

Results of the LACI multi-center trial

Limb Salvage Following Laser-Assisted Angioplasty for Critical Limb Ischemia (LACI) 2006

Though considered the “gold standard” treatment, bypass surgery is associated with significant morbidity and mortality: 37% of critical limb ischemia (CLI) patients may be considered poor surgical candidates and at high risk for limb loss. Advances in laser catheter design and refinement of recanalization techniques have resulted in improved results with laser-assisted angioplasty of complex peripheral arterial disease (PAD).

Objective

To evaluate the effectiveness of laser-assisted angioplasty for patients with critical limb ischemia who were poor candidates for surgical revascularization.

Methods

This multi-center prospective study was conducted from April 2001 to April 2002 and included 145 patients enrolled at 11 US and three German centers.

The primary end point was limb salvage (avoidance of a major amputation above the level of the ankle) among surviving patients at six months. Minor amputation was defined as an amputation leaving an ambulatory foot, i.e. below the ankle.

Results

145 patients with 155 critically ischemic limbs were enrolled. Median duration of CLI per patient was 13 weeks.

- Amongst 68 females and 77 males, occlusions were present in 92% of limbs
 - Mean age was 72 ± 10 years
- Procedural success was seen in 86% of limbs
 - Stents were implanted in 45% of limbs
- Major complications occurred in 12% of limbs; major dissection in 4%, acute thrombus in 3%, distal embolization in 3% and perforation in 2% cases
- At six month follow-up, limb salvage was achieved in 93% of surviving patients
 - Primary patency at 12 months was 75%

Conclusions

Laser angioplasty for CLI shows very good limb salvage rates in a very sick patient population who are unfit for traditional surgical revascularization.

Prospective investigational device exemption (IDE) summary

Principle investigator

John Laird, MD

Device

Philips CVX-300 excimer XeCl laser system

Study overview

- Laser angioplasty for critical limb ischemia
- Key inclusion criteria
 - At least one angiographically identifiable tibial artery
 - Poor candidates for surgical bypass due to absence of a suitable tautologous vein, lack of undiseased distal vessel > 1 mm in diameter and/or high risk of surgical mortality
- Key exclusion criteria
 - Patients with necrosis necessitating immediate amputation
 - Life expectancy < six months
 - Culprit lesions in a bypass graft, stents in culprit lesions
 - MI in the previous month, and renal insufficiency

Procedural success

Procedural success was defined as < 50% residual stenosis in all lesions in the treated limb.

Conclusions

Results showed that laser angioplasty achieved very high limb salvage rates in surviving patients and is the highest reported for endovascular therapy of complex peripheral disease:

- Procedural success: 83%
- Limb salvage rates of 93% at six months
- All patients received adjunctive balloon angioplasty, 45% of patients had a stent implantation
- Major complication rates were 12%