Tibioperoneal Stenting

New recanalization tools and techniques, including debulking and stenting, allow for the treatment of very complex lesions in the challenging infrageniculate region.

BY GIANCARLO BIAMINO, MD

Early reported experience with percutaneous transluminal angioplasty (PTA) of infrapopliteal vessels has resulted in limited success.[1,2] Despite recent reports showing primary success rates of greater than 80% to 90%, the validity of transcutaneous techniques in patients with stenoses or occlusions in the popliteal or infrageniculate arteries is still controversial.[3-20] The weakness of recent nonrandomized studies is, in many cases, the lack of clear protocol; poorly defined follow-up that does not differentiate between primary, primary-assisted, and secondary patency rates; and poor documentation of clinical improvement, which is not strictly related to the patency of the treated vessel.[21-22]

The incidence of peripheral artery obstruction disease (PAOD) is 20% in patients older than 65 years and is, therefore, increasing dramatically as the population ages. Approximately 30% to 50% of patients with PAOD become symptomatic, resulting in 4 million to 6 million Americans suffering from claudication. Fifteen percent to 30% of patients with lower-extremity arterial disease will progress from intermittent claudication to critical limb ischemia (CLI) over the course of their disease. CLI is associated with an extremely poor prognosis: only about half of the patients will survive without a major amputation 1 year after the onset of CLI (25% will have died and 25% will have required major amputation).

From an interventional perspective, nearly 70% of the arterial lesions are located in the femorotibial tract. Isolated lesions below the knee are present in only 15% of the cases. Approximately 30% of symptomatic PAOD patients have diffuse arterial disease affecting the femoropopliteal tract and the tibial arteries. The majority of CLI patients, most of whom are diabetics, have distal arterial disease with occlusions in the tibial arteries. Despite the presence of combined lesions in the SFA and the infrapopliteal arteries, it is routine in many interventional centers to treat only the obstructions in the SFA, hoping for an improved runoff through the collateral system. However, the most important goal for interventions in severe PAOD is to restore straight-line, pulsatile blood flow, which will relieve pain and achieve wound healing.

The complexity of the problems related to the optimal treatment modality of this patient cohort has to be reviewed in light of advances in interventional tools and techniques, and with the therapy goals in mind. As stated previously, the main goals in treating ischemic vascu-

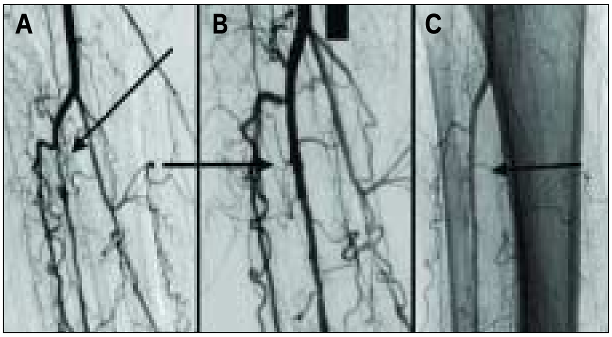

Figure 1. A 67-year-old woman had claudication of the right foot and was classified as Rutherford class 3. High-grade stenosis right anterior tibial artery (ATA) (A). She had unlimited walking capacity after stent placement (3-mm diameter, 20-mm length) (B). Angiographic control 6 months after stent implantation (C).

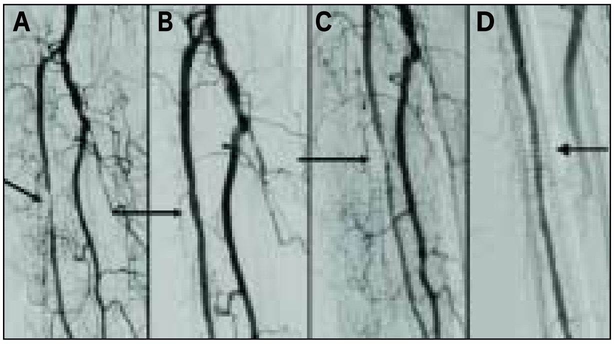

Figure 2. A 62-year-old man had claudication of the right calf and was classified as Rutherford class 3. He had high-grade stenosis in his right ATA (A), and no symptoms after stent placement (3-mm diameter, 20-mm length) (B). The patient had limited walking capacity (100 m) at 3-month follow-up due to in-stent stenosis (C), which was successfully dilated with a cutting balloon (D).

lar disease are the relief of pain, wound healing, or to regain or maintain ambulatory ability. Long-term primary patency is only a secondary goal in this fragile patient population.

