Percutaneous transluminal angioplasty versus surgery for limb-threatening ischemia

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This retrospective study compared the results of percutaneous transluminal angioplasty (PTA) with those of infrainguinal bypass procedures in patients with critical arterial ischemia to determine which procedure had superior patency, limb salvage, and durability. The records of 54 patients who underwent 54 PTAs and 56 patients who underwent 63 infrainguinal bypasses (29 femoropopliteal and 34 femorodistal) from 1981 to 1987 were reviewed. In each patient PTA or bypass was the initial vascular procedure. Patients in both groups were comparable with respect to age, sex, and the presence of diabetes, hypertension, obesity, hypercholesterolemia, and smoking. Mean follow-up was 40 months (4 to 88 months) for the PTA group and 28 months (6 to 78 months) for the surgery group. Thirty-nine of the 54 patients (72%) were initially improved after PTA, whereas 15 patients (28%) showed no improvement. During follow-up, 20 initially successfulPTAs reocluded. Thirty-two of 54 patients (59%) underwent subsequent procedures, which included repeat PTA (10) and distal bypass (14). Patency determined by noninvasive Doppler studies was 18% at 2 years. Limb salvage, which included such secondary procedures, was 78%. Two-year patency for femoropopliteal bypasses was 68% with a limb salvage of 90%. Femorodistal bypasses had a 2-year patency of 47% and a limb salvage of 74%. No perioperative deaths occurred. Twenty-one of the 63 patients (33%) had subsequent procedures, which included thrombectomy (5) and bypass revision (9). In patients treated for limb-threatening ischemia the 2-year patency after femoropopliteal bypass (68%) or femorodistal bypass (47%) is significantly better than that from PTA (18%, $p < 0.001$). Whereas limb salvage after PTA (78%) was not significantly different from that after femoropopliteal bypass (90%) or femorodistal bypass (74%), the PTA group required a significantly greater number of subsequent procedures compared to the surgery group (59% versus 33%, $p < 0.01$). The low patency rate and the need for subsequent procedures after PTA indicates that bypass procedures are more durable. (J Vasc Surg 1989;9:698-703.)

Both percutaneous transluminal angioplasty (PTA) and infrainguinal bypass procedures have been used to achieve limb salvage in patients with advanced peripheral vascular occlusive disease and limb-threatening ischemia. PTA is often used as the primary procedure in elderly patients or patients in poor condition in hopes of avoiding the morbidity associated with operation. The superiority of PTA over bypass procedures in this specific clinical setting has not been established; both the immediate success rate and the long-term durability of PTA have been questioned. Comparisons of the results of angioplasty and bypass surgery are invariably complicated by differences in the sites and types of lesions treated. In addition, many clinical reports include patients with a wide range of clinical presentations from intermittent claudication to gangrene, and varying criteria to determine success are used.

The purpose of this retrospective study was to compare the results of PTA with those of infrainguinal bypass procedures in a specific group of patients with atherosclerotic lesions of the superficial femoral artery (SFA) and popliteal artery. All patients had previously untreated critical arterial ischemia manifested by severe rest pain, ulceration, or gangrene. Patients with claudication were specifically excluded. Patency and limb salvage rates and the number of subsequent procedures were compared to determine whether PTA or bypass was the more effective and durable technique.
Table I. Comparison of risk factors in groups I and II

<table>
<thead>
<tr>
<th></th>
<th>Group I (n = 52)</th>
<th>Group II (n = 56)</th>
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<tbody>
<tr>
<td>Age</td>
<td>73 yr</td>
<td>68 yr</td>
</tr>
<tr>
<td>Diabetes</td>
<td>56%</td>
<td>66%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>67%</td>
<td>68%</td>
</tr>
<tr>
<td>Smoking</td>
<td>35%</td>
<td>48%</td>
</tr>
<tr>
<td>Cholesterol (&gt; 220 mg/dl)</td>
<td>58%</td>
<td>57%</td>
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Table II. Specific indications for treatment in groups I and II

