody>
</table>

Table VIII. Cumulative life-table analysis for secondary success rate

<table>
<thead>
<tr>
<th>Interval (months)</th>
<th>No. of limbs at risk</th>
<th>No. failed PTA</th>
<th>No. with drawn*</th>
<th>Interval success</th>
<th>Cumulative success%</th>
<th>SE%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>86</td>
<td>32</td>
<td>14</td>
<td>0.59</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>6-12</td>
<td>40</td>
<td>3</td>
<td>9</td>
<td>0.91</td>
<td>59</td>
<td>5.9</td>
</tr>
<tr>
<td>12-14</td>
<td>28</td>
<td>4</td>
<td>12</td>
<td>0.81</td>
<td>54</td>
<td>6.9</td>
</tr>
<tr>
<td>24-36</td>
<td>12</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>44</td>
<td>9.5</td>
</tr>
</tbody>
</table>

Table IX. Cumulative life-table analysis for limb salvage rate

<table>
<thead>
<tr>
<th>Interval (months)</th>
<th>No. of limbs at risk</th>
<th>No. failed PTA</th>
<th>No. withdrawn*</th>
<th>Interval success</th>
<th>Cumulative success%</th>
<th>SE%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>86</td>
<td>16</td>
<td>18</td>
<td>0.79</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>6-12</td>
<td>52</td>
<td>2</td>
<td>18</td>
<td>0.95</td>
<td>79</td>
<td>5</td>
</tr>
<tr>
<td>12-14</td>
<td>32</td>
<td>1</td>
<td>11</td>
<td>0.96</td>
<td>75</td>
<td>6.6</td>
</tr>
<tr>
<td>24-36</td>
<td>20</td>
<td>0</td>
<td>7</td>
<td>1</td>
<td>72</td>
<td>8.5</td>
</tr>
</tbody>
</table>

* No. of patients withdrawn due to the short time since PTA, loss to follow-up, or death
In ten limbs, secondary crural artery PTA was performed, which resulted in a slightly improved patency rate at 36 months (44% compared to 36%). The presence of diabetes, a preoperative ABPI less than 0.2, combined femorocrural PTA, the type of lesion (occlusion compared with stenosis) and the number of patent crural arteries after successful PTA (one compared with two or three) did not adversely affect the results. One patient required acute femorodistal reconstruction. Thirteen patients underwent elective infrainguinal bypass surgery due to reocclusion at a mean (SE) of 7.2 (3.9) months after PTA. Twenty patients underwent amputation at a mean (SE) of 4.7 (1.7) months (range 1–37 months) after reocclusion of PTA without any attempt at distal reconstruction because of severe distal atherosclerotic involvement. Among 49 patients who did not require surgical reconstruction or primary amputation after PTA, 15 died during the follow-up period (mean 10.8 months).

Results of infrapopliteal PTA through infrainguinal grafts

The median (range) ABPI measurements increased from 0.42(0.2-0.8) to 0.53(0.3-1.0) after technically successful PTA. The overall primary patency rate following PTA was 32% at the end of 3 years (Table X).

Table X. Cumulative life-table analysis for primary patency rate (57 procedures)

<table>
<thead>
<tr>
<th>Interval (months)</th>
<th>No.of limbs at risk</th>
<th>No.failed PTA</th>
<th>No.withdrawn*</th>
<th>Interval success</th>
<th>Cumulative success%</th>
<th>SE%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>57</td>
<td>23</td>
<td>1</td>
<td>0.59</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>6-12</td>
<td>33</td>
<td>10</td>
<td>1</td>
<td>0.69</td>
<td>59</td>
<td>6</td>
</tr>
<tr>
<td>12-18</td>
<td>22</td>
<td>2</td>
<td>3</td>
<td>0.90</td>
<td>41</td>
<td>3</td>
</tr>
<tr>
<td>18-24</td>
<td>17</td>
<td>1</td>
<td>2</td>
<td>0.93</td>
<td>37</td>
<td>0.6</td>
</tr>
<tr>
<td>24-30</td>
<td>14</td>
<td>1</td>
<td>3</td>
<td>0.92</td>
<td>35</td>
<td>0.4</td>
</tr>
<tr>
<td>30-36</td>
<td>10</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>32</td>
<td>0.5</td>
</tr>
</tbody>
</table>

