Percutaneous transluminal angioplasty of the arteries of the lower limbs: a 5 year follow-up

A. Gallino, F. Mahler, P. Probst, and B. Nachbur

ABSTRACT A total of 482 percutaneous transluminal angioplasties (PTAs) of the arteries of the lower limbs were performed in 411 patients between 1977 and 1983. The 5 year patency rate, calculated by the life table method, was 83% for iliac and 58% for femoropopliteal PTA. Clinical improvement after the procedure was confirmed by a significant drop of the arm-ankle pressure difference: 48 ± 5 mm Hg before vs 17 ± 5 mm Hg 2 years after iliac PTA (p < .01) and 73 ± 5 mm Hg before vs 28 ± 6 mm Hg after femoropopliteal PTA (p < .01). The majority of reocclusions occurred within the first year after angioplasty. Patients with stenoses or occlusions of less than 3 cm had a favorable long-term patency rate of 74%. Conversely, patients with femoropopliteal occlusions presenting with pain at rest, diabetes, occlusions of greater than 3 cm, or poor distal runoff had an elevated rate of reocclusion. Complications, which occurred in 8% of the patients in whom PTA was attempted, included local hemorrhage, dissection, embolism, and spasm necessitating surgical intervention in 2%. No deaths or amputations were a direct consequence of PTA. PTA of arteries of the lower limbs may thus be regarded as a valid complementary treatment to vascular surgery in patients with occlusive disease of the peripheral arteries. Circulation 70, No. 4, 619–623, 1984.

THE FIRST DESCRIPTION and report on the clinical application of transluminal angioplasty by Dotter and Judkins1 appeared in Circulation 20 years ago, but only after technical improvement in the original Dotter procedure was made by Grünzig2 did the method gain popularity. He developed a double-lumen catheter with a preshaped balloon that could be used in the treatment of arteries of the lower limbs,3 and that, a few years later, was modified for use in the coronary and renal arteries.4,5 Percutaneous transluminal angioplasty (PTA) could indeed represent an attractive alternative to conservative therapy or vascular surgery. However, as pointed out in recent articles on PTA,6–9 more studies on the long-term success and complication rate are needed to establish conclusively the place of the procedure in the treatment of patients with occlusive disease of the peripheral arteries.

Here we present a 5 year follow-up in 411 patients who underwent PTA of the arteries of the lower limbs and discuss the influence of different clinical and angiographic factors on early and late prognosis.

Patients and methods

A total of 482 PTAs of the arteries of the lower limbs were performed in 411 patients between 1977 and 1983. Bilateral PTA was performed in 19 patients; 40 femoral and 12 iliac procedures were performed in patients with reoccluded vessels who had undergone successful PTA previously (table 1). The latter were considered secondary procedures. Bilateral PTA was considered two separate procedures and redilatations were not considered in the follow-up analysis. The patients were initially assessed with respect to history and by physical examination, blood pressure in the ankle measured by Doppler ultrasound, recording of pulse volume, and arteriography. For each patient the decision to perform PTA was made by a team including a vascular surgeon, an internist, and a radiologist. Clinical characteristics of the patients and angiographic findings are reported in table 2.

PTA was performed with a double-lumen No. 9F catheter (Schneider Medintag) with a balloon segment 4 mm (femoral artery) or 8 mm (iliac artery) in diameter and 2 to 5 cm in length. After penetration of the occlusion in each patient, 5000 units of heparin was given through an arterial catheter. Standard treatment after angioplasty consisted, when possible, of anticoagulation with coumarin beginning 1 to 2 days after femoral PTA or aspirin after iliac PTA, both for 12 months; 51 patients (12%) received no medical treatment because of contraindications.

The initial result of the procedure was determined by angiographic examination performed immediately after PTA. Follow-up examinations included appraisal of symptoms, clinical examination, recording of pulse volume, and measurement of systolic ankle pressure by Doppler ultrasound. This measurement of ankle pressure has been shown to correlate well with direct pressure measurements in normal subjects and in patients with angiographically proven occlusive disease of the peripheral arteries.10 We chose to measure arm-ankle pressure difference...
TABLE 1
Procedures performed

<table>
<thead>
<tr>
<th></th>
<th>No. of patients</th>
<th>Total No. of PTAs</th>
<th>Bilateral PTAs</th>
<th>Redilatations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>411</td>
<td>482</td>
<td>19</td>
<td>52</td>
</tr>
<tr>
<td>Iliac</td>
<td>131</td>
<td>153</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Femoral</td>
<td>280</td>
<td>329</td>
<td>9</td>
<td>40</td>
</tr>
</tbody>
</table>

(DP) during the follow-up, as in the original work of Grünzig. In a previous study of 57 patients we found that changes in follow-up angiograms after PTA were well reflected by variations in DP. Follow-up examinations were performed 2 days, 3 and 6 months, and each year after PTA for a 5 year period. Early and long-term patency were considered to be present when an improvement in symptoms and in the results of clinical examination and a 50% reduction in the initial arm-ankle ΔP were observed. A procedure was considered an initial failure when the obstructive lesion had not been passed or dilated or the requirements for patency were not fulfilled at the first follow-up examination 2 days after PTA. Cases meeting these criteria at the subsequent follow-up examinations were considered late failures.

