Session IV
Aortic Valve Implantation: Part I

Transcatheter Aortic Valve therapy: tips & trick

Speaker - 20'

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S. Raffaele Scientific Institute, Milan, Italy
Percutaneous Aortic Valve

Edwards SAPIEN XT

- Bovine valve on balloon-expandable stent frame
- 23 mm and 26 mm
- 18F and 19F (NovaFlex delivery system)
- 26F sheath (Ascendra Transapical delivery system)

CoreValve ReValving® System

- Porcine valve in self-expandable nitinol stent
- 26 mm and 29 mm
- 18F sheath
- Repositionable
• High radial strength Cobalt Chromium Frame
• Bovine scallop leaflets, similar to those used in Carpentier PERIMOUNT™
• ThermaFix™ Anti-calcification Treatment
• 20mm, 23mm, 26mm, 29mm
• Low profile NovaFlex™ Catheter (18F)
Sapien XT + NovaFlex Delivery System

18 or 19 F profile: internal diameter
IMPLANTATION OF THE COREVALVE REVALVING SYSTEM

Current inflow sizes
26 mm and 29 mm

1: base
2: mid segment
3: outflow

Central coaptation*
Nadir leaflets
Skirt (12 mm high)
Cell (8 mm high)

Each cell (diamond) has 3 joints (distance between joints is 4 mm)

Cells in collapsed state - joints seen as a row (arrow)

Cell = 3 joints:
- at the base
- at the mid segment
- at the top

Joints are 4 mm apart
Total height of cell: 8 mm
Screening and decision making

Multislice CT with ecg-gating and contrast injection to evaluate: annulus, coronaries, aorta, iliacs and femorals arteries

Transesophageal echo to evaluate: annulus, ventricular function

Coronary arteriography when needed
By MDCT the aortic anulus is elipsoid with the coronal diameter larger than the sagittal diameter

Babaliaros et al. JACC Interv. 2008
Larger size valve: rationale

PHV23MM

PHV26MM
The variation in annulus size measurements made in the same patient using different investigative modalities.

**TTE: Parasternal long-axis view**

24 mm

**TEE: Left ventricular long-axis view**

25 mm

**MSCT: Sagittal view**

28 mm

**CT: Oblique transverse view**

26.5 mm
Edwards SAPIEN™/SAPIEN XT

Trans-apical  Trans-femoral

Trans-aortic

Trans-axillary

CoreValve ReValving®
Do we need Transesophageal Echo during the procedure?

TE echo and TT Echo should be available in the room with an experienced operator.

More monitoring and more on-line data means understanding unexpected complications, faster and appropriate interventions. We currently use TEE at the end of the implantation to evaluate the degree of residual AI and decide if postdilate. Echo distinguish perivalvular from central AI.
CoreValve:

With tortuous vessels, borderline femoral or iliac size
Annulus between 25-27 mm
Bicuspid aortic valve
Very asymmetric aortic annulus
Uncertain annular size
Need for axillary implantation

In other cases Sapien
Procedure - Screening

- Iliac-femoral access assessed by MSCT and by quantitative angiography
  - Femoral artery at the access size:
    - > 6 - 7mm for 18-19 F
  - Evaluate Calcium and possible elasticity of the vessels
Correct puncture site
Prostar 10XL after 9 F predilatation
One way to lower vascular complications

14-16 French becomes 18-19 French, the sheaths are available for CoreValve and for Sapien
TAVI with suboptimal femoral access

Solo Path
20 F. ID
Inflated 20 atm
Vascular Closure

0.18" wire advanced in SFA

PTA balloon

6 F sheath

18 F sheath
6 F short
TAVI

120 cm multipurpose diagnostic catheter

300 cm V18 or 0.018 or 0.014 Iron man
TAVT

5F Pigtail in ascending Aorta

Iron man or V18 in SFA
TAVI

Final Injection
Placing the stiff wire

- Amplatz Superstiff ST1
  *short floppy tip 1 cm*
- Alternative stiff wires: long floppy tips
- manually bending the stiff part into a pigtail shape
- Next, 18 French sheath (always over the stiff wire)
Balloon valvuloplasty