* No. of patients withdrawn due to the short time since PTA, loss to follow-up, or death

The majority of events, either re-intervention in patent grafts or graft occlusions, occurred during the initial 6-month period after PTA (23 out of 37 events). In eight patients, following graft occlusion after a mean (SD) (range) interval of 12.5 (13.5) (1–35) months, no further intervention or amputation was performed. Five of these patients had claudication and three had subcritical ischaemia at the time of their last visit (a median of 11 months
after occlusion). Sixteen additional endovascular interventions were required in ten patients. Twelve of these procedures were performed due to duplex-verified restenosis or occlusion at the site of previous PTA in patent grafts. These additional procedures resulted in a primary assisted patency of 53% at 3 years (Fig. 10).

![Graph showing cumulative primary and primary assisted life table patency. SE less than 10 at the end of 3 years and the numbers at risk are given.](image)

**Fig. 10** Cumulative primary and primary assisted life table patency. SE less than 10 at the end of 3 years and the numbers at risk are given.

Femorocrural or jump bypass grafting was performed following graft occlusion in one case and duplex-verified stenosis or occlusion at the site of PTA with patent graft in three cases. There were no significant differences in patency rates with respect to the graft material, the site of distal anastomosis, the status of distal runoff, the presence of diabetes mellitus, the type of lesion (stenosis or occlusion), combined PTA at the proximal anastomosis or graft, and the use of thrombolysis before dilatation. The limb salvage rate at 36 months was 83%.
There were six major amputations during the follow-up period. Two patients underwent amputation without reintervention at 1 and 7 months following PTA and graft occlusion due to poor distal runoff and CLI. Another patient with CLI was amputated with a patent but haemodynamically failed graft. In three patients major amputations were performed following re-intervention (two thrombolysis and distal PTA and one jump graft). The median (range) interval from the time of initial PTA and amputation was 5 (1–23) months.

**Accuracy of infrapopliteal arterial duplex scanning**

The overall correlation between selective femoral angiography and duplex scanning for crural and foot arteries is presented in Table XI.

**Table XI. Duplex scanning vs. angiography**

<table>
<thead>
<tr>
<th>Segment</th>
<th>n</th>
<th>Accuracy (%)</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>Kappa (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poplitea/below knee</td>
<td>40</td>
<td>88</td>
<td>79</td>
<td>92</td>
<td>85</td>
<td>83</td>
<td>0.76</td>
</tr>
<tr>
<td>TP trunk/crural/pedal</td>
<td>240</td>
<td>80</td>
<td>83</td>
<td>77</td>
<td>79</td>
<td>8</td>
<td>0.60</td>
</tr>
<tr>
<td>TP trunk/crural</td>
<td>180</td>
<td>80</td>
<td>83</td>
<td>76</td>
<td>78</td>
<td>80</td>
<td>0.59</td>
</tr>
<tr>
<td>TP trunk</td>
<td>40</td>
<td>80</td>
<td>71</td>
<td>87</td>
<td>80</td>
<td>80</td>
<td>0.62</td>
</tr>
<tr>
<td>Tibialis anterior</td>
<td>40</td>
<td>80</td>
<td>73</td>
<td>86</td>
<td>80</td>
<td>80</td>
<td>0.64</td>
</tr>
<tr>
<td>Tibialis posterior</td>
<td>40</td>
<td>80</td>
<td>84</td>
<td>76</td>
<td>84</td>
<td>74</td>
<td>0.61</td>
</tr>
<tr>
<td>Peroneal</td>
<td>40</td>
<td>76</td>
<td>93</td>
<td>58</td>
<td>71</td>
<td>89</td>
<td>0.57</td>
</tr>
<tr>
<td>Dorsalis pedis</td>
<td>40</td>
<td>88</td>
<td>85</td>
<td>89</td>
<td>79</td>
<td>92</td>
<td>0.71</td>
</tr>
<tr>
<td>Plantar arch</td>
<td>40</td>
<td>78</td>
<td>78</td>
<td>76</td>
<td>82</td>
<td>72</td>
<td>0.53</td>
</tr>
<tr>
<td>Pedal arteries</td>
<td>80</td>
<td>83</td>
<td>81</td>
<td>84</td>
<td>81</td>
<td>84</td>
<td>0.64</td>
</tr>
<tr>
<td>TP/crural/pedal*</td>
<td>200</td>
<td>83</td>
<td>86</td>
<td>80</td>
<td>82</td>
<td>84</td>
<td>0.66</td>
</tr>
</tbody>
</table>

