Treatment of Chronic DVT with EKOS: Reproducing ACCESS PTS Data in Every Day Clinical Practice

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Disclosure

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• **Honoraria received from**: Abbott Vascular, Boston Scientific Corp, BTG, Gore Vascular & Associates, Medtronic, Optimed.

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Prevalence - DVT & PTS

- VTE is estimated to cause at least 3 million deaths a year worldwide
- DVT 900,000 affected each year in U.S.A
- PTS occurs: %25-50 DVT pts who have been treated with appropriate AC
  - %8-10 develop severe PTS including ulcers
  - 600,000 venous ulcers/year
- Likely MILLIONS suffering from PTS

Who are the Patients Under Risk For the PTS?
Major Risk Factors for PTS

- More central occlusions: ↑ chance for PTS
- More central occlusions: ↑ ambulatory venous pressure
- Higher ambulatory pressures: ↑ severity of PTS

The more central occlusion = ↑ risk & severity of PTS
Post Thrombotic Syndrome

Direct Correlation: Ambulatory Venous Pressures & Severity of PTS

- 28 mmHg – Asymptomatic
- 36 mmHg – Varicosities
- 41 mmHg – Edema
- 47 mmHg – Hyperpigmentation
- 60 mmHg – Ulceration

- The greater pressure, the worse PTS

Current Standard of Care for PTS

• Those suffering from CVOD & PTS:

AC + ECS + Elevation ± wound care

Simply, NOT Sufficient..

Pts told ’Nothing we can do about it....
....We just have to live with it.
Millions are suffering from the pain and debilitating effect of PTS. There is nothing we can do… We just have to live with it.

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

M. Garcia¹, K. Sterling², M. Jaffe³, K. Ouriel⁴, S. R. Kahn⁴, A. Comerota⁵ as presented at the Society for Vascular Medicine (SVM) meeting, New Orleans, LA, June 2017.

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
Rationale for Intervention

If you can:

• Reduce the luminal obstruction
• Restore flow

You should be able to

• Reduce the venous hypertension
• Reduce the severity of PTS Sequale
• Improve the QoL
Patient Selection: Reserved for?

- Chronic Veno – Occlusive disease
- Symptomatic with PTS
- Failed conservative treatment: AC + ECS
- QoL limitations
Goal of Intervention

- Establish direct in-line flow
  - From calf to thigh
  - Thigh to pelvis
  - Pelvis to RA

- Flow is Key
to obtaining great results!
Anatomic Considerations

- Popliteal occlusion can be as devastating as iliofemoral occlusion in causing infrapopliteal PTS
Anatomic Considerations

- Axialization of the femoral vein (Collaterals to PFV) are often stated should be sufficient to prevent PTS

- But in many patients, these collaterals may not be sufficient enough to reduce the venous HTN, restore the flow, pressures and obtain QoL back to normal
Treatment of Chronic Deep Vein Thrombosis Using Ultrasound Accelerated Catheter-directed Thrombolysis

M. Dumantepe *, I.A. Tarhan, A. Ozler
Department of Cardiovascular Surgery, Memorial Atasehir Hospital, Istanbul, Turkey

- Single Center experience
- 12 Patients with Lower Extremity DVT > 28 days
- Mean Symptom duration 92 days
- EKOS System Delivering Alteplase
- Follow-up with Doppler US and Villalta Score
In a great majority of the cases, we achieved 70% or more recanalization or remodeling of the chronic clot.
Results

- 11/12 limbs (Complete 6/12, Partial 5/12) responding with significant clinical improvement
- 5/12 patients required angioplasty and stent implantation.

![Bar chart showing results distribution.](chart.png)
Follow-up

360 days US Patency ( % Remaining open)

- 1 mo: 11 of 11 (100%)
- 3 mos: 10 of 11 (91%)
- 6 mos: 10 of 11 (91%)
- 12 mos: 9 of 11 (83%)
- 15 mos: 8 of 11 (77%)
Chronic Venous Occlusions

Pre Planning

Successful Recanalization:

- 1. First and MOST IMPORTANT step- proper planning

Evaluate & Examine Patient

- Know anatomy, extent of occlusion central to peripheral aspect

- Obtain & review imaging: CTV, MRV

- Decide on access site
Chronic Venous Occlusions
Pre Planning

• Successful Recanalization:

2. Review imaging YOURSELF (CTV, MRV, DUS)

  - MUST know extent of disease

  - Plan appropriate steps before your intervene

  - Determine Access sites (Tibial vein, Popliteal V, CFV)
Access Site Determination

• Goal: To establish direct in-line flow from ankle to RA

• Would use lowest patent site for the access
  - Pop
  - GSV
  - FV
  - Tibial
  - IJ
3. Crossing the Occlusion:
   - Initially use 0.035 CTO Catheter (Navicross) + Stiff straight Glidewire
   - Support system (IE: Cook Triforce)
   - Re-entry devices
   - Sharp recanalization (Stiff wire, Rosch-Uchida needle)
   - Exchange for stiff working wire (Amplatz, Lunderquist)
After Chronic Occlusion Crossed

• 4. ’Prep’ the vessel:
  - Sequential PTA through occlusion to appropriate size
  - Place EKOS® system overnight
  - EKOS® + Balloon Angioplasty in combination with tPA;
    improves vein compliance and ability to expand
  - It does work in softening that scarred and noncompliant vessel
  - Why do we use tPA; if no thrombus in chronic DVT?