Technology has improved substantially during the last 5 years with the rapid introduction of new wires, debulking devices, balloons, and stents. Furthermore, endovascular specialists have adopted coronary techniques for interventions in the small infragenicular vessels that have higher rates of technical success. As a result, endovascular intervention has become a first-line therapy in complex arterial disease.

Nonetheless, in 2004, we lack evidence-based guidelines related to the indication for the stenting of tibial arteries. Furthermore, there are no dedicated stents for infrageniculate application. In cases in which stenting of tibial arteries is necessary, coronary balloon-premounted stents or peripheral self-expandable stents are used.

TECHNICAL ASPECTS

A key issue in the successful completion of a complex endovascular intervention is vascular access selection. Two standard approaches are available for femoral, popliteal, and tibial artery interventions: the crossover (contralateral) approach and the antegrade approach.

In our daily practice, we use the crossover approach in more than 80% of cases, which utilize dedicated sheaths with a length between 45 cm and 90 cm (6 F to 8 F). The advantages of this technique are lower rates of local complication, particularly in obese patients, easy navigation of the guidewire to the target lesions; and no compromise to blood flow because of compression of the contralateral CFA to achieve hemostasis after intervention.

Once the sheath is placed, the target lesion is crossed with an atraumatic 0.018-inch or 0.014-inch guidewire. It is important to select a guidewire with good trackability, steerability, and torqueability to allow the wire to drill through total occlusions. One limitation of this technique is the inability to cross a relevant number of total occlusions, particularly in the tibial region. As an alternative method of recanalization, excimer laser ablation can be used in a step-by-step manner. The guidewire and the appropriate laser catheter are sequentially advanced and activated under continuous saline infusion until the occlusion is crossed, transforming the total obstruction in a more easily dilated, focal stenosis.[23]

After passing the stenosis with the guidewire or after excimer laser debulking, the obstruction should first be treated with a standard PTA technique using only low-profile balloon catheters with hydrophilic coating. It is extremely important to stress the fact that, in tibial arteries, oversizing the balloon may be deleterious. Currently, stenting is only considered in cases of major or flow-limiting dissections that cannot be controlled by prolonged balloon inflations. Primary stenting is limited to more diffused restenoses or to heavily calcified lesions showing an evident tendency to recoil. In the majority of cases, coronary balloon premounted stents with a diameter of 2.5 mm to 4 mm are implanted in tibial arteries. The concern about the applicability of coronary stents in tibial arteries with regard to the potential crush of the stent by the surrounding tissues could not be confirmed by the clinical experience.

Self-expanding stents should be considered for more proximal vessel segments, including the tibioperoneal trunk and the popliteal artery. The postprocedural medical treatment is similar to the management of CHD patients and includes clopidogrel (75 mg/d) for at least 3 months and 100 mg of aspirin once daily for an unlimited period.

For some patients with complex lesions and impaired run-off, we recommend prolonging the postprocedural anticoagulation for 3 to 6 weeks with weight-adjusted, low-molecular-weight heparin. Finally, we must stress the fact that, for experienced and well-skilled interventionalists, the length and morphology of the lesions have less influence on the primary success rate.

PERSONAL EXPERIENCE

Between April 1998 and June 2000, we treated 365 lesions located below the knee in 282 patients who had Rutherford class 3 to 4 claudication. The global primary success rate was 93%. In this patient cohort, the primary patency rate after 12 months was 65.2%, the primary-

