Evidence for endovascular therapy of iliofemoral DVT: CAVENT, ATTRACT, CAVA and more to come

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Or rephrased…

“To lyse or not to lyse: that is the question:

Whether tis nobler in the mind to suffer

The raving pain or ulcer of post thrombotic syndrome

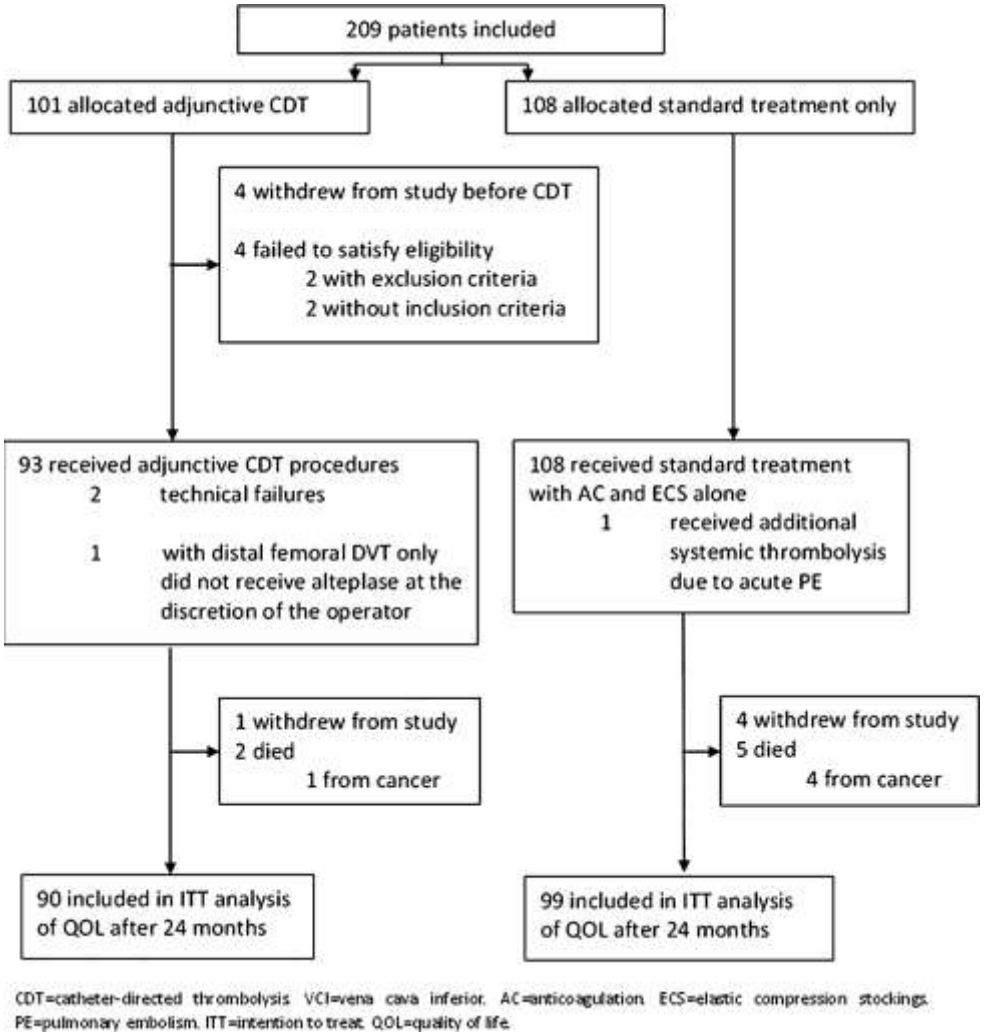
Or to take arms against the clot and by lysing end them? To lyse: To Live! “

with thanks for inspiration to Peter Neglen (and of course Shakespeare)

Long-term outcome after additional catheter-directed thrombolysis versus standard treatment for acute iliofemoral deep vein thrombosis (the CaVenT study): a randomised controlled trial

Tone Enden, Ylva Haig, Nils-Einar Kløw, Carl-Erik Slagsvold, Leiv Sandvik, Waleed Ghanima, Geir Hafsahl, Pål Andre Holme, Lars Olaf Holmen, Anne Mette Njaastad, Gunnar Sandbæk, Per Morten Sandset, on behalf of the CaVenT Study Group

CAVENT



CDT=catheter-directed thrombolysis. VCI=vena cava inferior. AC=anticoagulation. ECS=elastic compression stockings. PE=pulmonary embolism. ITT=intention to treat. QOL=quality of life.

