Laser Angioplasty for Critical Limb Ischemia

Laser angioplasty has the potential to be a valuable and feasible treatment option for patients with CLI.

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Critical limb ischemia (CLI) most commonly results from acute and chronic multilevel obstructions in the femoropopliteal and peroneal arteries and confers a high risk of major amputation.[1] Standard therapy has been surgical revascularization or primary amputation. However, these patients are often poor surgical candidates because of severe comorbidities, such as coronary artery disease, the absence of targets for bypass, or the lack of venous conduit for bypass. In recent years, endovascular therapy of complex multilevel lesions using various tools, such as PTA, stenting, and atherectomy, has been reported.[2-10] Laser-assisted angioplasty has been shown to be feasible in chronic obstructions of the femoropopliteal and infrapopliteal arteries in patients with claudication, and this therapy potentially offers an additional treatment option for patients with CLI.[11,12] This article discusses the results of two recently finalized studies of laser-assisted angioplasty in patients with CLI who were poor candidates for surgery.

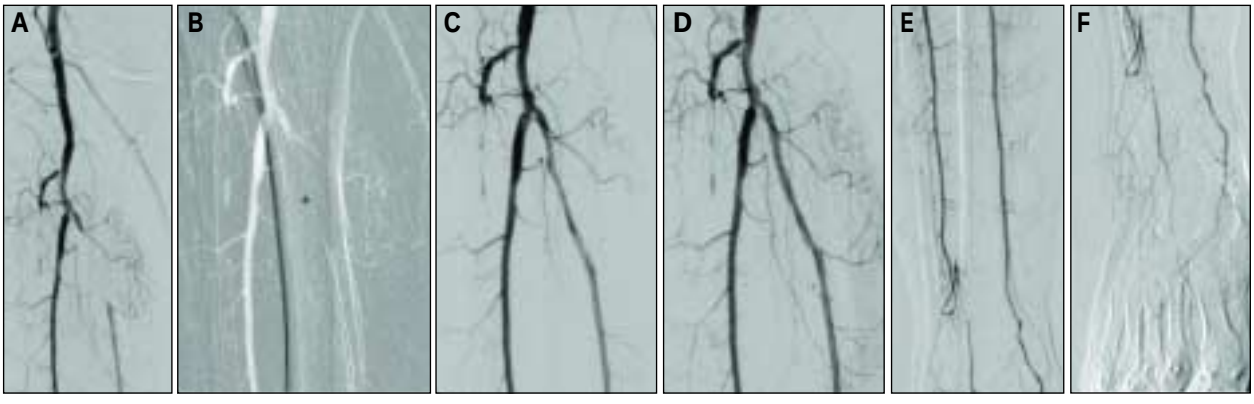

Figure 1. A 57-year-old man presented with rest pain and nonhealing ulcers of 11 months' duration. He was hypertensive, diabetic, obese, had hypercholesterolemia, a history of smoking, and had undergone a previous coronary bypass procedure. The preinterventional angiography showed occlusions of the anterior and posterior tibial arteries (A). The peroneal artery ends at the level of the malleolus. After laser atherectomy with a 1.7-mm excimer laser catheter (B,C) and PTA with a 3-mm, low-profile balloon (D), the posterior tibial artery could be successfully recanalized and straight-line flow to the foot was established (E,F).

TREATMENT

Treatment included standard guidewire technique and a step-by-step technique to cross lesions in the SFA, popliteal, and crural arteries. Excimer laser atherectomy, using a variety of laser catheter sizes ranging from 0.9 mm to 2.5 mm in diameter (CVX-300, Spectranetics, Colorado Springs, CO), was used to debulk lesions, as previously described.[12] Adjunctive balloon dilatation was used in almost all lesions (except a few crural lesions) followed by optional stent implantation to relieve flow-limiting residual stenoses. The goal was to achieve straight-line flow from the SFA origin to the foot through at least one crural artery. Procedure success was defined as residual diameter stenosis <50%, as determined by visual assessment of all treated lesions (Figure 1).

STUDY POPULATIONS AND RESULTS

Gray et al[13] recently published a pilot study evaluating the use of laser-assisted angioplasty with adjunctive PTA and stenting for bailout situations in patients with CLI. Four study sites in the US enrolled 23 patients with 25 critically ischemic limbs (Rutherford limb ischemia category 5 or 6). All patients typically presented with multiple infrainguinal lesions. The mean age of the patients was 70 ± 11 years. Seventy-eight percent of the patients had diabetes mellitus as a risk factor. A mean of 3.1±2 lesions (range, 1-8) with a mean lesion length of 6.2±6.7 cm (range, 0.2-32 cm) were treated.

In this study, acute procedural success was 88% (22 of 25 limbs). Ten limbs had a stent placed (40%). Two procedural failures underwent major amputation (rate, 8%). The ankle-brachial index acutely improved from 0.54±0.21 to 0.84±0.20 (P<.001). During the 6-month follow-up period, four patients died of cardiac events (17%) and one patient was lost to follow-up. According to life-table analysis, the limb salvage rate in the 22 successfully treated limbs was 69% (without) and 90% (with) additional bypass revascularization in four limbs. For the limbs in which a stent was placed, the 6-month limb salvage rate was 89%.

