Haemodynamic Results of Femoropopliteal Percutaneous Transluminal Angioplasty

A. Albäck¹, F. Biancar², S. Schmidt¹, P. Mikkola¹, I. Kantonen¹, S. Mätzke¹, S. Peltonen¹, O. Saarinen², E. Tierala², J. Edgren² and M. Lepäintalo¹

¹Division of Vascular Surgery and ²Department of Radiology, Helsinki University Central Hospital, Helsinki, Finland

Objectives: To determine the utility of percutaneous transluminal angioplasty (PTA) of the femoropopliteal segment in patients with claudication and critical leg ischaemia (CLI).

Design: Longitudinal observational study.

Setting: A university based vascular surgical centre.

Material: Ninety-five patients with stenosing or occlusive arterial lesions of the femoropopliteal segment underwent 52 primary PTA for claudication and 50 primary PTA for CLI.

Methods: The procedure was considered haemodynamically successful when the increase of immediate postprocedural ABI was 0.15 or more. The criterion for haemodynamic success during follow-up was an ABI having not decreased by more than 0.15 from the immediate postprocedural level. The run-off arteries were graded according to the scoring system proposed by the SVS/ISCVS.

Results: Among the technically successful procedures (83%), the haemodynamic success rate was 77% at 1 month, 55% after 1 year, and 51% after 2 years. The cumulative haemodynamic success rates were 83%, 66% and 61% in claudicants, and 70%, 42%, and 38% in CLI (p = 0.03). In patients with a run-off score \( \leq 7.5 \), the success rates were 84%, 67%, and 60%, respectively, whereas in those with a crural score > 7.5 these were 61%, 39%, and 39%, respectively (p = 0.04).

Conclusions: The haemodynamic results suggest that PTA to the femoropopliteal segment is seldom a procedure of choice for critically ischaemic legs with poor run-off. The run-off score is useful in identifying patients who may benefit from PTA.

Key Words: Claudication; Critical leg ischaemia; Femoropopliteal; Percutaneous transluminal angioplasty; Angiographic score.

Introduction

Percutaneous transluminal angioplasty (PTA) has emerged during the past three decades as a popular but controversial alternative to bypass surgery for the treatment of leg ischaemia. Immediate haemodynamic assessment as well as long-term follow-up with objective methods are mandatory to verify the success of any method of arterial reconstruction. According to the suggested reporting standards for lower extremity percutaneous procedures,¹² patency should be determined by objective means such as angiography, duplex, or appropriate pressure measurements, i.e. ankle-brachial index (ABI). Although colour-duplex has been recommended for postprocedural surveillance, haemodynamic evaluation using pressure assessment is reported to be the best objective method for the follow-up of endovascular interventions.³⁴

Herein, we report our results of femoropopliteal PTA in the treatment of both claudication and critical ischaemia (CLI). Moreover, we retrospectively evaluated the impact of the angiographic Ad Hoc scoring system⁵⁶ on the immediate and long-term results.

Materials and Methods

Patients with claudication or CLI who had their main lesions in the femoropopliteal segment and who did not undergo any previous angioplasty or vascular surgery were scheduled for this study. Ninety-five patients with 102 legs fulfilling these criteria were...
Table 1. Clinical data and preoperative risk factors.