*(50% or occlusion)*

The values were calculated according to the contingency table. For the TP/crural/pedal (50% or occlusion)% stenosis was graded into two groups: normal or ≤ 50%; > 50% or occlusion.

The duplex scanning of the tibioperoneal trunk, crural and pedal arteries had an accuracy of 80% with a Kappa value of 0.6. The sensitivity, specificity, positive predictive and negative predictive values were 83%, 77%, 79% and 81%, respectively. The specificity was relatively low for the peroneal artery (58%) compared to the anterior tibial (86%), posterior tibial (76%) and foot arteries (81%). The overall accuracy of duplex scanning for detection of significant stenosis or occlusion of the crural and foot arteries was 83%; Kappa values for various segments varied between 0.53 and 0.71, with the
highest value for the dorsal pedal artery and the lowest for the peroneal artery and the plantar arch.

**Selection of patients for infrainguinal PTA**

The number of arterial segments that were not examined or were non-diagnostic at the time of duplex scanning in the whole series is shown in Table XII. In three cases undergoing infrainguinal PTA where iliac duplex scanning was considered non-diagnostic, the spectral Doppler analysis of external iliac and common femoral arteries was normal in all. All these cases underwent angiography with cross-over technique and the patency of the iliac arteries was verified before infrainguinal PTA. The number of non-diagnostic or non-available scans at the crural level was higher than in the other segments.

Table XII. The number of arterial segments on the symptomatic side that were not examined or non-diagnostic at the time of duplex scanning in 162 limbs undergoing diagnostic angiography or infrainguinal PTA

<table>
<thead>
<tr>
<th>Segment</th>
<th>Duplex scanning</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not examined</td>
</tr>
<tr>
<td>Iliac arteries (n=162)</td>
<td>10 (6%)</td>
</tr>
<tr>
<td>SFA (n=162)</td>
<td>0</td>
</tr>
<tr>
<td>Popliteal artery (n=162)</td>
<td>0</td>
</tr>
<tr>
<td>Crural arteries (n=486)*</td>
<td>168 (35%)</td>
</tr>
</tbody>
</table>

* 486 crural arteries (anterior and posterior tibial, and peroneal) in 162 limbs

Forty-two procedures (57%) were performed at multiple arterial segments. Prediction of performing an infrainguinal PTA by duplex scanning and the outcome measures in patients who did not undergo PTA are summarised in Table XIII.
Table XIII. Prediction of performing an infrainguinal PTA procedure by duplex scanning and the outcome measures in patients who did not undergo PTA.

<table>
<thead>
<tr>
<th>Interpretation of duplex findings</th>
<th>Outcome measures</th>
<th>PTA (n=74)</th>
<th>No PTA (n=88)</th>
<th>Non-diagnostic (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA (n=74)</td>
<td>62/74 (84%)</td>
<td>5/74 (7%)</td>
<td>7/74 (9%)</td>
<td></td>
</tr>
<tr>
<td>No PTA (n=88)</td>
<td>10/88 (11%)</td>
<td>67/88 (76%)</td>
<td>11/8 (12.5%)</td>
<td></td>
</tr>
<tr>
<td>Conservative (n=20)</td>
<td>4/20 (20%)</td>
<td>12/20 (60%)</td>
<td>4/20 (20%)</td>
<td></td>
</tr>
<tr>
<td>Amputation (n=14)</td>
<td>2/14 (14%)</td>
<td>10/14 (71%)</td>
<td>2/14 (14%)</td>
<td></td>
</tr>
<tr>
<td>Surgical intervention (n=54)</td>
<td>4/54 (7%)</td>
<td>45/54 (83%)</td>
<td>5/54 (9%)</td>
<td></td>
</tr>
</tbody>
</table>

