Multilayer flow modulator Cardiatis stent in the treatment of complex aortic pathology. 5 years Bulgarian experience.

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Disclosure

Speaker name:

.....Ivo Petrov.................................................................

I have the following potential conflicts of interest to report:

☐ Consulting

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest
Edward Diethrich and Donald Reid at the opening ceremony of City Clinic 12.12.2012

Joined IHH group, 27 April 2016
Endovascular experience after 3 years of work:

• 5820 endovascular cases ("Head to toe") in the cathlab and the hybrid OR including:
  – CTO and Left main Coronary interventions
  – EVAR/TEVAR
  – TAVR
  – Intracranial aneurysms stenting and coiling
  – CAS
  – Radial approach for complex peripheral cases
  – Complex venous interventions (including May-Thurner, CCSVI)
  – Renal denervation
Endovascular treatment of Aorta. Our experience- 2008-2016:

Total: 273
Treatment of complex aortic diseases:
One of the biggest challenges of contemporary vascular medicine
Thoracoabdominal aortic aneurysms
Crawford classification
### Intervention for descending aorta aneurysms

#### Recommendations for diagnostic work-up of thoracic aortic aneurysm (TAA)

<table>
<thead>
<tr>
<th>Interventions on descending aortic aneurysms</th>
<th>IIA</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEVAR should be considered rather than surgery when anatomy is suitable.</td>
<td>IIA</td>
<td>C</td>
</tr>
<tr>
<td>TEVAR should be considered in patients who have descending aortic aneurysm with maximal diameter ≥55 mm.</td>
<td>IIA</td>
<td>C</td>
</tr>
<tr>
<td>When TEVAR is not technically possible, surgery should be considered in patients who have descending aortic aneurysm with maximal diameter ≥60 mm.</td>
<td>IIA</td>
<td>C</td>
</tr>
<tr>
<td>When intervention is indicated, in case of Marfan syndrome or other elastopathies, surgery should be indicated rather than TEVAR.</td>
<td>IIA</td>
<td>C</td>
</tr>
</tbody>
</table>
**Symptomatic AAA**

<table>
<thead>
<tr>
<th>Recommendations on management of patients with symptomatic abdominal aortic aneurysm (AAA)</th>
<th>Class&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Level&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>In patients with suspected rupture of AAA, immediate abdominal ultrasound or CT is recommended.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>In case of ruptured AAA, emergency repair is indicated.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>In case of symptomatic but non-ruptured AAA, urgent repair is indicated.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>In case of symptomatic AAA anatomically suitable for EVAR, either open or endovascular aortic repair is recommended.</td>
<td>I</td>
<td>A</td>
</tr>
</tbody>
</table>
Chimneys (PGs)
Historical Evolution

• Greenberg 2001: renal
• Criado 2003: arch (left carotid)
• Larzon 2004: arch (left carotid)
• Criado 2007: longer chimneys
• Malina 2008: chimneys
• Mayer-Lachat 2008: periscopes
• Lobato 2008: sandwich graft1
• Lobato 2009: sandwich graft2
• Kasirajan 2010: TAAA PGs
• Galvagni 2011: TAAA PGs
Complex debranching procedures before Endovascular graft implants
Secondary coiling procedures for sac isolation
CHIMNEY GRAFTS IN TAAA. FIRST EXPERIENCE IN BULGARIA
Chimney grafts in TAAA. First experience in Bulgaria.

1 Year follow-up
In the search for ever-decreasing invasiveness in the treatment of aortic diseases, the evolution of fenestrated and branched technology was initially promising. However, realistic assessment of fenestrated and branched technologies demonstrates that, just as in open and hybrid techniques, acceptable outcomes are only achievable in high volume specialist centers. Furthermore, even in such specialist centers, mortality and spinal cord ischemia risks are still considerable with this technique and offer no real advantage over open surgical techniques. Greenberg et al. reported a series of 633 patients undergoing endovascular repair (ER) who were matched according to the anatomical extent of disease with those having contemporary surgery. The mortality was similar at 30 days (5.7% for ER vs. 8.3% open, p=0.2) and at 12 months (15.6% ER vs. 15.9% open, p=0.9). Paraplegia rates were also similar between the groups (4.3% ER vs. 7.5% open, p=0.08).

