Ultrasound-Accelerated Thrombolysis For Chronic DVT: The ACCESS PTS Trial
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Disclosures
- BSC: speaker, consultant, research support, MAB
- BTG/EKOS: speaker, consultant, research support
- Cagen! Vascular: MAB, stockholder
- Cook: speaker, consultant
- Intact Vascular: MAB, stockholder
- Merit Medical: CMO, consultant, royalties
- Philips/Volcano: speaker, consultant, MAB
- Vesper Medical: MAB, BOD, consultant, stockholder

DVT & PTS: The Facts
- 1-2 per 1000 develop acute DVT/yr
- Population: US 326M, Global 7.6B
- 300,000-600,000 new, acute DVT cases/yr in US
- Up to 30% of DVT pts will develop PTS w/in 2 yrs despite therapeutic AC
- 84% of femoropopliteal DVT pts will develop PTS w/in 2 yrs (ATTRACT)
- Total PTS pts: extrapolate the data = 2.6M PTS in US & 60.8 M globally

Venous Disease - Pathophysiology

Femoralpopliteal Occlusions
- Femoral vein occlusions: Axialization may not always be adequate to decompress the elevated venous pressures
- Popliteal occlusions: can cause severe calf PTS ....main outflow from the calf

Rationale of Intervention
- If you can:
  - Reduce the luminal obstruction
  - Restore flow
- You should be able to:
  - Reduce the venous HTN
  - Reduce the severity of PTS sequelae
  - Improve QOL
Venous Hypertension

Changing the Chronic DVT Treatment Paradigm

ACCESS PTS: EKOS/BTG sponsored trial

Steering Committee:
- Mark J. Garcia MD - Study PI
- Michael R. Jaff DO – VasCore (Duplex US core lab)
- Ken Ouriel MD – Syntactx (venography core lab)
- Anthony Comerota MD – Safety Monitor
- Susan Kahn MD – Clinical Consultant
- Keith Sterling MD - Consultant

ACCESS PTS
- Prospective, multicenter study with 29 sites
- Patients with symptomatic LE DVT ≥6 months documented by US
- Must have minimum femoral DVT
- Isolated iliofemoral DVT excluded
- Failed minimum 3 mos conservative Rx (AC + ECS)

ACCESS PTS Protocol
- Wt-based enoxaparin pre-procedure - 1mg/kg BID (48 hrs pre)
- Appropriate access to obtain complete direct in-line flow
- If pop clean: pop access
- If pop diseased: tibial access
- Cross occlusion using standard CTO techniques/devices
- PTA to appropriate “normal” vessel size
- EKOS lysis @ 0.5-1.0 mg/hr overnight
- F/U w/ PTA +/- pelvic stenting (to lesser troc) as needed
- Discharged on Enoxaparin 1mg/kg BID x 1 mo & ECS
- Transition to oral agent @ 1 mo
- Initiate exercise program 2-3 days post-op
- F/U @ 30, 90, 180, 365 days w/ DiUS

Discharge
- ABCs
  - Activity: incl activity after 2 days
  - Blood thinner: Enoxaparin 1mg/kg/ 2x day x 1 mos -> OAC
  - Compression: ECS knee to 20-30 mmHg “out of bed” to “in bed”

Demographics
- N = 78 pts; 82 limbs
- DVT age: mean 13.2 mos
- Limb Lt = 60%, Rt = 40%
- TPA mean duration: 22.8 hrs
- Age mean: 54.6 yrs
- Gender: M=68%, F=32%
- Mean hospital stay: 3.4 days
- TPA mean dose: 18.5 mg
- 6% had revascularization events w/in 30 days
Patient Enrollment

- 1216 pts screened
- 113 pts consented
- 81 pts enrolled w/ ITT
- 78 pts treated
- 82 limbs treated
- * 78 pts & 82 limbs (4 pts had BLE DVT treated)
- 81 pts enrolled w/ ITT
- 85 limbs enrolled 4 pts bilateral
- 73 pts treated 4 pts bilateral
- 77 limbs evaluable 4 pts bilateral

DVT Location: 2/3 Infrainguinal Only

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ACCESS PTS: Primary Endpoint Results

- 1st Endpoint analysis:
  - Goal: ≥4 pt reduction in Villalta @ 30d in 50% treated
  - Actual: ≥4 pt reduction was seen in 66% of pts treated

Villalta Results: Mean Improvement 49% from Baseline @ 365d

- Baseline vs post-treatment follow-up intervals: $p<0.0001$

VCSS Results: Mean Improvement 42.7% from Baseline @ 365d

- Baseline vs post-treatment follow-up intervals: $p<0.0001$

VEINES-QOL Results: Mean Improvement 36.4% @ 365d

- Baseline vs post-treatment follow-up intervals: $p<0.0001$
Doppler Patency @ 365 Days

Venographic Results: Washout

Venous Thrombus Scores

Safety Endpoint

2 yo Fem-pop CVOD

F/U Intervention
ACCESS PTS Conclusions

- ACCESS PTS is a statistically significant study:
  - 1st endpoint reached: Villalta reduction of 4 $p=0.0051$
  - Villalta improvement @ 365d = 8.2 pts $p<0.0001$
  - VCSS improvement @ 365d = 5.7 pts $p<0.0001$
  - VENES-QOL improvement @ 365d = 19 pts $p<0.0001$
  - Improvement in TTW 4.2 to 2.9 sec. $p=0.009$
  - Persistent patency on US @ 365d (87-96%)

Can ACCESS PTS Change the Paradigm?

- I think so...
  - By removing luminal obstruction
  - Restoring flow
  - Vein function as a conduit with remodeling occurs
  - With continuous & persistent reduction & or resolution of venous hypertension
  - Significantly improved PTS sequelae seen out to 365 days

Summary

Endovascular intervention using ACCESS PTS protocol is a safe & effective treatment for recanalizing chronic venous occlusions

Hope is here for PTS patients.
ACCESS PTS results demonstrate that intervention on CVOQ is effective and should lead to further studies that will change the PTS treatment paradigm.