The MLFM Stent Has A Role In The Treatment Of Complex Aortic Aneurysms: What Is It And What More Do We Need To Know?

Christos D. Liapis
Professor (Em) of Vascular Surgery
Athens University Medical School
Director Vascular & Endovascular Clinic
Athens Medical Center

Complex aortic Aneurysms
Are the Results of Current Treatment Satisfactory?

Fenestrated and Branched Endografts

<table>
<thead>
<tr>
<th>Author</th>
<th>30-day Mortality</th>
<th>Paraplegia</th>
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</thead>
<tbody>
<tr>
<td>Anderson 2006</td>
<td>5%</td>
<td>31.1%</td>
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<tr>
<td>Greenberg 2006</td>
<td>0%</td>
<td>11.1%</td>
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<tr>
<td>Brist 2007</td>
<td>9.1%</td>
<td>0%</td>
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<tr>
<td>Winter 2008</td>
<td>18.5%</td>
<td>0%</td>
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<tr>
<td>Billing 2011</td>
<td>0%</td>
<td>0%</td>
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<tr>
<td>Trachiot 2009</td>
<td>6.7%</td>
<td>3.9%</td>
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<tr>
<td>Kapriel 2009</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Muhlin 2011</td>
<td>2.6%</td>
<td>1%</td>
</tr>
<tr>
<td>Chiyoko 2012</td>
<td>9.7%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Guillo 2012</td>
<td>8.9%</td>
<td>3.4%</td>
</tr>
<tr>
<td>MEAN</td>
<td>5.8%</td>
<td>2.2%</td>
</tr>
</tbody>
</table>

30-day Mortality: 20% REJECTION RATE

Open Procedures

30 day Mortality: 5-19% 1 Year Mortality: 16-31%


Hybrid Procedures

30-day Mortality: 13.9%


NO DISCLOSURES RELATED TO THE TOPIC
Chimney Graft Technique


30-day mortality: 4.3%
Renal impairment 11.8%
Myocardial infarction: 2.3%
Ischemic stroke: 3.2%
Type I endoleak: 14.0%

Flow Diverting Stents

Uncovered stents that

> Reduce
  - Turbulence
  - Flow velocity
  - Pressure

> Maintain laminar flow
  - Main artery

MLFM in Thoracoabdominal Aneurysms

Review of 43 suprarenal AAA and TAA

Aneurysm Thrombosis 40% (6 months)
Shrinkage 83% (12 months)
Branch Vessel Patency

Complications-Reoperations (9%)
- Intestinal Ischemia (Branch Vessel Thrombosis)
- Femoral Artery Pseudoaneurysm
- Type I Endoleak

MLFM in Thoracoabdominal Aneurysms

STRATO prospective, multicenter, nonrandomized trial

2010-2011, n=23 (Type II and III TAs)
12 months follow up (20 pts):
  - Aneurysm Thrombosis: Branch Vessel Patency: 75% (15/20)
  - Branch Vessel Patency: 96% (53/55)
  - Stable (<1cm) TAA diameter: 90% (18/20)
  - Residual aneurysm flow volume to total volume decreased by 28.9%
  - Mean ratio of thrombus volume to total lumen volume increased by 21.3% (n=17)
  - No ruptures

MLFM in Thoracoabdominal Aneurysms

MultiLayer Flow Modulator Registry

N=103 (380) with TAA (n=75), suprarenal AAA (n=15), arch aneurysms (n=7), type B dissection (n=6)

12 months results:
  - Aneurysm related survival = 91.7%
    - No ruptures
    - 4 consumptive coagulopathy = 3 deaths
  - Total survival = 86.8%
  - Branch vessel patency = 95.1%

MultiLayer Flow Modulator Registry

N=38
- 13 Dissecting TAA
- 6 Mycotic
- 4 Saccular
- 15 TAA

- Follow up = 10.0±6.9 m
- Mortality: 89.5%
- Aneurysm related mortality: 71.1%

Use of MLFMs outside the IFU


N=103 (380) with TAA (n=75), suprarenal AAA (n=15), arch aneurysms (n=7), type B dissection (n=6)

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    - 4 consumptive coagulopathy = 3 deaths
  - Total survival = 86.8%
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11/18/2015

**MLFM: Italian Multicenter Retrospective Experience**

- N=25 patients (4 Type II, 4 type III, 13 type IV, 4 juxtarenal)
- 30 day:
  - Mortality = 0%
  - 1 renal stent thrombosis
  - 1 bowel perforation
  - 1 paraplegia
- Follow up (mean 669 days)
  - Cumulative mortality: 25% (6/24 patients)
  - MLFM related deaths: 8.3% (n=2)
  - (Occlusion MLFM and occlusion SMA)
  - No ruptures
  - Secondary procedures = 16.6% (n=4)

**IFU for Implantation of MLFM**

- Proximal and distal landing >20 mm
- Treat all branch vessel stenoses beforehand
- Do not place MLFM into grafts (open / endovascular)

**IFU for Implantation of MLFM**

- Adequate overlapping
- The largest diameter MLFM always into the smaller
- Beware of oversizing

**Implantation within IFU**

**Implantation outside IFU**
Absolute Contraindications for MLFM

1. Symptomatic and Ruptured Aortic Aneurysms

2. Mycotic Aortic Aneurysms

Reported Ruptures after MLFM

- 82 yrs, Paranastomotic aneurysm
- 60 yrs, Type IV TAA (mycotic?)
- 76 yrs, Type II TAA (no proximal landing zone)


Conclusions I

- Current treatment of TAA (open, branched, hybrid, chimney) carries significant morbidity, mortality and limitations
- MLFM may be a solution for some high risk patients, with strict adherence to:
  1. Careful case selection -planning
  2. Placement only according to IFU
  3. Not use in ruptured or mycotic aneurysms

Conclusions II

- We need to know the size threshold for treatment of extra large aneurysms.
- We need to know the long term outcomes and effects of thrombus volume increase.
- Technical improvements (deployment, fixation, bifurcated grafts) are needed.
- The price of the graft seems extremely high (25,000€ in Europe) for one piece device.

Thank you for your attention