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Short Communication

Laser versus balloon angioplasty in endovascular management of infragenicular tibial arterial occlusion in critical limb ischemic TASC D: Six L Trial

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ABSTRACT

We aim to compare cool excimer laser-assisted angioplasty versus tibial balloon angioplasty (TBA) in critical limb ischemia (CLI) patients, with tibial artery occlusive disease. From June 2005 to October 2010, 1506 patients were referred with peripheral vascular disease. 80 patients underwent 89 endorevascularizations for tibial occlusions; 47 using TBA and 42 using cool excimer laser-assisted angioplasty. All patients were Rutherford Category 4, 5, or 6, with TASC D lesions.

Five-year sustained clinical improvement was enhanced with laser angioplasty (76%) compared to TBA (62%; $P = 0.1004$). Rate of revascularization performed due to progression of arteriosclerosis was significantly higher post-TBA ($P = 0.006$). Major adverse clinical events at 5 years were significantly more pronounced in TBA, 38% versus 66% ($P = 0.001$). Laser angioplasty patients had significantly improved quality time spent without symptoms of disease or toxicity of treatment (10.5 months; $P = 0.048$) with an incremental cost of €2073.19 per quality-adjusted life-year gained.

Tibial endovascularization bestows an exceptional outcome in CLI TASC D lesions. Both laser angioplasty and TBA impart recuperated clinical and technical success rates and are superior to bypass surgery. Laser is cost-effective with superior quality time spent without symptoms of disease or toxicity of treatment and quality-adjusted life-years. It offers superior quality of life, with enhanced immediate clinical improvement, reduced binary restenosis, and target lesion revascularization rates. It boosts outstanding survival rates, free from major clinical events at 5 years.

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1. Introduction

Before 2003, laser demonstrated poor results due to undeveloped technology, a lack of understanding of tissue interaction, and the use of incorrect techniques. This led to all lasers being banned for a decade. The aim of "Six L" is to compare the outcome of Cool Excimer Laser-Assisted Angioplasty (CELA) versus Tibial Balloon Angioplasty (TBA) in tibial vessel occlusion in patients with critical limb ischemia (CLI), TASC D lesions. The primary endpoint is Sustained Clinical Improvement (SCI) and Amputation-Free Survival (AFS). Secondary endpoints are binary restenosis, Target Extremity Revascularization (TER), and cost effectiveness.

1.1. *CELA: mechanism of action*

The absorption of laser light by tissue leads to a photoacoustic, photochemical, and photomechanical effect. This disrupts the molecular bond. The rapid conversion of water to water vapor produces an explosive increase in volume and generates stress waves. It rapidly removes the target thrombus and vaporizes procoagulant reactants, avoids a systemic lytic state, facilitates adjunctive balloon angioplasty and stenting as well as augmenting tissue plasminogen activator activity, and suppressing platelet aggregation kinetics.

2. Patients

2.1. *Demographics*

From June 2005 to October 2010, 1506 patients were referred with Peripheral Vascular Disease (PVD). Out of 406 patients treated with CLI over the 4-year period, 80 patients underwent 89 tibial procedures on emergency basis – 47 using TBA and 42 using CELA. All had TASC D lesions.

2.2. *Vascular-related risk factors*

We had more repeated procedures per tibial angioplasty than in the laser group (Table 1). 80% of all our patients were diabetic and a quarter of all patients had chronic renal insufficiency (Table 1).

2.3. *Clinical presentation*

All patients with CLI were Rutherford categories 4, 5, or 6 with TASC D lesions (Table 2). 66.6% of lesions were de-novo and occlusive (Table 3). There was no significance difference between groups regarding lesion length, inflow, or runoff (Table 3). 85% of patients had only one named diseased tibial artery (Table 3). 60% of all patients had no duplex proof of a patent vessel beyond the ankle.

3. Procedure technique

Concomitant proximal angioplasty was performed through the subintimal plane more commonly in the TBA group (Table 4). There was no difference in the number of stents inserted with both groups.

Table 1 – Demographics and vascular-related risk factors.

	TBA	CELA	P value
Patients	$n = 42$	$n = 38$	
Total procedures	$n = 47$	$n = 42$	
Total number of limbs	$n = 44$	$n = 40$	
Males:Females	25:17	22:16	
Age (years)	70 (48–96)	68 (52–86)	0.483*
Hypertension	69%	62%	0.231†
Hyperlipidemia	78%	77%	0.311†
Diabetes mellitus	82%	77%	0.276†
Smoking	90%	87%	0.317†
Ischemic heart disease	34%	37%	0.106†
Renal insufficiency ($Cr > 60$ mL/min/1.73 m^2)	24%	26%	0.398†
Homocysteine	12.9	13.6	0.254*
HbA1C	5.9	6.2	0.418*
Fibrinogen	5.6	5.8	0.406*

* P value using 2-tailed *t*-test.
† P value using Chi Square.

Table 2 – Clinical presentation, prior to procedure.

	TBA	CELA	P value
Patients	$n = 42$	$n = 38$	
Rutherford classification			0.274*
Rutherford category 6	$n = 2$	$n = 2$	
Rutherford category 5	$n = 31$	$n = 29$	
Rutherford category 4	$n = 9$	$n = 7$	
Mean ABI	0.39	0.35	0.391†
Mean digital pressure	0.21	0.17	0.284†

* P value using Mann–Whitney *U*-test.
† P value using 2-tailed *t*-test.

3.1. *TBA*

The main goal is to maximize the runoff and establish a continuous inline flow beyond the ankle. The anterior and posterior tibial arteries are the preferred targets. Total occlusions were crossed with 0.014″ (Submarine, Invatec, Roncadelle, Italy) or V18 guidewires (Boston Scientific, Natick, Massachusetts) supported with a Quick-Cross catheter (Spectranetics, Colorado Springs, Colorado). Long Invatec balloons (Roncadelle, Italy), 2.5 and 3.5 mm, are typically used with the length 80–220 mm. We crossed from the posterior tibial artery to the dorsalis pedis, creating a pedal arch loop to enhance the outflow and heal deep foot ulcers (Fig. 1). In some cases, the wire might extend through the transmetatarsal amputation to the exterior, and yield the exchange of catheters, balloons, and stents easier to handle (Fig. 2).

3.2. *CELA*

Slow laser catheter (CELA catheter; Spectranetics, Colorado Springs) advancement at the rate of 0.5 mm/s is required to maximally ablate the target tissue with saline infusion and multiple passes. Any attempt to rapidly advance the laser catheter defies the principle governing laser-induced plaque