Laser in Infrapopliteal and Popliteal Stenosis: Retrospective Review of Laser-Assisted Balloon Angioplasty vs. Balloon Angioplasty Alone for Below Knee Peripheral Artery Disease.

Overview

Excimer laser-assisted balloon angioplasty has emerged as one of the mainstay endovascular procedures for CLI with good short- and long-term outcomes. There is however limited data to show procedural and clinical success in below the knee disease.

Objective

To compare immediate procedural and peri-procedural outcomes of laser-assisted balloon angioplasty vs. balloon angioplasty alone in patients with CLI for revascularization of popliteal or infra-popliteal vessels.

Methods

The single high-volume retrospective study was conducted between 2007 and 2012 and included 731 consecutive patients, Laser-assisted balloon angioplasty in 398 patients and standard PTA in 333 patients.

The primary end points were: angiographic success, presence of a brisk distal flow post-procedure, and mean improvement in total lesions severity. The study used a new "Lesion Severity Score" algorithm that incorporates inflow and outflow to measure infra-popliteal lesion complexity.

Results

Sixty-five patients with intermittent claudication, stenotic lesions > 70% by visual In 731 patients, baseline demographics were similar in the laser-assisted balloon angioplasty (LABA) and standard PTA groups.

- 92.5% in LABA group had TASC-D lesions compared to 66.7% in PTA group. CTO patients were also high in LABA group (86.4% vs.49.5%).
- Use of LABA was associated with a 7 times greater likelihood of achieving <50% residual disease compared to balloon angioplasty alone.
- There was a 5 times greater likelihood of improvement in infrapopliteal lesion severity score than balloon angioplasty alone.
- All-cause adverse events occurred in 58 patients (4.0%). Procedural major events occurred in 20 patients (1.4%) and 4 deaths (0.28%).

Conclusions

Laser-assisted balloon angioplasty is significantly better at achieving angiographic success and improving lesion score compared to balloon angioplasty in a high risk population with total occlusions and TASC-D lesions.

LIPS 2013

Prospective IDE Summary

Principle Investigator

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Atherectomy Devices

- Turbo-Tandem 2.0 (Spectranetics®)
- 2.0 Turbo-Elite 0.9 to 2.3mm (Spectranetics®)
- CVX-300 Excimer XeCl Laser System (Spectranetics®)

Study Overview

- Laser-assisted balloon angioplasty vs. PTA for treatment of infra-popliteal vessels.
- Key Inclusion Criteria
  - All patients > 18 years of age with claudication or CLI
- Key Exclusion Criteria
  - All patients < 18 years of age and subsequent popliteal or infra-popliteal interventions in the same patient during the study period.

Procedural Success

- Procedural success was < 50% residual stenosis for popliteal/ infra-popliteal vessels.

Conclusions

- Results showed that Excimer laser-assisted balloon angioplasty can achieve excellent results in complex below the knee lesions:
  - 93% patients had TASC-D lesion in LABA group.
  - Procedural success: LABA, 97.1% vs. BA, 84.3%
  - Lesions severity score improvement: LABA, 97.2% vs. BA, 90.7%
  - In 93 patients with end stage renal disease, all patients in LABA achieved < 50% residual stenosis compared to 92.7% in PTA alone.
  - Post-procedure access site complication rates were similar between groups. Fewer distal embolization in LABA (0.5% vs. 3.3%)

Important Safety Information

Turbo-Elite

The Turbo-Elite Laser Catheter devices are indicated for use in the treatment of infrainguinal stenosis and occlusions. When used in conjunction with the Turbo-Booster and/or as an accessory to the Turbo-Tandem System, the devices are indicated for atherectomy of infrainguinal arteries.
The 0.014" and 0.018" Over-the-wire (OTW) Turbo-Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).

Potential adverse events associated with procedures used to treat PAD may include: a sudden, temporary or ongoing re-closure of the treated artery; blood clot or obstruction of the artery by plaque debris; a tear, rupture or damage to the artery (or nearby vein or nerve); minor bleeding or bruising at the entry site. Other complications may occur.

Rare but serious potential adverse events include: the need for urgent additional procedures or surgery due to bleeding, vascular damage, loss of blood flow or other complications; decrease or loss of kidney function due to contrast exposure; the need for amputation due to inability to restore blood flow; and infection, stroke, irregular heartbeat, heart attack or death.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

Turbo-Tandem

The 7 and 8 French Turbo-Tandem systems are indicated for atherectomy of infrainguinal arteries.

The 7 French Turbo-Tandem System is indicated for laser atherectomy of de novo or restenotic lesions in native infrainguinal arteries and for the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, with adjunctive Percutaneous Transluminal Angioplasty (PTA). A > 2.0mm pilot channel must be present for treatment using the Turbo-Tandem.

No long-term adverse effects on the arterial vessel wall, due to peripheral excimer laser recanalization, are known at this time.
Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at anytime during and/or after the procedure. Potential complications include but are not limited to: perforation of the vessel wall, major dissection, pseudo-aneurysm, arteriovenous fistula, spasm, distal embolization, thrombosis, reocclusion, hematoma at the puncture site, bleeding or Acute Limb Ischemia (ALI), any of which may require a reintervention, bypass surgery or amputation; infection, renal failure, nerve injury, stroke, myocardial infarction, arrhythmia, death and other.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

CVX-300

The CVX-300 is an excimer laser system approved for use in minimally invasive interventional procedures within the cardiovascular system and for the removal of problematic pacemaker and defibrillator cardiac leads.

Potential adverse events associated with procedures used to treat PAD may include: a sudden, temporary or ongoing re-closure of the treated artery; blood clot or obstruction of the artery by plaque debris; a tear, rupture or damage to the artery (or nearby vein or nerve); minor bleeding or bruising at the entry site. Other complications may occur.

Potential adverse events associated with procedures used to treat coronary artery disease may include: a tear, rupture, damage to the artery; a sudden, temporary or ongoing re-closure of the treated artery; blood clot or obstruction of the artery by plaque debris. Other complications may occur.

Potential minor adverse events associated with lead extraction procedures that may or may not require medical or surgical treatment include: a tear or damage to the blood vessels, the heart or its structures; bleeding at the surgical site; or collapsed lung.

Rare but serious adverse events that require emergency medical or surgical procedures may include: a tear or damage to the blood vessels, the heart, lungs or their structures; blood clot or obstruction of the blood vessels or lungs by debris or lead fragments. Other serious complications may include: irregular heartbeat, weakened heart muscle, infection, respiratory failure or complications associated with anesthesia, stroke or death.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

For important safety information, please visit www.spnc.com/IFU.

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