

# The ACCESS PTS Study

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ACCElerated thrombolySiS for Post-Thrombotic Syndrome using the Acoustic Pulse Thrombolysis EkoSonic(r) Endovascular System:

## Results of a Multi-center Study

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# Background & Purpose

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- *Post-thrombotic syndrome (PTS) occurs in up to 50% of patients (pts) with DVT despite appropriate anticoagulation.*
- *Chronic DVT and PTS can be debilitating, while reducing one's quality of life. When standard of care is ineffective, treatment options are limited.*
- *A multi-center, prospective, single-arm study evaluated the efficacy & safety of endovascular recanalization, including ultrasound-accelerated, catheter-directed thrombolysis (USCDT) in pts suffering from chronic DVT and PTS.*

# Materials & Methods

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## Inclusion criteria:

- femoral DVT diagnosed  $\geq 6$  months prior
- Villalta Score (VS)  $\geq 8$
- failure of 3 months conservative therapy
- The primary efficacy endpoint was a reduction in VS of  $\geq 4$  at the 30-d post-USCDT in  $\geq 50\%$  pts.
- The primary safety endpoints were major bleeding events within 72h of starting the procedure and pulmonary embolism (PE) within 30d post-USCDT.

## Exclusion criteria:

- isolated iliofemoral DVT
- high bleeding risk
- complete popliteal vein occlusion
- filling defect  $\geq 3$  cm into IVC

# Materials & Methods

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## Protocol

- *Wt-based enoxaparin BID pre-procedure*
- *Appropriate access to obtain complete direct in-line flow*
- *Cross occlusion using standard CTO techniques*
- *PTA diseased segments to appropriate “normal” vessel size*
- *EKOS lysis @ 0.5-1.0 mg/hr  $\geq$  12 hr*
- *F/U w/ PTA +/- pelvic stenting (to lesser troch) if 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/ DUS*

# Results

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

## Primary Endpoint:

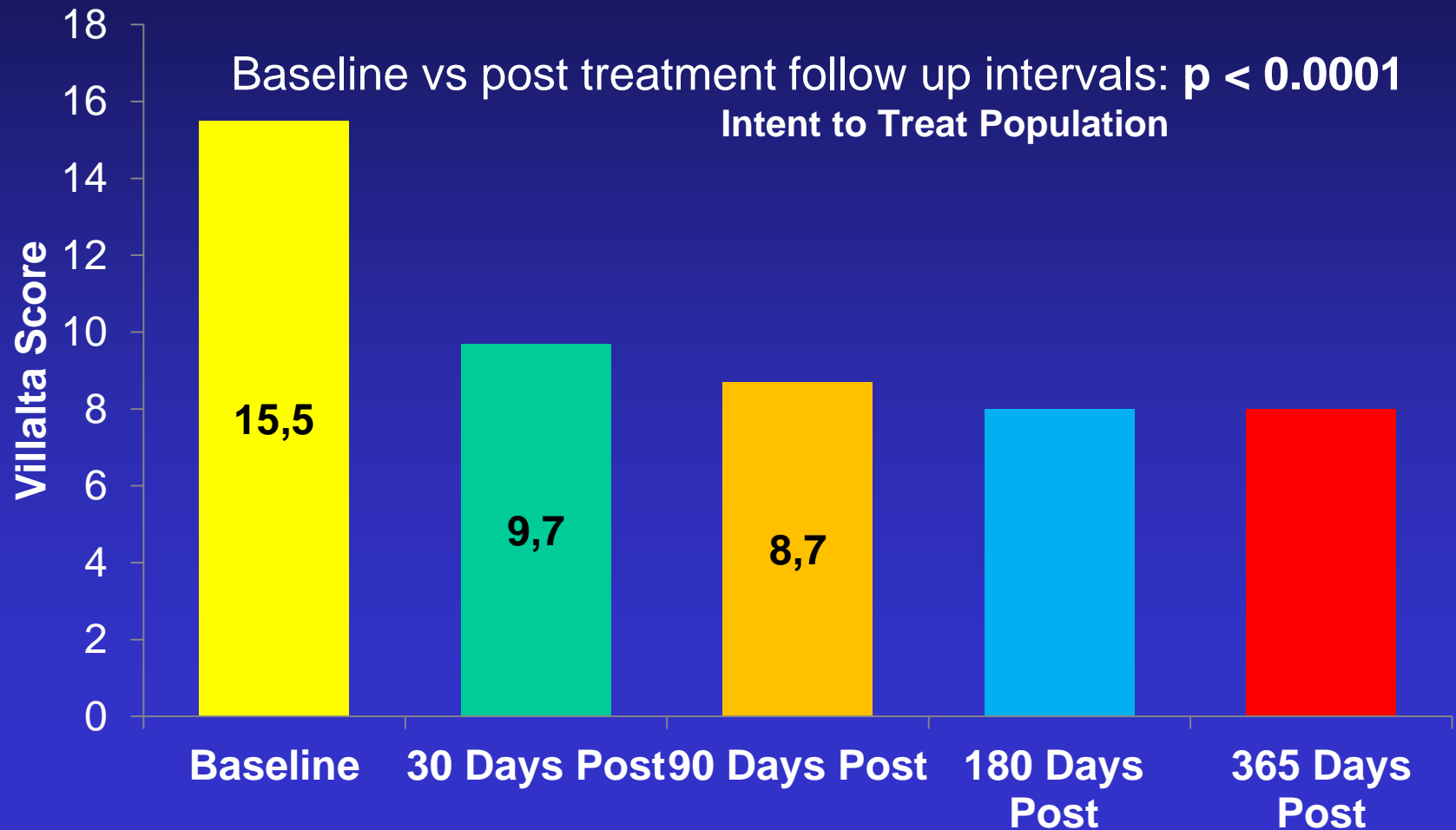
- 67% reached 1<sup>o</sup> endpoint of Villalta reduction of  $\geq 4$  ( $p = 0.003$ )

