Considerations for Optimal valve choice in TAVR

Park, Chang-Soon

Cardiology Division, Yonsei Cardiovascular Hospital, Yonsei University College of Medicine
Estimated Global TAVR Growth

In the next 10 years, TAVR growth will increase X4!

SOURCE: Credit Suisse TAVI Comment – January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW
Two TAVR Options

- Edwards Sapien3 Valve
- Bovine Pericardial Tissue
- Balloon expandable
- Intraannular
- Stainless Steel Frame
- Need rapid pacing
- PolyEthylene Terephthalate (PET)

- Medtronic EvoluteR/Pro
- Porcine Pericardial Tissue
- Supraanular
- Nitinol Frame-self expanding
- Recapture available
- External Wrap
Consider for Valve Choice

- Access Site/Size
- Anatomic Restrictions
  - Bicuspid aortic Valve
  - Valve in valve
  - Small aortic annulus
  - Distorted/Horizontal Ao
- Annular Rupture Risk
- High Risk Coronary
  - Implantation risks
  - Re-access to coronaries risk
  - Delayed Coronary Obstruction (DCO)

- Deployment technique
  - Post-dilatation rates
  - Repositioning
- Pacemaker Rate
- Risk for Structural Valve Deterioration
- Paravalvular regurgitation Rate
- Prosthesis-patient Mismatch
- Outcomes
### Clinical Need: Low Profile Access

<table>
<thead>
<tr>
<th>THV</th>
<th>Sheath ID (unexpanded)</th>
<th>Sheath OD (unexpanded) -&gt; will be expanded</th>
<th>Minimum Vessel Diameter*</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 mm SAPIEN 3 valve</td>
<td>14F (4.6 mm)</td>
<td>18F (6.0 mm)</td>
<td>5.5 mm</td>
</tr>
<tr>
<td>23 mm SAPIEN 3 valve</td>
<td>14F (4.6 mm)</td>
<td>18F (6.0 mm)</td>
<td>5.5 mm</td>
</tr>
<tr>
<td>26 mm SAPIEN 3 valve</td>
<td>14F (4.6 mm)</td>
<td>18F (6.0 mm)</td>
<td>5.5 mm</td>
</tr>
<tr>
<td>29 mm SAPIEN 3 valve</td>
<td>16F (5.3 mm)</td>
<td>20F (6.7 mm)</td>
<td>6.0 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>THV</th>
<th>In-line Sheath ID</th>
<th>In-line Sheath OD</th>
<th>External Sheath ID</th>
<th>Minimum Vessel Diameter*</th>
</tr>
</thead>
<tbody>
<tr>
<td>23mm, 26mm, 29mm EVOLUT R valve</td>
<td>14F (4.6 mm)</td>
<td>18F (6.0 mm)</td>
<td>18F (6.0 mm)</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>34mm EVOLUT R valve</td>
<td>16F (5.3 mm)</td>
<td>20F (6.6 mm)</td>
<td>20F (6.6 mm)</td>
<td>5.5 mm</td>
</tr>
<tr>
<td>23mm, 26mm, 29mm EVOLUT PRO valve</td>
<td>16F (5.3 mm)</td>
<td>20F (6.6 mm)</td>
<td>20F (6.6 mm)</td>
<td>5.5 mm</td>
</tr>
</tbody>
</table>
Sapien arch pass

Partial flex
Distal flex
Why Gentle Valve Passage Is Important?
Mechanism of Stroke after TAVR

- Primarily ischemic in nature due to either embolic events or cerebral hypoperfusion
- Embolic events
  - Aortic atheroma
  - Gaseous emboli
- Cerebral hypoperfusion
  - Watershed infarcts on CPB
- Multiple other etiologies postulated including atrial fibrillation, hyperglycemia, cerebral hyperthermia, etc.
Balloon Versus Self-Expandable Valve for the Treatment of Bicuspid Aortic Valve Stenosis

