Below-the-ankle Angioplasty is a Feasible and Effective Intervention for Critical leg ischaemia

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Abstract
Aim: Occlusion or severe stenosis of pedal and plantar arteries limits surgical options for critical limb ischaemia (CLI). Below-the-ankle (BTA) angioplasty is potentially useful as an adjunct to proximal angioplasty. In this study, the feasibility and outcome of this procedure were explored, as they have not been evaluated previously.

Methods: Patients’ demographics, indications, procedures and outcomes were recorded. Outcomes were determined by technical success, primary patency, limb salvage and amputation-free survival (AFS) rates.

Results: Between 2004 and 2008, 42 cases of BTA angioplasty were performed for 39 patients. Forty cases (95.2%) had CLI. Technical success was achieved in 88% of cases. At 6, 12 and 24 months, AFS was 70.7%, 60.9% and 57.1%, limb salvage was 84.9%, 81.9% and 81.9% and patient survival was 83.3%, 73.8% and 67.3, respectively. Seven major amputations (16.6%) were performed, four of which had failed angioplasty. Two patients required re-intervention. Univariate analysis showed insulin-dependent diabetics, occlusive lesions, failure of angioplasty and stage of other ulcers predicted of limb loss.

Conclusions: BTA angioplasty for pedal and plantar arterial occlusive disease is technically feasible. It has good medium-term clinical outcome and limb salvage in a group of patients with poor surgical options.

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The treatment options for patients with peripheral arterial disease (PAD) have increased. This is due to the technical and technological advancements in endovascular techniques, namely the introduction of extremely low-profile and dedicated devices and the development of subintimal angioplasty.1–3

Although angioplasty for infrapopliteal lesions has been discussed in many previous studies,4–9 no study has described the efficacy and outcome of below-the-ankle (BTA) angioplasty. To the best of our knowledge, only one report has presented the feasibility of angioplasty of the foot arteries.1,10,11 One report has even presented the experience of dorsalis pedis artery stenting in two cases.12

The development seen in the technologies used for angioplasty of the leg arteries and increasing expertise allowed the feasibility of BTA angioplasty. These developments have mirrored those used for coronary angioplasty.11,12

The aim of this study is to present the experience of BTA angioplasty in a single UK centre. We present the technical success, early- and medium-term outcomes, limb salvage rate and amputation-free survival (AFS).

**Patients and Methods**

We obtained a list of all patients who underwent pedal and/or plantar angioplasty at Selly Oak Hospital, University Hospital Birmingham NHS Foundation Trust, from January 2004 to November 2008. Patients were identified from a prospectively collected database (Dendrite Clinical Systems Ltd.). This list included names of patients, date of birth, hospital numbers, demographic data, co-morbidities, presentation, indication, date and type of intervention, degree of urgency, drugs administered during the procedure and their doses, side, site and type of lesions, intraluminal or subintimal dissection, maximum balloon dilatation, technical success, complications and post-procedural drugs. The list was organised on an Excel spreadsheet (Microsoft Office 2007).

A retrospective review of prospectively collected data was performed using the patients’ medical records. We recorded the presence of associated lesions and whether angioplastied or not, the degree of run off, the need for digital amputation or debridement, patency rate, clinical improvement, length of follow-up, limb salvage rate and survival.

Guidelines from the Joint Council of The Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery were used to assess procedural success and outcome.13

**Angioplasty**

It is our policy to perform angioplasty for the diseased dorsalis pedis and plantar arteries, if the lesion is suitable, to restore the continuity of blood flow to the foot. The indications of BTA angioplasty are the presence of tight stenosis (>70%) and/or a segmental occlusion where there is at least some filling of the target vessel beyond the occluded segment. We would not normally tackle a foot where there is no filling of named vessels beyond the occlusion. Percutaneous angioplasty was performed in all cases at the radiology department under local anaesthetic. This was done through an ipsilateral femoral approach except if there were associated ipsilateral or contralateral iliac lesions that required angioplasty at the same setting. In these situations, a contralateral femoral approach was used. Angioplasty was performed transluminally or subintimally depending on the nature and the position of the lesion. A 4-French vascular introducer was positioned to perform a preliminary angiographic study using the non-ionic iso-osmolar contrast medium Visipaque (iodixanol) 320 diluted up to 50%. A V-18™ Control Wire® 0.018-inch hydrophilic guide wire (Boston Scientific Corporation, Natick, MA, USA) was traversed through the arterial obstruction sites and 2–3 mm diameter 3–3.5 French shaft SAVVY® 4–10 mm long balloon catheter (Cordis Corporation, Miami Lakes, FL, USA) was used to dilate the arteries. Vessel re-canalisation was considered successful if direct flow was restored in the treated vessel with no residual stenosis >30% of the vessel diameter along the whole artery. During the procedure, sodium heparin (2000–5000 IU) bolus was infused into the arterial lumen; if vessel spasm occurred, a papaverine (15–30 mg) bolus was injected intra-arterially. Patients were prescribed dual anti-platelet therapy, aspirin 75 mg and clopidogrel 75 mg, for a month to be followed by lifelong aspirin 75 mg once per day unless contraindicated.