• Balloon catheters:
  ▪ Nucleus 12 F (Inoue like behavior)
    ➔ Stabilize position
  ▪ Z-med X 12 F
  ▪ Tyshak II (9 F to 25mm) but rated burst 1.0-1.5 atm
  ▪ Or other valvuloplasty balloons possible
  ▪ Ideal balloon length 40-60 mm

Rapid RV stimulation ~180 - 200 BPM (systolic pressure <60 mmHg), use lead with tip balloon or lead with screw (be careful of perforations) ➔ Stabilize position, less embolization?
Balloon valvuloplasty with Nucleus (balloon rupture !)
Balloon valvuloplasty using a 25 mm ZMed balloon and simultaneous dye injection in a 28 mm annulus (measured by CT)
Valvuloplasty: Rapid Pacing

5 mm/sec

25 sec.
Severe aortic regurgitation after valvuloplasty (incidence 2-5%).

Acute aortic regurgitation resulting in acute LV overload.

Acute LV failure / asystole or VF due to (Volume-loading of the LV)
Aortic regurgitation after delivery of the prosthesis

AR due to

- Prosthesis too deep
- Prosthesis not fully expanded
- Prosthesis too high

Implantation of a second valve for malpositioning which cannot be corrected
Aortic regurgitation due to an incorrect (too deep) implantation. The top pericardial skirt is below the base of the aortic root. As a result, there is aortic regurgitation due to operator related misplacement of the valve.
AR due to too deep prosthesis (paravalvular leakage)
Re-positioning using a Goose Neck 'snare' (15/20 mm) from femoral 6F
Controlled during continuous pulling by monitoring of the diastolic blood pressure
Valve misplacement CoreValve

Valve is too low:

1) snare the valve to pull it up

2) implant a second valve.

Valve is too high:

Retrival the valve to proximal position, keep the coronary ostial clear and position a second valve.
Valve misplacement Sapien

Valve is too low:

Implant a second valve

Valve is too high:

Implant a second valve
Generic Cardiac Complications

- LV perforation: pacemaker, nose of the delivery catheter, LV wire
- Dissection of the Aorta or of the anulus
- Injury to the mitral valve
- Obstruction of coronary ostia
- Arrhythmias
- AV block: 20% for CoreValve and 5% for Sapien
Coronary obstruction

(A) The very uncommon situation of a coronary ostium being obstructed by a stent strut.

(B) Bulky coronary leaflets that warrants further evaluation.

(C) Left main obstruction by a bulky coronary leaflet.

(D) Successful stenting of the left main coronary through an open cell of the valved stent.
Obstruction of coronary ostia

May occur at the time of valve implantation Sapien or during post-

Higher risk of occlusion in severely calcified valves and in low set coronary ostia, less than 12 mm above the annulus. In high risk conditions leave a guide catheter with wire in the left coronary

If the patient is sedated chest pain may be absent
Implantation of a covered self-expandable Viabahn stent 8/50 (8 F sheat)
In the left hand picture, a stenosis caused by excessive tension on the Prostar sutures is seen in the common femoral artery. Distal extravasation is also evident. Balloon inflation at two atmospheres for 5 minutes improved both issues significantly.
### Neurological Events at 30 Days and 1 Year

**All Patients (N=699)**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>30 Days</th>
<th>1 Year</th>
<th>p-value</th>
<th>30 Days</th>
<th>1 Year</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Stroke – no. (%)</td>
<td>16 (4.6)</td>
<td>8 (2.4)</td>
<td>0.12</td>
<td>20 (6.0)</td>
<td>10 (3.2)</td>
<td>0.08</td>
</tr>
<tr>
<td>Major Stroke – no. (%)</td>
<td>13 (3.8)</td>
<td>7 (2.1)</td>
<td>0.20</td>
<td>17 (5.1)</td>
<td>8 (2.4)</td>
<td>0.07</td>
</tr>
</tbody>
</table>

50% of neurological events occurred after 24 hrs from valve implantation and up to 1 yr.
November 2007 - July 2011

