Treating in-stent occlusions with the Rotarex catheter: The ROBINSON study

final 6-month results in 30 patients

Dr. Marc Bosiers

LINC 2017, Leipzig
Conflict of interest

☐ 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
Acute and subacute ischemia of the limb...

**Thromboembolectomy**
- Suboptimal results
- Increased morbidity and mortality

**Addition surgical treatment**

**Thrombus aspiration**
- Time-consuming
- Questionable efficiency
- Insufficient collateral clearing

**Chemical thrombolysis**
- Risk of complex hemorrhagic complications
- Complex and expensive [Intensive Care Unit]

**Mechanical thrombectomy**
- Minimally invasive option for rapidly recanalizing
- Lower complication rate
- Lower costs [No Intensive Care Unit]
The risk of complications increases with the duration of the infusion from 4% at 8 hours to 34% at 40 hours.
Technical success rate was 97.7%.
Mechanical thrombectomy

Rotarex mechanical debulking: The Leipzig experience in 1,200+ patients

**Intervention Feature**
- In-stent procedures
- Native ‘virgin’ arteries
- Surgical bypasses
- Reo procedures

338 Procedures

Rotarex mechanical debulking in in-stent procedures
Clinical Follow-up: 30-day results

<table>
<thead>
<tr>
<th>Major Adverse Events (MAE) to 30 postoperative day</th>
<th>Events</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>4</td>
<td>1.2</td>
</tr>
<tr>
<td>MI *</td>
<td>6</td>
<td>1.8</td>
</tr>
<tr>
<td>TLR **</td>
<td>9</td>
<td>2.7</td>
</tr>
<tr>
<td>TVR ***</td>
<td>3</td>
<td>0.9</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>7</td>
<td>2.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>29</td>
<td><strong>6.7</strong></td>
</tr>
</tbody>
</table>

Notes: * Major Adverse Event (MAE) is 30 postoperative day. Values are rate number (% of observations). **Rotational thrombectomy. ***Major Amputation.

Rotarex mechanical debulking in in-stent procedures
Clinical Follow-up: 12 months results

<table>
<thead>
<tr>
<th>Major Adverse Events (MAE) to 12-months</th>
<th>Events</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>31</td>
<td>9.2</td>
</tr>
<tr>
<td>MI *</td>
<td>7</td>
<td>2.1</td>
</tr>
<tr>
<td>TLR **</td>
<td>43</td>
<td>12.7</td>
</tr>
<tr>
<td>TVR ***</td>
<td>41</td>
<td>7.9</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>47</td>
<td>3.9</td>
</tr>
</tbody>
</table>

Notes: * Major Adverse Event (MAE) is 12 months. Values are rate number (% of observations). **Rotational thrombectomy. ***Major Amputation.
Product information

- Removal of the thrombotic occlusion material
- Aspiration into the side cutting windows
- Shredding of the occlusion material into miniscule particles
- Transport of debris out of the blood vessel
A Prospective, non-randomized, multi center, controlled physician-initiated trial: \textit{RO}tarex \textit{B}elgium \textit{IN-S}tent \textit{O}cclusio\textit{N}
Study design

• Study Objective: To evaluate the safety and efficacy of recanalization of acute and subacute femoropopliteal stent occlusions with the Rotarex® S catheter (Straub Medical)

• Primary Endpoint:
  - Efficacy endpoint: technical success of the Rotarex device, defined as removal of all thrombotic material, documented by angiography pre- and post-procedure: residual stenosis of the lesion <30%
  - Safety endpoint: Absence of procedure related complications: embolization, amputation, perforation or hemorrhage.
Participating centers

• BELGIUM
  • M. Bosiers, K. Deloose, J. Callaert - AZ Sint-Blasius, Dendermonde
  • P. Peeters, J. Verbist - Imelda Hospital, Bonheiden
  • L. Maene, R. Beelen - OLV, Aalst
  • K. Keirse - RZ Heilig Hart - Tienen
  • J. Hendriks, P. Lauwers – University Hospital Antwerp - Edegem
Inclusion criteria

Main inclusion criteria

• Symptomatic acute or subacute stent occlusion in the femoropopliteal artery
• Target Vessel Diameter $\geq 3.0$ mm and $\leq 8.0$ mm

30 out of 30 patients enrolled (100%)
Study overview

Timeline

<table>
<thead>
<tr>
<th>Medication</th>
<th>proc</th>
<th>disch</th>
<th>1 M</th>
<th>6 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rutherford</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duplex Ultrasound</td>
<td></td>
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</tbody>
</table>
# Patient Demographics

