Are we ready for a paradigm shift for treating acute DVT

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Disclosure

Speaker name:

............Baumgartner..............................................................

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ X Other(s)

Educational grand COOK

☐ I do not have any potential conflict of interest
Venous thromboembolism major health problem

PE-related increased mortality

30% recurrences

complications: **PTS*, ulcer, PAH, ven.claudication**

- 20 y cumulative PTS incidence / 25-40%
- 20 y cumulative venous ulcer incidence / 3.7%
- **5 y cumulative severe PTS incidence / 10%**

* chronic pain, swelling, heaviness, fatigue of affected limb; advanced PTS: venous claudication, stasis dermatitis, subcutaneous fibrosis, and skin ulceration
• 2004

6 European countries (F, D, I, E, S, GB)
761,000 DVT / y
370,000 associated mortalities / y
Analysis of 1,338 patients with acute deep venous thrombosis (DVT)

- Iliofemoral DVT (1-5) 38%
- Iliofemoral (at least 4-5) 24%*
  (*formed iliac / iliacaval 9%)
- Without calf/pop v. (3-5) 12%
- Femoropopliteal (1-3) 62%
- Isolated calf veins (1) 28%
Potentially all patients with iliofemoral DVT candidates for early clot removal

Of these, patients with no calf and popliteal vein thrombosis have better outcome following invasive treatment considered “ideal” candidates (present study, 12% of the total cohort)

About 80,000 ideal candidates for clot removal annually (Europe)
CTD plus anticoagulation vs anticoagulation alone to treat proximal deep vein thrombosis

propensity-matched, observational, USA

*Nationwide Inpatient Sample (NIS) files of the Agency for Healthcare Research and Quality (AHRQ)*

Healthcare Cost and Utilization Project

**primary outcome**

**secondary outcome**

90,618 pts

3,649 pts (4.1%)

in-hospital mortality

bleeding complications, length of stay, hospital charges

hospitalized for DVT

CDT
Rates of CDT in the United States

The trend of rate increase is significant ($P < .001$). CDT indicates catheter-directed thrombolysis.

50% OF IDEAL CANDIDATES
NOT A PROBLEM OF INTERVENTIONAL RESOURCES
Outcomes after CDT plus anticoagulation or anticoagulation (propensity-matched groups)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>CDT$^a$ (n = 3594)</th>
<th>Anticoagulation$^a$ (n = 3594)</th>
<th>OR (95% CI)$^b$</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>42 (1.2)</td>
<td>31 (0.9)</td>
<td>1.41 (0.88-2.25)</td>
<td>.15</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>642 (17.9)</td>
<td>408 (11.4)</td>
<td>1.69 (1.49-1.94)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>397 (11.1)</td>
<td>234 (6.5)</td>
<td>1.85 (1.57-2.20)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>GI bleed</td>
<td>59 (1.6)</td>
<td>56 (1.6)</td>
<td>1.08 (0.75-1.57)</td>
<td>.67</td>
</tr>
<tr>
<td>Intracranial hemorrhage</td>
<td>32 (0.9)</td>
<td>12 (0.3)</td>
<td>2.72 (1.40-5.30)</td>
<td>.03</td>
</tr>
<tr>
<td>Hematoma</td>
<td>86 (2.4)</td>
<td>20 (0.6)</td>
<td>4.54 (2.78-7.41)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>IVC filters</td>
<td>1250 (34.8)</td>
<td>561 (15.6)</td>
<td>2.89 (2.58-3.23)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Length of stay, mean (SD), d</td>
<td>7.23 (5.80)</td>
<td>5.02 (4.67)</td>
<td>2.27 (1.49-1.94)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Charges, mean (SD), $</td>
<td>85 094 (69 121)</td>
<td>28 164 (42 067)</td>
<td>57 417 (54 796-60 037)$^c$</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

therapy should be offered to patients with a low bleeding risk

bleeding complications, incl. ICH and blood transfusion rates, continued to be higher in the CDT group.

Learning curve and new pharmacomechanical therapies

CaVenT - CDT - Study

co-primary effect variables: iliofemoral patency @ 6 mo, frequency of PTS @ 24 mo

- Mean thrombolysis duration **2.4 ± 1.1 days**
- Dose: up to 20 mg t-PA/ day
- Stenting rate in CaVent: **17%**

20 bleeding complications related to CDT:
- 3 major (3.3%) and 5 (5.5%) clinically relevant

ARR of PTS @ 24 mo **14.4%** [95% CI 0.2–27.9]; NNT 7 [95% CI 4–502]

Enden T et al., Lancet 2012;379 (9810):31-8
BERN Registry:
fixed-dose t-PA (20mg/15h) followed by stenting of residual venous stenosis

<table>
<thead>
<tr>
<th>Stenting site</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Inferior vena cava</td>
<td>≥ 1 Stent (mean 1.9 ± 1.3 stents)</td>
<td>80 %</td>
</tr>
<tr>
<td>Common iliac vein</td>
<td></td>
<td>83 %</td>
</tr>
<tr>
<td>External iliac vein</td>
<td></td>
<td>71 %</td>
</tr>
<tr>
<td>Common femoral vein</td>
<td></td>
<td>30 %</td>
</tr>
<tr>
<td>Femoral vein</td>
<td></td>
<td>7%</td>
</tr>
</tbody>
</table>

Partency rates and PTS @ 12 months

- clinical outcome in CaVent @ 6 Monate
BERN Registry:
fixed-dose t-PA (20mg/15h) followed by stenting of residual venous stenosis

• complications in 10 pts. (11%; 95% CI, 6-20%)
• no symptomatic PE during hospital stay
• one **major bleeding** (1%; 95% CI, 0-6%)
• clinically relevant, **minor bleedings in 6 pts.** (7%; 95% CI, 3-14%); 4 access-related haematoma

Are we ready for a paradigm shift for treating acute DVT

acceptance related to:

• treatment that might reduce incidence of PTS, at the cost of bleeding complications

• no effect on PE related mortality shown

• no reduction in recurrence rate shown

• technical definition
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