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Claudication</th>
<th>CLI</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of legs</td>
<td>52</td>
<td>50</td>
</tr>
<tr>
<td>Sex M/F</td>
<td>33/19</td>
<td>17/33</td>
</tr>
<tr>
<td>Mean age (range)</td>
<td>68.0 (13.7)</td>
<td>71 (13.0)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>11</td>
<td>25</td>
</tr>
<tr>
<td>Smokers</td>
<td>28</td>
<td>13</td>
</tr>
<tr>
<td>Hypertension</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>CAD</td>
<td>12</td>
<td>22</td>
</tr>
<tr>
<td>CVD</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Mean preprocedural ABI (range)*</td>
<td>0.55 (0.16)</td>
<td>0.50 (0.21)</td>
</tr>
<tr>
<td>Mean popliteal run-off score (range)</td>
<td>1.0 (3.0)</td>
<td>4.0 (3.0)</td>
</tr>
<tr>
<td>Mean crural run-off score (range)</td>
<td>3.5 (5.0)</td>
<td>8.0 (5.0)</td>
</tr>
<tr>
<td>Stenoses/occlusions</td>
<td>18/34</td>
<td>18/32</td>
</tr>
<tr>
<td>Mean length of stenoses (range)*</td>
<td>1.3 (0.9)</td>
<td>0.8 (1.9)</td>
</tr>
<tr>
<td>Mean length of occlusion (range)*</td>
<td>3.5 (3.8)</td>
<td>2.4 (5.0)</td>
</tr>
<tr>
<td>Mean length of PTA (range)*</td>
<td>8.0 (10.0)</td>
<td>8.0 (8.2)</td>
</tr>
</tbody>
</table>

CAD: coronary artery disease; CVD: cerebrovascular disease; *in cm.

encountered in the Division of Vascular Surgery, Department of Surgery, Helsinki University Central Hospital from February 1991 to December 1993. According to the Fontaine classification the primary indication was claudication in 52 legs (51%), while 50 (49%) patients had critical leg ischaemia (CLI), of which there were 18 legs (17%) with rest pain, 28 legs (27%) with ulcer and four legs (4%) with gangrene. When applying the criteria of the SVS/ISCVS,5 25 patients had clinical findings and pressures representing critical ischaemia, while 25 patients had pressure measurements not fulfilling the critical leg ischaemia criteria, despite the presence of rest pain, ulcer or gangrene.

In the initial evaluation the following data were recorded: sex, age, history of previous vascular operations, smoking, coronary heart disease, diabetes, hypertension, cerebrovascular disease and clinical leg status. All patients underwent ankle pressure measurements and ankle pulse volume recordings. The ankle-brachial index (ABI) were calculated. Toe pressure measurements were performed in selected cases. During preprocedural diagnostic angiography the length of femoropopliteal stenoses or occlusions was determined, X-rays were also obtained to evaluate the inflow and outflow arteries. The clinical data and risk factors are listed in Table 1.

The procedure was performed in conjunction with the diagnostic angiography, after an antegrade puncture and the insertion of a 6 or 7 French introducer sheath (Cordis Comp., Miami, FL, U.S.A.) into the ipsilateral superficial femoral artery. The stenoses were primarily crossed using a 5F straight diagnostic catheter (Cordis Comp., Miami, FL, U.S.A.) and either a Terumo (Radifocus), a NaviGuide™ (Meadox, Surg, Med.) or a Teflon coated J-curved (Meditech) guidewire. A single or multiple dilatations, depending on the length of the lesion, were performed with a balloon catheter (Cordis Comp., Miami, FL, U.S.A.) that equalled the normal portion of the same artery, which varied between 4 and 8 mm. The balloon inflation was carried out with a 20 ml inflation device (Merit Medical System Inc., Salt Lake City, UT, U.S.A.) to a maximum pressure of 8 atmospheres. Occluded segments were crossed with the same equipment either through the thrombus or subintimally. Balloon dilatations were performed according to the length of the treated occlusion.

The procedures were defined as technical failures if the lesions could not be traversed with the guidewire, if the guidewire was placed subintimally without proper distal re-entry or if the treated segment was occluded on the completion angiogram. During both recanalisation and dilatation procedures, the patients received 5000 IU of heparin (Lovenchemiske Fabrik, Ballerup, Denmark). Post-PTA medical therapy consisted of a daily dose of 250 mg of acetylsalicylic acid.

