Focus on new approaches for the ascending aorta and the arch

10:18 – 10:24
How to manage aortic arch pathology: open, hybrid, chimney or fenestration  C. Shu

10:24 – 10:30
The current status of endovascular repair of ascending aorta and aortic arch  T. Köbel

10:30 – 10:36
Ascending aortic remodelling permits TEVAR in most ascending aneurysms  R. Kolvenbach

10:36 – 10:42
Comparison of two different techniques of isolated left subclavian artery revascularisation during “Zone 2” thoracic endovascular aortic repair  G. Pratesi

10:42 – 10:48
RelayBranch: Expanding TEVAR to a new class of patients  R. Heijmen

10:48 – 10:54
Register study for Zone 0 aortic arch aneurysm with Chimney/Sandwich technique: 8-year follow-up  A. Lobato

10:54 – 11:00
Updated results of the Nexus aortic stentgraft system  M. Lachat
Disclosure

Speaker: Mario Louis Lachat

I have the following potential conflicts of interest to report.
✓ Receipt of grants/research support
✓ Receipt of honoraria and travel support
✓ Shareholder in a healthcare company
Nexus – Modular System Approach
Brachiocephalic (BCT) Segment

Self Projecting Sleeve (SPS) Connection interface with the ascending module. The proximal end of the SPS designed with a large fenestration of ø30mm
Unique Features-Oriented Ascending Module

- Oriented Ascending Module
- Scalloped graft cover
- Anti-buckling spine on the outer curve
- Compressive Springs in the inner curve
- Inwardly bent cranial strut apesies
- Long outer curve
- Short inner curve
- Saw tooth shape cut
- M shape design
- Compressive Springs in the inner curve
Fixation zone of the ascending module (3cm)

Separation forces of the modules: mean 20N (SD 3) [ref 10N]
Nexus Delivery System

• 20 Fr
• Pre-curved, Pre-shaped
• Delivery system and tip

Nexus Main Module (NMM)  Nexus Ascending Module (NAM)
Delivery System Main Module

- Protective Tube & latching wire inside it
- “S” shaped
- Quick deployment button
- Deployment Knob
- DS flushing port
- Grip
- Capture release knob
Unique Features- Delivery system- flushing port

Stent Graft flushing port
Implantation technique

Trough & Trough GW 20 Fr sheath

Heparin bolus 300 IU/kg BW (ACT>300"
Anti-Trendelenburg for deployment optional
Implantation technique

Rapid Pacing
From screening to Implantation

1. Candidate CT Screening - Initial evaluation of major anatomical parameters
2. Candidate Suitable
3. Candidate Rejected
4. Virtual Model - Creation of exact elastomeric 3D reconstruction model of candidate's anatomy
5. Printer Model
6. Printer Model
7. Simulated Implantation at Endospan
8. Pre-Op Simulated Implantation session at physician site: presentation and training
Very accurate and useful simulation
Clinical Experience

49 implantations

5 Double Branch Device

44 Single Branch Device

4 Single Branch Device implanted in the LSA

40 Single Branch Device implanted in the BCT

18 FIM study

22 compassionate

Technical success rate 100% (49/49)
Case (72 yo men)
• EL la after TEVAR Zone 2-3
• Screened and accepted for Nexus
Procedural steps

First step
• RCCA-LCCA-LSA Bypass & LSA occluder

Second step 3 days later
• Nexus implantation

Discharged 4 days after Nexus
Nexus™ Study Design

- Open-label, non-randomized single-arm and investigational clinical study
- Clinical and CTA follow-up for five year post implantation
- Independent core lab Imaging review and CEC safety events adjudication

- 25 Patients implanted between August 2014 and December 2017
- Mean Follow-up: 12 months
Nexus™ Baseline Information

- Average Age (years): 73
- Male Gender: 84%
- Indication for Nexus treatment:
  - Aneurysms
    - Pseudo aneurysms
  - Dissections
    - Post type A surgery
  - Previous thoracic aortic surgery (52%)
    - Previous TEVAR (28%)
Procedural Data

Preparatory/ Concomitant Procedure

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>Double bypass RCC-LCC-LSA</th>
<th>Single bypass LCC-LSA</th>
<th>Single bypass RCC-LCC</th>
<th>Single bypass left axillary - LCC</th>
<th>Debranching LCC and RCC from ascending and wrapping</th>
<th>No preparatory procedure specifically to the Nexus</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

- Fourteen (14) patients, double bypass RCC-LCC-LSA was performed, usually ~7 days prior Nexus™ implantation
- Ten (10) patients, a parallel graft was implanted in parallel to the Nexus™ device in order to feed one of the supra aortic vessels

Nexus implantation data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>25</td>
</tr>
<tr>
<td>Access successful</td>
<td>25 (100%)</td>
</tr>
<tr>
<td>Deployment successful</td>
<td>25 (100%)</td>
</tr>
<tr>
<td>Procedural survival</td>
<td>25 (100%)</td>
</tr>
<tr>
<td>Endoluminal Repair Time – Mean</td>
<td>68 min</td>
</tr>
<tr>
<td>Procedure time (skin to skin)- Mean</td>
<td>186 min</td>
</tr>
</tbody>
</table>
Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>&lt; 30 days</th>
<th>&gt;30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>2 (8%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Aneurysm Related</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non-disabling Stroke *</td>
<td>2 (8%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Disabling Stroke</td>
<td>0</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Spinal Cord Ischemia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MI</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>1 (4%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Conversion</td>
<td>0</td>
<td>1 (4%)</td>
</tr>
</tbody>
</table>

* Both completely resolved by 30 days

Cause of Death:
- ventricular fibrillation (1) – day 21**
- cardiac arrest (1) – day 7**
- CVA (1) – 2.5 months

** Not device related
Conclusions

• Nexus is relatively simple procedure
  • Ease of implantation will allow for greater physician utility
• Early data for Nexus™ Aortic Arch Stent Graft System is encouraging
  • 100% immediate technical success rate
  • Excellent safety profile with no aneurysm related death
• Longer term data is needed to further study performance of Nexus™ Aortic Arch Stent Graft System

• CE approval expected Q1/2019
**Focus on new approaches for the ascending aorta and the arch**

10:18 – 10:24
How to manage aortic arch pathology: open, hybrid, chimney or fenestration  
C. Shu

10:24 – 10:30
The current status of endovascular repair of ascending aorta and aortic arch  
T. Köbel

10:30 – 10:36
Ascending aortic remodelling permits TEVAR in most ascending aneurysms  
R. Kolvenbach

10:36 – 10:42
Comparison of two different techniques of isolated left subclavian artery revascularisation during “Zone 2” thoracic endovascular aortic repair  
G. Pratesi

10:42 – 10:48
RelayBranch: Expanding TEVAR to a new class of patients  
R. Heijmen

10:48 – 10:54
Register study for Zone 0 aortic arch aneurysm with Chimney/Sandwich technique: 8-year follow-up  
A. Lobato

10:54 – 11:00
Updated results of the Nexus aortic stentgraft system  
M. Lachat