Other issues with fenestrated and branched technologies are the time delays from design to implantation and the prohibitively high cost. Even the more recent availability of "off-the-shelf" branched devices has failed to

Regardless of the mode of repair, the main issues with TAAA repair remain mortality, spinal cord blood supply, and visceral hemodynamic compromise. There are specific issues with contemporary endovascular repair relating to the adverse effect on aortic wall compliance, shear stresses, and pressures within the aneurysm sac caused by exclusion with relatively stiff covered endografts, which in turn not only increase rupture risk but also compromise spinal artery perfusion.

There is mounting evidence to suggest that exclusion of aneurysms may actually subject the sac to greater pressure, inducing an iatrogenically enhanced risk of rupture and pathological loss of branch patency rather than offering the patients a safe aortic repair. Evidence from the Malmö group suggests that stiff covered endografts, which do not in any way mimic the native arterial wall, may in actual fact have seriously adverse effects on relative intrasac pressures, pulsatile wall motion, and spinal perfusion, which can essentially cause more harm than good and enhance rather than decrease the risk of
search for ever-decreasing invasiveness in the treatment of aortic diseases, the use of fenestrated and branched techniques was initially promising. However, assessment of fenestrated and branched technologies demonstrates that, in open and hybrid techniques, outcomes are only achievable in a few specialist centers.\textsuperscript{3–5} Furthermore, in such specialist centers, mortality spinal cord ischemia risks are still acceptable with this technique and offer no advantage over open surgical techniques. Ling et al.\textsuperscript{6} reported a series of 633 undergoing endovascular repair (ER) matched according to the anatomy of disease with those having open surgery. The mortality was 30 days (5.7\% for ER vs. 8.3\% open, and at 12 months (15.6\% ER vs. 15.9\% could be that the technology itself is fundamentally flawed.

Regardless of the mode of repair, the main issues with TAAA repair remain mortality, spinal cord blood supply, and visceral hemodynamic compromise. There are specific issues with contemporary endovascular repair relating to the adverse effect on aortic wall compliance, shear stresses, and pressures within the aneurysm sac caused by exclusion with relatively stiff covered endografts, which in turn not only increase rupture risk but also compromise spinal artery perfusion.\textsuperscript{10,11}

There is mounting evidence to suggest that exclusion of aneurysms may actually subject the sac to greater pressure, inducing an iatrogenically enhanced risk of rupture and pathological loss of branch patency rather than offering the patients a safe aortic repair.
Aortic dissection
Case Report (from the past)

• Year 2002: D.S. 54-year-old male
• Clinical history:
  ✓ 10-year history of arterial hypertension
  ✓ Smoker
  ✓ 6-year history of Diabetes mellitus

✓ Admitted in critical clinical condition (hypotensive, anuric, unconscious, in pulmonary edema)
✓ Acute De Bakey type I aortic dissection and AoReg III degr. was diagnosed

Urgent surgical resection of the ascending aorta with Unigraft No30 implantation was done

anuria, subileus, inferior paraparesis even after open repair
Aortography (left radial approach)(July 2002):

- Multiple additional tears in the toracoabdominal aorta causing false lumen expansion and true lumen compression resulting in life threatening end organ
ENDOVASCULAR TREATMENT

• Implantation of two Wallstents 20x55мм, followed by postdilation with balloon Symmetry 18x40мм across the visceral vessels. (Wallstent was initially designed for aortic dissection)

• Femoral approach was used to deliver the stents and left radial approach for angiographic control and left subclavian artery marking.
• Implantation of two Wallstents 20x55мм, followed by postdilation with balloon Symmetry 18x40мм, 6 atm.

