ACCESS PTS STUDY

ACCElerated thromboloySiS for Post-Thrombotic Syndrome 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 centers)

Objectives

Evaluate the efficacy and safety of endovascular recanalization, 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 72h, PE ≤ 30 days

Method

Acoustic Pulse Thrombolysis™ Using EKOS®

Balloon Dilatation
• Patients underwent balloon dilatation of the occlusive DVT segments.

Infusion Protocol
• ≥ 12h Acoustic Pulse Thrombolysis™ then adjunctive therapy as needed
• 0.5 - 1.0 mg tPA/hr

Anticoagulation Protocol
• Enoxaparin (1 mg/kg BID) for 48h prior to and up to 90d post-Acoustic Pulse Thrombolysis™ treatment

Insertion of the Catheter System
• In vascular catheterization 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

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*Villalta Score measures the signs and symptoms of PTS

Imagine where we can go.
**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 23h of ultrasound therapy
- Met primary endpoint, reduction in Villalta Score ≥ 4 at 30d
- 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 72h and one PE occurred within 30d of the Acoustic Pulse Thrombolysis™ procedure

**Mean Villalta Score decreased 35.5% at 30 days**

<table>
<thead>
<tr>
<th>Pre-Procedure</th>
<th>15.9</th>
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<td>30 Days</td>
<td>9.8</td>
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P = 0.003

**N=60 for VEINES-QOL measurement

**CONCLUSION**

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