Three year experience with multilayer stent in the treatment of thoracoabdominal aneurysms – no evidence for aneurysm stabilization

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## Disclosures

I have the following potential conflicts of interest to report:

<table>
<thead>
<tr>
<th>Role</th>
<th>Company/Institution</th>
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<tr>
<td>Educational Program</td>
<td>W.L Gore &amp; Associates</td>
</tr>
<tr>
<td></td>
<td>Covidien</td>
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<tr>
<td>Consultant</td>
<td>Covidien</td>
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<tr>
<td>Stockholder</td>
<td>LeMaitre</td>
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Ruffino MA, Rabbia C; Italian Cardiatis Registry Investigators Group
Endovascular repair of peripheral and visceral aneurysms with the Cardiatis multilayer flow modulator: one-year results from the Italian Multicenter Registry

- 54 patients
- Complete aneurysm thrombosis 93%
- Diameter reduction @ 12 months = 63%
- No ruptures
Sherif Sultan et al
Early mid-term results of the first 103 cases of multilayer flow modulator stent done under indication for use in the management of thoracoabdominal aortic pathology from the independent global MFM registry

Outcome – effect on aortic sac

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Outcome @ 1 year
13.2% all-cause mortality
No aneurysm-related mortality
Outcome @ 1 year

10.7% reintervention rate due to stent shortening with retraction into the aneurysm

Sherif Sultan et al
Early mid-term results of the first 103 cases of multilayer flow modulator stent done under indication for use in the management of thoracoabdominal aortic pathology from the independent global MFM registry
Vaislic CD et al

One-year outcomes following repair of thoracoabdominal aneurysms with the multilayer flow modulator: report from the STRATO trial. J Endovasc Ther. 2014 Feb;21(1):85-95

- 100% technical success
- Stable aneurysm in 18/20 patients
- No aneurysm rupture
but they also reported

- 3 patients with type I endoleaks during follow-up
- Conclusion was device misplacement which contributed to incomplete MFM opening in each case
- Aneurysm expansion was defined, per protocol, as a >10 mm increase in the maximum diameter compared to discharge imaging
Örebro experience 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 initial patients
Survival – 3 years follow-up

- Total number 13 pts
  - Elective 9 pts
    - Ø 71 mm (58-94)
      - Alive 5 pts
      - Death 4 pts
  - Emergency 4 pts
    - Ø 70 mm (56-84)
      - Rupture 2 pts
      - Symptomatic 2 pts

- Death 2 pts
Survival – 3 years follow-up

Total number 13 pts

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Rupture 2 pts
Symptomatic 2 pts

2 were AAA-related
Survival – 3 years follow-up

Total number
13 pts

Elective 9 pts
Ø 71 mm (58-94)

Alive 5 pts
Death 4 pts

Emergency 4 pts
Ø 70 mm (56-84)

Rupture 2 pts
Symptomatic 2 pts

Death 2 pts
Death 2 pts
Thrombosed and stable @ 3m

Preop: 58 mm
1 week: 60 mm
1 month: 60 mm
3 months: 60 mm
>6 months increased size

6 months: 62 mm
12 months: 64 mm
18 months: 66 mm
24 months: 69 mm
Complete thrombosis formation in 1 pt
Branch vessel occlusion (3/29)

SMA and right renal patent

SMA and right renal occluded
SAE (elective group)

- 1 pt spinal infarction with paraplegia @ 15 m
- 1 pt cerebral infarction postop
- 1 pt died after open debranching @ 33 m
- 1 pt died due to multi-organ failure (occluded SMA and renal artery @ 39 m
- Reintervention rate 67% (6 out of 9 elective)
Change of aneurysm size

mm

Baseline 1 year 2 years 3 years

Pat 1 Pat 2 Pat 3 Pat 4 Pat 5 Pat 6 Pat 7 Mean
Change of aneurysm size

+ 6mm

mm
Change of aneurysm size

+ 6mm  + 4mm
Change of aneurysm size

+ 6mm  + 4mm  + 7mm
Summary

• MFM Registry, STRATO and Örebro trial all report an increase of aneurysm size
Summary

- MFM Registry
- STRATATO
- Örebro trial
Summary

• MFM Registry

• STRATO

• Örebro trial
Conclusion

• MFM stents have not proven efficacy or safety
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• Aneurysm growth cannot be prevented
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- Aortic aneurysms are contraindicated
Conclusion

- MLFM stents have not proven efficacy or safety
- Aneurysm growth cannot be prevented
- Branch vessel patency is not obligate
- Aortic aneurysms are contraindicated
- We urge the company to withdraw the product
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