Tone Enden et al. BMJ Open 2013;3:e002984

CAVENT

2 year follow up

- AC PTS 56%
- CDT PTS 41%
- Absolute Risk Reduction 15%
- Number Need to Treat = 7

5 year follow up

- AC PTS 71%
- CDT PTS 43%
- Absolute Risk Reduction 28%
- Number Need to Treat = 4

The results show a widening gap between CDT and AC in favour of CDT

20 bleeding complications related to CDT included three major and five clinically relevant bleeds.

	Additional catheter-directed thrombolysis (n=90)		Standard treatment only (n=99)		p value*
	n	% (95% CI)	n	% (95% CI)	
Post-thrombotic syndrome at 24 months†	37	41·1% (31·5–51·4)	55	55·6% (45·7–65·0)	0·047
Iliofemoral patency at 6 months†‡	58	65·9% (55·5–75·0)	45	47·4% (37·6–57·3)	0·012
Post-thrombotic syndrome at 6 months§	27	30·3% (21·8–40·5)	32	32·2% (23·9–42·1)	0·77

Post-thrombotic syndrome defined as Villalta score of 5 points or higher. *χ^2 test. †Co-primary outcomes. ‡Five patients had inconclusive patency assessments and one was lost to follow-up at 6 months. §Secondary outcome.

Table 2: **Short-term and long-term outcomes**

Enden T J Thromb Haemost 2009; 7 (8) 1268-1275

ATTRACT key data

- 692 patients enrolled (337 PCDT; 355 no-PCDT)
- 56 clinics
- 62% men; 38% women
- Median age: 53 years
- Mean thrombus removal: 74 %


BREXIT
GOOD LUCK, GREAT BRITAIN!

ATTRACT
SHORT-TERM OUTCOMES
PCDT vs no-PCDT, within 10 days:

- Major bleeding: 1.7% vs 0.3%; P = .049
- Any bleeding: 4.5% vs 1.7%; P = .034
- Leg pain: -1.62 vs -1.29; P = .019
  - At 30 days: -2.17 vs -1.83; P = .026
- Leg swelling: -0.26 vs +0.27; P = .024
  - At 30 days: -0.74 vs -0.28; P = 0.51
- No fatal or intracranial bleeds in either arm

ATTRACT
LONG-TERM OUTCOMES PCDT vs no-PCDT

- Post-thrombotic syndrome: 46.7% vs 48.2%; P = .56
- Iliofem 52% vs 48% p = ns (on villalta)
- Recurrent venous thromboembolism: 12.5% vs 8.5%; P = .09

ATTRACT- major criticisms

- Inclusion of Fem popliteal DVT patients
- Stent rate 30% (only 60% in IFDVT group) implies many lesions potentially missed (no IVUS)
- Selection bias- recruitment only 1/52 patients screened
- Mean 6 patients per centre
- PTS at 2 years an incredibly high 47%
- No imaging follow up- unacceptable

ATTRACT did demonstrate:

Positives

- No benefit in treating
  - older patients
  - those with lesser symptoms
  - Femoro-popliteal disease should not be treated
- However
  - IF has a benefit if VCSS the outcome (Circ paper)
  - Symptom improvement across the board on continuous data

Negatives

- Flawed recruitment
- Depowered IF DVT arm
- Heterogeneous treatment
- No IVUS
- No imaging follow up
- ENTIRE PREMISE-the OPEN VEIN hypothesis-was not tested