Insights From the BEAT International Collaborative Registry

Antonio Mangieri, MD; Didier Tchetchè, MD; Won-Keun Kim, MD; Matteo Pagnesi, MD; Jean-Malte Sinning, MD; Uri Landes, MD; Ran Kornowski, MD; Ole De Backer, MD; Georg Nickenig, MD; Alfonso Ielasi, MD; Chiara De Biase, MD; Lars Søndergaard, MD; Federico De Marco, MD; Matteo Montorfano, MD; Mauro Chiarito, MD; Damiano Regazzoli, MD; Giulio Stefani, MD; Patrizia Presbitero, MD; Stefan Toggweiler, MD; Corrado Tamburino, MD; Sebastiano Immè, MD; Giuseppe Tarantini, MD; Horst Sievert, MD; Ulrich Schäfer, MD; Jörg Kempfert, MD; Jochen Woehrle, MD; Francesco Gallo, MD; Alessandra Lanicchia, MD; Azeem Latib, MD; Francesco Giannini, MD; Antonio Colombo, MD

BACKGROUND: Large data comparing the performance of new-generation self-expandable versus balloon-expandable transcatheter heart valves in bicuspid aortic stenosis are lacking. We aim to compare the safety and performance of balloon-expandable and self-expandable transcatheter heart valves in the treatment of bicuspid aortic stenosis.


RESULTS: A total of 353 patients (n=242 [68.6%] treated with Sapien 3 and n=111 [68.6%] treated with Evolut R (n=70)/PRO (n=41) were included. Mean age was 77.8±8.3 years and mean Society of Thoracic Surgeons Predicted Risk of Mortality was 4.4±3.3%. Valve Academic Research Consortium-2 device success was similar between Sapien 3 and Evolut R/PRO (85.6% versus 87.2%; P=0.68). In the Sapien 3 group, 4 patients experienced annular rupture whereas this complication did not occur in the Evolut R/PRO group. After propensity score matching, Valve Academic Research Consortium-2 device success was similar between both groups (Sapien 3=85.7% versus Evolut R/PRO=84.4%; P=0.821). Both in the overall and in the matched population, no differences in the rate of permanent pacemaker implant were observed. At 1-year follow-up, the rate of overall death and cardiovascular death were similar between the 2 groups. In the unmatched population, the 1-year echocardiographic follow-up demonstrated similar rate of moderate-to-severe paravalvular aortic regurgitation (Evolut R/PRO 10.5% versus Sapien 3 4.2%, P=0.077); however, after propensity matching, the rate of moderate-to-severe paravalvular leak became significantly higher among patients treated with self-expandable valves (9.3% versus 0%; P=0.043).

CONCLUSIONS: Our study confirms the feasibility of both Sapien 3 and Evolut R/PRO implantation in bicuspid aortic valve anatomy; a higher rate of moderate-to-severe paravalvular aortic regression was observed in the Evolut R/PRO group at 1-year follow-up in the matched cohort, although patients treated with balloon-expandable valve had a higher rate of annular rupture.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.
Bicuspid valve

Balloon versus self-expandable transcatheter aortic valve implantation for bicuspid aortic valve stenosis: A meta-analysis of observational studies

(BEV: n = 620; SEV: n = 460)
Small Aortic Annulus in YUHS

Comparison of Transcatheter Aortic Valve Replacement between Self-Expanding versus Balloon-Expandable Valves in Patients with Small Aortic Annulus

Yong-Joon Lee, MD, Seung-Jun Lee, MD, Sung-Jin Hong, MD, Chi-Young Shim, MD, Chul-Min Ahn, MD, Jung-Sun Kim, MD, Byeong-Keuk Kim, MD, Gei-Ru Hong, MD, Young-Guk Ko, MD, Donghoon Choi, MD, Yangsoo Jang, MD, and Hyoong-Ki Hong, MD, PhD

Division of Cardiology, Department of Internal Medicine, Severance Cardiovascular Hospital, Yonsei University Health System, Seoul, Korea

ABSTRACT

Background and Objectives: Transcatheter aortic valve replacement (TAVR) has been reported as a good alternative for surgical aortic valve replacement in patients with small aortic annulus. Head-to-head comparisons of different transcatheter aortic valves in these patients are insufficient. We compared the outcomes after TAVR, between two different types of transcatheter aortic valves (self-expanding vs. balloon-expandable) in patients with small aortic annulus.

