4-Year Experience With MLFM Stents For The Treatment Of Complex Aortic Aneurysms: When They Do Not Work

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Disclosures

I have the following potential conflicts of interest to report:

Educational Program  W.L Gore & Associates
Stockholder       LeMaitre
Co-founder         Meliora-Vision

Örebro trial of 13 pts
Nov 2010 – Dec 2011

• Thoraco-abdominal  11
  – Crawford I  1
  – Crawford II  2
  – Crawford III 5
  – Crawford IV  3
• Juxtarenal  1
• EVAR–type I endoleak  1

Previous repair (6 pts)
Mean age 75 yrs (55-89)

Process

• Considered as compassionate cases by our team
• Graft planning together with Cardiatis company who reviewed the main part of the patients and also provided case technical support

3D braided stent of of chromium chobolt
Mechanism: Flow-modulator

Survival @ 4 years

Total number 13 pts
Elective  9 pts
Emergency 4 pts

Alive 3 pts
Death 6 pts
Rupture  2 pts
Symptomatic 2 pts

Death 2 pts
Death 2 pts
Survival @ 4 years

- Total number: 13 pts
  - Elective: 9 pts (Ø 71 mm (58-94))
  - Emergency: 4 pts (Ø 70 mm (56-84))
- Alive: 3 pts
- Death: 6 pts
- Rupture: 2 pts
- Symptomatic: 2 pts

Mortality

<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>MOF after open debranching procedure</td>
<td>32m</td>
</tr>
<tr>
<td>MOF (SMA and RRA occluded)</td>
<td>39m</td>
</tr>
<tr>
<td>Chronic renal failure (RRA and LRA occluded)</td>
<td>41m</td>
</tr>
<tr>
<td>All-cause (pneumonia and cardiac failure)</td>
<td>52m</td>
</tr>
</tbody>
</table>

Change of aneurysm size

- + 6mm
- + 6mm + 4mm
- + 6mm + 4mm + 7mm
SAE (elective group)
• 1 pt cerebral infarction postop
• 1pt spinal infarction with paraplegia @15 m

SAE (elective group)
• Reintervention rate 67% (6 out of 9 elective)

Have we missed something?
• Shortcoming due to an early stent generation?

Have we missed something?
• Shortcoming due to an early stent generation?

Have we missed something?
• Shortcoming due to learning curve

Have we missed something?
• Shortcoming due to learning curve

It is a responsibility the company must take

As physicians we should request products that work in most people’s hands
Have we missed something?

- Is the MLFM concept actually working but the stent can not achieve the effect

The best we can say

- Something is happening that might support the MLFM concept

Thrombosed and stable @ 3m

>6 months increased size
The best we can say

- Something is happening that might support the MLFM concept
  
  **BUT this stent is not reliable**

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**Conclusion**

- The Cardiatis stent has not proven efficacy or safety in thoraco-abdominal aneurysms

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- The Cardiatis stent has not proven efficacy or safety in thoraco-abdominal aneurysms
  
  - Aneurysm growth cannot be prevented
  
  - Branch vessel patency is not obligate

  - Long term follow-up is necessary
  
  - MLFM concept should be evaluated only in trials
Thank you!