<table>
<thead>
<tr>
<th></th>
<th>N = 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>23 (76.67%)</td>
</tr>
<tr>
<td>Age (min – max; ±SD)</td>
<td>71.24 (51.75 – 87.33; ±9.39)</td>
</tr>
<tr>
<td>Nicotine abuse (%)</td>
<td>22 (73.33%)</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>22 (73.33%)</td>
</tr>
<tr>
<td><strong>Diabetes mellitus (%)</strong></td>
<td><strong>10 (33.33%)</strong></td>
</tr>
<tr>
<td>Renal insufficiency (%)</td>
<td>4 (13.33%)</td>
</tr>
<tr>
<td>Hypercholesterolemia (%)</td>
<td>21 (70.00%)</td>
</tr>
<tr>
<td>Obesity (%)</td>
<td>9 (30.00%)</td>
</tr>
</tbody>
</table>
# Procedural & Lesion characteristics

<table>
<thead>
<tr>
<th></th>
<th>N = 30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedure time</strong></td>
<td>62.03 min (30.0 – 120.0; ±24.47)</td>
</tr>
<tr>
<td>(min-max ; ±SD)</td>
<td></td>
</tr>
<tr>
<td><strong>Scopy time</strong></td>
<td>19.21 min (8.00 – 36.70 ; ±8.31)</td>
</tr>
<tr>
<td>(min – max; ±SD)</td>
<td></td>
</tr>
<tr>
<td><strong>Contrast</strong></td>
<td>79.23 mL (20.00 – 150.00 ; ±33.46)</td>
</tr>
<tr>
<td>(min – max; ±SD)</td>
<td></td>
</tr>
<tr>
<td><strong>Cross-over performed</strong></td>
<td>30 (100.00%)</td>
</tr>
<tr>
<td>(%)</td>
<td></td>
</tr>
<tr>
<td><strong>Inflow Lesion</strong></td>
<td>1 (3.33%)</td>
</tr>
<tr>
<td>(%)</td>
<td></td>
</tr>
<tr>
<td><strong>Outflow lesion</strong></td>
<td>13 (43.33%)</td>
</tr>
<tr>
<td>(%)</td>
<td></td>
</tr>
<tr>
<td><strong>Lesion length</strong></td>
<td>170.50 mm (15.0 – 500.0; ±146.29)</td>
</tr>
<tr>
<td>(min – max; ±SD)</td>
<td></td>
</tr>
<tr>
<td><strong>Ref Vessel Diameter</strong></td>
<td>5.43 mm (4.00 – 7.00 ; ±0.63)</td>
</tr>
<tr>
<td>(min – max; ±SD)</td>
<td></td>
</tr>
<tr>
<td><strong>Calcified lesion</strong></td>
<td>6 (20.00%)</td>
</tr>
<tr>
<td>(%)</td>
<td></td>
</tr>
</tbody>
</table>
Efficacy endpoint

Technical success: residual stenosis of the lesion <30% after Rotarex treatment?

Yes 16
No 14

Additional treatment

Covered stent
Covered stent
Covered stent
Covered stent
BMS
BMS
BMS
DCB
DCB
DES
DES
Thrombolysis
DCB + BMS
VMI

FMRP - LINC 2017
Safety endpoint

Safety endpoint: Absence of procedure related complications?

Perforations?

- No: 29
- Yes: 1

Distal Embolization

- No: 26
- Yes: 4

Number of days between procedure and discharge:

- Mean = 2.93 days
- Median = 1 day

FMRP - LINC 2017 16
6-month Freedom from amputation

Freedom from Amputation

Cumulative Limb Salvage Rate (%)

Time (days)

Number at risk

92.3%
6-month Primary Patency

Primary Patency Rate

Cumulative Primary Patency Rate (%)

- 60%
- 70%
- 80%
- 90%
- 100%

Time (days)

- 0
- 30
- 60
- 90
- 120
- 150
- 180
- 210

Number at risk

- 30
- 28
- 25
- 25
- 24
- 18
- 15
- 3

Primary Patency Rate:

- 63.9%
- 59.7%
6-month Freedom from TLR

Freedom from Target Lesion Revascularization

Cumulative f-TLR rate (%)

Time (days)

Number at risk

0 30 28 26 26 25 20 16 4

100 80 60 40 20 0

67.9%
6-month PP – stand alone therapy vs additional treatment

Primary Patency - stand alone vs additional treatment

Cumulative Primary Patency Rate (%)

0 20 40 60 80 100

Time (days)

0 30 60 90 120 150 180 210

Number at risk

Group: 0
14 13 11 11 10 7 5 0

Group: 1
16 15 14 14 14 11 10 3

P = 0.4993

64.9%

52.4%
6-month Rutherford evolution
& what about the price...? Case example!

- **Thrombolysis**: €8,406
- **ROBINSON additional treatment**: €4,800
- **ROBINSON stand alone**: €4,012

Treatment cost (physicians):
- €3,374
- €1,689
- €1,700
Conclusion

Rotarex Mechanical Debulking seems to be a safe and effective option to treat (sub)acute in-stent restenosis occlusions in the SFA.

With less complication rates compared to thrombolysis

& less financial costs for the patient/institution
Treating in-stent occlusions with the Rotarex catheter: The ROBINSON study

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