• Femoral approach was used to deliver the stents and left radial approach for angiographic control and left subclavian artery marking.
Final result
Restored and centralized true lumen flow
• Restored abdominal branches flow
• Decreased flow in the false lumen
CLINICAL COURSE

1. Immediate hemodynamic stabilization

2. Recovery of renal function immediately after the procedure with a urine output of 1500 ml for the first hour.

3. Gradual recovery of the bowel function.

4. Complete recovery of the lower extremities' pulses bilaterally and resolving of the livedo reticularis.

5. Discharged on the 13th post-procedural day after rehabilitation and complete functional recovery.
Next day Follow up ultrasound
Thoracic Ao
Abdominal Ao
Abdominal Ao CT-scan

- Stent
- Celiac trunk
......10 years later:
After patient dropped from f-up, all in a sudden

• 2012: Uneventful 10 years follow-up,
• Normal renal function
• Normal ABI, the patient 66 y of age still working
10 years MSCT- angio follow up
Case report 2 (travel into the future :)

- White male 71 yo
- Admitted in hospital with persistent severe abdominal and peripheral ischemia with abdominal angina.
- History of previous surgical treatment for Type A Ao dissection (2 years before)
Case report 2 (travel into the future :)

CARDIATIS MFM

- White male 71 yo
- Admitted in hospital with persistent severe abdominal and peripheral ischemia with abdominal angina.
- History of previous surgical treatment for Type A Ao dissection (2 years before)
- Treatment for Type A Ao dissection with endovascular stent grafting
Streamlines inside an aneurysm without stent (left) and with porous wired stent (right, stent in blue). Steady computation.
Case report 2 (travel into the future :) 

- White male 71 yo
- Admitted in hospital with persistent severe abdominal and peripheral ischemia with abdominal angina.

- History of pervious surgical treatment for Type A Ao dissection (2 years before)
Diagnostic angiogram
(exremely compressed true lumen)
MFM implantation
Postdilatation needed
(true lumen extreme compression)
Final
CT- angio after 2- months
CT- angio after 6 and 12 months. Centralized blood flow. Complete distal healing, patent visceral vessels:
INTRODUCTION

During the period from May 2012 to February 2016, at the City Clinic Heart and Vascular Institute, 12 patients underwent implantation of the Multilayer Flow Modulator (MFM) (Cardiatis, Isnes, Belgium) in different aortic segments with complex pathology. The cases involved treatment of 10 thoracoabdominal aortic aneurysms (TAAA) (1 Crawford type I, 1 type III, 6 type IV, and 2 type V), 1 abdominal aortic aneurysm (AAA) extending distally into the left iliac artery, and 1 type A aortic dissection consequent to surgical treatment and compression of the true lumen with critical visceral and peripheral ischemia. All patients had clinical and anatomical characteristics placing them at significant risk for open surgery. Patient and aneurysm characteristics and baseline medical history are summarized in Table 7.1. The mean patient age was 65 years.
Cardiatis MFM experience in Bulgaria (2011-2015)
(Complex aortic pathology, multiple comorbidities, extremely high surgical risk)

<table>
<thead>
<tr>
<th>Total patients</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex M/F</td>
<td>12/0</td>
</tr>
<tr>
<td>Age</td>
<td>53-76 (65)</td>
</tr>
<tr>
<td>AH</td>
<td>11(91.7%)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>11(91.7%)</td>
</tr>
<tr>
<td>Pervious PCI/PTA</td>
<td>10(83.3%)</td>
</tr>
<tr>
<td>Previous TEVAR/EVAR</td>
<td>1(8.3%)</td>
</tr>
<tr>
<td>Previous open Ao repair</td>
<td>1 (8.3%)</td>
</tr>
</tbody>
</table>
City Clinic MFM experience. Treated pathology:

- Total patients: 12
- Aneurysm: 11 (91.7%)
- TAA: 10 (83.3%)
- AAA: 1 (8.3%)
- Dissection (type A with late critical end-organ ischemia): 1 (8.3%)
- Procedure success: 12/12 (100%)
MFM experience. In hospital results:

- Total No of stents implanted: 29 (2.4 per/p)
- Coverage of visceral and renal arteries: 10 (90.9%)
- X-ray time (min): 6-24 (14.1)
- Procedure time (min): 30-160 (50)
- General anesthesia: 0
- Conversion to open surgery: 0
- Mortality: 0
- MAE: 0
  - Neurological complications: 0
- ICU stay (day): 0
- Average hospital stay: 4.3d
MFM experience. Follow up:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device related failure</td>
<td>0%</td>
</tr>
<tr>
<td>Stent thrombosis (successful fibrinolysis and balloon recanalization)</td>
<td>2/29 (6.8%)</td>
</tr>
<tr>
<td>Secondary patency</td>
<td>29/29 (100%)</td>
</tr>
<tr>
<td>Preserved side branch flow</td>
<td>12/12 (100%)</td>
</tr>
<tr>
<td>Normal and normalized kidney function</td>
<td>12/12 (100%)</td>
</tr>
<tr>
<td>Mortality</td>
<td>1/12 (not related)</td>
</tr>
<tr>
<td><strong>Aorta related mortality</strong></td>
<td>0/12 (0%)</td>
</tr>
</tbody>
</table>

Additional late procedures (over 12 months later) 2/12 (16.6%)

1. One proximal dissection treated with Stent-graft
2. One distal aneurysm expansion treated with bare-metal extension
Established Superiority to Open Repair in TAAA STRATO Trial

<table>
<thead>
<tr>
<th>Clinical Success</th>
<th>6 months</th>
<th>12 months</th>
<th>24 months</th>
<th>36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aneurysm Exclusion</td>
<td>65% (13/20)</td>
<td>75% (15/20)</td>
<td>92% (12/13)</td>
<td>91% (10/11)</td>
</tr>
<tr>
<td>Aorta &amp; MFM Patency</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Branch Patency</th>
<th>12 months</th>
<th>24 months</th>
<th>36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>n=20</td>
<td>n=17 (13 follow-up)</td>
<td>n=13 (11 follow-up)</td>
</tr>
<tr>
<td>Celiac Trunk Patency</td>
<td>93% (13/14)</td>
<td>85% (11/13)</td>
<td>100% (11/11)</td>
</tr>
<tr>
<td>Secondary Patency</td>
<td>100% (14/14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Superior Mesenteric Artery Patency</td>
<td>94% (15/16)</td>
<td>100% (12/12)</td>
<td>100% (11/11)</td>
</tr>
<tr>
<td>Secondary Patency</td>
<td>100% (16/16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Renal artery Patency</td>
<td>100% (13/13)</td>
<td>100% (13/13)</td>
<td>91%* (10/11)</td>
</tr>
<tr>
<td>Right Renal Artery</td>
<td>100% (15/15)</td>
<td>100% (13/13)</td>
<td>100% (11/11)</td>
</tr>
</tbody>
</table>

* Preliminary results from French Strato trial – 1st generation device – Cases not eligible for open surgery or F/B EVAR due to several co-morbid conditions.

* Patient had Horton’s disease.
Case presentation 3
(Eccentric AAA)

- 73 y, male
- Comorbidities- history of SXCoAo, PCI +stents/DES/x2 in LAD. Arterial hypertension, hypercholesterolemia, aortic insufficiency II gr., episodes of paroxismal atrial fibrillation
- Diagnosed with a highly symptomatic abdominal aortic aneurysm, proven by echo doppler, CT and aortography.
CT-angio. Distal abdominal aorta aneurysm involving both iliacs. Extreme tortuosity.
MSCTA. Distal abdominal aorta aneurysm involving both iliacs. Tortuous iliac arteries:
Angiography
Aorto-uniiliac Cardiatis multilayer stent implantation fully covering the contralateral Common iliac artery:
Abdominal Aorta and both iliac arteries: patent
CT-angio after 6 and 12 months
Case 4: Aortic dissection and aortic aneurysm: are they different diseases?

PV, 67 y.
Symptomatic juxtarenal AAA
Relatively healthy appearance of the ThoAo
Included in the Streamliner trial
Aortic dissection and aortic aneurysm: are they different diseases?

PV, 67 y.
Next day: excellent almost immediate isolation of the AAA
Uneventful early f-up
Discharged on 3d postop day
Aortic dissection and aortic aneurysm: are they different diseases?

PV, 67 y.
1 week after:
- Went to hunters’ “mission”
- Acute back pain with vegetative symptoms during chasing a pig after shooting at it

- Excellent proximal apposition of Cardiatis MFM
- Active dissection tear of thoracic Aorta
PV, 67 y.
1 week after:
-Went to hunters’ “mission”
-Acute back pain with vegetative symptomatic during chasing a pig after shooting at it
-Admitted with persisting severe pain
Aortic dissection and aortic aneurysm: are they different diseases?

