CAVA Study: What do we expect?

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Disclosure

I have the following potential conflicts of interest to report:

- Receipt of grants/research support

  Medtronic, BD BARD, Cook, Ab medica, Bentley, Optimed, BTG

- Receipt of honoraria and travel support

  Medtronic, BD BARD, Cook, Ab medica, Bentley, Optimed, BTG

Ultrasound-Accelerated CAtheter-Directed Thrombolysis Versus Anticoagulation for the prevention of Post-Thrombotic Syndrome: The CAVA-Trial

P. Notten, MD, A.J. ten Cate-Hoek, C.W.K.P. Arnoldussen, R.H.W. Strijkers, A.A.E.A. de Smet, L.W. Tick, M.H.W. van de Poel, Wikkeling, L.J. Vleming, A. Koster, G. Jie, E.M.G. Jacobs, H.P. Ebben, M. Coppens, I. Toonder, H. ten Cate, C.H.A. Wittens

Study design

- Multicentre randomized controlled trial
- Prospective interventional study
- Assesor blinded, open label

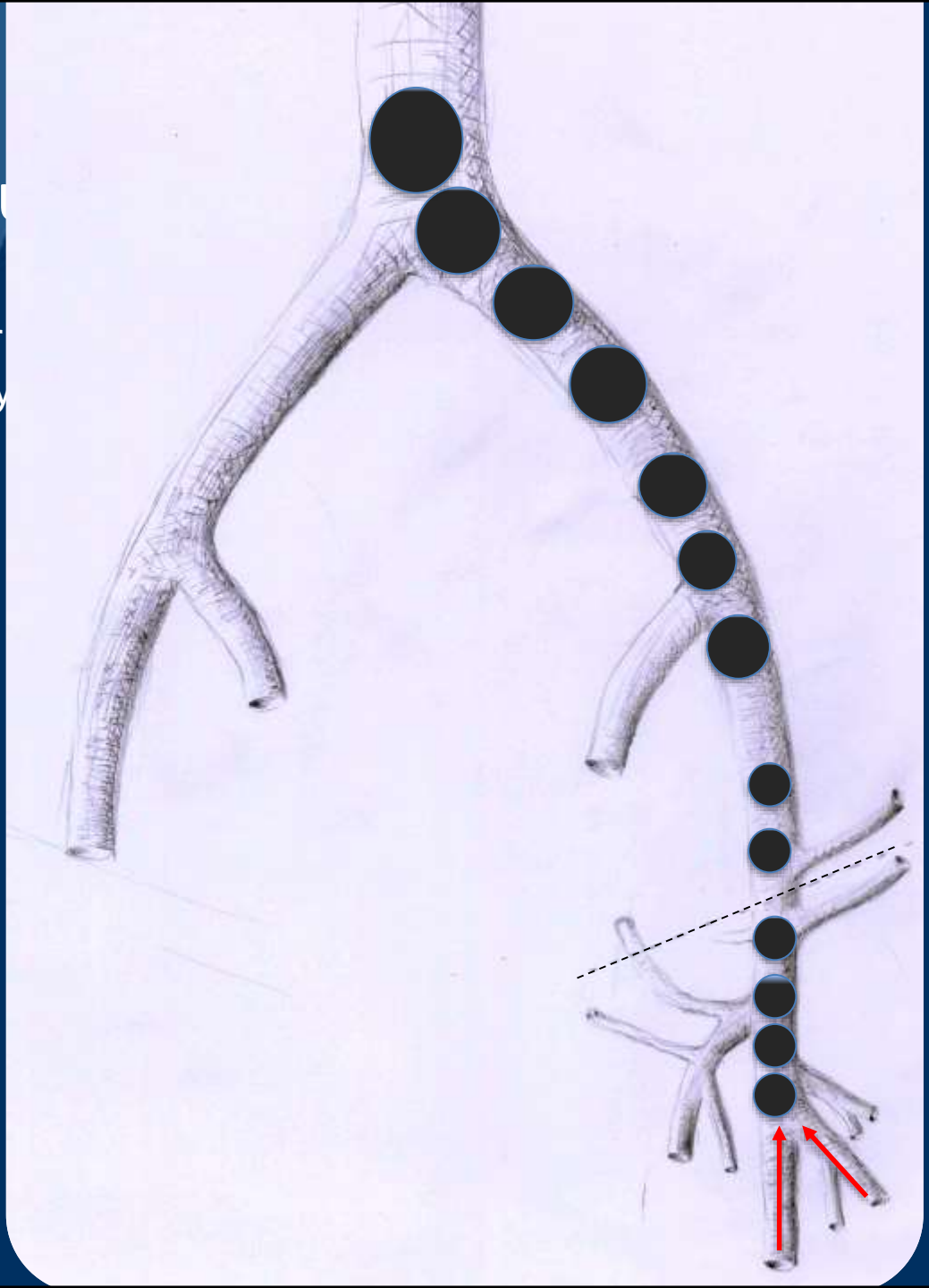
Outcome measure

- **Primary outcome measure**
  - Incidence of Post Thrombotic Syndrome after 1 year (Villalta)[1]
- **Secondary outcome measures**
  - Difference in development of Post Thrombotic Syndrome as defined by the ISTH after 1 year[2]
  - Severity of Post Thrombotic Syndrome (Villalta, VCSS)
  - The patient reported Health-Related Quality of Life (VEINES-QoL, SF36v2, EQ5D, and Pain Disability Index)
- **Safety outcome measures**
  - Major bleedings[3]
  - Recurrent Thrombosis
  - In Stent Thrombosis

1. Villalta et al. Haemostasis 1994
2. Kahn et al. J Thromb Haemost 2009
3. Schulman et al. J Thromb Haemost. 2005

St

- Patients with an iliofemoral or
  symptomatic less than 14 day



Inclusion

- June 2010 – November 2017
- 184 patients were included (2 patients / month)
- Follow up of 12 months

Inclusion Criteria	Exclusion criteria
• Age between 18-85 years • Objectively documented IFDVT • Acute stage IFDVT, complaints less than 14 days • Life ecpectancy longer thean 6 months • First thrombus in the affected limb	• Previous thrombosis of the affected limb • Varicosities / venous insufficiency CEAP classification C3 or higher • Severe hypertension (>180 / 100mmHg) • Active malignancy • History of GI bleeding within 12 months • History of CVA / central nervous system disease within 12 months • Major surgery within 6 weeks • eGFR < 30 ml / min