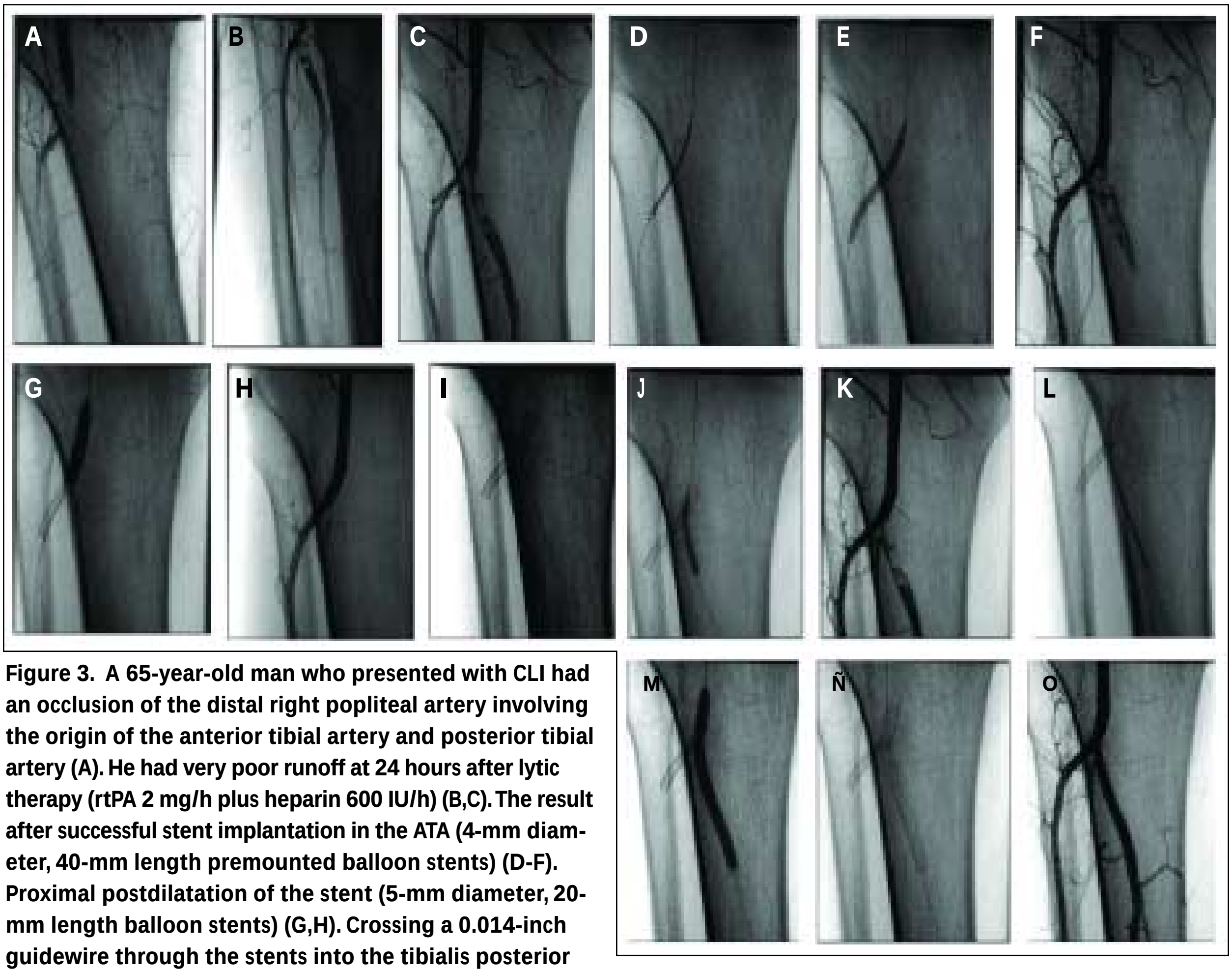

Figure 3. A 65-year-old man who presented with CLI had an occlusion of the distal right popliteal artery involving the origin of the anterior tibial artery and posterior tibial artery (A). He had very poor runoff at 24 hours after lytic therapy (rtPA 2 mg/h plus heparin 600 IU/h) (B,C). The result after successful stent implantation in the ATA (4-mm diameter, 40-mm length premounted balloon stents) (D-F). Proximal postdilatation of the stent (5-mm diameter, 20-mm length balloon stents) (G,H). Crossing a 0.014-inch guidewire through the stents into the tibialis posterior (I). After dilatation of the stent struts (J), the second stent (K,L) could be placed in the PTA. Delivery of the second stent (M) and reconstruction of the trifurcation (N) yields perfect angiographic results (O).

assisted rate was 81.2%, and the secondary patency rate 91.3%.

At this time, we used a stent only for 42 lesions (12%). This subgroup showed a 12-month primary patency rate of 69%. However, the clinical patency rate connected to a relevant improvement of the clinical status was 93%. The related limb salvage rate was 95%.

In a recent analysis of 51 consecutive tibial interventions that concluded with stenting of the target lesion (84 coronary stents, 3 mm to 4 mm in diameter [Flexmaster, Abbott Laboratories, Abbott Park, IL]), we observed a primary technical success rate of 100%.

After a mean follow-up of 10.7 months (range, 9 to 12 months), 48 of 51 patients were angiographically controlled. The primary patency rate (defined angiographically as a restenosis >50%) was 44.2% (23 of 48) (Figure 1).