504 Patients Screened for TAVI

SAVR
N=24
(4.8%)

TAVI
N=330
(65.5%)

BAV
N=23
(4.6%)

Medical Therapy
N=119
(23.6%)

Death
N=8
(1.6%)
Patients Undergoing TAVI
Nov 2007 - July 2011
N=330

Edwards SAPIEN™ *
N=199 (60.3%)

- Transfemoral
  N=169 (84.9%)
    - Transapical
      N=25 (12.6%)
    - Transaortic
      N=1 (0.5%)

- Transaxillary
  N=4 (2.0%)

CoreValve Revalving System®
N=131 (39.7%)

- Transfemoral
  N=99 (75.6%)

- Transaxillary
  N=30 (22.9%)

  - Transaortic
    N=2 (1.5%)

* Edwards SAPIEN™XT
N=108
## Baseline Characteristics according to Valve Type

<table>
<thead>
<tr>
<th></th>
<th>All N=268</th>
<th>SAPIEN™ N=169</th>
<th>CoreValve® N=99</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age; mean ± SD</td>
<td>79.7 ± 7.3</td>
<td>80.2 ± 7.8</td>
<td>78.9 ± 6.5</td>
<td>0.172</td>
</tr>
<tr>
<td>Male; n (%)</td>
<td>139 (51.9)</td>
<td>82 (48.5)</td>
<td>57 (57.6)</td>
<td>0.152</td>
</tr>
<tr>
<td>Hypertension; n (%)</td>
<td>192 (71.6)</td>
<td>117 (69.2)</td>
<td>75 (75.8)</td>
<td>0.253</td>
</tr>
<tr>
<td>Chronic Kidney Disease; n (%)</td>
<td>82 (30.7)</td>
<td>53 (31.4)</td>
<td>29 (29.6)</td>
<td>0.763</td>
</tr>
<tr>
<td>NYHA III/IV; n (%)</td>
<td>181 (68.0)</td>
<td>119 (71.3)</td>
<td>62 (62.6)</td>
<td>0.144</td>
</tr>
<tr>
<td>Ejection Fraction; mean ± SD</td>
<td>51.7 ± 13.2</td>
<td>53.0 ± 11.6</td>
<td>49.3 ± 15.3</td>
<td>0.023</td>
</tr>
<tr>
<td>Aortic Annulus; mean ± S D</td>
<td>23.6 ± 1.8</td>
<td>23.2 ± 1.6</td>
<td>24.3 ± 1.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Logistic EuroSCORE; mean ± SD</td>
<td>23.4 ± 16.5</td>
<td>22.9 ± 16.5</td>
<td>24.1 ± 16.5</td>
<td>0.583</td>
</tr>
<tr>
<td>STS-PROM Score; mean ± SD</td>
<td>8.0 ± 7.5</td>
<td>7.3 ± 5.9</td>
<td>9.3 ± 9.5</td>
<td>0.033</td>
</tr>
</tbody>
</table>

SAPIEN™XT 20.8±16.5%
SAPIEN™XT 7.3±6.5%
### VARC Outcomes According to the Valve Type: Safety & Efficacy

<table>
<thead>
<tr>
<th>Event</th>
<th>All N=268</th>
<th>SAPIEN™ N=169</th>
<th>CoreValve® N=99</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death; n (%)</td>
<td>10 (4.1)</td>
<td>4 (2.6)</td>
<td>6 (6.6)</td>
<td>0.127</td>
</tr>
<tr>
<td>Cardiovascular Death; n (%)</td>
<td>7 (2.9)</td>
<td>4 (2.6)</td>
<td>3 (3.3)</td>
<td>0.751</td>
</tr>
<tr>
<td>Stroke; n (%)</td>
<td>2 (0.7)</td>
<td>2 (1.2)</td>
<td>0</td>
<td>0.277</td>
</tr>
<tr>
<td>Myocardial Infarction; n (%)</td>
<td>2 (0.7)</td>
<td>0</td>
<td>2 (2.0)</td>
<td>0.064</td>
</tr>
<tr>
<td>Major Vascular Complication; n (%)</td>
<td>45 (16.8)</td>
<td>32 (18.9)</td>
<td>13 (13.1)</td>
<td>0.220</td>
</tr>
<tr>
<td>Life-Threatening Bleeding; n (%)</td>
<td>60 (22.4)</td>
<td>32 (18.9)</td>
<td>28 (28.3)</td>
<td>0.076</td>
</tr>
<tr>
<td>Major Bleeding; n (%)</td>
<td>88 (32.8)</td>
<td>57 (33.7)</td>
<td>31 (31.3)</td>
<td>0.685</td>
</tr>
<tr>
<td>Acute Kidney Injury Stage 3; n (%)</td>
<td>22 (8.2)</td>
<td>14 (8.3)</td>
<td>8 (8.1)</td>
<td>0.953</td>
</tr>
</tbody>
</table>
### VARC Outcomes According to Valve Type: Performance & Complications