The accuracy, sensitivity, specificity, negative and positive predictive values of duplex scanning in predicting the performance of infrainguinal PTA and the selection of lesions at various segments for PTA are given in Table XIV. Sixty-two limbs were correctly scheduled for PTA using the findings obtained from duplex scanning (62/74; 84%). However, in 24 cases undergoing PTA at multiple arterial levels, duplex scanning demonstrated either non-diagnostic findings or missed lesions in one of the arterial segments treated by PTA. The accuracy of duplex scanning in the selection of femoropopliteal and crural lesions for PTA was over 85%. However, the sensitivity of duplex scanning in the selection of popliteal and cural lesions for PTA was 49% and 38%, respectively, compared with 80% for SFA lesions.

Table XIV. The accuracy, sensitivity, specificity, negative and positive predictive values of duplex scanning in predicting performance of infrainguinal PTA and the selection of lesions at various segments for PTA

<table>
<thead>
<tr>
<th>Prediction of PTA</th>
<th>Accuracy</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance of PTA</td>
<td>86%</td>
<td>84%</td>
<td>89%</td>
<td>86%</td>
<td>87%</td>
</tr>
<tr>
<td>SFA PTA</td>
<td>90%</td>
<td>80%</td>
<td>94%</td>
<td>88%</td>
<td>90%</td>
</tr>
<tr>
<td>Popliteal PTA</td>
<td>85%</td>
<td>49%</td>
<td>97%</td>
<td>83%</td>
<td>85%</td>
</tr>
<tr>
<td>Crural PTA</td>
<td>91%</td>
<td>38%</td>
<td>95%</td>
<td>35%</td>
<td>96%</td>
</tr>
</tbody>
</table>
DISCUSSION

Femoropopliteal PTA

Endovascular intervention is at present generally accepted as an effective treatment modality in a substantial proportion of occlusive iliac artery lesions, but in the femoropopliteal segment its role is still the subject of debate (Blair 89, Durham 94, Fletcher 86, Martin 99, Jonston 92, Stanley 96, TASC 00, Parson 98). The relative simplicity of the procedure, the possibility of being able to recanalise long occlusions and the apparently low incidence of complications has encouraged the extension of indications for treatment of lower limb arterial insufficiency. Despite the recent enthusiasm for the procedure, demonstrated in wide application of PTA in the femoropopliteal segment, guidelines for selection and factors affecting outcome in limbs with CLI are controversial.

Procedure-related serious complications following PTA of the femoropopliteal lesions, either mortality or limb loss, have been reported in 0–2% of cases (Matsi 94, Hunink 93, Karch 00, Martin 99, Currie 94, Becquemin 94). The 30-day mortality rate was 4.3% in the present study. This is higher than in the previous reports and is possibly due to the inclusion of only those having critical lower limb ischaemia with a substantial number of elderly patients in poor general health. The early technical success rate varied between 78–100% in the previous reports, being low in long occlusions compared to short isolated lesions. The technical success rate in this study was 88%; 75% of failures occurred in those with superficial femoral artery occlusions 5 cm or more in length. Two patients underwent emergency bypass grafting but no limb loss was directly related to a failed procedure causing distal embolisation or thrombosis.