Methods: A total of 70 patients with severe aortic stenosis and small annulus (mean diameter ≤23 mm or minimal diameter ≤21 mm on computed tomography) underwent TAVR with either a self-expanding valve with supra-annular location (n=45) or a balloon-expandable valve with intra-annular location (n=25). The echocardiographic hemodynamic parameters after TAVR and 1-year follow-up were compared.

Results: Between the self-expanding and balloon-expandable valve-treated patients, the clinical outcomes including permanent pacemaker implantation (11.1% vs. 8.0%), acute kidney injury stage 2 or 3 (4.4% vs. 4.0%), and major vascular complication (4.4% vs. 0.0%) were similar without all-cause mortality, stroke, and life-threatening bleeding during 30-day follow-up. Compared with the balloon-expandable valve-treated patients, the self-expanding valve-treated patients presented larger effective orifice area (EOA) (1.46±0.28 vs. 1.75±0.42 cm², p=0.002) and indexed EOA (0.95±0.21 vs. 1.18±0.28 cm²/m², p=0.001), whereas mean aortic valve gradient (11.7±2.9 vs. 8.9±5.2 mmHg, P=0.005) and incidence of moderate prosthesis-patient mismatch (36.0% vs. 8.9%, p=0.009) were lower. These hemodynamic differences were maintained at 1-year follow-up.

Conclusions: TAVR with self-expanding valves was associated with superior hemodynamic outcomes compared with balloon-expandable valves in patients with small aortic annulus.

Keywords: Transcatheter aortic valve replacement; Aortic valve stenosis
The Evolut group presented larger EOA and iEOA, whereas mean aortic valve gradient was lower than the SAPIEN 3 group.

The differences in hemodynamic outcomes were maintained at 1-year follow up.
The Evolut group presented lower incidence of ≥moderate PPM than the SAPIEN 3 group. The incidence of ≥moderate paravavular leak was rare in both groups.
TABLE 1 Classification of Annular Rupture According to the Anatomical Location

1. Intra-annular
2. Subannular
   a. Injury of the free myocardial wall
   b. Injury of the anterior mitral leaflet
   c. Injury of the interventricular septum
3. Supra-annular
   a. Injury of the wall of a sinus of Valsalva
   b. Injury of the ostium of a coronary artery
   c. Injury of the sinotubular junction
4. Combined
   a. Intra-annular and supra-annular
   b. Intra-annular and subannular
   c. Intra-annular, supra-annular, and subannular

FIGURE 1 Simplified Schema of the “Device Landing Zone”

The aortic root (blue) and the left ventricular outflow tract (pink) form the “device landing zone.”
Calcification of the LVOT is not an isolated phenomena. It must be considered as a sign of severe degenerated Valves. Usually it can be detected together with extensive Calcification of the Annulus and Cusps.

Thoughtful Commentary: Severe LVOT Calcification and TAVR Markus Kasel, MD, PD  Structural Heart Disease Program
LVOT Calcification & TAVR: Annular Rupture

“Among a total of 1000 TAVI procedures, 6 patients (0.6%) had a rupture of the device landing zone:
4 Supraannular Ruptures, 1 Annular Rupture and 1 Subannular Rupture.“

Risk factors for „Annular Rupture“
- Supraannular: Flat Sinuses of Valsalva and severe calcifications of the Aortic Cusps
- Annular: Ellipsoid Annulus and bulky calcifications of the Annulus
- Subannular: Narrow LVOT and bulky calcification of the LVOT

Coronary Artery Disease Prevalence in TAVI Patients

- It is important to maintain access to the coronaries to treat coronary artery disease (CAD) long-term post-TAVI.
- CAD is highly prevalent in the TAVR population, possibly affecting 80% of the cohort.

