

ACCElerrated 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

- ≥ 12 hrs 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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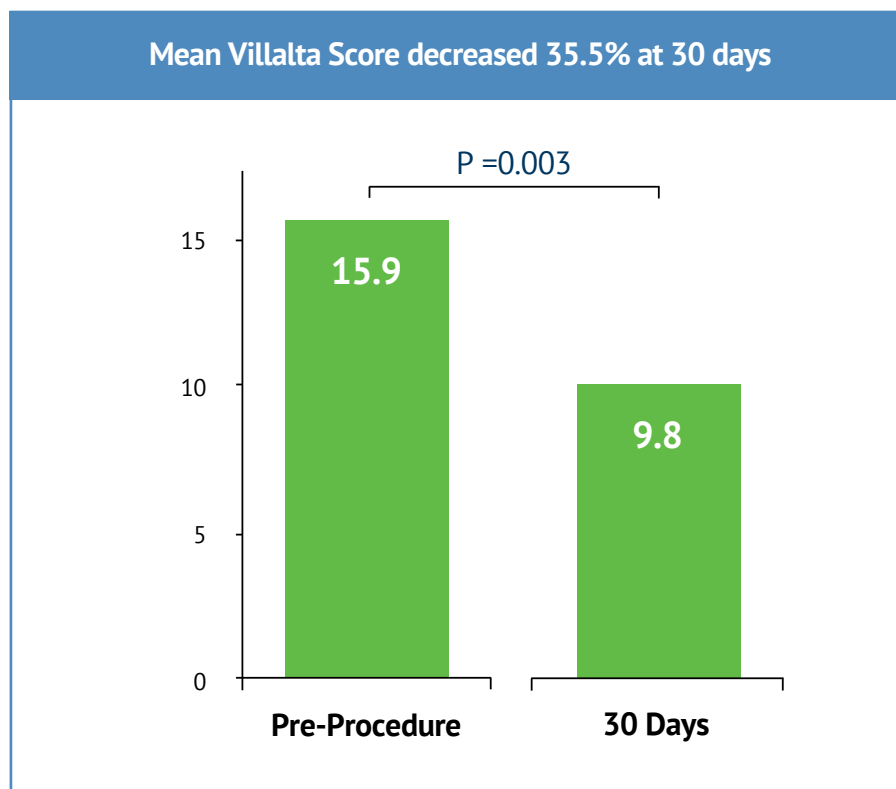
INDICATIONS FOR USE: The EkoSonic™ Endovascular Device, consisting of the Intelligent Drug Delivery Catheter™ (IDDC) and the MicroSonic™ Device (MSD), is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. All therapeutic agents utilised with the EkoSonic Endovascular System should be fully prepared and used according to the instruction for use of the specific therapeutic agent. Contraindications: Not designed for peripheral vasculature dilation purposes. This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition. See device instructions for use for complete prescribing information http://ekoscorp.com/international_enter.htm#Resources



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 occurred within 30 days of the Acoustic Pulse Thrombolysis™ procedure



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.

