Limb-salvage angioplasty in vascular surgery practice

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Objective: To assess outcomes of percutaneous infrainguinal arterial angioplasty for treatment of chronic limb-threatening ischemia (CLI) in poor surgical candidates.

Methods: A retrospective clinical analysis of 67 consecutively treated patients (76 limbs) with CLI over a 33-month period was performed. Patients were considered poor surgical candidates because of absent distal target vessels (31 limbs), severe comorbid conditions (36 limbs), or lack of an autologous vein for distal bypass (9 limbs). Limb salvage was defined as preservation of a functional foot without the need for a prosthesis. Technical success was defined as the ability to percutaneously recanalize the arterial segment with less than 30% residual stenosis. Clinical success was healing of ulcers or minor amputation sites, resolving rest pain, or avoiding a major amputation. Successful technical and clinical outcomes were correlated with patient demographics, clinical presentation, and TransAtlantic Inter-Society Consensus arterial lesion characteristics by using the Fisher exact test.

Results: Seventy-six limbs were treated for rest pain (n = 12), gangrene (n = 22), or nonhealing ulcers (n = 42). There were 40 men and 27 women. The mean age was 70 years (range, 36-94 years). Lesions were located in tibial (n = 55), popliteal (n = 6), and superficial femoral (n = 15) arteries. Arterial recanalization and limb salvage was achieved in 64 (83.5%) limbs. Technical failure (n = 12) correlated with TransAtlantic Inter-Society Consensus D lesions (P = .009) and the presence of occlusion (P = .027). Clinical failure (major amputation, n = 12) correlated with the presence of gangrene (P = .032) or the combination of diabetes, arterial occlusion, and gangrene (P = .018). The single variables of age, sex, diabetes, and renal failure did not adversely affect outcomes. There was one mortality (myocardial infarction), and there were two major morbidities (femoral artery pseudoaneurysm and sepsis).

Conclusions: Peripheral arterial angioplasty should be considered as an alternative to primary amputation in selected patients with CLI who are poor candidates for traditional surgical bypass. (J Vasc Surg 2005;41:988-93.)

Lower extremity bypass surgery is the gold standard for treatment of chronic critical limb ischemia (CLI). In recent years, despite a lack of level I clinical evidence to support it, there has been renewed interest in catheter-based treatment of lower extremity arterial occlusive diseases. This current enthusiasm is partly due to the substantial advances made in guidewire, balloon, and stent technology, as well as the availability of new antiplatelet drugs. Although vascular surgeons may be less enthusiastic than other vascular specialists (interventional cardiologists and radiologists), the use of percutaneous treatments for CLI is becoming more common. Low morbidity and mortality rates make percutaneous procedures attractive, although durable patency remains an issue. At our institution, limb-salvage angioplasty has been introduced as an alternative to primary amputation in selected poor surgical candidates with end-stage arterial occlusive disease. The purpose of this study was to evaluate the treatment outcomes after limb-salvage angioplasty for patients who otherwise would be candidates for primary amputation.

MATERIALS AND METHODS

This study was a retrospective clinical analysis of 67 consecutive poor-surgical-risk patients treated with percutaneous transluminal angioplasty (PTA) of the infrainguinal vessels for limb-threatening ischemia (76 limbs) over 33 months (January 2001 to November 2003). Patients were considered poor bypass operation candidates on the basis of the absence of an adequate greater saphenous vein for distal bypass, the presence of a poor distal bypass target vessel, or the presence of severe comorbid conditions. These comorbid conditions included recent myocardial infarction (<6 weeks), symptomatic coronary artery disease, renal insufficiency (creatinine level >2 mg/dL or dialysis dependent), or severe chronic obstructive pulmonary disease. No patient was excluded on the basis of the extent of arterial occlusive disease. Primary amputations were performed if patients were septic or had significant amount of soft tissue loss in the foot that might preclude foot salvage. Good-surgical-risk patients were offered infrainguinal arterial bypass.

