Can Mechanical Debulking Replace Surgery and Thrombolysis in Acute and Subacute Occlusions of the Lower Limbs?

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PRAGUE
Disclosure

Speaker name: Miroslav Bulvas

I have the following potential conflicts of interest to report:

- Consulting (Straub Medical)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Proctoring (Straub Medical)
WHY MECHANICAL ENDOVASCULAR REMOVAL OF THROMBES AND EMBOLIS?

to lower mortality and morbidity rates associated with surgical approach and thrombolysis in the therapy of acute and subacute ischemia of lower limbs
AIM OF THE STUDY

Limb threatening acute and subacute ischemia:
can be managed without thrombolysis and open vascular surgery?
MATERIAL AND METHODS

• Time interval: APR/2009 – APR/2015
• Number of patients: 316 (184m+ 132f)
• Age: 23 – 96 y. (mean: 71)

• Acute lower limb ischemia 203 (< 14d)
  threatened extremity IIB (73%), IIA (27%)
• Subacute lower limb ischemia 113 (15d-3m)
  critical limb ischemia, tissue defects, short claudication
MECHANICAL RECANALIZATION
TECHNIQUES USED

Debulking with Rotarex catheter 316 pts. (100 %)
(bypasses, aortoiliac and femoropopliteal segments)

the mode of action

• mechanical fragmentation of occlusive material

• aspiration

• transport outside the vessel
MECHANICAL RECANALIZATION TECHNIQUES USED

- Aspiration tromboembolectomy: 122 pts. (39 %)
  - residual filling defects
  - infrapopliteal acute occlusions
MECHANICAL RECANALIZATION TECHNIQUES USED

- Extraction with endomyocardial biopsy device: 26 pts. (8%)
  
  recalcitrant thrombi + emboli
  short eccentric residual stenoses
MATERIAL AND METHODS

- Femoro-popliteal segm. 231 pts (73 % of 316)
- Bypass (FP, cross. II-fem) 75 pts (24 %)
- Aorto-iliac segm. 37 pts (12 %)
- Deep fem. artery 32 pts (10 %)
- In-stent occlusion 74 pts (23 %)

- Mean occlusion length: 23 cm (range: 2-65; SD 14.8)

- Thrombosis 256 pts (81 %)
- Embolism 60 pts (19 %)
MATERIAL AND METHODS

- Rotarex 8F catheter: 252 pts (80 %)
- Rotarex 6F catheter: 78 pts (25 %)
- Ipsilateral approach: 283 pts (90 %)
- Crossover approach: 37 pts (12 %)
- No. of Rotarex passes: 3.4 (1-8)
- Mean Rotarex activation time: 2.3 min. (1-5)
ACUTE OCCLUSION OF FEMPOPL. ARTERIAL SEGMENT
ACUTE ISCHEMIA OF LOWER LIMBS

aortic bifurcation - saddle embolus
ACUTE OCCLUSION OF FEMORAL BIFURCATION
POPLITEAL ANEURYSM THROMBOSIS
FEMORO-POPLITEAL SEGMENT OCCLUSION
<table>
<thead>
<tr>
<th><strong>RESULTS</strong> (Rotarex)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Recanalization</td>
<td>316 pts (100%)</td>
</tr>
<tr>
<td>Without residual stenosis</td>
<td>52 pts (16%)</td>
</tr>
<tr>
<td>Residual percentage stenosis 0-30 %</td>
<td>138 pts (44%)</td>
</tr>
<tr>
<td>Mean resid. percentage stenosis</td>
<td>39 % (range: 0-90)</td>
</tr>
<tr>
<td>Mean length of resid. stenosis</td>
<td>3.8 cm (range: 0-40)</td>
</tr>
<tr>
<td>Adjunctive PTA</td>
<td>245 pts (78 % of 316)</td>
</tr>
<tr>
<td>Adjunctive stenting</td>
<td>139 pts (44 %)</td>
</tr>
<tr>
<td>Open surgery for ischemia</td>
<td>0</td>
</tr>
</tbody>
</table>
ORIGINAL OCCLUSION LENGTH vs. RESIDUAL STENOSIS AND STENT LENGTHS
## RESULTS