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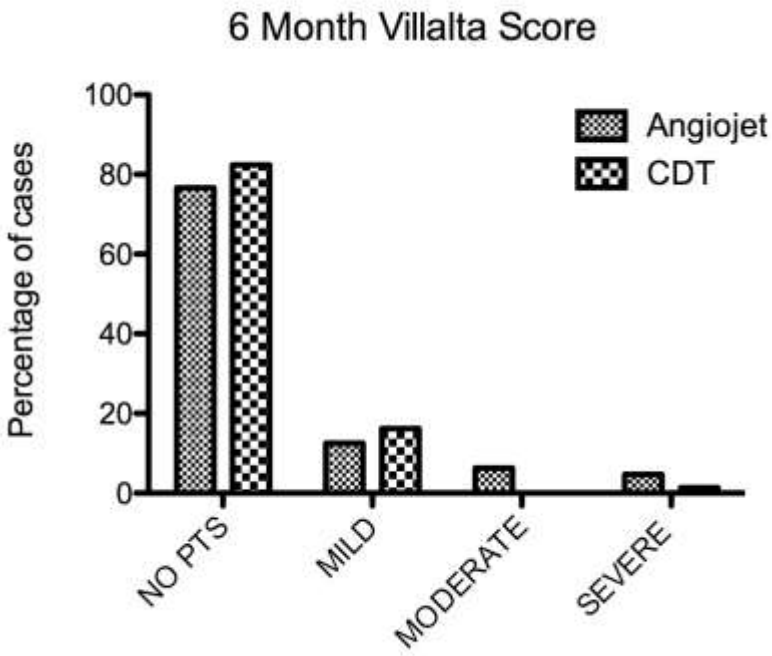
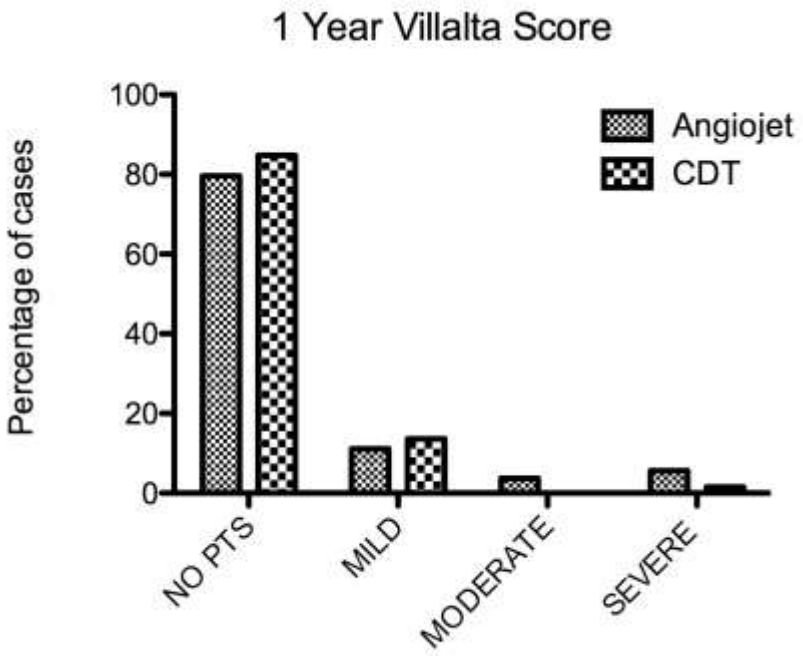
Modern Practice





Any PTS 18%

Mod –Severe < 5%

6 months p= 0.61

1 year p=0.75

CDT vs Angiojet

Bern, Copenhagen and others

CAVA

- Netherlands
- RCT of EKOS vs BMT
- 180 patients – 90 in each arm
- Completed Recruitment
- Results awaited

Clear-DVT

- Trial of Modern Practice
- Cohort followed by RCT
- Core Lab Adjudicated
- IVUS
- Duplex follow up

All truth passes through three stages. First, it is ridiculed. Second, it is violently opposed. Third, it is accepted as being self-evident.

— *Arthur Schopenhauer*

Conclusion

- Trial data still suggests Iliofem benefit
- Modern practice has evolved
- We need to evolve with data
- Await further studies as we have done with Coronary and Stroke

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