Patients with technically successful PTA procedures were all included in the prospective follow-up study. Duplex scans and ABI measurements were performed in all patients on the first postprocedural day. The procedure was considered an immediate haemodynamical success if the treated segment was anatomically patent and the ABI had increased by 0.15 or more from the preoperative value. The term immediate referred to the postprocedural in-hospital period. In the outpatient clinic the patients were evaluated clinically and with ABI measurements at 1, 3, 6, 9, and 12 months, and thereafter every 6 months. The criterion for haemodynamic success was an ABI that was increased, unchanged or decreased less than 0.15 compared to the maximum immediate postprocedural level. Objective haemodynamic success and failure in this report refer to these criteria. The median follow-up time was 18 months (interquartile range 27).

After completion of the follow-up study we also retrospectively evaluated the run-off status from the preprocedural diagnostic angiogram according to the system proposed by the Ad Hoc Committee on Reporting Standards, SVS/ISCVS.5 For the crural run-off score each of the crural arteries were given a raw score (a number from 0 to 3 depending on presence of stenoses or occlusion in the respective arterial segment), which was multiplied by a weighting factor (in this case the factor was always 1). To the sum of these three scores was added one giving a total run-off score of 1–10, where 1 refers to a normal run-off and 10 to a blind popliteal segment. The angiographic scoring was performed by one blinded radiologist (PM), without knowledge of the clinical results. As proposed by...
Peterkin et al., we calculated both the popliteal and crural run-off scores, the former being more simple and referring only to the status of the popliteal artery distal to the treated lesion.

Statistical analysis of data was facilitated by the use of the SPSS statistical software package (SPSS for Windows 7.0, SPSS Inc., Chicago, U.S.A.). Comparisons of the distribution of risks factors between subgroups were made with Chi-squared test for parametric factors. The distribution of non-parametric variables were expressed as the median and interquartile range (IR) and the significance was evaluated with the Mann–Whitney U-test. Cumulative haemodynamic success rates, the leg salvage and patient survival rates were calculated using the Kaplan–Meier life table method. The statistical significance for differences between subgroups were determined with the log rank test. The Cox regression model was used for multivariate analysis of the impact of preoperative risk factors on the haemodynamic outcome during follow-up, while a logistic regression model was used for immediate haemodynamic outcome. The results were expressed as the risk ratio (RR) and the p value. Receiver-operating characteristic (ROC) curves were used to define an appropriate cut-off value for the Ad Hoc scoring system. Four legs, where the ankle pressure measurement was disturbed by medial sclerosis, were excluded from the analysis regarding ABI.

Results

The technical success rate was 83%. Technical success included 27 dilatations and 16 recanalisations in claudicants, and 23 dilatations and 19 recanalisations in patients with CLI. Among the patients who had a technically successful procedure, an immediate haemodynamic success was obtained in 38 legs with claudication (74%) and in 32 critically ischaemic legs (64%). The median overall postprocedural ABI was 0.88 (IR 0.27) in claudicants and 0.83 (IR 0.25) in CLI patients with an increase from the preprocedural values of 0.32 and 0.33, respectively.

During the follow-up period, we observed a further increase of the ABI from the immediate postprocedural level in 25 claudicants (48%) and in 18 critically ischaemic legs (64%). The median overall postprocedural ABI was 0.88 (IR 0.27) in claudicants and 0.83 (IR 0.25) in CLI patients with an increase from the preprocedural values of 0.32 and 0.33, respectively.

The procedure resulted in a lower post-angioplasty ABI in four patients, one of whom required major amputation. The most common complication after PTA was a local haematoma which occurred in five patients (5%) and required surgical treatment in one case. Two patients with CLI died during the first postprocedural month, one of myocardial infarction after major amputation and the other of sepsicaemia due to peritonitis.