Limb salvage was defined as preservation of a functional foot without the need for a leg prosthesis. Clinical success was defined as resolving rest pain, healing of an ulcer or toe amputation site, or avoiding major amputation (below-knee amputation or above-the-knee amputation). Preprocedure and postprocedure ankle-brachial indices (ABIs) were used to evaluate hemodynamic improvement. An increase in ABI greater than 0.10 was considered significant. Duplex ultrasound study was used to follow up on...
superficial femoral artery lesions. Technical success was defined as arterial recanalization with less than 30% residual stenosis. Patients’ demographic data, their indications for intervention, the location and morphologic classification of the lesions treated, and the morbidity and mortality associated with the procedure were analyzed on the basis of the reporting standards recommended by the Society for Vascular Surgery-International Society for Cardiovascular Surgery Ad Hoc Committee.7 High-grade stenosis was defined as stenosis of greater than 50% detected by visual estimation. Technical success was defined as arterial recanalization with less than 30% stenosis by visual estimation. Morphologic classification of arterial lesions was based on the TransAtlantic Inter-Society Consensus (TASC) definitions.7 All patients were evaluated and underwent angioplasty by vascular surgeons from the section of vascular surgery at the University of Wisconsin. According to the morphologic appearance, the adequacy of the distal target artery was determined by the treating vascular surgeon. Postprocedure follow-up was scheduled at 1, 3, and 6 months and yearly thereafter. SAS software (SAS Institute, Cary, NC) was used for statistical analysis, and the Fisher exact test was used to evaluate significance (P < .05).

Angioplasty procedures were performed with patients under local anesthesia and intravenous sedation in a dedicated angiography suite equipped with a variable 8- to 15-inch image intensifier. Magnetic resonance angiography was used as previously described for open surgical revascularization as a preprocedural diagnostic tool to define the location of lesions and plan catheter access.8 All patients were started on clopidogrel bisulfate 75 mg daily 3 days before the procedure or 300 mg the day of the procedure in addition to acetylsalicylic acid (81-325 mg). Heparin anticoagulation to obtain an activated clotting time longer than 250 seconds was used in all patients before the lesions were crossed. Only high-grade stenoses or total occlusions were treated. Ipsilateral antegrade common femoral access was preferentially used (85%). An angled 0.035-inch Terumo Glidewire (Meditech, Natick, Mass) was used to create a subintimal dissection in occluded superficial femoral or popliteal arteries. This wire was allowed to form a loop at the tip and was advanced in conjunction with a multipurpose catheter or an angioplasty balloon catheter until the lesion treated. Ipsilateral antegrade common femoral access was started on clopidogrel bisulfate 75 mg daily 3 days before the procedure or 300 mg the day of the procedure in addition to acetylsalicylic acid (81-325 mg). Heparin anticoagulation to obtain an activated clotting time longer than 250 seconds was used in all patients before the lesions were crossed. Only high-grade stenoses or total occlusions were treated. Ipsilateral antegrade common femoral access was preferentially used (85%). An angled 0.035-inch Terumo Glidewire (Meditech, Natick, Mass) was used to create a subintimal dissection in occluded superficial femoral or popliteal arteries. This wire was allowed to form a loop at the tip and was advanced in conjunction with a multipurpose catheter or an angioplasty balloon catheter until the arterial lumen was entered distal to the occlusion. For infrapopliteal occlusive lesions, a low-profile (0.014 inch) coronary guidewire—Choice PT (Boston Scientific, Maple Grove, Minn), Hi_Torque Traverse (Guidant Corp, Santa Clara, Calif), or Cross-it 200 (Guidant Corp)—was used to cross a Maverick balloon (Boston Scientific) and used to cross the lesions. Once occlusive lesions were crossed, the guidewire was removed, and angiography was performed through the catheter to confirm the distal intraluminal position. Balloon angioplasties were performed by using 4- to 6-mm-diameter balloons in the superficial femoral and popliteal arteries and by using 2- to 3.5-mm-diameter by 2- to 10-cm-long low-profile SAVY balloons (Cordis, Warren, NJ) in the tibial vessels. Balloon inflation times varied from 15 to 60 seconds at 8 to 12 atm. Local arterial dissections were usually treated with prolonged low-atmosphere balloon inflations without stenting.