**Follow-up**

Patients who had digital amputation or wound debridement before or after BTA, stayed in the hospital until they showed signs of good healing. Patients who had BTA as day cases were discharged on the same day. Following discharge from the hospital, patients were seen in the outpatient clinic within 6 weeks. Thereafter, patients were followed-up according to their clinical condition. Patients with foot ulcers or wounds were followed-up until complete healing. Patients were discharged from the clinic if they were asymptomatic for a year. Follow-up depended on clinical evaluation of the vascularity of the foot. Detecting the pulse, manually or by Doppler, or duplex scanning, in addition to signs of wound healing, was the main method of assessment. Ankle brachial pressure index (ABI) was not relied on as two-thirds of patients were diabetics. Toe pressure and transcutaneous oxygen tension (TcPO2) were not performed as these do not include in the regular follow-up assessment in our centre. Patients who had major amputation were discharged from the clinic after the healing of their amputation stump.

**Statistical Analysis**

Major limb amputation was the primary endpoint. Univariate testing for clinical variables was performed by using the chi square test for proportions for nominal variables and Cochran’s test for trend for ordinal variables. P < 0.05 was considered significant. The time to major amputation and death was studied by applying Kaplan–Meier analysis to produce survival curves and the log-rank test was performed
to compare survival curves. The data were analysed with SPSS 16.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

From January 2004 to November 2008, we performed angioplasty for 3267 lesions in the radiology department at Selly Oak hospital for 1349 patients. Out of these, 42 cases of BTA angioplasty were performed for 39 patients. In two cases, both dorsalis pedis and plantar arteries were treated in the same foot. Table 1 shows the demographic data of these patients. Table 2 shows the breakdown of the lesions in different arteries.

Patients presented with critical limb ischaemia (CLI) in 95.2% of cases (40 legs). This was in the form of rest pain for more than 2 weeks, ulceration or gangrene. Patients were treated as urgent in patients in 71.4% and the remaining cases were treated as day cases. At time of intervention, 29 patients (74.4%) were older than 65.

In all cases, except one, the lesions were tackled through the ipsilateral approach. In this exceptional case, there was a contralateral iliac lesion that was treated in the same sitting. The dorsalis pedis and plantar arteries were involved in 71.4% and 33.3% of cases, respectively. (Figs. 1 and 2) In 38.1% of cases, the involved arteries showed occlusive lesions. In all 42 cases, there were associated lesions in one or more of the tibial arteries. The state of distal run off is shown in Table 3. The femoro-popliteal segments had associated lesions in 42.9% of cases. Associated femoro-popliteal and tibial arterial lesions were treated with the same procedure. Transluminal angioplasty (TLA) was performed in 40 cases and subintimal angioplasty (SIA) was performed in two cases. Rupture of the treated artery occurred in one case, which did not require surgical intervention. Angiographic success was achieved in 88% of cases and five cases (12%) had failed angioplasty (Fig. 3).

Eleven patients (26.2%) had toe amputation in the same admission. Major amputation in the form of below-knee amputation (BKA) was performed in seven cases (16.6%). Four were performed during the same admission and three had BKA at 4 weeks, 4 and 6 months, respectively. Limb loss was significantly greater in patients with occlusive than stenotic lesions (p < 0.001) and in those who had failed in comparison with successful angioplasty (p < 0.001) (Chi square test). Sex, diabetes mellitus, hypertension, chronic renal failure, smoking and high blood cholesterol were not significant risk factors for limb loss (Table 1). Mean follow-up was 15.37 months (SE 2.6).