![Bar chart showing the prevalence of CAD in different TAVI trials]

<table>
<thead>
<tr>
<th>Study</th>
<th>% with CAD at baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoreValve US Pivotal Trial ER (n=489)</td>
<td>81.8%</td>
</tr>
<tr>
<td>CoreValve US Pivotal Trial HR (n=390)</td>
<td>75.4%</td>
</tr>
<tr>
<td>PARTNER 1A TAVR (n=348)</td>
<td>74.9%</td>
</tr>
<tr>
<td>PARTNER IIB Sapien (n=276)</td>
<td>67.4%</td>
</tr>
<tr>
<td>PARTNER IIB Sapien XT (n=284)</td>
<td>65.5%</td>
</tr>
<tr>
<td>Sapien 3 IR (n=1077)</td>
<td>70.0%</td>
</tr>
<tr>
<td>SURTAVI (n=864)</td>
<td>62.6%</td>
</tr>
<tr>
<td>ADVANCE (n=1012)</td>
<td>57.8%</td>
</tr>
<tr>
<td>FRANCE 2 (n=3195)</td>
<td>47.9%</td>
</tr>
<tr>
<td>UK Registry (n=2588)</td>
<td>45.2%</td>
</tr>
<tr>
<td>SOURCE XT (n=2688)</td>
<td>44.3%</td>
</tr>
</tbody>
</table>


CoreValve is a trademark of Medtronic. Third party brands are trademarks of their respective owners.
Recent studies have shown that with current indications, PCI after TAVI is already required for at least 3.5-7% of patients.

### Frequency of need for PCI after TAVI

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients</th>
<th>Mean Follow-up</th>
<th>PCI Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Htun</td>
<td>403</td>
<td>15-month</td>
<td>6.9%</td>
</tr>
<tr>
<td>Allali</td>
<td>296</td>
<td>17.7-month</td>
<td>5.7%</td>
</tr>
<tr>
<td>Blumenstein</td>
<td>1000</td>
<td></td>
<td>3.5%</td>
</tr>
<tr>
<td>Katsanos</td>
<td>142</td>
<td>13-month</td>
<td>7.0%</td>
</tr>
<tr>
<td>Jeroudi</td>
<td>573</td>
<td></td>
<td>3.5%</td>
</tr>
</tbody>
</table>

- Single center retrospective studies report 3.5% to 7% within 13 to 18 months.
- The authors from the various studies report TAVI patients who are treated post-TAVI for progressive CAD in their centers.
- The overall number of post-TAVI intervention could be therefore higher since patients may receive treatment in other centers.
Engagement of CA

10 Fr
Training Heartroid
PPM: Length of MS

- Close proximity of the aortic valve to the cardiac conduction system\(^1\)
- Distance between non-coronary cusp and His-bundle: on average, 6.3 mm
- Distance varies among individuals, but is usually $<10$ mm

\(^1\) Igawa O. Circ J 2009; 73 Suppl I: 257.
Permanent Pacemaker at 30 Days

- SAPIEN PARTNER 1 (N=2559): 6.80%
- SAPIEN XT PARTNER 2B (N=284): 6.4%
- Sapien XT PARTNER 2A (N=1011): 8.5%
- SAPIEN 3 P2 S3 HR (N=583): 13.3%
- SAPIEN 3 P2 S3i (N=1078): 10.1%

Adapted from Nazif T. TVT 2017
Pacemaker: Medtronic Evolut-R

Permanent Pacemaker at 30 Days

- CoreValve ADVANCE (N=1,015): 26.3%
- CoreValve Extreme Risk (N=489): 21.6%
- CoreValve High Risk (N=390): 19.8%
- Evolut R CE Study (N=60): 11.7%
- Evolut R US Study (N=241): 16.2%
- Evolut Pro US Study (N=60): 10.0%