<table>
<thead>
<tr>
<th></th>
<th>Group I (54 limbs)</th>
<th>Group II (63 limbs)</th>
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</thead>
<tbody>
<tr>
<td>Severe rest pain</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Ulceration</td>
<td>21</td>
<td>30</td>
</tr>
<tr>
<td>Gangrene</td>
<td>15</td>
<td>15</td>
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METHODS

We reviewed the records of patients at the University of Chicago Hospitals who underwent either angioplasty of the SFA and popliteal artery or infrarenal bypass as their initial vascular procedure for limb-threatening ischemia. All procedures were performed between 1981 and 1987. The study groups included 52 patients who underwent 54 angioplasties on 54 limbs (group I) and 56 patients who underwent 63 bypasses on 63 limbs (group II). All patients came for treatment of severe rest pain, ischemic ulceration, or gangrene.

Segmental lower extremity pressures and Doppler ultrasound flow-velocity waveforms were obtained in all patients before treatment. Transfemoral aortoiliac and lower extremity arteriography was performed by means of Seldinger technique. Atherosclerotic obstructive lesions were evaluated with respect to the site of the lesion (proximal SFA, middle SFA, distal SFA, and popliteal) and the type of stenosis (focal or multiple) or length of occlusion (short <5 cm or long >5 cm). Distal runoff was classified as poor (0 to 1 vessel patent) or good (2 to 3 vessels patent).

The decision to proceed with PTA or bypass as the initial treatment modality was made after review of each patient’s clinical and angiographic data by a team of vascular surgeons and interventional radiologists. In general, selection was based on the extent of the occlusive disease, the technical feasibility of the procedure, and the severity of the patients’ associated medical conditions. For example, patients with serious systemic disease that substantially increased the operative risk would frequently undergo PTA as initial procedures, whereas patients with long segment occlusions and no contraindication to surgery would usually be selected for bypasses as the first procedures.

In patients treated initially with PTA, selective arteriography was performed after dilatation to document the angiographic result and to delineate collateral and distal outflow vessels. Criteria for technically successful PTA included angiographic evidence of recanalization of an occluded or stenotic arterial segment and improvement in the perfusion of distal collateral and outflow vessels. Patients were given heparin intravenously for 48 to 72 hours after dilatation and subsequently were given 325 mg of aspirin per day.

Whether PTA or bypass was performed, hemodynamic success was defined as an improvement in ankle/brachial index (ABI) >0.15 or defined as improvement in the Doppler flow velocity waveform if calcified vessels precluded accurate segmental pressure measurements. Clinical success was determined by relief of symptoms, satisfactory wound healing, and avoidance of major amputation. Hemodynamic and clinical evaluations were repeated at 3-month intervals after angioplasty or surgery.

Statistical analysis of data was performed by means of the life-table method to determine long-term patency and limb salvage rates. The statistical significance of any differences between treatment groups was determined by means of Student’s t test and chi-square analysis. Data are reported as mean ± SD.

RESULTS

Group I: Percutaneous transluminal angioplasty

Fifty-two patients (21 men, 31 women, mean age of 73 years) underwent 54 angioplasties of the SFA and popliteal artery in 54 limbs. Twenty-nine patients (56%) had insulin-dependent diabetes and 35 had hypertension (67%). Thirty patients (58%) had cholesterol levels >220 mg/dl. One third of the patients smoked at least one pack of cigarettes per day for longer than 10 years (Table I).

The indications for treatment with PTA were rest pain (18 patients, 33%), ulceration (21 patients, 39%), and gangrene (15 patients, 28%) (Table II). The type and location of the atherosclerotic lesions are listed in Tables III and IV. Stenotic lesions were treated in 19 limbs (35%), whereas 35 dilatations (65%) were performed on short or long segment
Table III. Type of atherosclerotic lesions

<table>
<thead>
<tr>
<th></th>
<th>Group I (n = 54)</th>
<th>Group II (n = 63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focal stenosis</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Multiple stenoses</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td>Short occlusion</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>Long occlusion</td>
<td>23</td>
<td>37</td>
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</table>

Table IV. Location of atherosclerotic lesions

<table>
<thead>
<tr>
<th>Location</th>
<th>Group I (n = 54)</th>
<th>Group II (n = 63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal SFA</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Middle SFA</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Distal SFA/popliteal artery</td>
<td>41</td>
<td>37</td>
</tr>
<tr>
<td>Diffuse</td>
<td>4</td>
<td>11</td>
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occlusions. Most lesions (45 patients, 76%) were located in the distal SFA or popliteal artery. Poor distal runoff was present in 42 limbs (78%), which reflected the severity of the occlusive disease in this group.