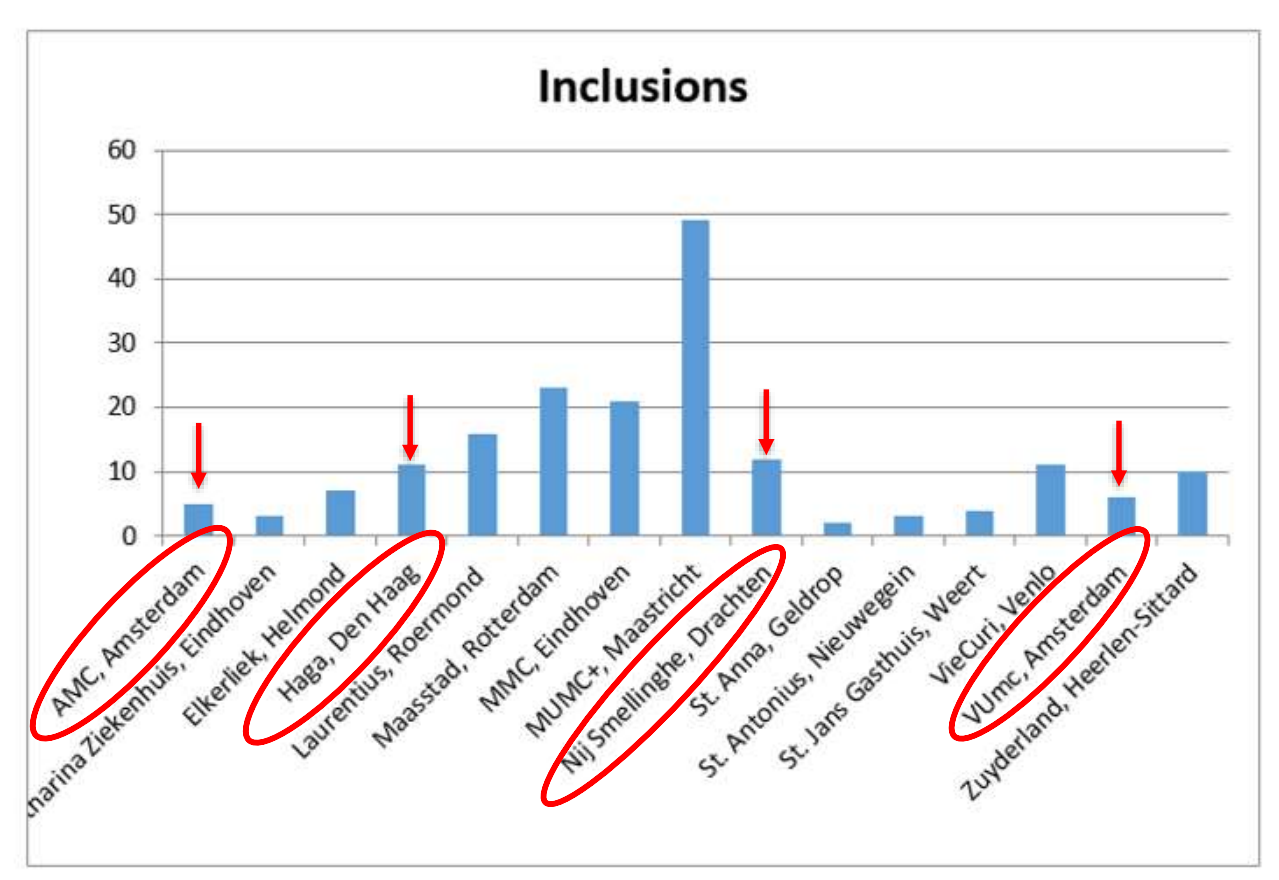
Participating centres

Centres randomizing patients

1: Maastricht University Medical Center, Maastricht
2: Zuyderland Medical Center, Heerlen-Sittard
3: Laurentius Hospital, Roermond
4: VIeCuri Hospital, Venlo
5: St.Anna Hospital, Geldrop
6: Máxima Medical Center, Eindhoven-Veldhoven
7: Catharina Hospital, Eindhoven
8: Elkerliek Hospital, Helmond
9: Maasstad Hospital, Rotterdam*
10: St.Antonius Hospital, Nieuwegein
11: Haga Hospital, Den Haag*
12: Nij Smellinghe Hospital, Drachten*
13: St.Jans Gasthuis, Weert
14: Amsterdam University Medical Center, AMC, Amsterdam*
15: Amsterdam University Medical Center, VuMC, Amsterdam*

Centres performing Ultrasound-Accelerated Catheter-Directed Thrombolysis

Participating centres



Treatment arms

Conservative:
Early anticoagulant therapy, compression therapy and mobilization

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Early anticoagulant therapy, compression therapy and mobilization

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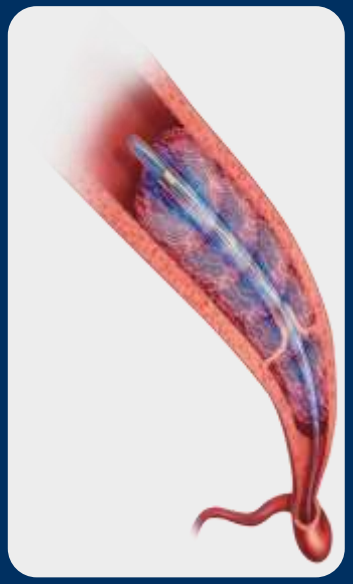
Interventional:
Additional Ultrasound-Accelerated Catheter-Directed Thrombolysis (Ekos Endowave ® system)

Treatment

Ultrasound-Accelerated Catheter-Directed Thrombolysis (EKOS)



<u>Urokinase</u> bolus dose:

- Unilateral DVT → (bolus dose of 250,000 U)
- Bilateral DVT → (bolus dose of 125,000 U per leg)

<u>Urokinase</u> perfusor settings:

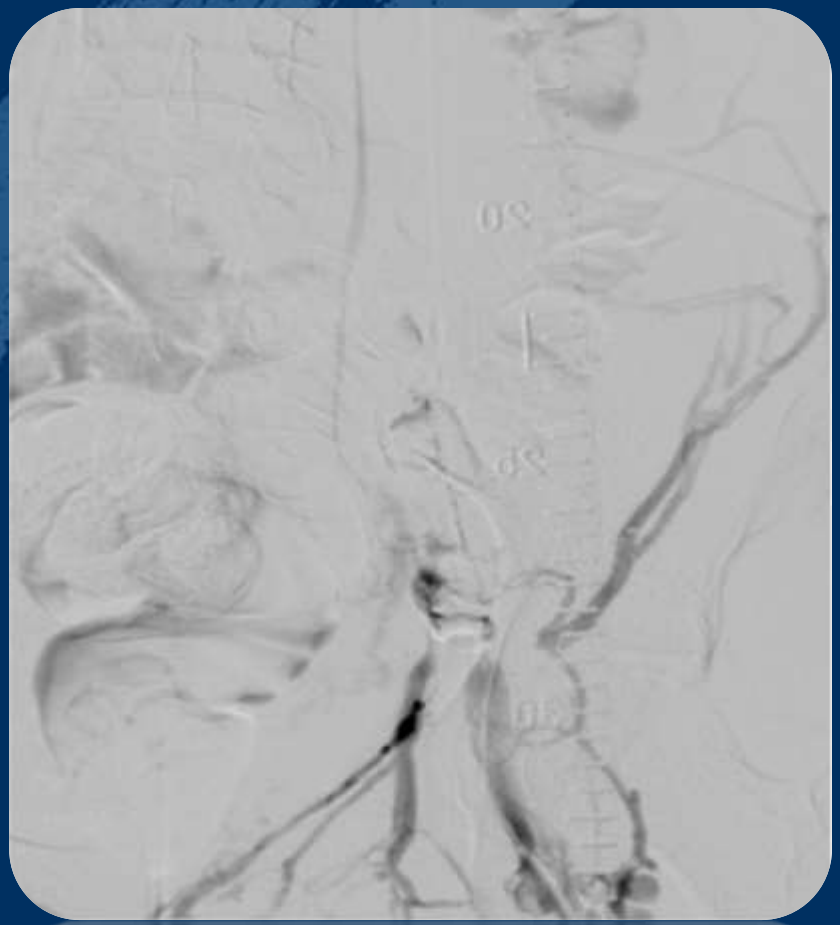
- Unilateral DVT → administer 100,000 U/ hour
- Bilateral DVT → administer 50,000 U/ hour/ leg