#### Transfemoral Only

<table>
<thead>
<tr>
<th>AR Severity</th>
<th>SAPIEN™</th>
<th>SAPIEN™ XT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=63</td>
<td>N=105</td>
</tr>
<tr>
<td>0</td>
<td>10 (15.9)</td>
<td>41 (39.0)</td>
</tr>
<tr>
<td>1</td>
<td>36 (57.1)</td>
<td>41 (39.0)</td>
</tr>
<tr>
<td>2</td>
<td>13 (20.6)</td>
<td>22 (21.0)</td>
</tr>
<tr>
<td>3</td>
<td>4 (6.3)</td>
<td>1 (1.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complication</th>
<th>All</th>
<th>SAPIEN™</th>
<th>CoreValve®</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prosthetic AR 3/4+; n (%)</td>
<td>12 (4.6)</td>
<td>6 (3.7)</td>
<td>6 (6.2)</td>
<td>0.352</td>
</tr>
<tr>
<td>Prosthetic valve SBE; n (%)</td>
<td>1 (0.4)</td>
<td>0</td>
<td>1 (1.0)</td>
<td>0.191</td>
</tr>
<tr>
<td>Conduction disturbances &amp; arrhythmia; n (%)</td>
<td>61 (22.8)</td>
<td>24 (14.2)</td>
<td>37 (37.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Permanent Pacemaker Implantation; n (%)</td>
<td>38 (14.2)</td>
<td>10 (5.9)</td>
<td>28 (28.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Coronary Obstruction; n (%)</td>
<td>1 (0.4)</td>
<td>1 (0.6)</td>
<td>0</td>
<td>0.443</td>
</tr>
</tbody>
</table>
### VARC Outcomes According to Valve Type: Composite Endpoints

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</thead>
<tbody>
<tr>
<td><strong>Device Success; n (%)</strong></td>
<td>252 (94.0)</td>
<td>162 (95.9)</td>
<td>90 (90.9)</td>
<td>0.099</td>
</tr>
<tr>
<td><strong>Combined Safety Endpoint; n (%)</strong></td>
<td>177 (66.0)</td>
<td>113 (66.9)</td>
<td>64 (64.6)</td>
<td>0.711</td>
</tr>
<tr>
<td><strong>Combined Efficacy Endpoint at 1 year; n (%)</strong></td>
<td>122 (77.2)</td>
<td>70 (77.8)</td>
<td>52 (76.5)</td>
<td>0.846</td>
</tr>
<tr>
<td><strong>All cause mortality at 1 year; n (%)</strong></td>
<td>17 (10.8)</td>
<td>8 (9.0)</td>
<td>9 (13.2)</td>
<td>0.396</td>
</tr>
</tbody>
</table>

* 158 Patients Eligible

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SAPIEN™XT 98.6%
Patients undergoing TAVI are very frail, most of the complications considered minor become major when they occur in these patients.

There is the need for meticulous attention to any detail even the minor ones.

Be always ready to take action when there is a complication and acknowledge that an inappropriate solution to the first complication will not be forgiven.
Problems still open

Degree of residual AI

Durability of the valves

Risk of stroke higher than surgery and potentially not fully resolved with cerebral protection during the procedure