At 6, 12 and 24 months, AFS was 70.7%, 60.9% and 57.1%, respectively. Limb salvage rate was 84.9%, 81.9% and 81.9% and patient survival rate was 83.3%, 73.8% and 67.3 at the same periods, respectively (Figs. 4, 5 and 6).

Discussion

Revascularisation by means of percutaneous transluminal angioplasty (PTA) has become the first line of management for patients with PAD. In patients with CLI, the aim of revascularisation is to provide sufficient blood flow to relieve rest pain and/or allow healing of the ischaemic foot lesion.14,15 The ideal revascularisation is the one that avoids a general anaesthesia, poses a lesser systemic stress and has fewer serious complications.2

PAD is more common in diabetics and presents at young age with minimal sex difference. It is usually multilevel, more distal and progresses faster to CLI.10 Diabetic patients are significantly less able to develop arterial collaterals and this explains why the majority of patients with CLI are diabetics.17,18 The anatomical distribution of PAD is specific in diabetics. In one study examining 417 CLI diabetic patients with ischaemic foot lesions undergoing lower limb angiography, 74% of lesions were in below-the-knee (BTK) arteries. A total of 66% of these lesions were occlusive in nature and all BTK arteries were occluded in 28%.19

Patients with CLI commonly present with lesions in BTA arteries. Occlusion of dorsalis pedis and plantar arteries is a serious cause of CLI. This anatomical pattern may prohibit distal bypass for limb salvage or render it unsafe.11,13 We believe, like others, that establishing the continuity of blood flow to at least one foot artery is essential for healing of ischaemic foot lesions.11,13 Therefore, we have been performing BTA angioplasty at our centre since 2004 for all patients with lesions in the dorsalis pedis and/or plantar arteries that are suitable for angioplasty. During the period of 5 years, we performed 42 foot angioplasties mainly for CLI. In our protocol, PTA was the first-choice procedure for revascularisation. Improvements in the development of devices and the operator’s skills have led to increased success rates for BTA

Table 1 Demographic data of 39 patients.

<table>
<thead>
<tr>
<th>Category</th>
<th>Number (%)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>26 (66.6)</td>
<td>0.205</td>
</tr>
<tr>
<td>Mean age</td>
<td>72.41</td>
<td>–</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>26 (66.7)</td>
<td>0.058</td>
</tr>
<tr>
<td>Hypertension</td>
<td>27 (69.2)</td>
<td>0.884</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>34 (87.2)</td>
<td>0.863</td>
</tr>
<tr>
<td>Smoking</td>
<td>31 (79.5)</td>
<td>0.41</td>
</tr>
<tr>
<td>Chronic Renal Failure</td>
<td>6 (15.3)</td>
<td>0.072</td>
</tr>
</tbody>
</table>

* p-value was measured by a Chi squared test to assess significance for limb loss.

Table 2 Number of treated stenoses or occlusions in each artery from January 2004 to November 2008.

<table>
<thead>
<tr>
<th>Artery</th>
<th>Number of lesions angioplastied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infra-renal Aorta</td>
<td>16</td>
</tr>
<tr>
<td>Iliac arteries</td>
<td>552</td>
</tr>
<tr>
<td>Superficial Femoral artery</td>
<td>1499</td>
</tr>
<tr>
<td>Profunda femoris artery</td>
<td>47</td>
</tr>
<tr>
<td>Popliteal artery</td>
<td>418</td>
</tr>
<tr>
<td>Tibio-peroneal trunk</td>
<td>141</td>
</tr>
<tr>
<td>Anterior Tibial artery</td>
<td>221</td>
</tr>
<tr>
<td>Posterior Tibial Artery</td>
<td>113</td>
</tr>
<tr>
<td>Peroneal artery</td>
<td>126</td>
</tr>
<tr>
<td>Graft angioplasty</td>
<td>90</td>
</tr>
<tr>
<td>Dorsalis Pedis artery</td>
<td>30</td>
</tr>
<tr>
<td>Plantar artery</td>
<td>14</td>
</tr>
</tbody>
</table>
angioplasty. The characteristics of instruments used for this technique are extremely low-profile with the tip tapered to a 3-French crossing profile and varying balloon lengths (120–210 mm). It is worth noting that the use of over-the-wire technique provided superior pushability characteristics.