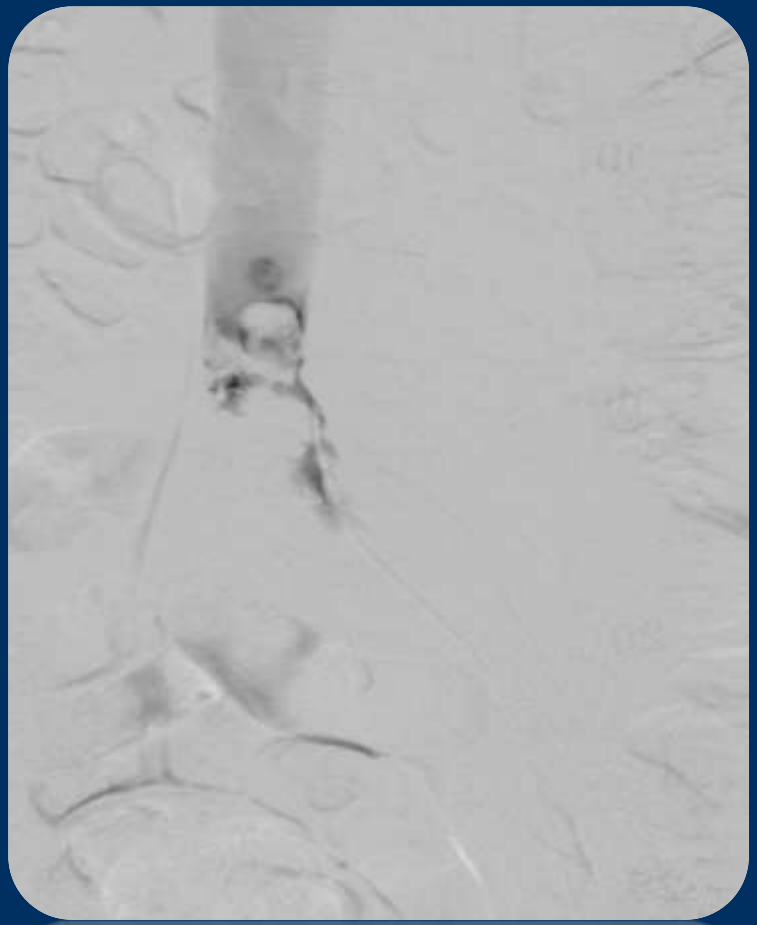
Treatment control

- Venography alone used to assess residual thrombus after Lysis

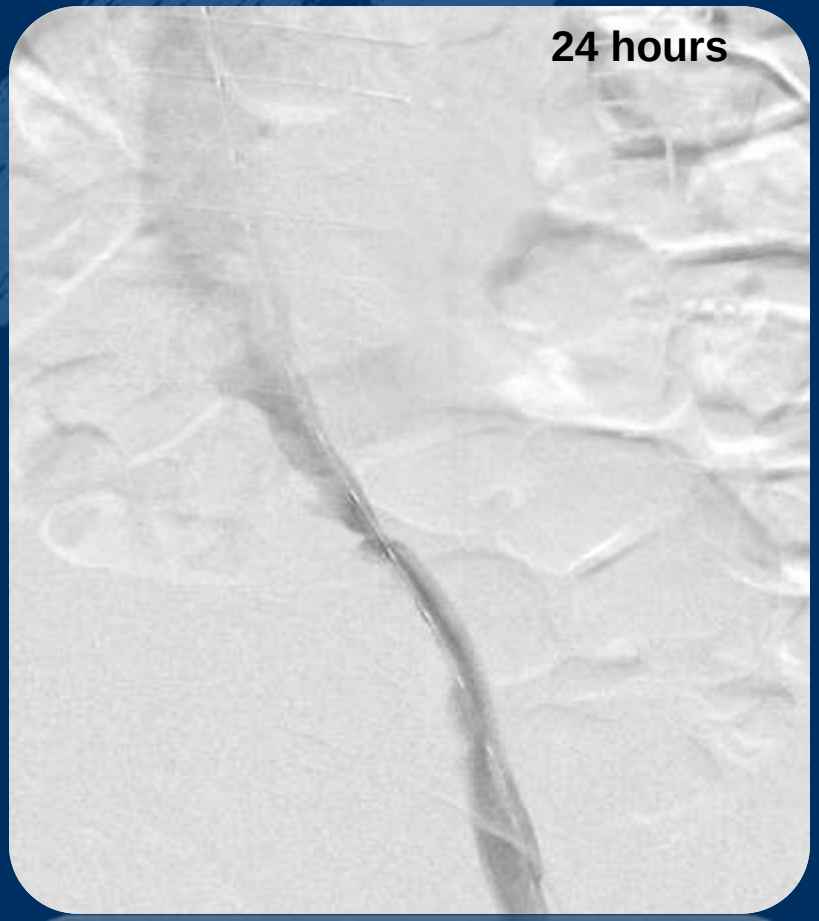
1. GOOD	> 90 % patency (= completely open)
2. MODERATE	50 - 90 % patency
3. POOR	< 50 % patency
4. UNSUCCESSFUL	0 % patency (no change after 48 hours)

