Valve-in-valve TAVI Implantation

Eberhard Grube MD, FACC, FSCAI

Universitätsklinikum Bonn, Bonn, Germany
Hospital Alemão Oswaldo Cruz, São Paulo, Brazil
Stanford University, Palo Alto, California, USA
Why Valve-in-Valve?

• Growing need for treatment options for patients with failed bioprosthetic valve as population ages, life expectancy improves, and use of bioprosthetic valves increases

• Operative mortality for elective redo aortic valve surgery is generally low (2% to 7%), but it can increase to more than 30% in high-risk and non-elective patients

• Because transcatheter aortic valve (TAV)-in-surgical aortic valve (SAV) implantation represents a minimally invasive alternative to conventional redo surgery, it may prove to be safer and just as effective as redo surgery

• Prospective comparisons with a large number of patients and long-term follow-up are required to confirm these potential advantages

Most Common Reasons for Bioprosthetic Valve Failure

1. Wear and tear
2. Calcific degeneration
3. Pannus
4. Endocarditis
5. Thrombus

Wear and tear (A) and calcification (B) are the most common reasons for bioprosthetic valve failure.

References:
CoreValve in Failed Hancock 23mm
CoreValve in Failed Hancock 23mm
CoreValve in Failed Hancock 23mm
CoreValve in Failed Hancock 23mm
CoreValve in Failed Carpentier 22mm in a Patient with Severely Impaired LVEF
Sapien in Failed Bioprosthesis

Figure 2. A, Fluoroscopic images during positioning of a transcatheter valve (SAPIEN 23-mm THV). The wire frame of a degenerated surgical bioprosthesis (Carpentier-Edwards 23 mm) is visible. The prosthetic sewing ring below the valve struts is radiolucent. B, The balloon-expandable THV is deployed and fixed within the sewing ring. C, Aortography demonstrates a competent valve (patient 0).

Dimensions of Stented Bioprosthetic Valves

(A) Diagrammatic representation of stented bioprosthetic valve dimensions where
- A: outer stent diameter
- B: inner stent diameter
- C: prosthesis height
- D: outer sewing ring diameter.

(B) Inferior (ventricular) view of stented bioprosthesis.

(C) Side view of stented bioprosthesis.

### Bioprosthetic Valves Sizing Chart

(Per manufacturer) ¹

<table>
<thead>
<tr>
<th>Valve Label Size</th>
<th>Valve Type/Model (Manufacturer)</th>
<th>Sewing Ring External Diameter, mm</th>
<th>Stent Outer Diameter, mm</th>
<th>Stent Internal Diameter, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>Soprano (Sorin Biomedica)</td>
<td>26</td>
<td>21</td>
<td>17.8</td>
</tr>
<tr>
<td>19</td>
<td>Magna (Edwards Lifesciences)</td>
<td>24</td>
<td>19</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Perimount (Edwards Lifesciences)</td>
<td>26</td>
<td>19</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Mosaic (Medtronic)</td>
<td>25</td>
<td>19</td>
<td>17.5</td>
</tr>
<tr>
<td></td>
<td>Hancock Ultra (Medtronic)</td>
<td>24</td>
<td>19</td>
<td>17.5</td>
</tr>
<tr>
<td></td>
<td>Hancock II (Medtronic)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Mitroflow (Sorin Biomedica)</td>
<td>21</td>
<td>18.6</td>
<td>15.4</td>
</tr>
<tr>
<td></td>
<td>Trifecta (St. Jude Medical)</td>
<td>24</td>
<td>19</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Epic/Blocor (St. Jude Medical)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Epic Supra/Blocor Supra (St. Jude Medical)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>20</td>
<td>Soprano (Sorin Biomedica)</td>
<td>28</td>
<td>23</td>
<td>19.8</td>
</tr>
<tr>
<td>21</td>
<td>Magna (Edwards Lifesciences)</td>
<td>26</td>
<td>21</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Perimount (Edwards Lifesciences)</td>
<td>29</td>
<td>21</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Mosaic/Hancock II (Medtronic)</td>
<td>27</td>
<td>21</td>
<td>18.5</td>
</tr>
<tr>
<td></td>
<td>Hancock/Hancock Ultra (Medtronic)</td>
<td>26</td>
<td>21</td>
<td>18.5</td>
</tr>
<tr>
<td></td>
<td>Mitroflow (Sorin Biomedica)</td>
<td>23</td>
<td>20.7</td>
<td>17.0</td>
</tr>
<tr>
<td></td>
<td>Trifecta (St. Jude Medical)</td>
<td>26</td>
<td>21</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Epic/Blocor (St. Jude Medical)</td>
<td>N/A</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Epic Supra/Blocor Supra (St. Jude Medical)</td>
<td>N/A</td>
<td>21</td>
<td>21</td>
</tr>
<tr>
<td>22</td>
<td>Soprano (Sorin Biomedica)</td>
<td>30</td>
<td>25</td>
<td>21.7</td>
</tr>
<tr>
<td>23</td>
<td>Magna (Edwards Lifesciences)</td>
<td>28</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>Perimount (Edwards Lifesciences)</td>
<td>31</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>Mosaic/Hancock II (Medtronic)</td>
<td>30</td>
<td>23</td>
<td>20.5</td>
</tr>
<tr>
<td></td>
<td>Hancock/Hancock Ultra (Medtronic)</td>
<td>28</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>Mitroflow (Sorin Biomedica)</td>
<td>26</td>
<td>22.7</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Trifecta (St. Jude Medical)</td>
<td>28</td>
<td>23</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Epic/Blocor (St. Jude Medical)</td>
<td>N/A</td>
<td>23</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Epic Supra/Blocor Supra (St. Jude Medical)</td>
<td>N/A</td>
<td>23</td>
<td>23</td>
</tr>
</tbody>
</table>