Out of the 42 procedures, five failed. In two of these cases, it was not possible to cross the lesion and, in one case, it was not possible to traverse the arterial lumen distal to the lesion. In the last two cases, there was immediate re-occlusion after SIA. Four of these five patients had BKA. Recurrence of symptoms occurred in two cases and re-intervention in the form of repeat angioplasty was performed at 6 and 9 months, respectively.

Fusaro et al.\textsuperscript{10} restored the continuity between plantar and dorsalis pedis arteries using SIA in an 84-year-old lady who presented with ischaemic foot ulcer. Fusaro also described a pedal–plantar loop technique.\textsuperscript{1} He used this technique as he could not cross the occluded dorsalis pedis artery. He used a perforator branch to reach the plantar artery and hence the posterior tibial artery. This technique of using the collateral arteries has been used in coronary intervention.\textsuperscript{20} Patients in both reports were diabetics. One

Figure 1  a: Foot angiography showing severe stenosis of DP artery, b: DP angioplasty using 2 mm balloon, c: completion angiography.

Figure 2  a: multiple stenosis of the plantar artery, b: balloon angioplasty of plantar artery using 2 mm balloon, c: completion angiography.
case showed complete healing of the ulcer at 4 months with no outcome reported about the second case.

Kawarada and Yokoi\textsuperscript{12} attempted to establish ‘one straight-line flow’ to the pedal arch by dorsalis pedis angioplasty. However, there was immediate dissection of the dorsalis pedis artery in one case and recurrent occlusion of the other case after 13 days. Kawarada and Yokoi used bare metal coronary stents to establish the antegrade flow from the anterior tibial artery to the dorsalis pedis artery. Dorsalis pedis pulse continued to be present up to 3 and 12 months, respectively. In the absence of randomised clinical trials to judge this technique, we believe that stenting of the dorsalis pedis artery should be a last option because the incidence of in-stent restenosis in such small arteries would be high and might compromise further intervention.

In our series, complete resolution of rest pain was achieved following BTA angioplasty. Wound healing was complete within 6 months after the procedure. Recurrence of symptoms requiring BTA re-angioplasty occurred in two cases. In one other case, recurrent symptoms required repeated angioplasties of a femoro-popliteal bypass graft, while the dorsalis pedis artery remained patent.

Our patients, like patients from other reports, underwent BTA angioplasty in addition to proximal, mainly tibial, angioplasty. This is because localised disease affecting the foot arteries with no proximal lesions does not, or rarely, exists. This could raise the question whether the results are due to BTA angioplasty or proximal angioplasty. We believe both proximal and distal angioplasties contribute to clinical improvement because four of the five patients (80\%) whose BTA angioplasty failed required BKA.

**Limitations**

One of the limitations of this study is that patients were discharged from the clinic after the disappearance of symptoms. However, we overcame this by reviewing their

<table>
<thead>
<tr>
<th>Run off arteries</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (no run off artery)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>1 (one run off artery)</td>
<td>28 (66.7)</td>
</tr>
<tr>
<td>2 (two run off arteries)</td>
<td>10 (23.8)</td>
</tr>
<tr>
<td>3 (three run off arteries)</td>
<td>3 (7.1)</td>
</tr>
</tbody>
</table>

**Figure 3** a: complete occlusion of Plantar artery, b: lesion was successfully dissected subintimally and ballooned using 3 mm balloon, c: immediate re-occlusion.

**Table 3** State of run off.

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**Figure 4** survival curve showing Amputation-Free Survival.

One of the limitations of this study is that patients were discharged from the clinic after the disappearance of symptoms. However, we overcame this by reviewing their
medical records to find any suggestion of the return of symptoms. Patients were contacted to make sure they were not referred to another hospital with recurrent symptoms. Another limitation is the absence of an objective method, such as toe pressure or TcPO2, to assess the outcome of the procedure. This is because we do not use these tests in day-to-day clinical practice. We rely on the clinical outcome represented by improvement of symptoms, healing of tissue loss, presence of pulses, good vascularity of the foot and patency of the arteries in duplex scanning.

**Conclusion**

BTA angioplasty is feasible. It provides good medium-term clinical outcome in a group of patients with limited treatment options. It is used as an adjunct to proximal angioplasty to increase the limb salvage rate. A randomised control trial is needed to establish the evidence-based results of this technique.

**Conflict of Interest/Funding**

None.

**Acknowledgement**

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**References**