RESULTS

Over 33 months, 76 limbs in 67 consecutive patients were percutaneously treated for CLI. During the same period, 150 patients underwent infringuinal bypass operations, and 110 patients had primary amputations. The mean age was 70.5 years (range, 36-94 years). There were 40 male patients and 27 female patients. Patient demographics and comorbid conditions are listed in Table I. The median length of hospital stay was 1 day, and the average follow-up time was 8.8 months (range, 1-33 months).

Indications for treatment included nonhealing ulcers in 42 limbs, gangrenous digits in 22 limbs, and rest pain in 12 limbs. All patients were in Rutherford clinical category6 4 or 5 (Table II). None of these patients had had a previous bypass operation. The TASC morphologic classification of the treated lesions was as follows: A, n = 8; B, n = 15; C, n = 18; and D, n = 35. There were 40 total occlusions and 36 stenoses. Treated lesions were in the tibial arteries in 55 limbs, the popliteal artery in 6 limbs, and the superficial femoral artery in 15 limbs (Table III). Multilevel angioplasties were performed in 18 limbs. Patients qualified as poor risk for bypass surgery on the basis of a lack of a distal target vessel in 31 limbs, severe comorbid conditions in 36 patients (recent myocardial infarction in 12, renal insufficiency in 27, and dialysis dependence in 12), and lack of an autologous vein (greater saphenous vein) for distal bypass in 9 limbs.

On the basis of intention to treat, technical success was achieved in 64 limbs (83.5%). All technical failures were due to an inability to cross the lesions. No stents were used. Of the 12 technical failures, 6 limbs were bypassed, 4 required primary amputation, and 2 patients refused any further therapy. Of these two, one had ArtAssist (ACI Medical) pneumatic compression, and the ulcer healed; the other patient died a few months later. Of the six patients who underwent revascularization, two have died, two underwent below-the-knee amputation, and two are alive with intact limbs. Technical failures were correlated with TASC D lesions (P = .009) and the presence of a complete occlusion (P = .027).

The limb-salvage rate was 83.5%. There were 12 major amputations. Limb loss occurred in four patients after
technical failure and in eight others despite a technically successful angioplasty. Limb loss was due to infection in four patients (despite initial clinical improvement), recurrent disease in two, and lack of clinical improvement in two. Major amputation correlated with the clinical presence of digital gangrene \((P/H11050.032)\) or the combination of diabetes, arterial occlusion, and gangrene \((P/H11050.018)\). The presence or absence of diabetes or renal failure alone did not significantly affect technical failure or limb loss. The presence of renal failure showed a trend toward significance in limb loss \((P/H11050.08)\). All patients with rest pain had resolution of their symptoms after angioplasty. Seventy-three percent of toe amputation sites healed primarily. Age, sex, history of diabetes, and renal failure did not adversely affect clinical or technical outcomes.

During follow-up, the recurrence of clinical symptoms (clinical recurrence) correlated with recurrent arterial stenosis in four patients. In two patients (50%), repeat percutaneous treatment was successful, whereas in the other two, the inability to perform repeat PTA led to a major amputation. Both of these patients had recurrent tibial occlusive disease. All recurrences, as well as clinical failures that led to major amputation, occurred within 6 months of primary angioplasty. Noninvasive vascular testing with serial ABI measurements for follow-up of these patients was useful in only 50% of the cases, because the other half had incompressible vessels. There was a significant increase in ABI after successful angioplasty. In patients with compressible vessels, ABI increased from a preprocedure mean of 0.54 to a postprocedure mean of 0.83 (mean increase by 0.29; range, 0.1-0.62). Duplex ultrasound evaluation of the superficial femoral artery was routinely performed.