The LACI 2 Trial

A recently finalized prospective registry (LACI 2) at 14 sites in the US and Germany enrolled 145 patients, with 155 critically ischemic legs, who were poor candidates for bypass surgery. Two thirds of the patients were diabetic. The mean age was 72±10 and 53% of the patients were male. A mean of 2.7±1.4 lesions were treated per leg, comprising a combination of stenoses and occlusions in 71% of legs, with a mean length of 6.1±5.6 cm per lesion. Acute procedure success was seen in 86% of legs, while straight-line flow to the foot ensued in 89%. Optional stenting was performed in 45% of legs for flow-limiting residual stenoses. At 6-month follow-up, death occurred in 10% of patients, and nine major amputations were observed in survivors. By survival analysis, limb salvage was achieved in 110 of 119 (92%) patients or 118 of 127 (93%) legs. The stented subgroup had a higher frequency of procedure success versus the nonstented subgroup (93% vs 79%; P=.01) and trended toward a better limb salvage rate (83% vs 71%; P=.09) (Table 1) (Figure 2).

DISCUSSION

These two studies show that an excellent limb salvage rate was achieved in a population with severe arterial disease and poor surgical options, despite multiple comorbidities typically found in this patient cohort for laser-assisted angioplasty. The studies are the first to investigate the effect of a combined endovascular approach in a selected patient cohort with acute and chronic critical limb ischemia defined as poor candidates for vascular surgery. The high technical success rate in both studies confirms the previously reported results for laser-assisted angioplasty for claudicants.[11,12]

In contrast to former studies, the LACI studies enrolled patients with multilevel obstructive disease with the goal of achieving straight-line flow from the SFA origin to the foot through at least one crural artery.[2-10] It was demonstrated that a combined therapeutic strategy—excimer laser atherectomy, balloon angioplasty, and optional

Figure 2. Case example from the LACI 2 trial demonstrating complete wound healing after successful excimer laser-assisted recanalization. Initial presentation (A). Status at 3-month follow-up (B). Status at 6-month follow-up (C).

TABLE 1. SIX-MONTH SURVIVAL WITH LIMB SALVAGE IN CLI

	Whole Cohort	Without Stent	With Stent
Gray et al[13]	69% (90%)*	nr	89%
LACI 2	76% (82%)†	71%	83%
TOPAS Surgery	74%		
TOPAS Local Lysis	66%-80%††		

**With additional surgery during follow-up; †excluding 11 patients lost to follow-up; ††three different doses of urokinase; nr = not reported; TOPAS = Thrombolysis or Peripheral Arterial Surgery[14]*

stenting—can be successfully applied to virtually all vascular disease states commonly found in CLI patients. Pretreatment with the laser removed the thrombus burden and provided luminal gain through occlusions or tight stenoses, thereby simplifying the vascular milieu and reducing the chance for balloon-induced distal embolization and dissection.[12] The investigators stented only where necessary, with particularly frugal infrapopliteal use, because the long-term effects of stenting low in the limb remain uncertain. However, patients who received a stent tended to have better limb salvage rates compared to the nonstented group.

The 6-month limb salvage rates (up to 93%) for the surviving patients in the two study cohorts are much better than in most reports using single-balloon angioplasty.[2-10]

Acute limb-threatening ischemia is often induced by thromboembolic accidents. However, in a reasonable proportion of these patients, acute limb-threatening ischemia is caused by local thrombosis based on multilevel obstructive disease. This subset of patients is mostly treated either by surgery or local lysis, with or without additional balloon angioplasty. In the TOPAS study[14] comparing vascular surgery and local lysis for the treatment of predominantly acute CLI, 6-month amputation-free survival rates were 66% to 80% for the lysis group (three different doses of urokinase [Abbott Laboratories, Abbott Park, IL]) and 74% for the surgical group. In addition to a better limb salvage rate, the combined percutaneous approach, including laser atherectomy, is less invasive than surgical procedures and can be easily repeated in case of restenosis. Thrombus ablation by local lysis is accompanied by more severe complications than mechanical debulking using laser atherectomy.

Sole medical therapy of CLI, including prostanoids, failed in 38% to 81% of the treated patients and therefore should be limited to patients in whom an interventional approach is not an option.[15,16]

CONCLUSION

Intravascular treatment of complex arterial disease, typically comprising multilevel stenoses and occlusions, can be successfully delivered in the vast majority of cases using a combined endovascular approach, including laser atherectomy. Few in-hospital serious adverse events occurred during a short index hospitalization. Survival during follow-up was within expected norms. An excellent limb salvage rate was achieved in a population with poor surgical options, despite multiple comorbidities that are typical in this patient cohort. A randomized trial comparing various interventional techniques in limb salvage is required to evaluate the true value of the combined interventional approach in this subset of patients. ■

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