Adapted from Nazif T. TVT 2017

### Other clinical endpoints

<table>
<thead>
<tr>
<th></th>
<th>Balloon-expandable valve (n=121)</th>
<th>Self-expanding valve (n=120)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>21 (17.5%)</td>
<td>19 (16.5%)</td>
<td>0.73</td>
</tr>
<tr>
<td>Repeat hospitalization for heart failure</td>
<td>30 (28.9%)</td>
<td>26 (22.5%)</td>
<td>0.75</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2 (1.6%)</td>
<td>7 (6.1%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Bleeding</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life threatening</td>
<td>21 (17.3%)</td>
<td>18 (16.2%)</td>
<td>0.77</td>
</tr>
<tr>
<td>Major</td>
<td>28 (26.3%)</td>
<td>20 (22.0%)</td>
<td>0.26</td>
</tr>
<tr>
<td>Minor</td>
<td>17 (14.3%)</td>
<td>12 (10.4%)</td>
<td>0.37</td>
</tr>
<tr>
<td>Vascular complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td>14 (11.6%)</td>
<td>14 (12.1%)</td>
<td>0.89</td>
</tr>
<tr>
<td>Minor</td>
<td>5 (4.2%)</td>
<td>3 (2.6%)</td>
<td>0.51</td>
</tr>
<tr>
<td>New pacemaker</td>
<td>28 (25.4%)</td>
<td>40 (40.4%)</td>
<td>0.01</td>
</tr>
</tbody>
</table>
Paravalvular Leak I

Delivering on the changing expectations of TAVI

11.8%
PARTNER 1B²
N=179

SAPIEN valve

3.7%
PARTNER IIa³
N=872

SAPIEN XT valve

0.8%
PARTNER 3₄
N=487

SAPIEN 3 valve

Moderate or severe PVL at 30 days

Reference
Paravalvular Performance II

ADVANCED SEALING AT 30 DAYS

<table>
<thead>
<tr>
<th></th>
<th>None/Trace</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoreValve</td>
<td>55.3%</td>
<td>35.7%</td>
<td>7.3%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Evolut R</td>
<td>61.6%</td>
<td>32.6%</td>
<td>5.7%</td>
<td>0%</td>
</tr>
<tr>
<td>Evolut PRO</td>
<td>72.4%</td>
<td>27.6%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Evolut PRO PVL at 30 Days
0% Moderate & 0% Severe PVL

NOTE: PVL performance data represent different device performance in different trials; comparison of results is for illustration purposes only and may not be indicative of clinical performance.

<table>
<thead>
<tr>
<th>Clinical and anatomical condition</th>
<th>Choice between Evolut R/Pro vs Sapien 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small or diseased transfemoral access route</td>
<td>&gt;</td>
</tr>
<tr>
<td>Horizontal ascending aorta</td>
<td>&lt;</td>
</tr>
<tr>
<td>Coronary artery obstruction</td>
<td>&gt;</td>
</tr>
<tr>
<td>Coronary artery access</td>
<td>&lt;</td>
</tr>
<tr>
<td>Heavy or unfavorable calcification of aortic valve</td>
<td>&gt;</td>
</tr>
<tr>
<td>Small annulus</td>
<td>&gt;</td>
</tr>
<tr>
<td>Small sinotubular junction</td>
<td>&gt;</td>
</tr>
<tr>
<td>Risk of AV conduction</td>
<td>&lt;</td>
</tr>
<tr>
<td>Valve-in-valve TAVR</td>
<td>&gt;</td>
</tr>
<tr>
<td>Severe LV dysfunction</td>
<td>&gt;</td>
</tr>
<tr>
<td>Valve size selection based on echocardiography</td>
<td>&gt;</td>
</tr>
</tbody>
</table>
Conclusion

• The recent generation self-expandable and balloon-expandable valves were both effective and safe regarding clinical outcomes.

• The decision of the TAVR valve depends on the opinion and experience of the heart team.

• It is recommended to select the type of valve in consideration of the patient's aortic valve, heart function, and the condition of the aorta and blood vessels in the access path before the procedure.
With the Love of God, Free Humankind from Disease and Suffering