## Safety Endpoint:

- 1 major bleed - (1.3%) Related to AC (died at 32 days of multi-organ failure)
- Recurrent DVT N = 3 (3.8%)
- PE N = 1 in 30 days (1.3% - 0 during hospitalization)

# Villalta Results

mean improvement 47.9% from baseline @ 360d



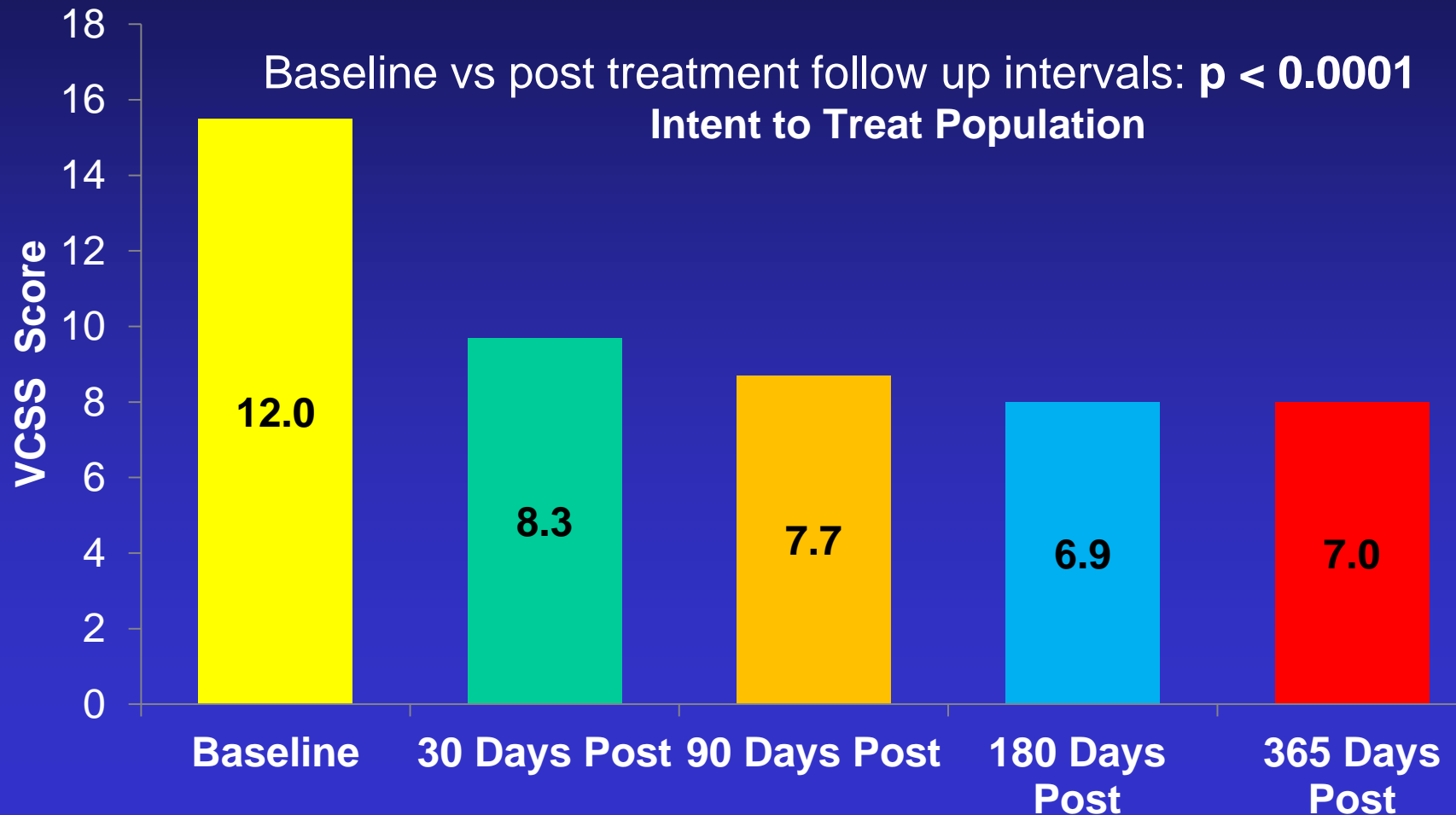
# Results: Villalta Scale

	<b>N (L)</b>	<b>Mean</b>	<b>Δ from Baseline</b>	<b>% Change</b>	<b>P from Baseline</b>
Baseline	82	<b>15.5</b>	-	-	-
30 d Post	79	<b>9.7</b>	<b>-5.9</b>	<b>34.8%</b>	<b>&lt;0.0001</b>
90 d Post	74	<b>8.7</b>	<b>-7.0</b>	<b>42.5%</b>	<b>&lt;0.0001</b>
180 d Post	69	<b>8.0</b>	<b>-7.9</b>	<b>48.6%</b>	<b>&lt;0.0001</b>