There was one (1.5%) perioperative death due to myocardial infarction, and there were two (3%) major morbidities. A femoral artery puncture site pseudoaneurysm was treated with ultrasound-guided thrombin injection, and one patient developed sepsis after successful thrombolysis of a tibial artery PTA site. Images in Figs 1 to 6 illustrate a case of CLI with multilevel disease treated percutaneously.

DISCUSSION

Up to 40% of extremities with ischemic nonhealing ulcers, gangrenous digits, or rest pain may require a major amputation within 6 months of onset unless successfully revascularized.\(^9\) Infragenual lower extremity bypass surgery for limb salvage is the gold standard treatment for these conditions. However, surgical bypass may not be a good option for patients with limited life expectancy, poor

### Table II. Outcome by clinical presentation

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. limbs</th>
<th>Technical failure</th>
<th>Major amputation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gangrene</td>
<td>22</td>
<td>13%</td>
<td>31%*</td>
</tr>
<tr>
<td>Ulcer</td>
<td>41</td>
<td>22.5%</td>
<td>12%</td>
</tr>
<tr>
<td>Rest pain</td>
<td>13</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*\(P = 0.32\).

### Table III. Outcome by lesion location and morphology

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. limbs</th>
<th>Technical failure rate</th>
<th>Major amputation rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occlusion</td>
<td>40</td>
<td>25%*</td>
<td>17.5%</td>
</tr>
<tr>
<td>Stenosis</td>
<td>36</td>
<td>5.5%</td>
<td>13.8%</td>
</tr>
<tr>
<td>Location of lesion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SFA</td>
<td>16</td>
<td>6.25%</td>
<td>6.25%</td>
</tr>
<tr>
<td>Popliteal</td>
<td>3</td>
<td>33.3%</td>
<td>0</td>
</tr>
<tr>
<td>Tibial</td>
<td>57</td>
<td>17.5%</td>
<td>19.3%</td>
</tr>
<tr>
<td>TASC classification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>8</td>
<td>0</td>
<td>12.5%</td>
</tr>
<tr>
<td>B</td>
<td>15</td>
<td>0</td>
<td>13.3%</td>
</tr>
<tr>
<td>C</td>
<td>18</td>
<td>11%</td>
<td>11.1%</td>
</tr>
<tr>
<td>D</td>
<td>35</td>
<td>28%†</td>
<td>20%</td>
</tr>
</tbody>
</table>

SFA, Superficial femoral artery; TASC, TransAtlantic Inter-Society Consensus.

*\(P = 0.027\).

†\(P = 0.009\).
distal target vessels, a lack of an adequate autologous venous conduit, or significant comorbid conditions. Although there is a role for primary amputation in patients who are poor candidates for surgical revascularization, the morbidity and mortality associated with major amputation remain high. Therefore, alternative treatment for patients with limb-threatening ischemia should be considered whenever arterial bypass is not possible or is hazardous. In the 1980s, studies on vasoactive drugs as an alternative treatment for CLI were unsuccessful. Early experience with PTA for limb salvage was poor. In recent years, because of improved competency and experience of vascular specialists, as well as the advances made in catheter and guidewire technology, catheter-based treatment of lower extremity arterial occlusive disease has shown significantly improved limb-salvage outcomes. Although to date there is no level I evidence that defines the role of infrainguinal arterial angioplasty for limb salvage as compared with bypass surgery, a few retrospective studies have addressed this issue. Blair et al reported comparable limb-salvage rates with PTA and bypass surgery in the treatment of limb-threatening ischemia—78% vs 81%, respectively, at 2 years—despite a very low patency rate in the PTA group. Contemporary reports on PTA suggest that high technical and clinical success rates are possible.