• Anticoagulation: I start prior to procedure:
  Enoxaparine 1 mg/kg BID
The Protocol: Day 2

- Infusing overnight 0.5-1.0 mg/hr tPA @ EKOS® Lysis
- Follow-up venography and further PTA to the expected size of the vessel.
- Much more compliant vessels that responds better to the angioplasty at the second day
- central stenting if needed (as low as lesser trochanter)
- Discharged on Enoxaparin 1 mg/kg BID x 1 month & ECS
- Transition to oral agent @ 1 month
- Initiate exercise program 2-3 days post op
Discharge

- **ABC’s**
  - **Activity**- increase activity (encourage exercise) after 2 days
  - **Bloodthinner**– Enoxaparine (1 mg/kg/BID) x 1 month
    +/- ASA 100 mg / day
    if patent @ 1 month = transition to NOAC
    (rivaroxaban 20 mg/day)
  - **Compression**: ECS knee-hi 20-30 mmHg from out of the bed to in bed
Single Center Experience

- Patients with symptomatic Femoro-popliteal DVT > 6 Months
- Failure of min 6 months conservative therapy (AC + EC)
- Villalta Score > 8

*Primary Efficacy Endpoint* was reduction in Villalta Score of >6 point at the 30 day compared to baseline in at least 50% of patients

*Primary Safety endpoint* were major bleeding events within 72 h of starting the procedure and PE within 30 days Post UACDT
**Results**

- No: 162 Chronic fem-pop DVT patients
- DVT Age: mean 26.2 Months
- tPA mean dose: 21.3 mg
- tPA mean duration: 23 hrs

- Pt men age: 44.6 yrs
- Gender: M: 72%, F: 28%
- Limb: Left: 60%, Right: 40%
- Mean Hospital Stay: 3.3 days

**Primary endpoint:** 75% (122/162) Pts reached > 6 point of Villalta reduction of \( p<0.001 \)

**Safety endpoint:**
- N= 1 Major bleeding (epistaxis), N= 9 (5.5%) minor bleeding
- Recurrent DVT: N= 6 (3.7%)
- Pulmonary Embolism: N=0, Death: N=0
Results

- **Patency**
  - Primary: %69.7
  - Asist. primary: %80.5
  - Secondary: %82.1

- **Improvement in Venous Claudication**: %88

- **Freedom From Ulceration**: %91 (80/88)
Results: Villalta Scale

Baseline vs Post treatment Follow up intervals: $p<0.0001$

Mean Villalta improvement from baseline

<table>
<thead>
<tr>
<th>Time</th>
<th>Villalta Score</th>
</tr>
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<tbody>
<tr>
<td>Baseline</td>
<td>17.3</td>
</tr>
<tr>
<td>30 Days</td>
<td>11.1</td>
</tr>
<tr>
<td>90 Days</td>
<td>7.8</td>
</tr>
<tr>
<td>180 Days</td>
<td>6.5</td>
</tr>
<tr>
<td>365 Days</td>
<td>7.0</td>
</tr>
</tbody>
</table>
**VCSS Results**

Baseline vs Post treatment Follow up intervals: p<0.0001

Mean VCSS score reduction

- Baseline: 13.5
- 30 Days: 8.2
- 90 Days: 7.7
- 180 Days: 6.5
- 365 Days: 5.4
VEINES-QOL Results

Baseline vs Post treatment Follow up intervals: p<0.0001

Mean VEINES QOL improvement
Chronic DVT Case Examples
3 Year Old Chronic DVT

- 55 yo Male with severe PTS
- AC + ECS
- Non healing venous wounds
- Hyperpigmentation & LDS
- Villalta Score = 30
- DUS = Chronic Fem-pop Occlusive disease
No More Suffering @ 2 month

Villalta score 30 → 8
Case # 2

• 53 yo M w/DVT left leg since 2013 (5 years)
• Non healing Ulcer X 4 years
• Villalta score total: 28
• DUS = Chronic occlusive disease from popliteal to the iliac vein
• EKOS® Pop → iliac vein (50 cm Treatment zone)
• tPA (Alteplase) dose 22 mg x 24 hrs
Doppler US showed complete patency between the popliteal vein until the IVC
postoperative 2 weeks
Case # 3

- 45 years old Female w/DVT on her left leg
- **87 days** post diagnosis of ilio-femoro-popliteal DVT after her abdominoplasty operation
- Coumadin & irregular use of ECS
- In venography, no filling was observed between the popliteal vein & iliac vein.
Case # 4

- 35 Year old male patient
- Venous stent implanted 18 months ago due to subclavian vein stenosis
- Irregular use of Anticoagulation
- The Venous stent was thrombosed after 4 months of placement
- No intervention up to now.
Conclusion

• For Patients suffering from Chronic Veno-occlusive Disease & PTS
  - Safe & effective treatment is available
  - in the appropriate setting

PTS treatment protocol:
  - Does reduce the PTS scores @sequale (Villalta& VCSS)
  - Does improve QoL (VEINES sym/score)

It is time stop saying... Nothing can be done
Thank you very much for your attention...