CAVA Study: What do we expect?

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LINC 2019
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

Study design

- Multicentre randomized controlled trial
- Prospective interventional study
- Assessor 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

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Study population • Patients with an iliofemoral or caval deep vein thrombosis, symptomatic less than 14 days
Inclusion

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

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

Centres randomizing patients

1: Maastricht University Medical Center, Maastricht
2: Zuyderland Medical Center, Heerlen-Sittard
3: Laurentius Hospital, Roermond
4: VleCuri 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

- AMC, Amsterdam
- Eimerik, Eindhoven
- Haga, Den Haag
- Laurens, Rotterdam
- Maastricht, Roermond
- MUMC, Maastricht
- Nijmegen, Geldrop
- St. Anna, Nieuwegein
- St. Jan, Heerlen
- Venlo, Venlo
- VUMc, Amsterdam
- Zuyderland, Heerlen-Sittard
Treatment arms

Conservative:
Early anticoagulant therapy, compression therapy and mobilization

+ Interventional:
Additional Ultrasound-Accelerated Catheter-Directed Thrombolysis (Ekos Endowave® system)
Urokinase bolus dose:

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

Urokinase 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)
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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