365 d Post	64	<b>8.0</b>	<b>-8.5</b>	<b>47.9%</b>	<b>&lt;0.0001</b>

Change in Villalta Score: **p < 0.0001** (95% CI) at each interval  
(using Mixed Model Repeated Measure -MMRM)

# VCSS Results

mean improvement 42.3% from baseline @ 365d





# Results: VCSS

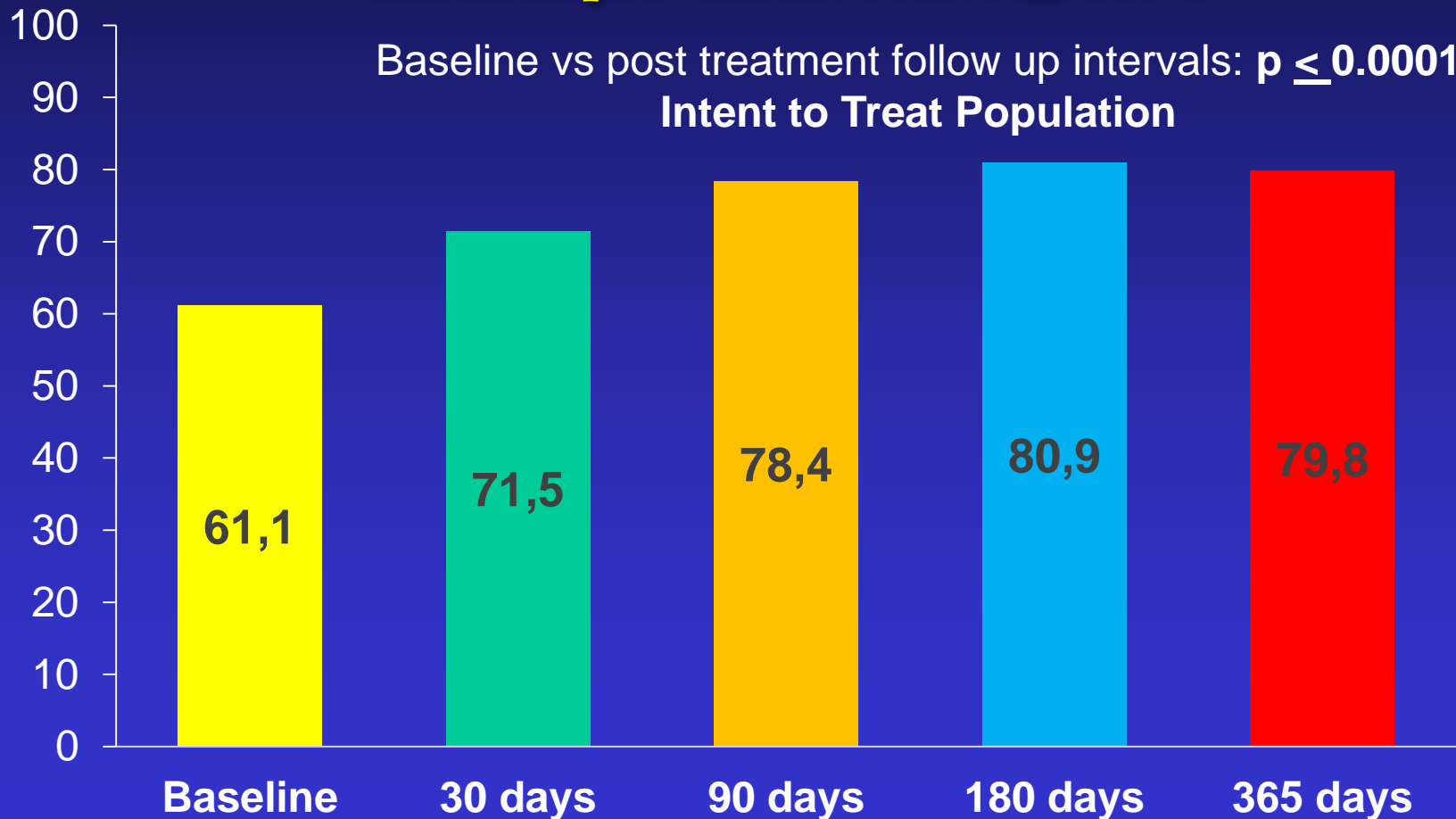
	<b>N (L)</b>	<b>Mean</b>	<b>△ from Baseline</b>	<b>% Change</b>	<b>P from Baseline</b>
Baseline	82	<b>12.0</b>	-	-	-
30 d Post	79	<b>8.3</b>	<b>-3.8</b>	<b>27.0%</b>	<b>&lt;0.0001</b>
90 d Post	73	<b>7.7</b>	<b>-4.5</b>	<b>31.4%</b>	<b>&lt;0.0001</b>
180 d Post	70	<b>6.9</b>	<b>-5.2</b>	<b>40.7%</b>	<b>&lt;0.0001</b>
365 d Post	63	<b>7.0</b>	<b>-5.7</b>	<b>42.3%</b>	<b>&lt;0.0001</b>