Mid- and long-term results of infrainguinal PTA depend on several factors, mainly clinical and anatomic ones. Some studies imply that the results were worse in limbs with CLI compared to those with claudication (Hunink 93, Albäck 98, London 95). Although the definition of CLI has not been uniform in many of these studies, it should be noted that there are no universally accepted guidelines to grade those with severe ischaemic symptoms and ankle pressures greater than 50 mm Hg. Subcritical ischaemia might be an alternative. In the present study, no attempts beyond the clinical presentation were made to grade severe ischaemia as subcritical or critical, but those with disabling claudication without rest pain and/or ulcers were excluded. Hunik et
al (1993) demonstrated a 5-year patency rate of 55% in claudicants compared
to 29% in those with CLI. Albäck et al (1998) showed a similar trend in
patients with CLI (patency rates of 61% versus 38% at 2 years).

Of the anatomical factors, the type of lesions dilated and the status of distal
runoff vessels have been pointed out to influence the results of
femoropopliteal PTA. A statistically significant difference was noted between
patients undergoing PTA for stenosis versus occlusion in several previous
studies (Matsi 94, Hunink 93, Karch 00, London 95, Currie 94, Melliere 01).
However, Murray et al (1987) showed that occlusions that can be crossed
with a guide wire have a better patency rate than stenosis. The results of our
study showed a significantly worse outcome in limbs with occlusions
compared to those with stenotic lesions. The cumulative primary patency at 5
years was only 12% for superficial femoral artery occlusions longer than 5
cm in length, compared to 32% for shorter occlusions. On the basis of these
observations, we consider occlusions longer than 5 cm as unsuitable for
conventional PTA.

Subintimal angioplasty has been used with satisfactory results by Bolia et al
(1998) even in the treatment of long occlusive lesions, but these excellent
results are yet to be verified by others. The use of thrombolysis in an attempt
to reduce the length of occlusion prior to PTA in limbs with chronic
occlusions is also controversial with regard to the selection of patients
(Weaver 96). A small, randomised trial demonstrated no difference between
enclosed thrombolysis and PTA versus PTA alone in the treatment of
femoropopliteal occlusions (Nicholson 98, Capek 91). Our experience with
thrombolysis in chronic occlusions is limited. It was used only in five patients
in the present series with successful outcome only in two cases.

The status of distal runoff has been shown to influence outcome after
femoropopliteal PTA (Flueckinger 92, Horwath 90, London 95, Sivanthan
94, Ray 95). In a study by Albäck et al (1998), the haemodynamic success
rate was 60% at 2 years in limbs with good runoff defined by the
SVS/ISCVS criteria, compared to 38% in limbs with poor runoff. The
number of patent crural arteries or the status of foot vessels did not show any
significant influence on the patency rates in the present study. It should be
noted that the majority of patients in this study had severe infrapopliteal and
pedal atherosclerosis and that the numbers in each group are probably not
sufficient for an assessment of patency rates and the status of runoff with
respect to the type of lesions dilated.
The overall patency rate following femoropopliteal PTA in the present study was lower than in most of the previous reports (Capek 91, Johnston 92, Hunink 93, London 95, Ray 95, Currie 94, Martin 99, Stanley 96, Parsons 98, Karch 00, Jackson 01). It is important to note that patency rates in the majority of previous studies were based on the findings obtained mainly from clinical and haemodynamic evaluations, not routinely on results of duplex scanning or angiography of the dilated segment. It is reasonable to assume that the real patency rates of the segment where the intervention was made might be less than the patency rates based on clinical evaluation, as some patients experienced clinical improvement despite restenosis or occlusion. Nearly 80% of the procedures in the present study were followed by duplex scanning and the majority of patients that did not undergo duplex scanning had obvious clinical signs of occlusion of the dilated segment in the early post-PTA period. Duplex scanning might also have an important role in the detection of residual stenosis and repeated PTA may extend the interval of clinical success.

**Crural artery PTA**

The application of PTA in arteries below the knee initially suffered from certain technical disadvantages related to the larger size of catheters required to restore an adequate lumen, but the introduction of suitable-sized catheter shafts and balloons in recent years has made it technically possible to dilate stenosis of the crural arteries. With the introduction of a low-friction guide wire it has also been possible to recanalise occluded arteries in the lower leg.