A satisfactory angiographic result of PTA was obtained in 51 of 54 limbs. Three lesions could not be dilated. ABI improved from 0.40 ± 0.18 to 0.63 ± 0.30. In 19 cases (35%) limb salvage was achieved by this single procedure. In 32 cases (59%) the angioplasty either occluded within 1 month or failed to provide sufficient hemodynamic or clinical benefit. When the outcomes of the 35 failures were considered, it was determined that 3 patients required no further therapy, 8 patients underwent early amputation, and 24 patients underwent a variety of secondary and tertiary procedures including repeat PTA (10) and infrainguinal bypass (19).

The average length of follow-up was 40 months (range 4 to 88 months). The 2-year patency of PTA was 18% as calculated by the life-table method. Whereas overall limb salvage in group I was 78% (42/54), this reflected the success of subsequent bypass procedures in 16 patients (30%). Limb salvage from primary or secondary angioplasty alone was only 48%, and only 35% of limbs (19/54) were successfully salvaged with a single angioplasty. The mortality during follow-up was 13 of 52 patients (25%), and no deaths were related to the PTA itself.

Group II: Infrainguinal bypass surgery

Fifty-six patients (30 men and 26 women, mean age 68 years) underwent 63 bypasses in 63 limbs. Operative procedures included 29 femoropopliteal bypasses and 34 femorodistal bypasses. The proportion of bypass patients with significant risk factors for atherosclerosis was comparable to the PTA group (Table I). The indications for surgical intervention were also comparable to those for angioplasty, although occlusions longer than 5 cm comprised 59% of the bypass group and only 43% of the PTA group (p = ns). The distribution of the lesions and the number of runoff vessels in the surgery group matched that of the angioplasty group (Tables IV and V).

Saphenous vein was the conduit used in 13 of 29 femoropopliteal bypasses (45%); polytetrafluoroethylene (PTFE) was used in 16 cases (53%) because saphenous vein was unavailable or inadequate. Distal anastomoses were placed above the knee in 10 patients and below the knee in 19 patients. In situ technique was used in 11 bypasses; reversed vein grafts were used in two. Twenty-nine of the 34 femorodistal bypasses (85%) were performed with saphenous vein (23 in situ, 6 reversed), whereas PTFE was used in five (15%). ABI increased from 0.38 ± 0.14 to 0.79 ± 0.21 after femoropopliteal bypass and from 0.50 ± 0.97 ± 0.21 after femorodistal bypass. Major perioperative complications occurred in five patients (8%), although there was no perioperative mortality.

Follow-up was from 6 to 78 months with mean follow-up 28 months. Twelve of 56 patients (21%) died during this period. Twenty-three of 29 femoropopliteal bypasses (79%) remained patent without revision. The 2-year patency determined by life-table method was 68%; 83% of vein grafts and 52% of PTFE grafts were patent at 2 years (p = ns). Six bypasses occluded and underwent thrombectomy or revision. Amputation was necessary in three of these cases.

Seventeen of 34 femorodistal bypasses (50%) remained patent without further revision. Two-year patency ascertained by life-table method was 47%. In five patients bypasses occluded, but no secondary reconstructions were performed. Three of these patients required amputation. Twelve bypasses subsequently underwent thrombectomy or revision; six patients eventually required amputation.
Overall, 40 of the 63 limbs at risk (64%) were salvaged by a single bypass procedure, whereas one or more additional procedures were necessary in 11 limbs (17%). Hence, total limb salvage in patients initially treated by bypass was 81%. Secondary procedures for failures or impending occlusions of bypass grafts were also moderately successful; nine of 18 patients (50%) were able to avoid amputation.

