Update On EKOS “ACCESS PTS”
Trial For Post-Thrombotic Syndrome

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 thrombus
  - Does not act on existing thrombus
  - Can lead to PTS

- Post-thrombotic syndrome (PTS)
  - Up to 40% of those on anticoagulation will develop PTS after 1st episode of DVT
  - Sciatica, aching, edema, varicosities, discoloration, ulceration
  - Estimated socioeconomic burden of up to $3 billion annually
  - ~MILLIONS suffering from PTS in US alone

PTS Can Be Devastating

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 worse 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
  - 68 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)
- 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

Results

US Patency
- 1 mo: 95 of 100 (95%)
- 3 mos: 71 of 77 (92%)
- 6 mos: 57 of 65 (88%)
- 12 mos: 30 of 38 (79%)
- 24 mos: 11 of 19 (58%)

2013 Villalta Results
- N= 31 consecutive pts
- Preprocedure: 13.1
- Postprocedure:
  - 1 month: 5.2
  - 3 mos: 2.6
  - 6 mos: 2.1
  - 12 mos: 1.9

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

Developing Evidence

ACCESS PTS: EKOS/BTG sponsored trial

Steering Committee:
- Mark Garcia MD - Study PI
- Michael Jaff DO – core lab duplex US
- Ken Guest MD – core lab venography
- Anthony Comerota MD – Safety Monitor
- Susan Kahn MD – Clinical Consultant

ACCESS PTS

- Prospective, multicenter study
- 200 Patients with symptomatic LE DVT x 6 months
- US documented DVT
- Failed minimum 3 mos conservative Rx (AC + ECS)
- Villalta ≥ 8

Outcomes of treating chronic deep vein thrombosis with intervention including thrombolytic infusion with the EkoSonic System

- Primary Endpoints:
  - Clinical: Reduction of 4 on Villalta 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

Enrolled 72 of 200
Treated 41
Failure to Cross 1

As of 11-17-2015

Imagine the Value Added

When we can eradicate PTS!!!

www.chronicdvtstudy.com