It is generally accepted that crural artery PTA should be performed only in limbs with CLI. The place of crural artery PTA in limbs with claudication, performed mainly as a combined proximal and distal procedure in order to improve the distal runoff, is still controversial.

A high technical success rate (88%) and a low complication rate of crural artery PTA were observed in the present study, and these results are in agreement with other reports (Bolia 94, Durham 94, Schwarten 88, Brown 93, Horwath 90, Bakal 90, 96, Saab 92, Bull 92, Sivananth 94, Flueckiger 92, London 95, Dorros 90). It seems plausible that the high technical success rate in occluded arteries is related to the small diameter of the occluded crural artery, which makes it relatively easy to find the thrombosed lumen with a guide wire. The problem of distal embolisation from the site of PTA in the femoral or popliteal arteries was abolished when the order of PTA procedures
was changed. We believe that manipulating catheters and guide wires through a dilated area may dislodge atherosclerotic material. The large groin haematomas all occurred when large introducers with 2.3mm (7 French) shafts were used early in the series for superficial femoral artery angioplasty. No amputations were directly related to a technical failure of the PTA.

Although the patients in this series were followed with regular ABPI measurements, the decision on patency was based on categorical improvement in clinical status in those limbs with falsely elevated ankle pressures. One should also be aware of the fact that, especially in those limbs with combined femoropopliteal and crural artery PTA, clinical and/or ABPI improvements do not necessarily mean that crural arteries are patent. Serial duplex scanning, which has been commonly used in recent years, might offer better follow-up evaluation. It might also be useful for the detection of restenosis. Reintervention before total occlusion in such cases might provide better secondary patency rates, as seen in previous reports (Bergamini 95, Lundell 95, Vroegindeweij 95, Veith 90).

There is only limited experience of long-term cumulative patency rates of crural artery PTA in patients with CLI (TASC 00). The reported limb salvage rate at 24 months of 60–86% (Wagner 98, Boyer 00, Soder 00, Danielsson 01, Wolfle 00) is well in accordance with the result in the present study (75%).

Our overall primary patency rate of 36% at 36 months might be considered poor though, compared with reported patency rates of femorodistal bypass graftings in patients with CLI (around 80% with vein grafts at 3 years) (Gentile 96, TASC 00, Blair 89, Veith 86, Taylor 90, Martin 99, Parson 98, Hunink 94, Bolia 94, Sanchez 94, Wolfle 00). On the other hand, it should be noted that in this series 20 patients underwent amputation after failed crural artery PTA without any attempt at distal reconstruction, due to severe distal atherosclerotic involvement; this demonstrates a high-risk group for limb loss that is not suitable for initial reconstructive surgery. In the present study, the satisfactory limb salvage rate at 36 months might be overestimated, due to a probably false definition of CLI solely according to clinical presentation because of falsely elevated ankle pressures.
Infrapopliteal PTA through infrainguinal grafts

Infrainguinal bypass grafting is the most established type of intervention for treatment of limbs with CLI affecting femoropopliteal and crural arteries. Graft failures occur due to various causes. It is beyond the scope of this thesis to discuss this issue in detail but, in summary, failures in the first month are usually due to technical problems or incorrect patient selection. Between the first and 24 month, intrinsic graft lesions either in the graft (vein grafts) or at the anastomotic sites, irrespective of the graft material, are essentially induced by myointimal hyperplasia (Davies 94). After two years, progressive atherosclerotic disease might lead to stenosis or occlusion of the runoff arteries. According to several series, 20–50% of these lesions are responsible for haemodynamic failure or graft occlusion (Gutierrez 87, Palumbo 91, McLafferty 95, Bergamini 95, Davies 94, London 93, Grigg 88, Houghton 97).