Analysis of long-term patency rate was performed by the life table method. There were 33 dropout; 22 patients (5%) died, and 11 patients (2.6%) were inaccessible during the follow-up period. Early and long-term patency rates were calculated as percentages of primary PTA procedures attempted and are summarized in figure 1. Values at time 0 are early patency rates and are plotted, along with the values during the follow-up, as percentages of the attempted PTAs (100%). The number of patients participating in the study at the beginning of each time interval of the follow-up is also indicated.

The clinical result was evaluated separately in a group of 140 consecutive patients who could be observed as a group for a 2 year period after undergoing femoral PTA. Because the majority of reocclusions occurred during the first year after angioplasty the analysis of the influence of different clinical and angiographic factors on early and late prognosis was performed with data from these 140 patients only (table 3).

Results

Patency rates. A total of 134 iliac and 251 femoral PTAs were initially successful, corresponding to early patency rates of 95% for the iliac and of 87% for the femoral arteries, respectively, as shown in figure 1. Patency rates 1 year after attempted PTA were 86% for the iliac and 61% for the femoral procedures, whereas the 5 year patency rates were 83% and 58%, respectively. Patency rates 5 years after PTA as percentages of successful rather than of attempted procedures were 87% for iliac and 67% for femoral PTAs. The patency rates did not change substantially after the first year of follow-up. The mean follow-up time was 29 months for patients who underwent femoral and 25 months for those who underwent iliac PTA.

Figure 2 demonstrates that the arm-ankle ΔP decreased after PTA and remained significantly lower during the follow-up period: 48 ± 5 mm Hg before vs 17 ± 5 mm Hg 2 years after iliac PTA (p < .01) and 73 ± 5 mm Hg before vs 28 ± 6 mm Hg 2 years after femoropopliteal PTA (p < .01).

Of the 140 patients undergoing femoral angioplasty 61% presented with claudication and 39% presented with pain at rest or gangrene; 2 years after PTA 69% had no symptoms, 23% had claudication, and only 8% had pain at rest or gangrene.

Table 3 summarizes early and late patency rates with respect to different clinical and angiographic factors. Patients with femoropopliteal occlusions presenting with pain at rest, diabetes, occlusion of greater than 3 cm, or poor distal runoff had an elevated rate of reocclusion. There was a trend in patency rate favoring male patients, but it was not statistically significant.

Complications, consequences of failures, and amputations. Complications occurred in 39 patients (8% of the patients in whom PTA was attempted), as reported in detail in table 4. Surgical intervention was necessary in nine patients (1.9%), but no fatal complications and no amputations were the direct result of PTA.

Of a total of 45 patients in whom early failure was documented (9% of the patients in whom PTA was attempted), 34 underwent vascular bypass surgery and the result in each was comparable to that reported in the literature for primary surgical treatment; the remaining nine patients were treated conservatively. The 82 patients in whom late failure was documented

TABLE 2
Clinical and angiographic findings

<table>
<thead>
<tr>
<th></th>
<th>Total (n)</th>
<th>Age (yrs)</th>
<th>Male (%)</th>
<th>Diabetes (%)</th>
<th>Claudication (%)</th>
<th>Pain at rest/ gangrene (%)</th>
<th>Stenosis (%)</th>
<th>Occlusions &gt;3 cm (%)</th>
<th>≤1 patent calf arteries (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral</td>
<td>280</td>
<td>68 ± 10</td>
<td>53</td>
<td>52</td>
<td>61</td>
<td>39</td>
<td>59</td>
<td>23</td>
<td>41</td>
</tr>
<tr>
<td>Iliac</td>
<td>131</td>
<td>54 ± 9</td>
<td>95</td>
<td>26</td>
<td>92</td>
<td>8</td>
<td>100</td>
<td>0</td>
<td>—</td>
</tr>
</tbody>
</table>

Clinical and angiographic findings are given as percentages of the patients undergoing femoral and iliac PTA, respectively. Percentage of patent calf arteries was evaluated only in patients undergoing femoral PTA.

^Mean ± SD.
after PTA were treated by redilatation (n = 52), vascular bypass surgery (n = 14), and conservative treatment (n = 16). The patency rates 2 years after redilatation were comparable to those after primary PTA (80% for the iliac and 58% for the femoral redilatations). The results of vascular surgery performed during the follow-up because of late failure were not affected by results of the previously attempted PTA.

Late amputations within the follow-up period were performed in nine patients (2.2%). All but one of these patients presented with pain at rest or gangrene before PTA; the exception was a patient with severe claudication.

