


EKOS™ Acoustic Pulse Thrombolysis Treatment

ACCESS PTS DATA SUMMARY



**“ PLEASE stop saying
nothing can be done
– there is hope with
ACCESS PTS! ”**

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THE ACCESS PTS STUDY

M. Garcia et al. J Am Heart Assoc. 2020; 9:e013398. DOI: 10.1161/JAHA.119.013398.¹

PATIENT CRITERIA

Iliofemoral DVT
diagnosed ≥ 6 months

PTS with a
Villalta Score ≥ 8

Failure of 3 months of
conservative therapy

RECRUITMENT

75*
patients

79*
limbs

18
centers

OBJECTIVE

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^{2,3} at 30 days
post EKOS™ treatment

SAFETY

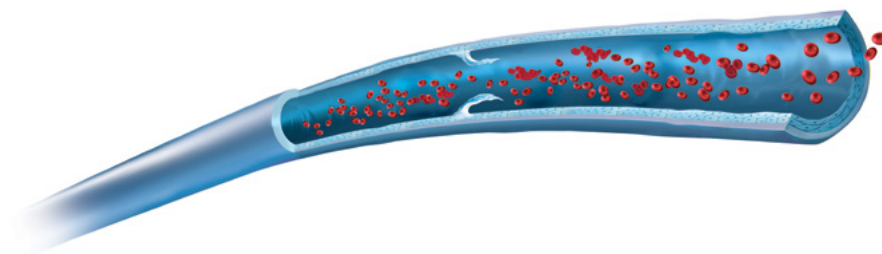
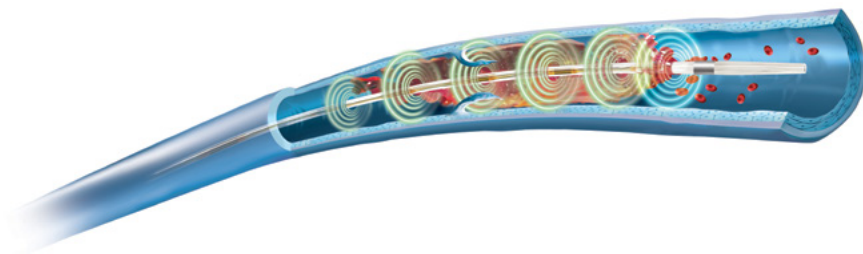
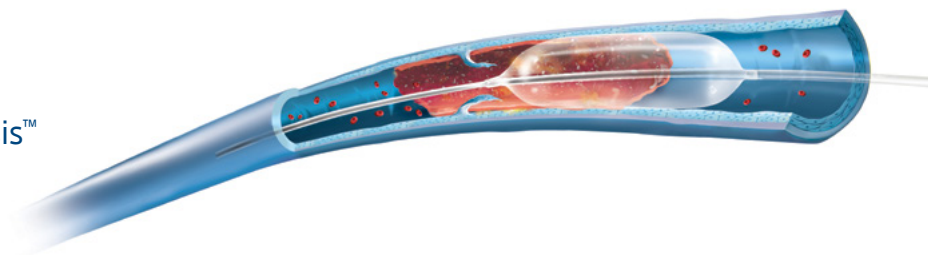
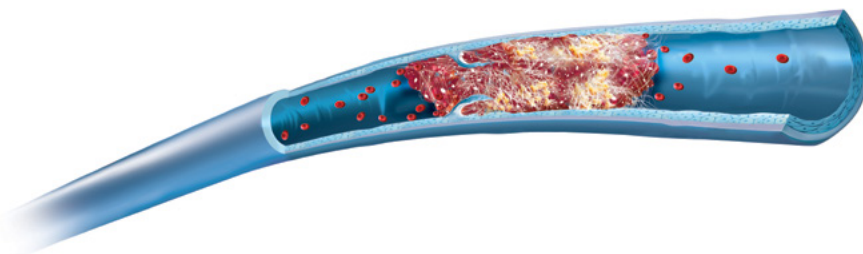
as measured by
major bleeding within
72 hrs, PE ≤ 30 days

*81 patients enrolled, 78 patients (82 limbs) received intervention; of this, 75 patients (79 limbs) were included in the primary efficacy endpoint analysis..