PV, 67 y.
Immediate interposition of Valiant Captiva -telescopied to the previously implanted MFM -completely isolating the entry tear
Aortic dissection and aortic aneurysm: are they different diseases?

PV, 67 y.
Immediate interposition of Valiant Captiva completely isolating the entry tear telescoped to the previously implanted MFM
MFM implantation: Detailed imaging, exact measurements, simulation and planning is crucial for optimal final result (next case planned for Monday):
Conclusion:

• The treatment of complex thoracoabdominal aortic pathology is a real challenge because of the high natural mortality/morbidity

• The implantation of Cardiatis multilayer stent in the treatment of such complex aortic pathology is effective and safe.
Conclusion:

- This treatment allows preservation of blood flow in the branches arising from the stented area.
- The early and mid-term follow-up results are promising.
- We need more systematic procedural and clinical data in order to establish (personal believe: most probably to expand) the exact indications of this novel technology.
Thank you for your attention!
Significant Mortality and Morbidity even with staged approach

<table>
<thead>
<tr>
<th>Author (reference)</th>
<th>Year</th>
<th>Patients</th>
<th>TAAA/arch</th>
<th>Mortality 30 days</th>
<th>Permanent paraplegia</th>
<th>Overall morbidity</th>
<th>Median follow up (months)</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee(^5)</td>
<td>2005</td>
<td>17*</td>
<td>17/0</td>
<td>24%</td>
<td>0</td>
<td>25%</td>
<td>8</td>
<td>100%</td>
</tr>
<tr>
<td>Resch(^6)</td>
<td>2006</td>
<td>13</td>
<td>13/0</td>
<td>25%</td>
<td>0</td>
<td>46%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Black(^7)</td>
<td>2006</td>
<td>22</td>
<td>22/0</td>
<td>13%</td>
<td>30%</td>
<td>54%</td>
<td>8</td>
<td>NA</td>
</tr>
<tr>
<td>Zhou(^8)</td>
<td>2006</td>
<td>31</td>
<td>15/16</td>
<td>3.2%</td>
<td>0</td>
<td>9.6%</td>
<td>16</td>
<td>90%</td>
</tr>
<tr>
<td>Chiesa(^9)</td>
<td>2007</td>
<td>13(^*)</td>
<td>13/0</td>
<td>23%</td>
<td>0</td>
<td>31%</td>
<td>14.9</td>
<td>76.9%</td>
</tr>
<tr>
<td>Bockler(^10)</td>
<td>2008</td>
<td>28</td>
<td>28/0</td>
<td>14.3%</td>
<td>0</td>
<td>59%</td>
<td>22</td>
<td>70%</td>
</tr>
<tr>
<td>Quinones</td>
<td>2008</td>
<td>20</td>
<td>17/3</td>
<td>0</td>
<td>6.6%</td>
<td>32%</td>
<td>16.6</td>
<td>76%</td>
</tr>
</tbody>
</table>

Combined endovascular and surgical approach (CESA) to thoracoabdominal aortic pathology: A 10-year experience

William Quinones-Raslitch, MD, Juan Carlos Jimenez, MD, Brian DeRubesio, MD, and Wesley S. Moore, MD, Los Angeles, Calif.
When the MFM May Not Be Effective: Due to Technical Errors

- Lack of sufficient proximal and distal healthy zone to avoid peri-MFM leak
  (it needs at least 3cm for enough sealed wall apposition)

- Lack of sufficient overlapping; It needs at least 5 cm. (the overlapping in front the branches does not effect the lamination of the flow)

- The large size must be inserted in the small one to avoid endoleak type III

- The Stenosed branches must be treated prior to MFM deployment
Aortic Explant Histology (9 months)
Prove of Endothelialization

Macro photographs of the explant and location of histologic sections. Explant at 9 months

Endothelialization
Fillinger et al. 2003, showed that the peak wall stress is increased by the asymmetry of the aneurysm. Shang et al. 2015, associated local wall thickness with finite element analysis.

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