Acute and Subacute Ischemia of Lower Limb – Can Mechanical Debulking Replace Surgery and Thrombolysis?

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Disclosure

Speaker name: Miroslav Bulvas

Potential conflicts of interest to report:

Proctoring for Straub Medical AG
ACUTE LIMB ISCHEMIA threatens patient’s limb and life
CURRENT GUIDELINES

OPEN SURGERY (OS) preferred in IIB

THROMBOLYSIS (TL) in milder symptoms (IIA, I)

PERCUTANEOUS MECHANICAL DEVICES as useful adjunctive techniques to accelerate TL or when OS and TL are not feasible.
Open surgery preferred:
ALI + SLI, consecutive, 2009-2015, initial therapy: ROTAREX DEBULKING CATHETER
n=316, 184 m; mean age 71 (23-96) yrs
Target occlusion origin

Concomitant lesions

Target arteries (n=316, mean length 23 cm)

Patent calf vessels
RISK PROFILE: ALI + SLI
(N=316)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Hypertension</td>
<td>75%</td>
</tr>
<tr>
<td>Smoking</td>
<td>54%</td>
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<tr>
<td>Cardiac disease</td>
<td>42%</td>
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<tr>
<td>Hyperlipid</td>
<td>39%</td>
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<tr>
<td>Diabetes</td>
<td>31%</td>
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<tr>
<td>Arrhythmias</td>
<td>26%</td>
</tr>
<tr>
<td>Cerebrovascular</td>
<td>25%</td>
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<tr>
<td>Renal insufficiency</td>
<td>23%</td>
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<tr>
<td>Malignancy</td>
<td>7%</td>
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TYPICAL FEATURES OF A PATIENT WITH ALI
(in “real life” setting)

- Elderly, at high surgical risk, serious concomitant disease
- Multisegmental arterial disease
- Long supratibial target occlusion (artery, bypass)
- Thrombotic origin with underlying lesion(s): *adjunctive therapy*
- Severe tibioperoneal disease (*poor candidate for surgery*)
- Immediately threatened extremity
- Critical time to reperfusion (*poor candidate for thrombolysis*)
- Critical limb ischemia in SLI patients
Randomized Studies: 
Surgery vs. Thrombolysis 
(meta-analysis, 1283 pts)

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<thead>
<tr>
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<th>SURGERY</th>
<th>THROMBOLYSIS</th>
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<tbody>
<tr>
<td>30-day mortality</td>
<td>8.2% (4.9-17.5)</td>
<td>4.6% (0-12.3)</td>
</tr>
<tr>
<td>30-day limb salvage</td>
<td>87% (56-98)</td>
<td>88% (36-91)</td>
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<tr>
<td>Major haemorrhage</td>
<td>3.3% (0-5.1)</td>
<td>8.8% (0-11.8)</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>1.3% (0-1.8)</td>
</tr>
</tbody>
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No overall difference in limb salvage or death at 30 days, six months or one year (patients with milder symptoms)

_Berridge DC et al. 2013, Cochrane Database_
SURGERY: CURRENT DATA

30d mortality 13 – 18%
Intrahospital major adverse events 20%
30d – 90d amputation: 14 - 18 %

1 year mortality 21%
1 year limb loss 24%

Taha AG et al. 2015 (296 pts)
Baril DT et al 2013 (323 pts)
Kempe K et al. 2014 (170 pts)
MAJOR LIMITATIONS

OPEN SURGERY: invasiveness, serious cardiopulmonary complications, technical limitations

THROMBOLYSIS: serious hemorrhage, brain attack, slow therapeutic effect
CAN WE AVOID THROMBOLYSIS?


- Direct administration of thrombolytics during rheolytic procedure: 67% (*Leung DA, 2015*)
- Mortality: 0-9.3%; technical success: 61.4-92.8%; amputation rate 30d: 4-11.6%
- Antiembolic filter recommended (*Spiliopoulos S, 2012*) whenever technically feasible
CAN WE AVOID THROMBOLYSIS?

ROTAREX *(Straub Medical)*: combines thrombectomy + atherectomy potential

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Mortality Rate</th>
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<tr>
<td>Thrombolysis:</td>
<td>0 - 14%</td>
</tr>
<tr>
<td>Open surgery:</td>
<td>0 - 5.3%</td>
</tr>
<tr>
<td>30 days mortality rate:</td>
<td>0 - 1%</td>
</tr>
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</table>
ROTAREX IN THERAPY OF ACUTE AND SUBACUTE ISCHEMIA OF LOWER LIMBS

Technical success: 92-100 %
Amputation rate: 0-34%

infra-aortic arteries:
  Zeller T 2003

fem-pop. arterial segments:
  Due SR 2005; Wissgott C 2008
  Staněk F 2013; Freitas B 2017
  Bérczi V 2002

fem-pop. bypasses:
  Lichtenberg M 2012; Wissgott C 2013
MECHANICAL DEBULKING ADVANTAGE

- Low invasiveness
- Prompt reperfusion
- Immediate treatment of concomitant lesions
- Low rate of serious hemorrhage
- No need to place the patient in an intensive care unit
- No contraindications
SUMMARY

• Mechanical debulking cannot fully replace open surgery and thrombolysis in the therapy of acute and subacute ischemia of lower limbs.

• Used as an initial treatment, it can substantially decrease mortality rate in ALI + SLI patients with therapeutic efficacy comparable to thrombolysis and surgery.

• Mechanical debulking can shift open surgery and thrombolysis into the category of adjunctive techniques.