Discussion

Our results indicating a reasonably good long-term prognosis after PTA of the arteries of the lower limbs in patients with arterial occlusive disease are in accordance with previous reports.2, 9, 13-25 From a clinical point of view a remarkable improvement in the symptoms occurred: before femoral PTA approximately two-thirds of the patients had claudication and one-third had pain at rest, whereas 2 years after PTA two-thirds of the patients had no symptoms. These clinical results were corroborated by the significant improvement of the arterial pressures in the ankle during the follow-up period.2, 7 We found recently that the arm-ankle ΔPs correlate well with the angiographically detected changes in the arteries and represent a reliable long-term follow-up criterium after PTA.11

The 5 year patency rates of 83% after iliac PTA and 58% after femoropopliteal PTA are slightly lower than those reported after aortoiliac surgery (72% to 92%)27, 28 and femoropopliteal bypass surgery (59% to 78%).29-34 but slightly above the patency rate after thromboendarterectomy.35 However, in our analysis the technical failures were regarded as early losses of patency whereas in general only successful operations are evaluated in the surgical literature. Excluding technical failures our patency rate 5 years after PTA would

![Graph](image)

**FIGURE 2.** Arm-ankle ΔP before and after femoral (○-○) and iliac (●-●) PTA. Values at time 0 correspond to the ΔP immediately after PTA. *p < .01 compared with before PTA. Significance was calculated by means of Student’s t test.

### TABLE 3

<table>
<thead>
<tr>
<th>Sex</th>
<th>Diabetes</th>
<th>Pain at rest/gangrene</th>
<th>Patent calf arteries (occlusion &lt;3 cm)</th>
<th>Stenoses (occlusion ≥3 cm)</th>
<th>Occlusions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>F</td>
<td>−</td>
<td>+</td>
<td>&gt;1</td>
</tr>
<tr>
<td>n</td>
<td>74</td>
<td>66</td>
<td>72</td>
<td>68</td>
<td>84</td>
</tr>
<tr>
<td>Early success (%)</td>
<td>87</td>
<td>82</td>
<td>89</td>
<td>78</td>
<td>89</td>
</tr>
<tr>
<td>Long-term success (%)</td>
<td>63</td>
<td>58</td>
<td>68</td>
<td>42</td>
<td>74</td>
</tr>
</tbody>
</table>

*Early (2 days) and late (2 years) patency rates after femoral PTA for different subgroups of patients who could all be followed for a 2 year period according to different initial factors.

The significance of differences was determined by chi-square test as follows: *p < .05; p < .01.
TABLE 4
Complications and surgical interventions

<table>
<thead>
<tr>
<th>Complications</th>
<th>Surgery needed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>fp</td>
</tr>
<tr>
<td>Hematoma</td>
<td>16</td>
</tr>
<tr>
<td>Dissection</td>
<td>8</td>
</tr>
<tr>
<td>Embolism</td>
<td>9</td>
</tr>
<tr>
<td>Spasm</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
</tr>
</tbody>
</table>

fp = femoropopliteal; il = iliac.

increase to 87% for iliac and to 67% for femoral procedures. When only patients with isolated stenosis or short occlusions of the femoral arteries were considered, we found a definitely higher long-term patency rate than in patients with longer lesions. Patients with isolated stenoses of iliac or femoral arteries therefore seem, from a technical point of view, ideal candidates for PTA. On the other hand, the presence of any one of several factors (pain at rest or gangrene, diabetes, occlusions exceeding 3 cm, or poor runoff) appeared to result in a poorer long-term prognosis for patients undergoing femoral PTA.

Severe complications of these procedures were rare when compared with vascular surgery\(^ {27, 28}\): no fatal complications and no amputations were the direct result of PTA. With the back-up of a vascular surgeon PTA thus proved safe, and even if effects of PTA procedures are not as long lasting as those of surgery, the consequences of failure are also not as deleterious. The danger of relapse seems to be particularly high during the first 12 months after angioplasty. However, in the majority of patients with reocclusions, PTA could be repeated successfully, and in those in whom angioplasty was no longer feasible, vascular surgery could still be performed. PTA is therefore not a competitive but a complementary procedure to vascular surgery. Secondary prevention should probably be kept in mind in the early vulnerable phase after PTA. However, no definite statement on this controversial subject\(^ {1, 21, 25, 36, 37}\) can be made on the basis of the present report, and an adequate study is still necessary.

The fact that angioplasty does not require surgery and is performed in patients under local anesthesia obviously significantly reduces risk of morbidity and duration and cost of hospitalization, as shown in a recent report.\(^ 6\) Patients with isolated stenosis in whom the decision to operate seems premature because of relatively mild symptoms seem to be ideal candidates for PTA. This approach is justified by our previous observation that many symptomatic stenoses of the superficial femoral arteries progress rapidly to total occlusions.\(^ {38}\) PTA may also represent a therapeutic chance for those critically ill patients in whom surgical intervention is hazardous. For patients in whom PTA or surgery can be considered, the present analysis may help to identify the appropriate candidates for PTA. Considering the favorable 5 year success rate and safety and economy, PTA of the arteries of the lower limbs may be regarded today as a valid modality in the treatment of occlusive disease of the peripheral arteries.

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References

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