ACCESS PTS STUDY

EKOS™

ACCElerated thrombolySiS for Post-Thrombotic Syndrome (PTS) using the Acoustic Pulse Thrombolysis™ EkoSonic™ Endovascular System – Initial Results of a Multi-Center Study

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Patients

Iliofemoral DVT diagnosed ⩾6 months

PTS with a Villalta Score* ⩾8

Failure of 3 months of conservative therapy

(n = 73 patients, 77 limbs; 18 centres)

Objectives

Evaluate the efficacy and safety of endovascular recanalisation, including Acoustic Pulse Thrombolysis™, in patients with chronic DVT suffering from PTS:

- **Efficacy** – as measured by reduction in Villalta Score* at 30 days post EKOS™ treatment
- **Safety** – as measured by major bleeding within 72hrs, PE ⩽30 days

Method

Acoustic Pulse Thrombolysis™ Using EKOS™

Balloon Dilatation

- Patients underwent balloon dilatation of the occlusive DVT segments

Infusion Protocol

- ⩾ 12hrs Acoustic Pulse Thrombolysis™, then adjunctive therapy as needed
- 0.5 - 1.0mg tPA/hr

Anticoagulation Protocol

- Enoxaparin (1mg/kg BID) for 48hrs prior to and up to 90 days post-Acoustic Pulse Thrombolysis™ treatment

Insertion of the Catheter System

- In vascular catheterisation lab
- Venous access – access site determined by the extent of occlusive disease
- 0.035" guidewire and angiographic catheter to cross occlusion
- Once the occlusion has been successfully crossed, balloon dilatation of the chronic clot shall be performed to create working space and to macerate the hard thrombus
- Guidewire removed and EKOS™ ultrasonic core inserted
- Infusions started then ultrasound turned on

*Villalta Score measures the signs and symptoms of PTS

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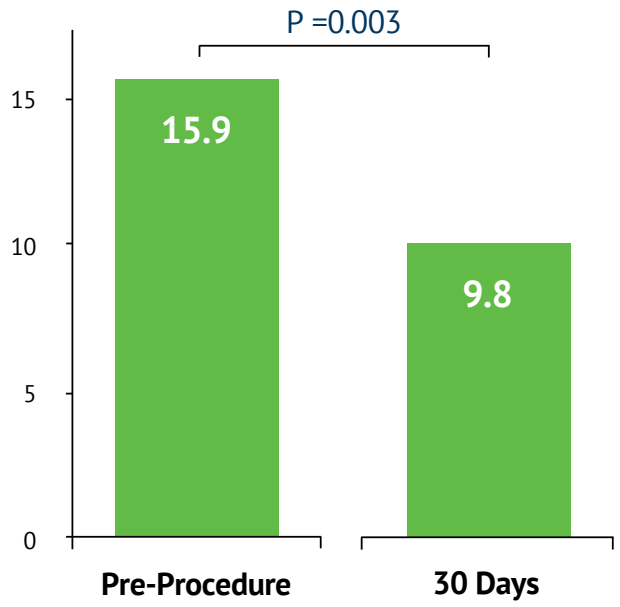
Key Results

Chronic DVT patients with PTS treated with balloon dilatation and EKOS™ therapy showed:

- Clinically significant improvements in the signs and symptoms of PTS at a low tPA dose: 18.5mg ±7.5 and an average of 23hrs of ultrasound therapy
- Met primary endpoint, reduction in Villalta Score ≥4 at 30 days
- 35.5% improvement in the signs and symptoms of PTS at 30 days (as measured by Villalta Score)
- Mean VEINES-QOL score improved by 21% at 30 days**
- One major bleed occurred within 72hrs and one PE occured within 30 days of the Acoustic Pulse Thrombolysis™ procedure

Mean Villalta Score decreased 35.5% at 30 days



CONCLUSION

EKOS™ therapy with balloon dilatation has been shown to be effective and safe in improving the signs and symptoms of PTS.

**N=60 for VEINES-QOL measurement

Imagine where we can go.

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