Spinal cord protection by selective spinal artery coil embolization –
update on the PAPA-ARTIS trial

PAPAartis
fighting spinal cord injury

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LEIPZIG
The author declares no conflict of interest

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Open surgery, staged repair:
SCI reduction from 15% to 0%
Editor’s Choice — The Impact of Early Pelvic and Lower Limb Reperfusion and Attentive Peri-operative Management on the Incidence of Spinal Cord Ischemia During Thoracoabdominal Aortic Aneurysm Endovascular Repair

B. Maurel a, N. Delclaux a, J. Sobocinski a, A. Hertault a, T. Martin-Gonzalez a, M. Moussa b, R. Spear a, M. Le Roux a, R. Azzaoui a, M. Tyrrell b, S. Haulon a,*

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Endovascular, staged Repair
SCI reduction “10fold” — from 25% to 2.4%
EVIDENCE OF ARTERIOGENESIS

Graphs showing vessel diameter distribution for T9-T13 and L1-L5 regions with corresponding images of micrographs.
THE STAGED REPAIR

Minimally Invasively
MIS²ACE

PRIMING COLLATERAL REGENERATION!
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 733203 and the German Research Foundation.
Statistical Monitoring Report for PAPAartis

for the trial

Paraplegia Prevention in Aortic Aneurysm Repair by Thoracoabdominal Staging with "Minimally-Invasive Staged Segmental Artery Coil-Embolization": A Randomized Controlled Multicentre Trial
PAPAartis
NCT03434314

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Date: 2020-12-15
patent segmental arteries / patient
# of MIS²ACE-sessions / patient

## MIS²ACE procedure

Table 2: Specifics of the MIS²ACE sessions. Note that inconsistencies in the database are expected until all queries have been resolved. SA=segmental arteries

<table>
<thead>
<tr>
<th></th>
<th>Session I</th>
<th>Session II</th>
<th>Session III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>31</td>
<td>13</td>
<td>8</td>
</tr>
<tr>
<td>Dosis area product (Gy \times cm²)</td>
<td>150 ± 181</td>
<td>87 ± 90</td>
<td>86 ± 70</td>
</tr>
<tr>
<td>Duration of session (hours)</td>
<td>1.8 ± 1.1</td>
<td>2.0 ± 1.0</td>
<td>2.0 ± 1.2</td>
</tr>
<tr>
<td>Number of occluded SA (not pairs)</td>
<td>3.0 ± 2.4</td>
<td>3.1 ± 1.7</td>
<td>2.5 ± 1.2</td>
</tr>
<tr>
<td>&gt; 7 pairs occluded</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Number of coils/plugs</td>
<td>12.4 ± 12.9</td>
<td>14.2 ± 12.0</td>
<td>12.5 ± 11.1</td>
</tr>
<tr>
<td>Number of sessions terminated early</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Number of sessions with complications</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
„Time to repair“
(time since randomization)

Figure 6: Time to repair or end of study. If a multiple staged repair was used, the last stage of repair is taken. For repairs not (yet) documented, the date from randomization till now is used.
Data quality and safety: high

6 Data Quality

6.1 Neurological assessments at baseline

Table 3: Completeness of neurological baseline data. Sites are considered to have provided data if a date for the CRF was entered.

<table>
<thead>
<tr>
<th>Site</th>
<th>Neurological examination</th>
<th>mRS-9Q</th>
<th>Symptoms mRS-9Q</th>
<th>MoCA</th>
<th>Barthel-Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aachen (n=9)</td>
<td>5</td>
<td>8</td>
<td>3</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Bern (n=2)</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Freiburg (n=4)</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Hamburg (UKL) (n=6)</td>
<td>6</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Innsbruck (n=2)</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Leipzig (HZL) (n=12)</td>
<td>9</td>
<td>9</td>
<td>5</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Leipzig (UKL) (n=22)</td>
<td>19</td>
<td>20</td>
<td>9</td>
<td>19</td>
<td>20</td>
</tr>
<tr>
<td>Milan (n=3)</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Munich (LMU) (n=6)</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Munich (TU) (n=1)</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Münster (n=5)</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

7 Safety

There have been 236 adverse events (115 MIS²ACE, 121 control) from 50 patients (27 MIS²ACE, 23 control), 97 of which are serious adverse events (43 MIS²ACE, 54 control). There were 7 AEs that are possibly related to MIS²ACE, 66 possibly related to the repair and 93 related to repair.
4.2 Details of complications

- Pain, Thorax left site, after coiling TH8 left - resolved after morphin

4.3 Time between sessions
Out of 13 documented cases, the mean ± sd time between MIS²ACE sessions 1 and 2 was 23 ± 13 days. There were 0 instances in which it was less than 5 days. Out of 7 documented cases, the time between sessions 2 and 3 was 16 ± 9 days. There were 0 instances in which it was less than 5 days.

4.4 Acute back pain
There were 1 instances of acute back pain during the MIS²ACE procedure amongst 1 patients. There were 49 documented cases without back pain amongst 30 patients.

4.5 Radiation
The total DAP per patient over all sessions was 207 Gy × cm² and there were 7 patients with more then 300 Gy × cm².

Figure 4: Dosis area product (DAP) over all MIS²ACE sessions per patients.