**Infrapopliteal intervention** 195 pts (62 % of 316)  
(for additional chronic and /or acute lesions)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA</td>
<td>78 pts</td>
<td>(40 % of 195)</td>
</tr>
<tr>
<td>Stenting</td>
<td>35 pts</td>
<td>(18 % of 195)</td>
</tr>
<tr>
<td>Aspiration</td>
<td>103 pts</td>
<td>(53 % of 195)</td>
</tr>
<tr>
<td>Bioptome extraction</td>
<td>26 pts</td>
<td>(13% of 195)</td>
</tr>
<tr>
<td>Thrombolysis</td>
<td>29 pts</td>
<td>(9 % of 316)</td>
</tr>
<tr>
<td>Surgery</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>revascularization</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>fasciotomy</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>retroperitoneal or groin bleeding</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>amputation</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>necrectomy</td>
<td>13</td>
<td></td>
</tr>
</tbody>
</table>
SUBACUTE ISCHEMIA
(the Rutherford classification)

![Graph showing subacute class before vs. subacute class after with mean values: (3.8) and (1.2).]
ANKLE-ARM INDEX *(Doppler)*

![Boxplot and histograms showing the distribution of ankle-arm index (AAI) before and after treatment.](image)
PATENT CALF VESSELS
BEFORE AND AFTER THE THERAPY

![Graph showing the comparison of patent calf vessels before and after therapy.](image-url)
<table>
<thead>
<tr>
<th></th>
<th>30 days</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td><strong>No. of patients</strong></td>
<td>316 (100 %)</td>
<td>199 (87 % of 229)</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td>1 (0.3 % - thrombolysis)</td>
<td>8 (4.0 % of 199)</td>
</tr>
<tr>
<td><strong>Reocclusion</strong></td>
<td>18 (6 % of 316)</td>
<td>43 (22 % of 199)</td>
</tr>
<tr>
<td><strong>Reintervention</strong></td>
<td>9 (3%; 0 + 9)</td>
<td>38 (19 %; 12 + 26)</td>
</tr>
<tr>
<td>(surg + endovasc.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Amputation</strong></td>
<td>15 (4.7 % of 316)</td>
<td>17 (8.5 % of 199)</td>
</tr>
<tr>
<td><strong>Amput. free survival</strong></td>
<td>95 %</td>
<td>87 %</td>
</tr>
</tbody>
</table>
COMPLICATIONS

• major 11 pts (3.5 % of 316)
  death (1) - intracerebral bleeding + thrombolysis, groin hematoma (5), retroperitoneal bleeding (2), compartment syndrome (3)

• minor 59 pts (19 % of 316)
  - periph. embolization 40 (13 % of 316)
  - arterial perforation (Rotarex) 6 (2 % of 316)
  - groin hematoma, rethrombosis, compartment sy 36 (11 % of 316)
SUMMARY

- With the Rotarex device, we have reestablished blood flow in 100% of aortoiliac, femoropopliteal arterial segments and bypasses.

- In 78% of those recanalized vessels, adjunctive endovascular techniques (PTA, stenting, atherectomy) were applied at the sites of residual stenoses.

- Additionally, 62% of patients required non-Rotarex infrapopliteal intervention.
SUMMARY

• One death (0.3 % of 316) was associated with thrombolysis.

• Frequency of major complications was low and all minor complications were solved by endovascular or conservative means.

• Open surgery to manage limb ischemia was not necessary or not possible and thrombolysis was used to treat infrapopliteal occlusions in 29 patients (9 % of 316).
CONCLUSION

- Rotarex debulking is an efficient, safe and rapidly working technique for therapy of acute and subacute ischemia of lower limbs.

- It has a good potential to reduce number of thrombolytic and open surgery procedures together with their risks and opens the way for immediate treatment of residual and parallel lesions.

- Additional extraction techniques were necessary for best results.
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