Comparisons of groups I and II

The 2-year patency after PTA (18%) was significantly lower than patency after femoropopliteal (68%) or femorodistal bypass (47%) ($p < 0.001$, Fig. 1). The limb salvage rates for patients initially treated with PTA (78%) were not significantly different from those of patients initially treated with femoropopliteal bypasses (90%) or femorodistal bypass (74%). However, only 35% of limbs undergoing PTA were salvaged by PTA alone, whereas 63% of limbs in group II were salvaged by a single bypass procedure ($p < 0.01$).

DISCUSSION

Both PTA and bypass procedures have allowed limb salvage in patients with advanced atherosclerosis despite the presence of multiple obstructions, long segmental occlusions, poor distal runoff, and gangrene. PTA has been advocated as both an adjunct and an alternative to surgical therapy, which indicates that its role in treating specific patient populations continues to evolve.$^{5-8}$

The effect on limb salvage of selecting PTA or bypass as the initial procedure in patients with limb-threatening ischemia has not been determined. Doubilet and Abrams$^9$ advocated the combined use of angioplasty and surgery for iliac and femoral disease, and they proposed that all patients with appropriate lesions undergo angioplasty first, followed by surgery only if PTA failed. In their review of reported cases, patients were not grouped according to the severity of their symptoms. Martin et al.$^{10}$ reported similar 2-year patency rates for superficial femoral PTA and femoropopliteal bypass and concluded that PTA was an acceptable alternative to bypass for SFA occlusions <4 cm. The limb salvage rate was not reported and patients with rest pain and claudication were combined in the analysis.

Our study focused specifically on patients with critical arterial ischemia and threatened limb loss. In this population the 2-year patency after PTA (18%) was significantly lower than after femoropopliteal (68%) or femorodistal bypass (47%). The results for PTA are also poorer than many previously reported series of femoropopliteal PTA, which include patients with claudication and describe long-term patency rates of 50% to 80%.$^{2,3,11-13}$ Although overall limb salvage in patients in group I (78%) was comparable to that of patients after bypass (group II,
81%), this was a direct result of secondary interventions that included both repeat PTA and bypass procedures.

The low patency rate for PTA and the need for subsequent procedures to achieve limb salvage clearly indicate that PTA is not as durable as infragenital bypass in patients with limb-threatening ischemia. In a similar study of patients with severe distal ischemia, Glover et al.\(^8\) reported a limb salvage rate of 71% when PTA was combined with bypass procedures but only a 34% limb salvage from PTA alone. Borozan et al.\(^4\) also reported inferior long-term results with PTA. In contrast, Wilson et al.\(^14\) reported a randomized trial comparing PTA with surgery and concluded that each therapy produced equally durable results. It must be noted that Wilson's conclusions may not apply to patients with severe lower extremity ischemia since 60% of the patients in this study had claudication alone.

It was disquieting to note that the outcomes of PTA did not parallel the generally accepted notion that dilation of short stenoses is more successful and durable. In fact, the 2-year patency of long segment occlusions (23%) exceeded that of focal stenosis (0% patent at 2 years). In this regard, it is noteworthy that Cambria et al.\(^15\) noted that both diabetes and poor outflow vessels adversely affected the patency of percutaneous angioplasty. Furthermore, this effect was most prominent in patients with limb-threatening ischemia as compared to those with claudication. Indeed, 78% of our patients treated with PTA had poor distal outflow, and 56% of patients had insulin-dependent diabetes.

It is appropriate to consider whether failure of PTA makes the chance of subsequent successful distal bypass less likely. Review of our results would suggest that this is not the case. Ten of the 13 bypass procedures performed after failure of PTA were indeed successful. Hence, it is reasonable to conclude that PTA can be considered an initial treatment in patients at high risk for more invasive procedures. Since the failure rate is high, modest expectations must be maintained by both the treating physician and patient. Furthermore, especially in patients being treated for critical arterial ischemia, very careful follow-up must be exercised since most angioplasties occlude within 6 months.