The overall haemodynamic success rate, excluding technical failures, was 77% at 1 month, 55% after 1 year, and 51% after 2 years. The cumulative primary haemodynamic success rates in claudicants were 83%, 66%, and 61%, wherein the cumulative primary haemodynamic success rate in CLI were 70%, 42%, and 38%, respectively (p = 0.03) (Fig. 1). The leg salvage rate in CLI was 91%, 84%, and 80%, at 1 month, 1 year and 2 years, respectively. One leg was amputated during the fourth postoperative month and another after 16 months in patients with initially claudication as the indication for the procedure. The overall survival rates were 98%, 97%, and 95%, respectively. At 1-year and 2-year follow-up, 97% and 95% of claudicants survived with their legs, while 81% and 71% of patients with CLI were alive with legs, respectively (p = 0.01).
Patients with claudication did not differ significantly from those with CLI as to the length of stenosis, the length of occlusion or the length of dilated arterial segment. The length of stenosis was significantly shorter in the legs with immediate haemodynamic success (median 1.0 cm, IR 1.4) compared to those with failure (median 3.3 cm, IR 2.7), \( p = 0.009 \). The length of occlusion and the length of dilated arterial segment did not differ significantly in terms of immediate haemodynamic outcome.

The median values of both popliteal \( p<0.001 \) and crural \( p<0.001 \) score values were significantly better in claudication compared with CLI. There was a significant difference in the Ad Hoc crural score in the legs with immediate haemodynamic success (median 4, IR 7) compared to those with immediate haemodynamic failure (median 7.5, RI 5.4) \( p = 0.03 \). The ROC curve for crural score in predicting immediate haemodynamic success had an area under the curve of 73% (s.e. 0.26), the best cut-off point of the method was 7.5, the sensitivity was 0.58 and the specificity was 0.74. In the subgroup of patients with an angiographic crural score of less or equal to 7.5, we found that the haemodynamic success rates at 1 month, 1 year, and 2 years were 84%, 67%, and 60%, respectively. At the same intervals, in the subgroup of patients with angiographic crural score more than 7.5 the patency rates were 61%, 39%, and 39%, respectively \( p=0.04 \) (Fig. 2). The patients defined as having critical leg ischaemia and fulfilling the SVS/ISCVS criteria for pressures, had a median preoperative ABI of 0.39 (IR 0.24), while the patients with symptoms of critical ischaemia not fulfilling pressure criteria had a median ABI of 0.57 (IR 0.22), \( p = 0.001 \). However, both groups had the same median crural score of 8.0 (IR 4.8 and 5.0, respectively), and were therefore analysed together.

Of the preoperative risk factors investigated with multivariate analysis only recanalisations (RR 3.35, \( p = 0.03 \)) and the crural score (RR 1.3, \( p = 0.04 \)) showed an independent significant impact on the immediate haemodynamic success. The most important independent risk factors for the long-term haemodynamic result were smoking (RR 4.2, \( p = 0.04 \)) and the crural score (RR 1.3, \( p = 0.058 \)) according to multivariate analysis.

**Discussion**

The exact role of PTA in the treatment of femoropopliteal occlusive disease is hard to be defined. Because of the lack of properly conducted studies showing its efficacy, it has been regarded as an experimental procedure.\(^7\)

![Fig. 2. Cumulative patency after PTA in the subgroups of patients with a crural score less or equal to 7.5 and those with a crural score more than 7.5 \( p = 0.04 \). (--) Crural score >7.5; (■) crural score >7.5-censored; (---) crural score ≤7.5; (○) crural score ≤7.5-censored.](image)