Three patients refused the control angiography. In contrast to the angiographic results, clinical improvement was maintained in 80% (41 of 51) patients. Twenty patients with stenoses were successfully redilated during their follow-up angiography. Consequently, the primary-assisted patency rate was 84% (Figure 2).

THE LACI TRIAL

The primary endpoints of the multicenter LACI (Excimer Laser Angioplasty in Critical Limb Ischemia) trial were limb salvage and total survival at 6 months in a cohort of patients with CLI who were considered poor candidates for bypass, indicated by at least one of the following conditions: (1) absence of venous autologous graft; (2) poor (diffusely diseased or <1 mm diameter) or no distal vessel available for graft anastomosis; or (3) high risk of surgical mortality, as evidenced by the American Society of Anesthesiologists (ASA) physical class 4 or higher. Furthermore, the lesions had to involve only the femoropopliteal tract and/or the tibial arteries. For all patients, the treatment consisted of excimer laser angioplasty plus PTA and optional stenting.

One hundred forty-five patients with 155 critically ischemic limbs and 423 lesions were enrolled at 14 sites. All patients were classified as Rutherford class 4 to 6. Of the 423 lesions, 41% were in the SFA, 15% were in the popliteal artery, and 41% were in infrapopliteal arteries. Seventy percent of the cases had a combination of stenoses and occlusions. In this complex cohort, the procedural success showing a straight-line flow to the foot was established in 89%. Laser use provided approximately 50% of the net lumen gain, with a higher tendency below the knee. A stent was implanted in 45% of all cases (n = 70, not stented = 85). The percentage of implantation by location was 61% in the SFA, 38% in the popliteal artery, and 16% in the tibial artery (Figure 3).[24]

The rate of survival with limb salvage was 93%. Independently from the location, stents improved the acute results significantly (straight-line flow in 96% of stented lesions vs 84% of unstented, *P*=.02). Stenting positively affected the limb salvage rate (4% of unstented vs 7% of stented). In this very important trial, it has been demonstrated that the use of stents below the knee is safe and effective for recanalizing complex lesions.

CONCLUSIONS

The use of stents below the knee is effective and safe, permitting implantation whenever necessary in a bailout situation. Currently, primary stent implantation should be limited to patients with restenosis or with very calcified lesions and an inadequate result after PTA. The literature indicates that the role of PTA and stenting in lesions below the knee is increasing, and the results are encouraging.[25,26] Dedicated development of stent devices that are suitable for popliteal and, in particular, tibial arteries is urgently expected. Well-designed trials demonstrating the validity of stenting in tibial arteries are mandatory before guidelines for their use may be defined.

Finally, it is absolutely uncertain if, when, and where the use of drug-eluting stents may result in a breakthrough. Nevertheless, personal experience and much data from the literature suggest that an endovascular approach should be considered before surgery in infrageniculate lesions,[6,11,25,27] not only for limb salvage, but also for severe claudication. Endovascular intervention is safe in this fragile patient population, with fewer serious complications than surgery, and the long-term results are comparable with the surgical approach.[28] ■