There are no universally accepted guidelines for the detection and management of inflow, graft or runoff-related problems. Atherosclerotic disease affecting the inflow arteries is usually managed with endovascular intervention, as the results of iliac artery PTA are satisfactory. On the other hand, surgical interventions are preferred for the treatment of femoral artery or proximal anastomotic stenosis. The choice of treatment between endovascular or surgical intervention, with regard to intrinsic lesions located in the graft itself, depends on the time interval after surgery and the policy of the centre. Contradictory results have been reported in those with graft stenosis treated by endovascular techniques and it seems that a randomised study is needed (Wittemore 91, London 93, Tonessen 98, Taylor 91, Houghton 97, Perler 90, Gonsalves 99, Hoksbergen 99). The lesions affecting the distal anastomoses or the runoff vessels that jeopardise the graft patency can be successfully managed by surgical intervention, mainly by a jump graft to a patent distal artery with a primary patency rate at 3 years of about 80% (Bandyk 91, Sullivan 96, Veith 84, Nehler 94, Avino 99). However, these procedures are more technically demanding than the surgical management of more proximal lesions and many of these patients do not have suitable vein conduits for reconstruction because of having undergone several operations. Endovascular interventions might be an alternative in those cases and that was the reason for the separate analysis of the results of distal PTA through infrainguinal bypass grafts in the present study. Previously, few studies, with limited numbers of patients, have been reported on the use of PTA in the runoff arteries following infrainguinal bypass grafting (Thomson 98, Favre 96, London 93, Tonesson 98, Taylor 91, Houghton 97, Perler 90, Sanchez
In these studies, the results of runoff PTA were difficult to interpret as the series included graft lesions at other locations and separate analysis was not performed. Sanchez et al (1994) have compared patency rates at various locations. There was no difference in patency rates at 6 months between patients undergoing PTA at proximal anastomosis, mid graft or distal anastomosis.

The results of this thesis demonstrated a high technical success rate (91%) and no major complications directly related to the procedure. The primary patency rates following PTA at 12 and 36 months were 41% and 32%, respectively. Several additional PTA procedures were required due to restenosis or reocclusion at the PTA sites in order to achieve 53% primary assisted patency. Duplex scanning plays an important role in the detection of these lesions and surveillance is strongly recommended. Analysis of several anatomical factors such as the site of PTA, the type of lesion, the status of runoff, the presence of diabetes and the use of thrombolysis before PTA in occluded grafts did not show a subgroup with significantly lower patency rates. It should be noted that the numbers in each group were limited. Early or late failures of PTA did not negatively affect the possibility of performing bypass surgery. Some patients underwent amputation following occlusion of the reconstruction, mainly due to extensive distal atherosclerosis, which made surgical intervention technically impossible.

The present study does not permit any firm conclusion regarding the selection of treatment modality in infrainguinal grafts with stenotic or occlusive lesions at the distal anastomosis or in the runoff arteries. We did not attempt to compare the results of PTA with surgical interventions, due to the fact that the severity of lesions in the runoff arteries was not anatomically comparable. During the study period we preferred to perform PTA according to the previously mentioned selection criteria as the choice of initial treatment. A prospective randomised trial might offer better guidelines, but unfortunately it is not possible to perform a single-centre study due to the limited number of patients.

**Accuracy of infrapopliteal duplex scanning**

The rationale behind noninvasive vascular diagnosis with duplex scanning is for it eventually to replace diagnostic angiography which has been considered the ‘gold standard’ for diagnosis of peripheral vascular disease. Angiography provides the necessary information for strategic planning for endovascular or surgical intervention but, on the other hand, it is invasive and is not without
complications (Hessel 81, Bettman 97, Waugh 92, Bonn 96). Satisfactory and reliable arterial mapping of the lower extremity with duplex scanning might provide the necessary information for the selection of patients for endovascular interventions or surgical reconstructions without the need for conventional diagnostic angiography.