TAVI in Failed TAVI

First Valve-in-Valve Direct Transaortic CoreValve Implantation in an Insufficient Sapien Valve

Bas T. G. van der Lienden, MD,* Ben M. Swinkels, MD,* Robin H. Heijmen, MD, PntD,† E. Gijs Mast, MD,* Thom L. De Kroon, MD;† Jurriën M. ten Berg, MD, PntD

Nieuwegein, the Netherlands

10 months post implantation, patient experienced symptoms with moderate-to-severe central insufficiency; redo successfully performed with CoreValve by direct aortic access

5.5 years post CoreValve implantation, patient presented with HF symptoms; echo revealed critical AV-stenosis due to heavily calcified bioprosthetic valve leaflets. CoreValve ViV successfully implanted.

Transcatheter Aortic-Valve Implantation for the Treatment of Degenerative Bioprosthetic Surgical Valves: Results from the Global Valve-in-Valve Registry


Patients undergoing VIV procedures in 38 sites in Europe, North-America, Australia, New Zealand and the Middle-East (n=195)

4 patients enrolled after data lock* were not analyzed

CoreValve (Medtronic, MN, USA) n=120

Edwards-SAPIEN (Edwards Lifesciences, CA, USA) n=71

30-days outcome (n=191)

1-year outcome (n=78)

## Baseline Demographics at Time of VIV

<table>
<thead>
<tr>
<th></th>
<th>CoreValve group</th>
<th>Edwards-SAPIEN group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=120</td>
<td>n=71</td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>77.2 ± 11.1</td>
<td>78.4 ± 9.7</td>
<td>0.44</td>
</tr>
<tr>
<td>Gender (% male)</td>
<td>51.7</td>
<td>52.1</td>
<td>1.0</td>
</tr>
<tr>
<td>LogEuroSCORE</td>
<td>30.8 ± 19.7</td>
<td>31.4 ± 17.2</td>
<td>0.83</td>
</tr>
<tr>
<td>STS score</td>
<td>14.0 ± 13.9</td>
<td>10.3 ± 9.4</td>
<td>0.01</td>
</tr>
<tr>
<td>Diabetes Mellitus (%)</td>
<td>34.5</td>
<td>21.1</td>
<td>0.05</td>
</tr>
<tr>
<td>Peripheral Vascular</td>
<td>17.7</td>
<td>22.5</td>
<td>0.41</td>
</tr>
<tr>
<td>Disease (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic Renal Failure (%)</td>
<td>43.3</td>
<td>52.1</td>
<td>0.24</td>
</tr>
<tr>
<td>Previous stroke (%)</td>
<td>13.3</td>
<td>9.9</td>
<td>0.48</td>
</tr>
</tbody>
</table>

