Procedural and Clinical Outcomes in TAVR for Bicuspid Versus Tricuspid AS

Sung-Han Yoon, MD
On behalf of the Bicuspid AS TAVR Registry Investigators

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Disclosure Statement of Financial Interest

Sung-Han Yoon, MD

Within the past 12 months, I or my spouse/partner have had no financial interest/arrangement or affiliation with any organization(s).
Background

- TAVR indication is expanding into a lower-risk population
- The prevalence of bicuspid aortic valve is higher in a younger population
- Bicuspid AS has been excluded from randomized trials
- There is limited data comparing outcomes of TAVR for bicuspid versus tricuspid AS

Methods

- The Bicuspid AS TAVR multicenter registry was used to compare the procedural and clinical outcomes between bicuspid and tricuspid AS
- Propensity-score matching was applied
- Procedural and clinical outcomes were assessed according to VARC-2 criteria
## Participating Institutions (N = 33)

<table>
<thead>
<tr>
<th>Nation</th>
<th>Institution</th>
<th>Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>St. Paul’s Hospital</td>
<td>Danny Dvir, Philipp Blanke, Jonathon Leipsic, John G. Webb</td>
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<tr>
<td>Denmark</td>
<td>Rigshospitalet University Hospital</td>
<td>Ole de Backer, Lars Sondergaard</td>
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<td>France</td>
<td>Institute Cardiovasculaire Paris Sud</td>
<td>Takahide Arai, Bernard Chevalier, Thierry Lefevre</td>
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<td>France</td>
<td>Hospital Cardiologique Lille</td>
<td>Thomas Modine</td>
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<td>Centre Hospitalier Universitaire Henri Modor</td>
<td>Masao Takahashi, Emmanuel Teiger</td>
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<tr>
<td>Germany</td>
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<td>Johannes Ziegelmueller, Sabine Bleiziffer</td>
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<td>Florian Deuschl, Niklas Schofer, Ulrich Schaefer</td>
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<td>Hidehiro Kaneko, Christian Butter</td>
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<td>Philipp Ruile, Gregor Pache, Franz-Josef</td>
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<td>Buntaro Fujita, Stephan M. Ensminger</td>
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<td>Germany</td>
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<td>Tobias Schmidt</td>
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<td>Erik W. Holy, Mohamed Abdel-Wahab</td>
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<td>Azeem Latib, Antonio Columbo</td>
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<td>Marco Barbanti, Corrado Tamburino</td>
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<td>Seung-Jung Park</td>
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<td>Leiden University Medical Center</td>
<td>William K.F. Kong, Victoria Delgado, Jeroen J. Bax</td>
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<td>Switzerland</td>
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<td>Smriti Saraf, David Hildick-Smith</td>
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<td>Brian K. Whisenant</td>
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<tr>
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<td>Cedars-Sinai Heart Institute</td>
<td>Raj Makkar</td>
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</tbody>
</table>
Exclusion
• 15 patients with missing data

Study Design

Bicuspid AS
(n = 561)

Exclusion
• 1330 patients with missing data

Tricuspid AS
(n = 5876)

Bicuspid AS
(n = 576)

Tricuspid AS
(n = 4546)

Propensity-Score Matching

Bicuspid AS
(n = 546)

