Catheter-Directed Thrombolysis In Acute Iliofemoral Vein Thrombosis, A Prospective Randomized Controlled Trial

A. Balbola, MSc, A. Bahaey, MD,
A Mahrouky, MD  H. Soliman, MD, & M. El Maadawy, MD
Vascular Surgery Unit
Cairo University
Disclosure

I have the following potential conflicts of interest to report:

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

I do not have any potential conflict of interest
• Post-thrombotic manifestations developed in as many as 20% to 80% of patients following lower extremity DVT
• A 7-23% of patients of PTS develops severe form of the disease
• Ulceration occurs in 4% to 6%

Persistent venous obstruction and venous valvular reflux are determinants for the development of PTS
• Early removal of thrombus may improve deep venous flow, reduce the occurrence of valvular reflux, and therefore, reduce the incidence of PTS.

• Among several methods of thrombus removal, CDT is burgeoning.

• A few head to head studies, comparing CDT to the conventional therapy, is available to date.
• We randomly distributed 50 acute iliofemoral DVT patients between CDT & conventional therapy
• Mean follow-up period of 10.78 months
• Data were available for 45 patients; 22 in the CDT group, and 23 in the control group
Demographic and baseline clinical characteristics were similar in both groups
Inclusion Criteria:
- Age below 70 years
- Onset of symptoms within the past 14 days
- Objectively verified iliofemoral DVT

Exclusion criteria:
- Bleeding diathesis
- Renal impairment
- H of subarachnoid or intracerebral Hge
- Recurrent IFDVT
- Severe anemia
- Pregnancy/7d postpartum
- life expectancy less than 2 years
- Current malignancy
- thrombocytopenia
- 14 days post major surgery/trauma
- Drug abuse or mental disease
Control Group

- Enoxaparin (clexane®; Sanofi, France) 1 mg/kg/12 hours
- Oral warfarin (Marevan; GlaxoSmithKline, UK) at daily dose of 5 mg.
- Target INR of 2.0 to 3.0.
- LMWH was stopped when the patient’s INR is 2.0 or above for at least 24 hours.
- Warfarin was continued for at least 3 months.
Technical Data

Sonar-guided popliteal vein puncture
• alteplase (Actilyse®; Boehringer-Ingelheim, Ingelheim am Rhein, Germany)

• Forceful injection of initial 10 ml, followed by 1 ml/H for 40 hours

• Heparinized saline 300 units/H
• Total thrombus score was obtained.
• The contrast enhanced image was optically examined and given a score from 0 to 2, where:
  • 0 = open vein,
  • 1 = partially occluded vein, and
  • 2 = completely occluded vein.
• **Thrombolysis grade** =
  \[
  \text{total thrombus score before CTD} - \text{total thrombus score after CDT}) \div \text{total thrombus score before CTD} \times 100.
  \]

• Whereas, grade I thrombolysis (ineffective lysis) = \( \leq 50\% \)
• Grade II thrombolysis (partial lysis) = 50\%-89\% and
• Grade III thrombolysis (complete lysis) = \( \geq 90\% \).
For patients in the CDT group:

- Complete lysis (grade III) : 15 patients (68.18%),
- Grade II lysis (50%–90% lysis) : 6 patients (27.27%)
- Grade I lysis (ineffective lysis) occurred in a single patient (4.55%)
- Culprit iliac vein stenotic lesions were in 14/15 patients with grade III lysis
- Stenting in 11 patients
<table>
<thead>
<tr>
<th></th>
<th>Catheter-directed thrombolysis (n = 22) N (%)</th>
<th>Standard treatment (n = 23) N (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleeding</td>
<td>0</td>
<td>1 (4.35%)</td>
<td>1</td>
</tr>
<tr>
<td>Minor bleeding</td>
<td>5 (22.73%)</td>
<td>1 (4.35%)</td>
<td>0.096</td>
</tr>
<tr>
<td></td>
<td>Catheter-directed thrombolysis (n = 22) N (%)</td>
<td>Standard treatment (n = 23) N (%)</td>
<td>P-value</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------------------------</td>
<td>----------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>2 (9.09%)</td>
<td>1 (4.35%)</td>
<td>0.608</td>
</tr>
<tr>
<td>Recurrent DVT</td>
<td>2 (9.09%)</td>
<td>1 (4.35%)</td>
<td>0.608</td>
</tr>
<tr>
<td></td>
<td>At One Month</td>
<td>At Six Months</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-------------------------------------------</td>
<td>--------------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CTD Group</td>
<td>Control Group</td>
<td>P Value</td>
</tr>
<tr>
<td>Iliac Vein Patency</td>
<td>18/22 (81.2%)</td>
<td>10/23 (43.48%)</td>
<td>P = 0.003</td>
</tr>
<tr>
<td>Femoral Vein Reflux</td>
<td>10/22 (45.45%)</td>
<td>18/23 (78.26%)</td>
<td>P = 0.023</td>
</tr>
</tbody>
</table>
Relation between immediate thrombolysis grade and 6-months patency after CDT

<table>
<thead>
<tr>
<th>Grade I lysis (n=1)</th>
<th>Iliac vein patency at 6 months N(%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0.0302</td>
</tr>
<tr>
<td>Grade II lysis (n=6)</td>
<td>5(83.33%)</td>
<td></td>
</tr>
<tr>
<td>Grade III lysis (n=15)</td>
<td>14(93.33%)</td>
<td></td>
</tr>
</tbody>
</table>
Relation between the form of endovenous intervention and 6-months iliac vein patency

<table>
<thead>
<tr>
<th>Endovascular therapy</th>
<th>Iliac vein patency at 6 months</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDT only (n=8)</td>
<td>6 (75.00%)</td>
<td></td>
</tr>
<tr>
<td>CDT and balloon angioplasty only (n=3)</td>
<td>3 (100%)</td>
<td>0.462</td>
</tr>
<tr>
<td>CDT, balloon angioplasty, and stent (n=11)</td>
<td>10 (90.91%)</td>
<td></td>
</tr>
</tbody>
</table>
Severity grading of PTS at 6-months using the Villalta score in each of the CDT group and the control group

<table>
<thead>
<tr>
<th>Villalta severity category</th>
<th>Catheter-directed thrombolysis (n=22)</th>
<th>Standard treatment (n=23)</th>
<th>p value</th>
<th>Absolute risk Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-thrombotic syndrome</td>
<td>7 (31.82%)</td>
<td>12 (52.17%)</td>
<td>0.167</td>
<td>20.35%</td>
</tr>
<tr>
<td>Mild (score 5-9)</td>
<td>5</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate (score 10-14)</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>---</td>
</tr>
<tr>
<td>Severe (score &gt;14)</td>
<td>0</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Conclusion

• CTD in the treatment of iliofemoral DVT is as safe as the conventional therapy and well tolerated
• CTD significantly increases iliac vein patency and decreases the incidence of venous reflux
• Therefore, it is attained by a 20% risk reduction of the development of PTS
• However, it does not have more protection than conventional therapy against recurrent thrombotic events
THANK YOU
Catheter-Directed Thrombolysis In Acute Iliofemoral Vein Thrombosis, A Prospective Randomized Controlled Trial

A. Balbola, MSc, A. Bahaey, MD, A Mahrouky, MD, H. Soliman, MD, & M. El Maadawy, MD
Vascular Surgery Unit
Cairo University