Until recently, there has been little reliable information concerning long-term results associated with this technique. Patency rates at 4 years of 68% to 73% in femoropopliteal occlusions and 54% to 61% in femoropopliteal stenoses have been reported.\(^8,9\) However, patency is difficult to be assessed uniformly, and it has been shown that, by applying different criteria, the patency rates at a certain point may range from 42% to 82%.\(^10\) ABI changes have been widely accepted as an objective and quantitative method for assessment of the success of PTA.\(^3,4,11,12\) In our institution a change of ABI of 0.15 or more has been identified as the smallest significant change\(^13\) and it forms the basis of the present study. Even though it has been suggested that the ABI criteria alone is reliable in determining patency,\(^5\) we have evaluated the outcome as haemodynamic success. To determine the anatomic success a method showing morphology is mandatory. For the patient, however, the haemodynamic improvement is more relevant, particularly since a notable proportion of patients were treated for a stenotic arterial segment. Furthermore, it is not obvious that an endovascular procedure to a single arterial lesion, even with an anatomic improvement, improves the haemodynamic state of multilevel disease which is usually the case in CLI. In this report we have therefore concentrated on the haemodynamic outcome of the procedures.
To determine the utility of PTA in the treatment of chronic critical leg ischaemia, Matsi\textsuperscript{14} reported cumulative leg salvage rates of 56% at 1 year, 49% at 2 years, and 49% at 3 years. Regrettably the criteria for PTA failure, in his study, were the need for surgical revascularisation or the need for major amputation. In our series, we observed considerably better leg salvage rates than haemodynamic success rates which clearly illustrates that the use of leg salvage for assessment of the outcome of PTA is far from adequate. Furthermore, in a previous study we have demonstrated that 54% of 105 patients with objectively verified chronic critical leg ischaemia did not have to be amputated during 1 year of surveillance despite the fact that their arterial inflow to the ischaemic leg could not be improved by any type of revascularisation.\textsuperscript{15}

CLI, determined according to the Fontaine classification, revealed a haemodynamic success rate far worse than in claudicants. These data are not in accordance with the encouraging results reported by other authors\textsuperscript{16,17} and this may be due to the use of a stricter criterion for haemodynamic success.

The evidence of an association between the Ad Hoc crural scoring system and the clinical leg status, and the immediate and long-term results of PTA, confirmed how the extension of the atherosclerotic disease influenced the success of the procedure. Furthermore, it stresses the need for a reliable preprocedural grading system of the disease as a means to identify those patients who may benefit from the procedure and those who should be treated by primary surgical revascularisation.

On multivariate analysis the Ad Hoc crural score affected both the short-term and the long-term result. Contrary to the findings by Johnsson et al.\textsuperscript{18} occlusion and stenoses did not have different outcomes. These authors also found run-off an important predictor of outcome, but they used a simple binominal grading system. In univariate analysis the length of the stenosis was significantly shorter in patients with immediate haemodynamic success compared to those with failure. However, this result could not be confirmed on multivariate analysis, probably because of the fact that only 35% of the patients had a stenosis impaired the model. In addition we found that some patients with critical leg ischaemia as well as claudicants experienced an increase of ABI of more than 0.15 from the immediate postprocedural value. Interestingly, most of them had a preprocedural score value of less than 7.5. Therefore, even if the ROC curve had a large standard error, it showed that the Ad Hoc scoring system may be used to stage the arterial disease and identifying those patients whose arterial tree distal to the femoropopliteal lesion is suitable for immediate and a further long-term haemodynamic improvement. Since other techniques, such as magnetic resonance angiography, may detect patent run-off vessel segments not being opacified by contrast angiography, it could improve the resolution of the angiographic scoring system by identifying vessels which may be responsible for an overestimation of the degree of the disease as well as those cases with an apparent high preprocedural score and yet favourable outcome, as sporadically seen in our series.

In conclusion, although this study is not randomised, haemodynamic results suggest that a PTA procedure to the femoropopliteal segment is seldom appropriate as a treatment modality in patients with both critical leg ischaemia and poor run-off. The Ad Hoc crural score is useful in identifying those patients who may benefit from PTA.

Acknowledgements

We wish to thank Maritta von Bell, R.N., and Päiviikki Määttäla, R.N., for their skilful performance of the pressure measurements in the Vascular Laboratory, Anita Mäkela, R.N., and Maritta von Bell, R.N. for their assistance in the collection of the material, and Jukka Ollgren, M.S., for help with the statistical analysis. This study was supported by a grant from the Helsinki University Central Hospital Research Fund.

References

10. MATSI PJ, MANNINEN HI. Impact of different patency criteria on long-term results of femoropopliteal angioplasty: analysis of 106


Accepted 15 January 1998