Acute Peripheral Arterial Occlusion: Intra-Arterial Thrombolysis With a Micro-Porous Balloon Catheter.

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Disclosure

I do not have any potential conflict of interest
Arterial thrombolysis and percutaneous transluminal angioplasty are now alternatives to surgical embolectomy for the management of acute arterial occlusions.


*van den Berg JC. Thrombolysis for acute arterial occlusion.*

Fibrinolysis benefits

Table I. Summary of major outcome of the 3 large randomized trials\textsuperscript{2,3}

<table>
<thead>
<tr>
<th>Trial</th>
<th>Limb salvage at 6 mon, %</th>
<th>Limb salvage at 12 mon, %</th>
<th>Survival at 6 mon, %</th>
<th>Survival at 12 mon, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Surgical</td>
<td>Endo</td>
<td>P value</td>
<td>Surgical</td>
</tr>
<tr>
<td>Rochester trial</td>
<td>NA</td>
<td>NA</td>
<td>...</td>
<td>82</td>
</tr>
<tr>
<td>STILE\textsuperscript{a}</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALI &lt;14 d</td>
<td>70</td>
<td>88.9</td>
<td>.02</td>
<td>NA</td>
</tr>
<tr>
<td>Ischemia &gt;14 d</td>
<td>97</td>
<td>87</td>
<td>.01</td>
<td>NA</td>
</tr>
<tr>
<td>STILE subanalysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occluded bypass</td>
<td>NA</td>
<td>NA</td>
<td>...</td>
<td>70</td>
</tr>
<tr>
<td>Native artery occlusion</td>
<td>100</td>
<td>93.3</td>
<td>&lt;.05</td>
<td>100</td>
</tr>
<tr>
<td>TOPAS\textsuperscript{b}</td>
<td>74.8</td>
<td>71.8</td>
<td>.43</td>
<td>69.9</td>
</tr>
</tbody>
</table>

NA, Not available; NSS, not statistically significant; STILE, surgery vs thrombolysis for ischemic lower extremity; TOPAS, Thrombolysis or Peripheral Arterial Surgery.

\textsuperscript{a}In STILE results: survival column corresponds to composite end point (trial stopped).

\textsuperscript{b}In TOPAS results: limb salvage column corresponds to amputation-free survival.

van den Berg

Protocols of in situ fibrinolysis:

• Expose the patients to the risk of major bleeding complications

• Require a stay in an intermediate care or intensive care unit
Risk of major bleeding complications

- 4% at 8h
- 34% at 36h

Table III. Complications related to thrombolytic therapy

<table>
<thead>
<tr>
<th>Complication</th>
<th>Incidence, %</th>
<th>Overall</th>
<th>Urokinase</th>
<th>rt-PA*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemorrhagic stroke</td>
<td>1-2.3</td>
<td>0.6</td>
<td>2.8</td>
<td></td>
</tr>
<tr>
<td>Major hemorrhage</td>
<td>&lt;5.1</td>
<td>6.2</td>
<td>8.4</td>
<td></td>
</tr>
<tr>
<td>Minor hemorrhage</td>
<td>14.8</td>
<td>21.9</td>
<td>43.8</td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>&lt;1</td>
<td>3</td>
<td>5.6</td>
<td></td>
</tr>
<tr>
<td>Pericatheter thrombosis</td>
<td>3-16.7</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Catheter-related trauma</td>
<td>1.2-1.4</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Compartment syndrome</td>
<td>2</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Distal embolization</td>
<td>&lt;1</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

NA, Not available; rt-PA, recombinant tissue plasminogen activator.

*Ouriel.4,18

bDissection and false aneurysm.
Admission of high risk patients with acute peripheral arterial occlusions in intermediate care unit becomes a real challenge (especially very old patients !)
Alternative therapy

• Fast Track Fibrinolysis with new in situ method using a micro-porous balloon catheter

• Objectives:
  – Reduction of fibrinolytic agent
  – No need of intermediate care unit stay
Clearway™ catheter (Maquet)

Low-pressure micro-porous polytetrafluoroethylene balloon catheter
Clearway™ catheter

- **Low pression balloon** for distorsion of the thrombus
- **Porous** for in situ delivering of the fibrinolytic agent at a high local concentration in a large diffusion surface
- Efficient in coronary arteries fibrinolysis (COCTAIL II study, INFUSE-AMI study)
Method of revascularization

• First Attempt of Endoluminal remove of thrombus with 7F aspiration catheter
Method of revascularization

- Fibrinolysis of persistent thrombus: infusion at 4 atm of urokinase with physio and iodine (clearway catheter) until complete flow restoration on angiography.
Assessment of efficacy

**Acute Peripheral Arterial Occlusion: Prospective Study Evaluating Intra-Arterial Thrombolysis With a Micro-Porous Balloon Catheter**

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Evaluation of Balloon Catheter-Guided Intra-Arterial Thrombolysis for Acute Peripheral Arterial Occlusion

Etiology of occlusion

• Embolism (60%)
  – Atrial fibrillation with an ineffective oral anticoagulant therapy \( n = 10 \) (40%)
    Mean age: \( 80.2 \) years (45-92)
  – Thrombus in the aortic arch
  – Mitral valve disease
  – Patent foramen ovale
In situ stent thrombosis 20%

paraneoplastic thrombosis (10%)

Thrombosis of a popliteal aneurysm 5%

Atherosclerotic plaque (5%)
Results

• Reduction of
  – Urokinase dose needed
    (82,000 vs. 260,000 IU/cm of thrombus) \( p = 5.10^{-6} \)
  – Infusion time
  – ICU hospital stay: 1,1 [0-1] vs 3,9 [0-5] \( p = 0.049 \)
Case report 1

• Patient, 65 years
• Acute ischemia 3 days after lung bilobectomy for adenocarcinoma
• atrial fibrillation
• Left Popliteal thrombosis
• Sheath 7F
• Clearway 4-50
• Injection 1500000 d’actosolv
• Blood flow restoration 2 arteries
• No blood loss in chest tube
Case report 2

• Patient 79 years old
• Right Critical limb ischemia
• femoro popliteal bypass with reversed saphena vein.
• Acute pain 9 days following surgery
• US: acute thrombotic occlusion
Illustration

Cross over, 7F Destination sheath, bypass recanalization
Fibrinolysis:
Clearway 5-60;
inflation 100 000 units urokinase x 6
Control
Final angiogram
Conclusion

• fibrinolysis with Clearway™:
  – Preferred method in high-risk situation?
    - elderly patients
    - post operative thrombosis
  – Short learning curve