Valve in Valve Procedures

CoreValve

Edward-SAPIEN

62.8%  37.2%

n=120  n=71

Valve in Valve Procedures

CoreValve

- Device Size
  - 29mm: n=24 (20%)
  - 26mm: n=96 (80%)

- Access
  - TAX: n=10 (8%)
  - TAO: n=2 (2%)
  - TF: n=108 (90%)

- Anesthesia
  - LA: n=61 (50.8%)
  - GA: n=59 (49.2%)

Edwards-SAPIEN

- Device Size
  - 26mm: n=58 (82%)
  - 23mm: n=13 (18%)

- Access
  - TAP: n=49 (69%)
  - TF: n=22 (31%)

- Anesthesia
  - LA: n=11 (14.5%)
  - GA: n=60 (84.5%)

TF= Transfemoral; TAP= Transpical; TAX= Transaxillary; TAO= transaortic; GA= General Anesthesia; LA= Local Anesthesia

Valve in Valve Procedures

### TEE usage

- **CoreValve**
  - TEE: n=46 (38.3%)
- **Edwards-SAPIEN**
  - TEE: n=50 (70%)

### Pre-Balloon Inflation

- **CoreValve**
  - Pre-balloon: n=20 (16.7%)
- **Edwards-SAPIEN**
  - Pre-balloon: n=36 (50.7%)

---

Valve in Valve Procedures
Implantation success

CoreValve: 96.7%
Edwards-SAPIEN: 91.5%

$P = 0.12$

Valve in Valve Procedures
Intraprocedural Results

- **Attempted Valve Retrieval**: 10%
- **Need for a 2nd TAVR valve**: 7.5% CoreValve, 9.9% Edwards-SAPIEN
- **Post TAVR balloon inflation**: 16.7% CoreValve, 5.6% Edwards-SAPIEN

P = NS

P = 0.03

### Valve in Valve Procedures
#### Intraprocedural Results

<table>
<thead>
<tr>
<th></th>
<th>CoreValve</th>
<th>Edwards-SAPIEN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ostial Coronary Obstruction</strong></td>
<td>3.3%</td>
<td>4.2%</td>
</tr>
<tr>
<td><strong>Need for An Emergent Surgery</strong></td>
<td>0.8%</td>
<td>4.2%</td>
</tr>
</tbody>
</table>

- **P = NS**
- **P = 0.11**

Valve in Valve Procedures
30-day outcome

Median Duration of hospital stay - 8 days

<table>
<thead>
<tr>
<th></th>
<th>CoreValve</th>
<th>Edwards-SAPIEN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All cause mortality</strong></td>
<td>7.5%</td>
<td>12.7%</td>
</tr>
<tr>
<td><strong>CV mortality</strong></td>
<td>5.8%</td>
<td>11.3%</td>
</tr>
</tbody>
</table>

P = 0.24

P = 0.18

Valve in Valve Procedures
30-day outcome

<table>
<thead>
<tr>
<th></th>
<th>CoreValve</th>
<th>Edwards-SAPIEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Vascular Complications*</td>
<td>2.5%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Need for a Permanent Pacemaker</td>
<td>9.3%</td>
<td>5.8%</td>
</tr>
<tr>
<td>Stroke*</td>
<td>1.7%</td>
<td>2.9%</td>
</tr>
</tbody>
</table>

Lower than in most CoreValve registries

* VARC definition

Post Procedural Gradients
CoreValve Device

Mean Aortic-Valve Gradients (mmHg)

Surgical Bioprosthesis Internal Diameter (mm)

In small surgical bioprosthesis (<20mm ID)- 25.9% had elevated gradients


* Mean aortic-valve gradient > 20mmHg.
1-year Kaplan Meier Survival Curves of patients who underwent VIV procedures

Log rank $p=0.08$

Survival Probability (%)

Time (months)

93% 91%
87% 79%

Curevalve
Edwards

Conclusions

- The VIV procedure, although feasible, is technically demanding and should be reserved for highly experienced centers.

- The technique is clinically effective in most patients, with 1-year results comparable with other TAVR cohorts.

- Significantly elevated post procedural gradients are common after VIV procedures, especially in relatively small bioprosthetic devices treated with currently available Edwards-SAPIEN valves.

- Possible impact of elevated gradients on valve durability should be examined in long-term.