

LEONARDO 2015

High energy laser angioplasty on coronary lesions

Early outcome of high energy Laser facilitated coronary angioplasty ON hARD and complex calcified and balloOn resistant coronary lesions (LEONARDO)

Overview

The 0.90 mm X-80 xenon–chlorine (excimer) laser coronary atherectomy catheter (ELCA X80) was used to pretreat a series of complex coronary lesions, including calcified stenoses, chronic total occlusions and non-compliant plaques. Such complex lesions can be difficult to adequately treat with balloon angioplasty and/or intracoronary stenting alone, due to initial device crossing or balloon dilatation failure.

Objective

To examine the acute procedural outcome of ELCA-facilitated coronary angioplasty in a cohort of patients presenting with chronic total occlusions, calcified plaques and/or balloon-resistant lesions.

Methods

Eighty patients with 100 lesions were enrolled by four centers, and ELCA was performed on 96 lesions. Safety and effectiveness data were compared between patients treated with standard laser therapy (SLT = 60 fluence @ 40 hertz) and those treated with increased laser therapy (ILT = 60 fluence @ 80 hertz and/or 80 fluence @ 80 hertz).

The primary endpoint (laser success) was defined as the ability of the X80 catheter to cross the lesion. The secondary endpoints included:

- Procedural success, defined as reduction of the target lesion to < 50% residual diameter stenosis after adjunctive therapy, as measured by quantitative coronary analysis (QCA)
- Clinical success, defined as reduction of the target lesion to < 50% residual diameter stenosis after adjunctive therapy as measured by QCA with absence of major adverse cardiac events (MACE) at hospital discharge.

Results

Overall, laser success, the primary endpoint of the study, was obtained in 90 lesions (93.7%). Furthermore, dividing the study's population according to the indicated lesion type at laser angioplasty:

- The primary endpoint was reached in 96.4% of the cases with calcified lesions (53/55)
- 93.7% of the cases with initial balloon dilatation failure (30/32), and
- 77.8% of the cases with chronic total occlusion (7/9)
- Of the 6 failures to cross, 4 lesions were subsequently crossed with balloons and/or stents suggesting laser induced plaque modification (94/96 total lesions crossed 97.9%)

Regarding the secondary endpoints:

- 91.7% procedural success
- 90.6% clinical success
- 1/96 (1%) MACE reported – NQWMI – post ventricular fibrillation/CPR

Conclusions

ELCA X80 catheters delivering the current safety and effectiveness in the treatment of CTO, calcified and non-dilatable lesions. If required by dense lesion morphology, the ILT energy levels delivered by this catheter seem to improve device ablation performance without increasing procedural complications. The range of energy delivery capability of the X80 catheter allowed for successful percutaneous coronary intervention (PCI), with low procedural complication, in the complex lesion types presented in this study, including 33% of lesions presenting as prior balloon dilatation failures.

Prospective study summary

Principal investigator

Vittorio Ambrosini, MD

Atherectomy devices

- Philips 0.90 mm ELCA catheter
- Philips CVX-300 excimer laser system

Overview and inclusion criteria

- Target lesion with ≥80% stenosis by visual examination
- Angiographic evidence of calcification or a CTO
- Absence of acute coronary syndrome 3 months prior to index procedure

Procedural success

Procedural success defined as reduction of the target lesion to < 50% residual diameter stenosis after adjunctive therapy, as measured by QCA.

Conclusions

- ELCA X80 catheters operated at maximum energy output levels is safe and effective for calcified lesions, CTO and non-balloon dilatable lesions.
- Use of the higher energy output levels (ILT), using 60–80 fluence at a frequency of 80 Hz, improved ablation performance without increasing procedural complications.

Important safety information

ELCA and ELCA X-80

Indications: The laser catheters are intended for use either as a stand-alone modality or in conjunction with percutaneous transluminal coronary balloon angioplasty (PTCA) in patients who are acceptable candidates for coronary artery bypass graft (CABG) surgery. The following indications for use, contraindications and warnings have been established through multicenter clinical trials. The Philips CVX-300 Excimer laser system and the multi-fiber laser catheter models are safe and effective for the following indications: occluded saphenous vein bypass grafts, ostial lesions, long lesions (greater than 20mm in length), moderately calcified stenosis, total occlusions traversable by a guidewire, lesions which previously failed balloon angioplasty, restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy. These lesions must be traversable by a guidewire and composed of atherosclerotic plaque and/or calcified material. The lesions should be well defined by angiography.

Contraindications: Lesion is in an unprotected left main artery. Lesion is beyond acute bends or is in a location within the coronary anatomy where the catheter cannot traverse. Guidewire cannot be passed through the lesion. Lesion is located within a bifurcation. Patient is not an acceptable candidate for bypass graft surgery.

Potential adverse events: Use of the Philips CVX-300 Excimer laser system may contribute to the following complications: dissection of the arterial wall, perforation, acute reclosure, embolization, aneurysm formation, spasm, coronary artery bypass graft surgery, thrombus, myocardial infarction, arrhythmia, filling defects, death. No long term adverse effects of ELCA are known at this time.

Risks: The primary endpoint defined in the laser angioplasty of restenosis stents (LARS) randomized trial was the absence of major adverse cardiac events (MACE) at 6 months: Death; myocardial infarction; coronary artery bypass surgery. Procedural complications include: any dissection, acute thrombus, haziness, no reflow, arrhythmia, acute vessel closure, occlusion of side branch, occlusion non-target, coronary spasm, coronary embolism, coronary perforation, laser/stent damage, balloon/stent damage, and other serious.

Caution: Federal law restricts this device to sale by or on the order of a physician

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.

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.