Change in VCSS Score : **p < 0.0001** (95% CI) at each interval  
(using Mixed Model Repeated Measure -MMRM)

# VEINES-QOL Results

mean improvement 36.2% @ 365 d

Baseline vs post treatment follow up intervals:  $p \leq 0.0001$   
Intent to Treat Population



# Results: VEINES-QOL

	<b>N (L)</b>	<b>Mean</b>	<b>△ from Baseline</b>	<b>% Change</b>	<b>P from Baseline</b>
Baseline	63	<b>61.1</b>	-	-	-
30 d Post	62	<b>71.5</b>	<b>10.5</b>	<b>21.3%</b>	<b>&lt;0.0001</b>
90 d Post	58	<b>78.4</b>	<b>16.5</b>	<b>32.5%</b>	<b>&lt;0.0001</b>
180 d Post	55	<b>80.9</b>	<b>19.2</b>	<b>36.5%</b>	<b>&lt;0.0001</b>
365 d Post	52	<b>79.8</b>	<b>19.7</b>	<b>36.2%</b>	<b>&lt;0.0001</b>

Change in VEINES-QOL Score : **p < 0.0001** (95% CI) at each interval  
(using Mixed Model Repeated Measure -MMRM)

# Results Summary:

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## ACCESS PTS is a Statistically Significant Study:

- 67% reached 1<sup>o</sup> endpoint of Villalta reduction of 4 ( $p = 0.003$ )
- Villalta improvement @ 30d = 6 pts & 35% ( $p < 0.0001$ )
- Villalta improvement @ 365d = 8 pts & 48% ( $p < 0.0001$ )
- VCSS improvement @ 30d = 3.8 pts & 27% ( $p < 0.0001$ )
- VCSS improvement @ 365d = 5.7 pts & 42% ( $p < 0.0001$ )
- VEINES QOL improvement @ 30d = 10 pts & 21% ( $p < 0.0001$ )
- VEINES QOL improvement @ 365d = 19 pts & 36% ( $p < 0.0001$ )

\*\* Final evaluation will include DUS patency & venographic improvement

# Conclusions

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For Pts suffering from Chronic Veno-Occlusive Disease & PTS:

- Endovascular intervention using USCDT with PTA
  - safe & effective treatment for recanalizing chronic venous occlusions
- ACCESS PTS treatment protocol:
  - **Statistically** improves PTS scores & sequelae (Villalta & VCSS)
  - **Statistically** improves QOL (VEINES-QOL)

*There is hope for PTS patients who have failed standard of care therapy*

# References

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1. ACCESS PTS Trial. [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) identifier: NCT02159521
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