It has been suggested that the cost of PTA is only a fraction of that of surgical treatment for femoropopliteal lesions. Some have gone so far as to predict that performing angioplasty rather than surgery in all suitable candidates would save more than $180 million per year for femoropopliteal lesions alone.\(^16\) The results of our study and others would suggest that such savings are vastly overstated. Most patients undergoing angioplasties eventually require femoropopliteal or distal reconstructions. Indeed it is possible that avoiding angioplasty and performing the definitive procedure first may actually be more cost-effective.

A major limitation of this report or any other retrospective study is that treatments are selected after careful evaluation of each patient's appearance and pathologic characteristics. By definition, the groups are different even if the differences are difficult to specify. Nonetheless, during our review it was clear that most patients reported herein could have been treated with either PTA or bypass. Indications for treatment, length and location of lesions, and quality of distal outflow were similar.

In conclusion, femoropopliteal PTA for limb-threatening ischemia can attain limb salvage despite poor long-term patency when such procedures are combined with repeat angioplasty or bypass surgery or both. The necessity for these subsequent procedures must be considered in planning treatment for individual patients. Finally, because of the high failure rate for angioplasty, it is most appropriate that the vascular surgeon continue to be the principal decision maker as regards the choice of initial therapy.

We express our appreciation to Mrs. Kathy Skurauskis for preparation of the manuscript.

REFERENCES

9. Doubier P, Abrams HL. The cost of underutilization: per-

DISCUSSION

Dr. John L. Glover (Royal Oak, Mich.). The treatment groups in this series generally seem comparable, since each had a mortality rate of about 25% during the follow-up period. Clearly, PTA was neither as durable nor as effective in achieving limb salvage as was surgery alone or surgery in conjunction with PTA. On the other hand, there was successful limb salvage in approximately one third of the patients who received only PTA, so it was safe, therapeutically appropriate, and cost-effective under certain circumstances.

I think it will be difficult to select a particular group of patients, and my first question is whether you have any comments concerning how that may be done. Our experience is much like your own, and we found that the most reliable indication of successful PTA was improvement of the Doppler waveform to normal or nearly so. Since durability is another matter, I would appreciate your comments regarding patient selection. You encountered patients whose initial PTA failed, yet they never had limb amputation despite the fact that no operations or additional PTAs were performed. Could you tell us about these patients in your series? Finally, did you base a bypass on PTA in any cases, and how did it work out? In other words, did you dilate an iliac lesion before femoropopliteal or distal grafting, and if so, what were the results?

Dr. Mossa. Regarding patient selection, we found that the length of the occluded segment was not a good predictor of outcome. Patients with long occlusions seemed to do at least as well as those with short, segmental lesions, a feature that was surprising to us. However, only one third of these patients are likely to benefit from PTA, so most of those who have this type of atherosclerotic disease probably will require bypass. I do not have a good explanation for the group who had unsuccessful PTAs but avoided amputation without further treatment.

Dr. Krishna Jain (Kalamazoo, Mich.). I have two questions. First, how did you define critical ischemia? Your criteria may influence your conclusions, especially in the group who did not require amputation despite unsuccessful PTA. Also, I am not sure that this kind of retrospective analysis is necessarily a fair comparison. In our own practice we sometimes recommend at least an attempt at proximal PTA in some patients who are poor candidates for distal bypass because of small-vessel disease. Would you agree that a prospective study needs to be done?

Dr. Mossa (closing). There were several patients in our series who had more disease than others and were biased toward either surgery or PTA. Nevertheless, we reviewed each of these patients in detail with the radiologist and felt that most of them were candidates for either surgery or PTA.

Concerning our definition of critical ischemia, all of our patients had intractable rest pain, ulcerations, or gangrene. We excluded anyone who had only limiting claudication or even atypical kinds of rest pain, and most of our patients had ankle/brachial indices on the order of 0.30 to 0.35 before their procedures.

I agree that a prospective study is needed to determine the value of either PTA or surgery in specific patient groups. Additionally, I think we should look more closely at cost analysis because our data and those already presented by Dr. Glover seem to indicate that the degree of limb salvage achieved by PTA alone is not particularly good. A proper study might show that failed PTAs only add to the cost of subsequent surgical procedures.