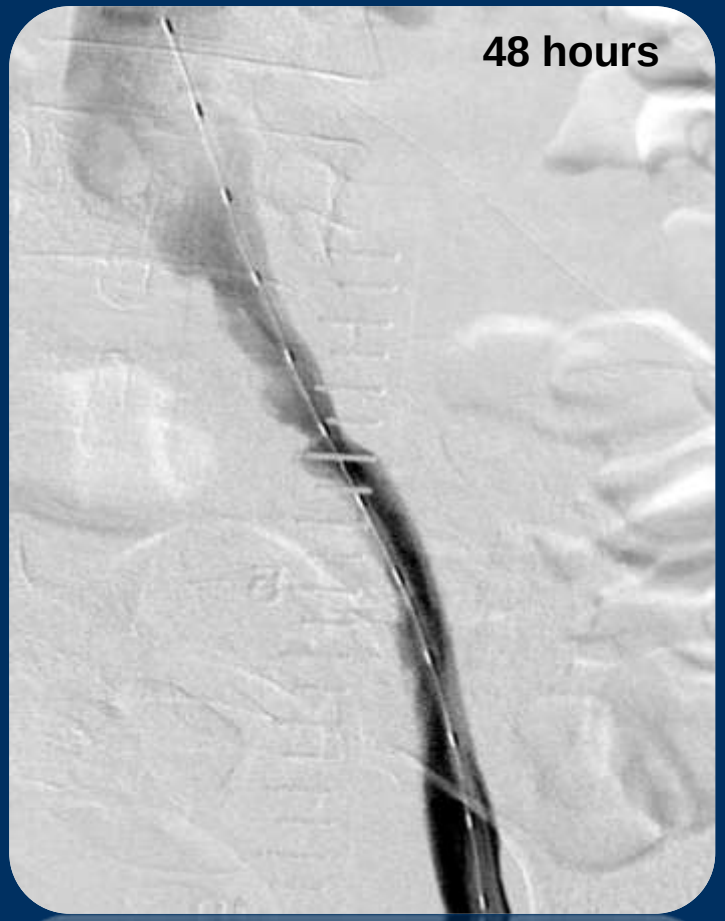
Case



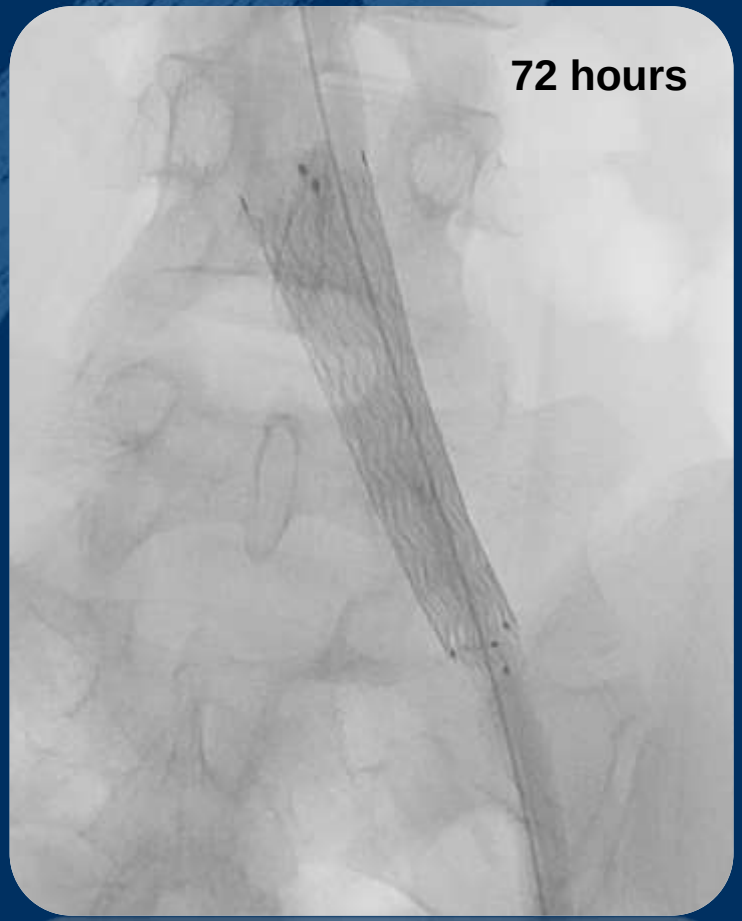


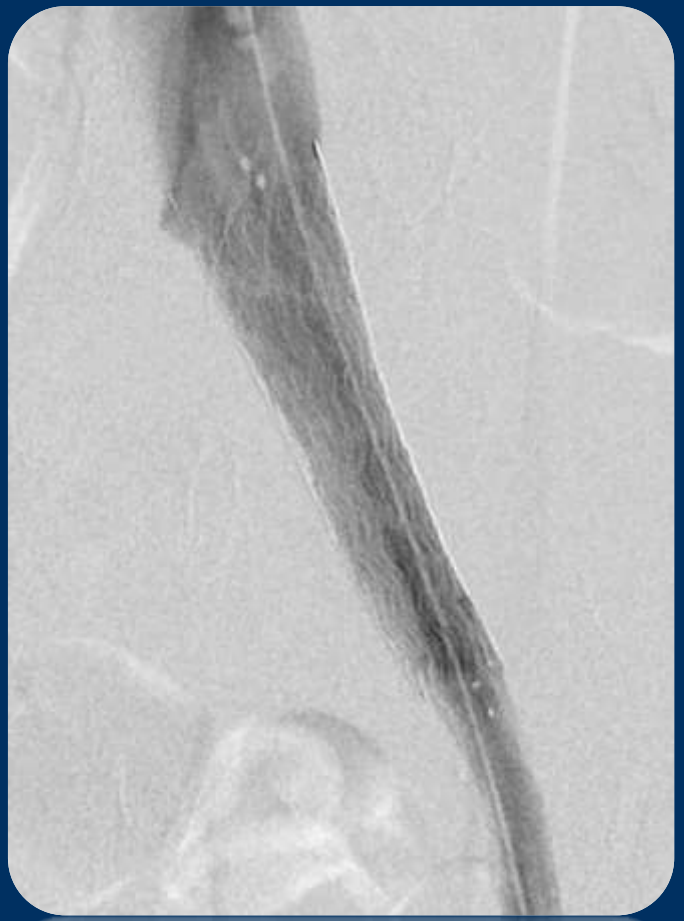
Case





Case





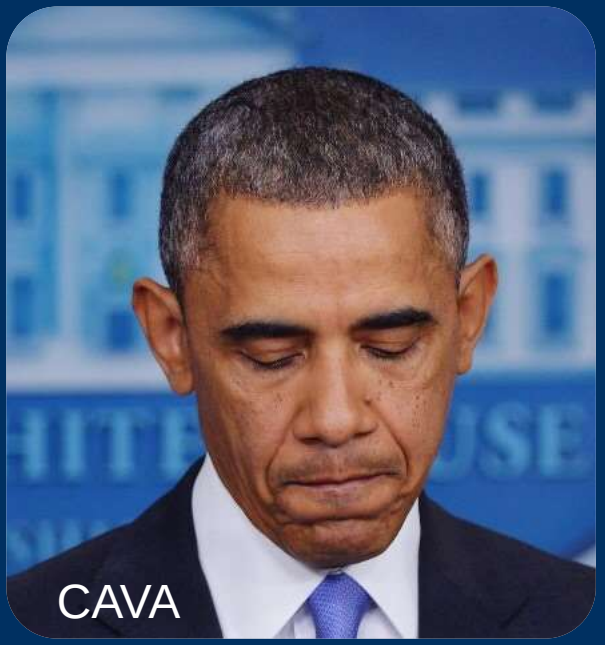
Advantage

- Clearly defined proximal DVT--> homogeneous study population (contrary to ATTRACT and CaVenT)

Disadvantages

- Many centres with low expertise
- 1 year follow up is too short (shorter than ATTRACT and CaVenT)
- Slow and lengthy patient recruitment (stringent inclusion criteria)
- Venography alone was used to assess residual thrombus (no IVUS)
- Usage of non dedicated venous stents (inclusion from 2010)

What do we expect?



I am afraid to be disappointed again

Thank you very much

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