Ultrasound Enhanced Thrombolysis For Older DVT: Update From The ACCESS PTS Study

Mark J Garcia, MD, MS, FSIR

Disclosures:

- Honoraria/Speaker: BSC, BTG/EKOS, Cook
- Research Support: BSC, BTG/EKOS, Cook
- Consultant: Merit Medical
- Royalties: Merit Medical

VTE & PTS: Prevalent Problem

- Deep venous thrombosis (DVT)
  - ~950,000 new cases in US annually
  - Classic medical treatment
    - Anticoagulation
    - Only prevents progression of thrombosis
    - Does not act on existing thrombus
    - Can lead to PTS
- Post-thrombotic syndrome (PTS)
  - Up to 50% of those on anticoagulation will develop PTS after 1st episode of DVT
  - Swelling, aching, edema, varicosities, discoloration, ulceration
  - Estimated socioeconomic burden of up to $3 billion annually
  - Likely MILLIONS are suffering from PTS


PTS Can Be Devasting

Rationale for ACCESS PTS

- For those suffering from PTS:
  - Medical management is NOT sufficient
  - When there are chronic venous changes in the vein restricting/obstructing outflow... venous pressures will increase
  - Severity of PTS symptom is directly proportional to the degree of ambulatory venous pressures:
    - The higher the pressure, the more severe the symptoms
  - Symptoms + chronic venous disease... consider intervention

Rationale

- GOAL OF INTERVENING ON CHRONIC DVT:
  - Relieve the obstruction by restoring flow in the occluded venous segment, thus decreasing the venous pressures and subsequently the severity of PTS
  - The question that needs to be answered is....
  - Can we reduce post thrombotic sequelae & improve the QOL in those suffering from PTS

"ACCESS PTS"
How Did We Get Here

Background: 2012 SIR
- Retrospective, single center review
- 106 patients and 122 limbs treated
  - 66 M, 40 F
  - Mean age 57; range 13-96 years old
  - 105 lower extremities
  - IVC involvement in 25
- All w/ symptoms > 1mo
- Documented DVT by US
- DVT defined as chronic by age of sx onset > 1mo
- All with varying degrees of PTS sequelae
  - Pain & swelling ➔ ulcer & gangrene (≥ CEAP 3)
  - All c/o lifestyle limitations

Garcia, et al. SIR. 2012 abstract presentation

Results

Technical success:
A) Ability to cross occlusion: 120/122
98%

B) Ability to restore flow: 118/122
97%

Results

Clinical Success:
Symptomatic Improvement
- Mean follow-up 2 yrs 7 mo
- 104/122 limbs:
  97 (93%) reported significant improvement
  7 (7%) unchanged
  0 worse
- 18 were lost to follow-up

Significant Improvement
Unchanged
Worse

Results

US Patency
- 1 mo: 95 of 100 (95%)
- 3 mos: 91 of 77 (92%)
- 6 mos: 97 of 65 (98%)
- 12 mos: 30 of 38 (79%)
- 24 mos: 11 of 19 (58%)

Pilot Venographic Clearance Analysis

Analysis performed by Syntactx, Inc.
Example

- 65 yo F in 1998 had hysterectomy w/ left iliac vein rupture
- Vasc surgeon unable to repair, ligated
- Immediately developed pain & swelling
- Extensive LLE DVT
- Anticoagulation & ECS x 12 yrs
- Severe limitations in activity and poor QOL
- Referred for eval & management

12-Year-Old DVT

Post Treatment

5-Year F/U US

"Extremely happy" w/ result
Active w/ treadmill & cycling
Rare & minimal Sxs
Vilalta >20 to 2

Developing Evidence

ACCESS PTS : EKOS/BTG sponsored trial
- Mark Garcia MD - Study PI
- Michael Jaff DO – core lab duplex US
- Ken Ouriel MD – core lab venography
- Anthony Comerota MD – Safety Monitor
- Susan Kalvin MD – Clinical Consultant

ACCESS PTS

- Prospective, multicenter study
- Patients with symptomatic LE DVT x 6 months
- US documented DVT
- Failed 3 mos conservative Rx (AC + ECS)
- Vilalta >8
Outcomes of treating chronic deep vein thrombosis with intervention including thrombolytic infusion with the EkoSonic System

Primary Endpoints:
- Clinical: Reduction of 4 on Vilalta scale @ 30 days compared to baseline in at least 50% of subjects
- Technical: Increase in blood flow calculated by time to washout in the affected segments, Baseline vs Post-EkoS Treatment
### Study Sites & Enrollment

<table>
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<tr>
<th>Access PTs Sites</th>
<th>Principal Investigator</th>
<th>Site Name</th>
<th>Location</th>
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<tr>
<td>John Aruny</td>
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As of 11-17-2015

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### Imagine the Value Added

When we can eradicate PTS!!!