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

METHOD

1. Anticoagulation with Enoxaparin (1 mg/kg BID) for 48 h prior to Acoustic Pulse Thrombolysis™ treatment
2. Cross the chronic occlusion
3. Perform balloon dilatation of the occlusive DVT segment to create working space and to crack the hard thrombus
4. ≥ 12 h Acoustic Pulse Thrombolysis™ therapy, using the EKOS™ device with 0.5-1.0 mg tPA/hr
5. Adjunctive therapy as needed and Enoxaparin (1mg/kg BID) up to 90 d post Acoustic Pulse Thrombolysis™ treatment
6. Educate patients on the **ABCs**
Activity
Blood thinners
Compression



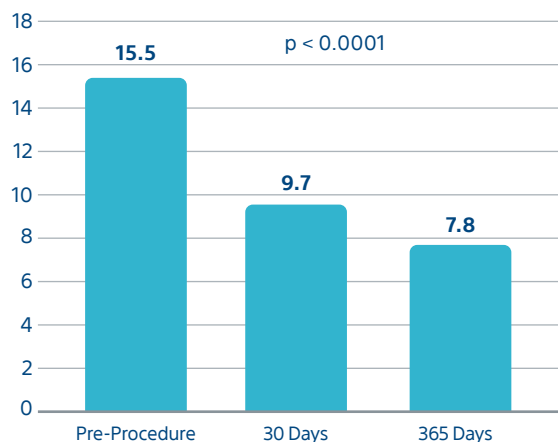
THE ACCESS PTS STUDY

KEY RESULTS

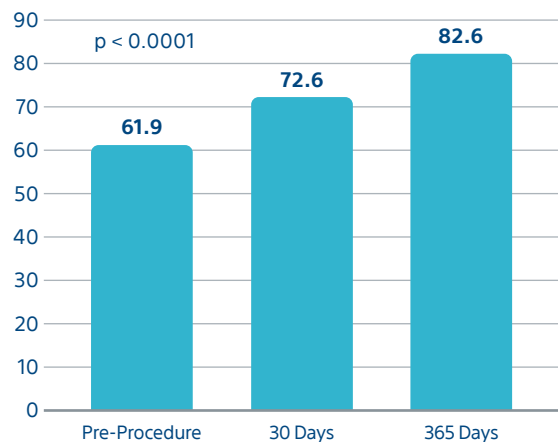
Chronic DVT patients with PTS treated with balloon dilatation and EKOS™ therapy showed:

- Clinically significant improvements in the signs and symptoms of PTS at a low tPA dose: 18.5 mg ± 7.5 and an average of 23 h of ultrasound therapy¹
- Met primary endpoint, reduction in Villalta Score ≥4 at 30 days in at least 50% of patients with a mean improvement of 48.9% at 365 days¹
- Mean VEINES-QOL Score improved by 21% at 30 days and 39% at 365 days¹
- One major bleed occurred within 72 h and one PE occurred within 30 days of the Acoustic Pulse Thrombolysis™ procedure, only four patients developed a new DVT post 30 days¹

Mean Villalta Score decreased 48.9% at 365 days



Mean VEINES-QOL Score improved 39% at 365 days



CONCLUSION

Acoustic Pulse Thrombolysis™ treatment with venoplasty is the ONLY proven treatment regimen for chronic DVT patients with PTS to improve quality of life with long-term data

References:

1. M. Garcia et al. J Am Heart Assoc. 2020; 9:e013398. DOI: 10.1161/JAHA.119.013398.
2. Villalta S, Bagatella P, Piccioli A, et al. Assessment of validity and reproducibility of a clinical scale for the post-thrombotic syndrome Haemostasis 1994;24:158a.
3. Kahn, Sr. The Villalta PTS scale (sometimes called the Villalta-Prandoni scale) has been adopted by the International Society on Thrombosis and Haemostasis (ISTH) as a standard to diagnose and grade the severity of PTS in clinical studies (2016).

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EKOS Acoustic Pulse Thrombolysis Treatment

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INDICATIONS FOR USE:** The EkoSonic Endovascular System is indicated for the: Ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism. • Infusion of solutions into the pulmonary arteries. • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. All therapeutic agents utilized 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. **POTENTIAL COMPLICATIONS:** Vessel perforation or rupture • Distal embolization of blood clots • Vessel spasm • Hemorrhage • Hematoma • Pain and tenderness • Sepsis/ Infection • Thrombophlebitis • Tricuspid and pulmonic valve damage • Pulmonary infarct due to tip migration and spontaneous wedging, air embolism, and/or thromboembolism • Right bundle branch block and complete heart block • Intimal disruption • Arterial dissection • Vascular thrombosis • Drug reactions • Allergic reaction to contrast medium • Arteriovenous fistula • Thromboembolic episodes • Amputation • Pneumothorax • Perforation of the pulmonary artery. • Cardiac Arrhythmias – most frequently occurring during placement, removal or following displacement into the right ventricle. PI-726201-AA

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Peripheral Interventions

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