Midterm results with Multilayer flow modulator Cardiatis stent in the treatment of complex aortic pathology

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Disclosure Statement of Financial Interest

I, Ivo Petrov
DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Malperfusion syndrome in Aortic dissection

• Aortic type
• Distal type

- still high mortality rate despite well-established treatment guidelines
- additional tears, critical true lumen compression with end-organ ischemia can compromise acute and chronic clinical outcomes after surgical or endovascular treatment
- patent false lumen is an independent predictor of long-term mortality and aortic events in both type A and type B AD
- surgical mortality was mainly related to unstable patients with pre and post-operative organ malperfusion (1)
- late outcomes: connected with progressive enlargement of the false lumen of the aortic arch and ascending aorta leading to reintervention

- predictive factors for thrombosis of the false lumen were age >70 years old and valve-sparing aortic root reconstruction (2)

References:

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

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 ischemia
**ENDOVASCULAR TREATMENT**

- Implantation of two Wallstents 20x55 мм, followed by postdilation with balloon Symmetry 18x40 мм across the visceral vessels.
- Femoral approach was used to deliver the stents and left radial approach for angiographic control and left subclavian artery marking.

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**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.
...15 years later:
After patient dropped from f-up, all in a sudden

- 2017: 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 (jump 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)

Case report 2 (travel into the future :)

Diagnostic angiogram

Case report 2 (travel into the future :)

CARDIATIS MFM
Patency of side branches
The endothelial cells stop at the edge of the lumbar arteries.

Postdilatation needed (true lumen extreme compression)

Color-coded Doppler of the abdominal aorta. Normal flow into the abdominal aorta and visceral arteries. Thrombosis of the false lumen.

CT-angiography after 6 and 12 months. Centralized blood flow. Complete distal healing, patent visceral vessels:
6 months
12 months
Patients and aneurysm characteristics and baseline medical history

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number (%) or mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>69.3 (53-76)</td>
</tr>
<tr>
<td>Male sex</td>
<td>21 (100%)</td>
</tr>
<tr>
<td>Indication (TAAA)</td>
<td>10 (47.6%)</td>
</tr>
<tr>
<td>Type I TAAA</td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td>Type II TAAA</td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td>Type IV TAAA</td>
<td>6 (28.6%)</td>
</tr>
<tr>
<td>Type V TAAA</td>
<td>2 (9.6%)</td>
</tr>
<tr>
<td>Juxtarenal</td>
<td>8 (38%)</td>
</tr>
<tr>
<td>AAA</td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td>Type A/A dissection</td>
<td>5 (23.8%)</td>
</tr>
<tr>
<td>Total aortic aneurysm</td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td>Previous PTCA/EVAR</td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td>Previous ascending aorta surgery</td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td>Arterial hypertension</td>
<td>19 (90.5%)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>19 (90.5%)</td>
</tr>
</tbody>
</table>

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Early and midterm results:

- Device-related failure: 0%
- Stent thrombosis (successful fibrinolysis): 1/39 (2.5%)
- Secondary patency: 38/39 (97.4%)
- Preserved side branches flow: 20/21 (95%)
- Normal and normalized kidney function: 21/21 (100%)
- General mortality: 2/21 (4%)
- Aorta-related mortality: 0/21 (0%)
- Death of another cause (pancreatic cancer): 1/21 (8.3%)
- Additional late procedures: 3/21 (16.6%)

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Established Superiority to Open Repair in TAAA - STRATO Trial

<table>
<thead>
<tr>
<th>Variable</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% (20/20)</td>
<td>100% (20/20)</td>
<td>100% (13/13)</td>
<td>100% (11/11)</td>
</tr>
<tr>
<td>Branch Patency</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Celiac Trunk Patency</td>
<td>93% (13/14)</td>
<td>85% (11/13)</td>
<td>100% (12/12)</td>
<td>100% (11/11)</td>
</tr>
<tr>
<td>Superior Mesenteric artery Patency</td>
<td>100% (13/13)</td>
<td>100% (12/12)</td>
<td>100% (11/11)</td>
<td></td>
</tr>
<tr>
<td>Right Renal artery Patency</td>
<td>100% (15/15)</td>
<td>100% (13/13)</td>
<td>100% (11/11)</td>
<td></td>
</tr>
</tbody>
</table>

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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
- Admitted with persisting severe pain

Immediate interposition of Valiant Captiva telescoped to the previously implanted MFM, completely isolating the entry tear.
48y male with acute dissection type A. Uncontrolled hypertension, severe chest pain
Extreme true lumen compression

Fully Endovascular under local anesthesia
type A aortic dissection repair

CTA, 1 month after MFM implantation

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

Conclusion:
• The implantation of Cardiatis multilayer stent in the treatment of complex aortic pathology is effective and safe.
• 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 the exact indications of this novel technology