The experience with duplex scanning for the diagnosis of crural artery lesions is limited (Moneta 92, Koelemay 98, Larch 97, Ascher 99, Aly 98, Sensier 98). Duplex scanning for the evaluation of pedal arteries has not been studied previously. The overall accuracy of cruropedal artery duplex scanning in comparison with selective angiography in this study was 80%. The accuracy of duplex scanning was similar for the crural and pedal arteries. The relatively low specificity for the peroneal artery is probably due to difficulties in obtaining satisfactory visualisation of this artery, which is located at a deeper level. This study also demonstrated the feasibility of obtaining reliable evaluation of distal runoff vessels such as the dorsal pedal arteries and plantar arch, especially in limbs with CLI and low ankle pressures. The accuracy of duplex scanning in the crural arteries was slightly lower in study V, despite the experience of the laboratory and the fact that duplex equipment has been improved in recent years. It should be noted that the prospective comparative study IV was performed by the most experienced vascular technicians or physicians. They used the most optimal equipment available in the laboratory. Such optimal conditions are not always obtained for all duplex scans in daily activity, for various reasons. The number of patients undergoing lower limb duplex scanning is increasing tremendously and it might be occasionally difficult to maintain high diagnostic quality in many vascular laboratories.

**Selection of patients for infrainguinal PTA**

Appropriate location of the lesions by duplex scanning permits the use of selective angiography, such as antegrade puncture of the femoral artery, which eliminates the need for retrograde angiography and PTA can be performed at the same session. This also lowers the amount of contrast agent given during the endovascular procedure as renal insufficiency is a feared complication, especially in patients with elevated serum creatinine levels. Several previous studies have demonstrated the value of duplex scanning in the selection of patients for PTA at various arterial segments in the lower extremity (Moneta 92, Karacagil 94, 96, Varty 96, Bodily 96, van der Zaag 98, Ascher 99, Schneider 99, Kohler 90, van der Heijden 93, Lai 95, Ramaswami 99, Katsamouris 01, Aly 99). Although the accuracy of duplex scanning was not perfect in some studies, it has been suggested that when the
findings were combined with clinical information, it can be safely used as a screening tool to select appropriate lesions for endovascular procedures. MR angiography has also been successfully used for this purpose (Cambria 97, Wikström 00, Schmiedl 96, Baum 95, Owen 92, Yin 95, Carpenter 92, Levy 98, Sarkar 98). It seems that successful application of such noninvasive modalities in patients with lower limb arterial insufficiency requires an institutional validation of MR angiography or duplex scanning against conventional angiography.

The results of this study demonstrated that duplex scanning can safely be used for the selection of patients for infrainguinal endovascular procedures. However, the findings should be interpreted cautiously due to the retrospective nature of the study. Even though the findings obtained from duplex scanning and angiography were subjected to blind analysis by two different investigators, selection bias could not be completely avoided. The accuracy of duplex scanning in the selection of femoropopliteal and crural lesions for PTA was over 85%. However, the sensitivity of duplex scanning in the selection of popliteal and crural lesions for PTA was 49% and 38%, respectively, compared with 80% for SFA lesions. The accuracy of duplex scanning in the diagnosis of multiple distal lesions that were treated by PTA was relatively low: in 39% of patients who were correctly selected for PTA, duplex scanning misdiagnosed one of the multiple lesions treated by PTA. The number of cases undergoing diagnostic angiography where the lesions were not amenable to PTA or surgical intervention could be diminished either by further experience in duplex scanning or by the use of MR angiography in cases that have non-diagnostic duplex scans.
CONCLUSIONS

1. The results of infrainguinal PTA performed for treatment of subcritical or CLI seemed to be inferior to the results of open surgical interventions reported in the literature. However, due to the fact that the PTA procedure does not preclude the performance of bypass grafting, it might be an alternative to surgical intervention in limbs with stenotic lesions. PTA might also be considered in patients with high surgical risk and limited life expectancy, having short occlusive lesions (< 5 cm).

2. PTA at the distal anastomotic site or runoff arteries following infrainguinal bypass grafting is technically feasible and offers satisfactory but inferior results compared to surgical revisions reported in the literature. As the complications with regard to technical failures did not affect the possibility of performing surgical intervention, PTA might be considered as an alternative for a selected group with suitable lesions.

3. Duplex scanning can safely be used for the selection of patients for infrainguinal PTA. The sensitivity of duplex scanning in the selection of lesions for PTA was less satisfactory in the popliteal and crural arteries compared to the superficial femoral arteries.
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