EXCImer Laser Randomized Control Study for the Treatment of FemoropopliTEal In-Stent Restenosis

Overview

Femoropopliteal stenting has shown superiority to percutaneous transluminal angioplasty (PTA) for lifestyle-limiting claudication and critical limb ischemia, though treating post-stenting artery re-obstruction, or in-stent restenosis (ISR), remains challenging.

Objective

To evaluate safety and efficacy of excimer laser atherectomy with adjunctive PTA (ELA+PTA) versus PTA alone for treating chronic PAD patients with femoropopliteal bare nitinol ISR.

Methods[1-3]

The multicenter, prospective, randomized controlled EXCITE ISR trial was conducted across 40 United States centers. Patients with Rutherford Class 1 to 4 and lesions of target lesion length ≥4 cm, vessel diameter ≥5 mm were enrolled and randomly divided into ELA+PTA and PTA groups by 2:1 ratio.

The primary efficacy endpoint was target lesion revascularization (TLR) at 6 month follow up. The primary safety endpoint was major adverse event (MAE, death, amputation or TLR) at 30 days post-procedure. Patients were treated using Turbo-Tandem and, if a 2mm pilot channel did not exist prior to treatment, a Turbo-Elite catheter was used to create a pilot channel as an accessory to Turbo-Tandem.

Results[1-3]

Study enrollment was stopped at 250 patients due to early efficacy demonstrated at a prospectively specified interim analysis.

- A total of 169 ELA+PTA subjects (62.7% male; mean age 68.5 ± 9.8 y) and 81 PTA patients (61.7% male; mean age 67.8 ± 10.3 y) were enrolled.
- Mean lesion length was (19.6 ±12.0 cm vs. 19.3±11.9 cm) and (30.5% vs. 36.8%) patients exhibited total occlusion.
- ELA+PTA subjects demonstrated superior procedural success (93.5% vs. 82.7%) with significantly fewer procedural complications.
- ELA+PTA and PTA subject 6-month freedom from TLR was 73.5% vs. 51.8% and 30-day MAE rates were 5.8% vs. 20.5% ($P < 0.0007$), respectively.[4]

Conclusions

The EXCITE ISR trial is the first of its kind, a large prospective randomized atherectomy clinical trial. Excimer laser atherectomy with adjunctive balloon angioplasty results in significantly better acute and midterm efficacy and safety outcomes for treatment of peripheral femoropopliteal ISR compared to conventional PTA alone in all lesion types examined in this research.

EXCITE ISR

Clinical Trial Summary[1-3]

Principle Investigators

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Atherectomy Devices

- Turbo-Tandem™ (Spectranetics®)
- Turbo Elite™ (Spectranetics®)

Study Overview

- Key Inclusion Criteria
  - ISR lesion ≥ 4 cm
  - RCC 1-4
  - RVD ≥ 5.0 mm
  - ≥ 1 patent tibial artery
- Key Exclusion Criteria
  - Target lesion extends >3 cm beyond stent margin
  - Untreated inflow lesion
  - Grade 4 or 5 stent fracture
- Follow-up
  - Discharge, 30 days, 6 months and 1 year post-procedure

Procedural Success

- ELA+PTA demonstrated superior procedural success (93.5% vs. 82.7%; $P = 0.01$).

Conclusions

Initial results show ELA with adjunctive PTA is superior to PTA alone for the treatment of femoropopliteal ISR:

- Complicated lesions averaging 19 cm in length
- Significantly higher procedural success rate: ELA + PTA 93.5% vs. PTA alone 82.7%, p=0.01
- Superior safety vs. PTA alone: MAE at 30 days ELA +PTA 5.8% vs. PTA alone 20.5% p<0.001
- Significantly higher rate of freedom from TLR (at 6 months): ELA + PTA 73.5% vs. PTA Alone 51.8%, p<0.005

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Important Safety Information

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.

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.

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

REFERENCES

[1] Turbo-Tandem Instructions for Use, http://www.spectranetics.com/physicians/peripheral-vascular-intervention/ifu-library/, July 2014.

[2] EXCITE Trial Clinical Study Report, Spectranetics data on file, July 2014.

[3] Dippel NCVH 2014, New Orleans, LA. http://www.ncvh.org/ncvh-2014-live-cases.html.

[4] Major adverse events are defined as all cause death, major amputation in the target limb, or target lesion revascularization (TLR) (surgical or interventional) from procedure to 30 days (± 7 days).

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