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1. Schwarten DE, Cutcliff WB. Arterial occlusion disease below the knee: treatment with percutaneous transluminal angioplasty performed with low-profile catheters and steerable guidewires. *Radiology.* 1998;169:71-74.
2. Sprayregen S, Sniderman KW, Sos TA, et al. Popliteal artery branches: percutaneous transluminal angioplasty. *AJR.* 1980;135:945-950.
3. Wagner HJ, Rager G. Infrapopliteal angioplasty: a forgotten region. *Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr.* 1998;168:415-420.
4. Treiman GS, Treiman RL, Ichikawa L, et al. Should percutaneous transluminal angioplasty be recommended for treatment of infrageniculate popliteal artery or tibioperoneal trunk stenosis. *J Vasc Surg.* 1995;22:457-463; discussion 464-465.
5. Matsagas MI, Rivera MA, Tran T, et al. Clinical outcome following infra-inguinal percutaneous transluminal angioplasty for critical limb ischemia. *Cardiovasc Intervent Radiol.* 2003;26:251-255.
6. Faglia E, Mantero M, Caminiti M, et al. Extensive use of peripheral angioplasty, particularly infrapopliteal, in the treatment of ischemic diabetic foot ulcers: clinical results of a multicentric study of 221 consecutive diabetic subjects. *J Intern Med.* 2002;252:225-232.
7. Silva MB Jr, Hobson RW 2nd, Jamil Z, et al. A program of operative angioplasty: endovascular intervention and the vascular surgeon. *J Vasc Surg.* 1996;24:963-971; discussion 971-973.
8. Saab MH, Smith DC, Aka PK, et al. Percutaneous transluminal angioplasty of tibial arteries for limb salvage. *Cardiovasc Intervent Radiol.* 1992;15:211-216.
9. Brown KT, Moore ED, Getrajdman GI, et al. Infrapopliteal angioplasty: long term follow-up. *J Vasc Intervent Radiol.* 1993;4:139-144.
10. Wack C, Wolfle KD, Loeprecht H, et al. Percutaneous balloon dilatation of isolated lesions of the calf arteries in critical ischemia of the leg. *Vasa.* 1994;23:30-34.
11. Sivananthan UM, Browne TF, Thorley PJ, et al. Percutaneous transluminal angioplasty of the tibial arteries. *Br J Surg.* 1994;81:1282-1285.
12. Desgranges P, Kobeiter K, d´ Audiffret A, et al. Acute occlusion of popliteal and/or tibial arteries: the value of percutaneous treatment. *Eur J Vasc Endovasc Surg.* 2000;20:138-145.
13. Kandarpa K, Becker GJ, Hunink M, et al. Transcatheter interventions for the treatment of peripheral atherosclerotic lesions: part I. *J Vasc Intervent Radiol.* 2001;12:683-695.
14. Dorros G, Jaff MR, Mathiak L, et al. Tibioperoneal (outflow lesions) angioplasty can be used as primary treatment in 235 patients with critical limb ischemia: five year follow-up. *Circulation.* 2001;104:2057-2062.
15. Bull P. Distal popliteal and tibioperoneal transluminal angioplasty: long-term follow-up. *J Vasc Intervent Radiol.* 1992;3:545-553.
16. Danielsson G, Albrechtsoon U, Norgren L, et al. Percutaneous transluminal angioplasty of crural arteries: diabetes and other factors influencing outcome. *Eur J Vasc Endovasc Surg.* 2001;21:432-436.
17. Brillu C, Picquest J, Villapadierna F, et al. Percutaneous transluminal angioplasty for management of critical ischemia in arteries below the knee. *Ann Vasc Surg.* 2001;15:175-181.
18. Soder HK, Manninen HI, Jaakkola P, et al. Prospective trial of infrapopliteal artery balloon angioplasty for critical limb ischemia: angiographic and critical results. *J Vasc Intervent Radiol.* 2000;11:1021-1031.
19. Jamsen T, Manninen H, Tulla H, et al. The final outcome of primary infrainguinal percutaneous transluminal angioplasty in 100 consecutive patients with chronic critical limb ischemia. *J Vasc Intervent Radiol.* 2002;13:455-463.
20. Balmer H, Mahler F, Do DD, et al. Angioplasty in chronic critical limb ischemia: factors affecting clinical and angiographic outcome. *J Endovasc Ther.* 2002;9:403-410.
21. Baird RN, Bradley MD, Murphy KP. Tibioperoneal angioplasty and bypass. *Acta Chir Belg.* 2003;103:383-387.
22. Ansel GM, George BS, Botti Jr CF, et al. Infrapopliteal endovascular techniques: indications, techniques, and results. *Curr Intervent Cardiol Rep.* 2001;3:100-108.
23. Scheinert D, Laird JR, Biamino G, et al. Excimer laser-assisted recanalization of long, chronic superficial femoral artery occlusions. *J Endovasc Ther.* 2001;8:156-166.
24. Laird JR. Final LACI report. Presented at TCT 2003, Washington, DC: September 2003.
25. Gray BH, Laird JR, Ansel GM, et al. Complex endovascular treatment for critical limb ischemia in poor surgical candidates: a pilot study. *J Endovasc Ther.* 2002;9:599-604.
26. Ansel GM. Endovascular treatment of femoral and popliteal arterial occlusive disease. *J Invasive Cardiol.* 2000;12:382-388.
27. Wolfle KD, Bruijnen H, Reeps C, et al. Tibioperoneal arterial lesions and critical foot ischemia: successful management by the use of short vein grafts and percutaneous transluminal angioplasty. *Vasa.* 2000;29:207-214.
28. Wolfle K, Schaal J, Rittler S, et al. Infrainguinal bypass grafting in patients with end-stage renal disease and critical limb ischemia: is it worthwhile. *Zentralbl Chir.* 2003;128:709-714.