Long-term results of multilayer stent in thoraco-abdominal aneurysms. Aneurysm continue to grow – but is it something in it?

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I have the following potential conflicts of interest to report:

Co-founder Meliora-Vision
Co-founder MV Arterica
MLFM Concept

- Reconstruction instead of exclusion
- Blood flow is allowed through a stent mesh
- Modulates laminar flow within the aneurysm sac
- Stagnant blood flow leads to thrombosis
- Perfusion is maintained into side branches
Self-expandable wire mesh
Survival @ 6 years

Total number 13 pts

Elective 9 pts
Ø 71 mm (58-94)
- Alive 1 pt
- Death 8 pts

Emergency 4 pts
Ø 70 mm (56-84)
- Rupture 2 pts
- Symptomatic 2 pts
- Death 2 pts
<table>
<thead>
<tr>
<th>Cause of death</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown</td>
<td>2m</td>
</tr>
<tr>
<td>Unknown</td>
<td>11m</td>
</tr>
<tr>
<td>TAAA-related (MOF after open procedure)</td>
<td>32m</td>
</tr>
<tr>
<td>TAAA-related (intestinal ischemia; SMA+RRA occl)</td>
<td>39m</td>
</tr>
<tr>
<td>TAAA-related (chronic renal failure; RRA+LRA occl)</td>
<td>41m</td>
</tr>
<tr>
<td>All-cause (pneumonia and cardiac failure)</td>
<td>52m</td>
</tr>
<tr>
<td>All-cause (pulmonary)</td>
<td>71m</td>
</tr>
<tr>
<td>All-cause (Septicemia)</td>
<td>80m</td>
</tr>
</tbody>
</table>
Preop
2 year follow-up
Change of aneurysm size

Baseline: 71 mm
88 mm @ 3 yrs
SAE

- 1 pt cerebral infarction postop
- 1 pt spinal infarction with paraplegia @15 m
- 2 pts died from SMA occlusion
- Reintervention rate 67% (6 out of 9)
Have we missed something?

- Shortcomings due to an early stent generation?
- Shortcomings due to learning curve
The best we can say

- Something is happening that might support the MLFM concept
Thrombosed and stable @ 3m

Preop | 1 week | 1 month | 3 months
58 mm | 60 mm | 60 mm | 60 mm
<table>
<thead>
<tr>
<th>Time</th>
<th>Size (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;6 months</td>
<td>Increased size</td>
</tr>
<tr>
<td>6 months</td>
<td>62 mm</td>
</tr>
<tr>
<td>12 months</td>
<td>64 mm</td>
</tr>
<tr>
<td>24 months</td>
<td>69 mm</td>
</tr>
<tr>
<td>36 months</td>
<td>81 mm</td>
</tr>
</tbody>
</table>
Further increase 3 – 6 yrs

36 months
81 mm

72 months
105 mm
• 14 pts, 2011 - 2014 (6 PAA, 8 TAAA)
• 50% all-cause mortality; 1 confirmed rupture (22.8 m)
• 72% increased in aneurysm size (11mm)
• 35% reinterventions
• No episodes of branch vessel ischemia
Three-Year Outcomes With the Multilayer Flow Modulator for Repair of Thoracoabdominal Aneurysms: A Follow-up Report From the STRATO Trial

Claude D. Vaissic, MD¹, Jean Noël Fabiani, MD, PhD², Sidney Chocron, MD, PhD³, Jacques Robin, MD⁴, Victor S. Costache, MD, PhD⁵, Jean-Pierre Villenot, MD, PhD⁶, Jean Marc Alsac, MD², Pascal N. Leprince, MD, PhD⁷, Thierry Unterseeh, MD⁸, Eric Portocarrero, MD⁶, Yves Glock, MD, PhD⁹, and Hervé Rousseau, MD, PhD¹⁰ for the STRATO Investigators Group

- 23 pts, type II and III TAAA (2010-2011) prospective multicenter non-randomized
- 30% all-cause mortality; no confirmed rupture (3 yrs)
- Mean aneurysm diameter increased from 68-74 mm (3 yrs)
- 43% reinterventions
- 2 pts had occlusion of visceral branches
Conclusion

• The Cardiatis stent has not proven efficacy, safety or reliability in thoraco-abdominal aneurysms
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• The Cardiatis stent has not proven efficacy, safety or reliability in thoraco-abdominal aneurysms
• Aneurysm growth cannot be prevented
• Branch vessel patency is not obligate
• New MLFM concepts should be evaluated only in trials
Thank you