Some authors recommend that infrainguinal PTA be offered as the first line of treatment in most patients with CLI. This idea is supported by Dorros et al, who achieved a technical success rate of 94% and a limb-salvage rate of 91% at 5 years. Although this exceptionally high success rate has not been reproduced by many other investigators, technical and limb-salvage rates of 70% to 80% at 1 to 2 years are not uncommon. At the University of Wisconsin, we have used infrainguinal arterial angioplasty as part of our endovascular program for treatment of limb-threatening ischemia since 2001. This treatment option is offered to patients considered high risk or poor candidates for surgical bypass. We hypothesized that infrainguinal

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**Fig 3.** Superficial femoral artery occlusion.

**Fig 4.** After percutaneous revascularization.
PTA in these high-risk patients may lead to a significantly improved limb-salvage rate with low morbidity and mortality when compared with primary amputation in patients who are considered poor surgical candidates.

Our technical and clinical success rate was 83.5% each, which is similar to that reported in the literature. Technical failures were due to an inability to cross the lesions with guidewires. Not surprisingly, technical failure correlated with the worst lesion morphology (TASC D), and clinical failure correlated with the worst clinical presentation (gangrenous digits). One third of the patients in our series who presented with gangrenous digits required a major amputation, and this was significantly more than those who presented with rest pain only (0%) or ulcer (12.5%). This is not significantly different from the 60% limb salvage achieved 1 year after bypass operation in the presence of established forefoot gangrene.20

In the literature, the reported morbidity and mortality rate associated with percutaneous arterial revascularization seems low.3,19 In this series, the morbidity and mortality rates were 3% and 1.5%, respectively. Goshima et al21 reported that infrainguinal bypass surgery is often complicated by prolonged recovery, multiple reoperations (up to 48.9%), and multiple readmissions (49.3%). Moreover, according to Baldwin et al,22 if reoperations were due to early graft failure (<30 days), then limb-salvage rates were as low as 25%. On the basis of these unfavorable surgical bypass results, some authors recommend a percutaneous attempt as the initial treatment for patients with CLI. This recommendation is also supported by the fact that failed PTA does not negatively affect future surgical bypass.4,15 Others recommend PTA in CLI only in patients considered to be high risk for bypass surgery.13,14 According to our results, patients with stenoses or TASC A and B lesions, irrespective of their comorbid conditions, should be considered for percutaneous treatment, whereas patients with TASC D lesions in the tibial vessels may benefit from percutaneous treatment only if they are poor surgical candidates.

During follow-up, of the four recurrent lesions, repeat PTA failed in two, and this ultimately led to limb loss. In a report by Faglia et al,3 of 14 patients with recurrent lesions, 10 (71%) responded to a repeat angioplasty. We have found that close follow-up, particularly in the first year, is the key to successful outcomes, because all failures in our series occurred within the first 6 months of treatment. This follow-up is primarily clinical and evaluates ulcer healing, resolution of rest pain, or healing of the amputation site. This is similar to reports by Gordon et al,23 in which there
was a 100% patency rate at 3 years if restenoses had not occurred by 6 to 12 months. In addition to clinical follow-up, we found that ABI measurements can be reliable in up to 50% of patients.

One unanswered question regards the effect of stents on long-term patency. Drug-eluting stents seem promising in the coronary circulation but have yet to show improved outcomes in peripheral arteries.\textsuperscript{24} In our series, stents were not used. Whenever extensive local dissections were encountered after PTA, prolonged balloon inflations were usually effective. Our decision not to use stents was based on the poor results reported in the literature.\textsuperscript{25,26}

This was a retrospective study with a relatively small number of patients and short-term follow-up. These results may not apply to low-surgical-risk patients with CLI. Our study suggests a need for a randomized clinical trial between PTA and bypass surgery.

CONCLUSION

This study does indicate that limb-salvage angioplasty can be successfully achieved with low morbidity and mortality rates in high-risk or poor-surgical-risk patients. The limb-salvage rate was 83.5% in a group of patients destined for major amputation. Patients with gangrenous digits were more likely to require a major amputation. Age, diabetes, and renal insufficiency did not independently affect clinical outcomes. Vascular surgeons should consider limb-salvage angioplasty before performing primary major amputation in patients who are unfit for bypass surgery.

REFERENCES


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