Tricuspid AS
(n = 546)
## Baseline Characteristics

### Demographics

<table>
<thead>
<tr>
<th></th>
<th>Bicuspid AS (n = 546)</th>
<th>Tricuspid AS (n = 546)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>77 ± 8</td>
<td>77 ± 8</td>
<td>0.91</td>
</tr>
<tr>
<td>Male</td>
<td>63%</td>
<td>61%</td>
<td>0.48</td>
</tr>
<tr>
<td>NYHA class III / IV</td>
<td>80%</td>
<td>82%</td>
<td>0.48</td>
</tr>
<tr>
<td>STS score, %</td>
<td>4.6±4.6</td>
<td>4.3±3.0</td>
<td>0.29</td>
</tr>
<tr>
<td>Logistic EuroSCORE, %</td>
<td>16.1±12.0</td>
<td>16.9±13.9</td>
<td>0.58</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>Bicuspid AS (n = 546)</td>
<td>Tricuspid AS (n = 546)</td>
<td>P value</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>-----------------------</td>
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<tr>
<td>Diabetes mellitus</td>
<td>23%</td>
<td>23%</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Creatinine, mg/dl</td>
<td>1.2±0.9</td>
<td>1.2±0.7</td>
<td>0.81</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>15%</td>
<td>16%</td>
<td>0.93</td>
</tr>
<tr>
<td>Prior CVA</td>
<td>14%</td>
<td>13%</td>
<td>0.53</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>18%</td>
<td>15%</td>
<td>0.23</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>11%</td>
<td>12%</td>
<td>0.70</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>52 ±15</td>
<td>52 ±15</td>
<td>0.99</td>
</tr>
<tr>
<td>Procedure</td>
<td>Bicuspid AS (n = 546)</td>
<td>Tricuspid AS (n = 546)</td>
<td>P value</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------</td>
<td>------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Transfemoral access</td>
<td>86%</td>
<td>86%</td>
<td>0.93</td>
</tr>
<tr>
<td>Device</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Early generation devices</strong></td>
<td>59%</td>
<td>59%</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Sapien XT</td>
<td>28%</td>
<td>28%</td>
<td>0.77</td>
</tr>
<tr>
<td>CoreValve</td>
<td>30%</td>
<td>31%</td>
<td>0.73</td>
</tr>
<tr>
<td><strong>New generation devices</strong></td>
<td>41%</td>
<td>41%</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Sapien 3</td>
<td>29%</td>
<td>30%</td>
<td>0.94</td>
</tr>
<tr>
<td>Lotus</td>
<td>8%</td>
<td>9%</td>
<td>0.73</td>
</tr>
<tr>
<td>Evolut R</td>
<td>4%</td>
<td>3%</td>
<td>0.32</td>
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</table>
Procedural Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Bicuspid AS (n = 546)</th>
<th>Tricuspid AS (n = 546)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Root Injury</td>
<td>1.6</td>
<td>0.0</td>
</tr>
<tr>
<td>Second Valve Implantation</td>
<td>4.8</td>
<td>1.5</td>
</tr>
<tr>
<td>Paravalvular Leak</td>
<td>10.4</td>
<td>6.8</td>
</tr>
<tr>
<td>New Pacemaker</td>
<td>15.4</td>
<td>15.4</td>
</tr>
</tbody>
</table>

- p = 0.004
- p = 0.002
- p = 0.04
- p > 0.99
Procedural Outcomes

Device Success

Bicuspid AS  Tricuspid AS

Incidence (%)

p = 0.002

85.3  91.4

Device Success
30-day Clinical Outcomes

- 3.7% 3.3% (30-day Mortality)
- 2.9% 1.8% (Stroke)
- 2.0% 3.5% (Bleeding)
- 2.9% 2.9% (Major Vascular Complication)
- 2.0% 0.9% (AKI stage 2 or 3)

P-values:
- 0.87
- 0.33
- 0.20
- >0.99
- 0.21

(n = 546)
# Device Evolution

<table>
<thead>
<tr>
<th>Device</th>
<th>Sapien XT</th>
<th>CoreValve</th>
<th>Sapien 3</th>
<th>Lotus</th>
<th>Evolut R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bicuspid vs Tricuspid AS</td>
<td>155 vs 150 (28% vs 28%)</td>
<td>165 vs 171 (30% vs 31%)</td>
<td>160 vs 162 (29% vs 30%)</td>
<td>43 vs 47 (8% vs 9%)</td>
<td>23 vs 16 (4% vs 3%)</td>
</tr>
</tbody>
</table>

**Table:**
- **Early Generation Devices:** Sapien XT, CoreValve
- **New Generation Devices:** Sapien 3, Lotus, Evolut R

**Notes:**
- Task-specific devices are compared in terms of technical specifications and performance metrics.
Early Generation devices
Procedural Outcomes
Early Generation Devices

Aortic Root Injury: Bicuspid AS (n = 320) 2.2%, Tricuspid AS (n = 321) 0.0%
Second Valve Implantation: Bicuspid AS 7.2%, Tricuspid AS 2.2%
Paravalvular Leak: Bicuspid AS 15.9%, Tricuspid AS 10.3%
New Pacemaker: Bicuspid AS 14.7%, Tricuspid AS 13.7%

Significance levels: p = 0.02, p = 0.003, p = 0.03, p = 0.72
Procedural Outcomes
Early Generation Devices

Incidence (%)

- Bicuspid AS
- Tricuspid AS

p = 0.005

Device Success

Incidence (%)

78.4
86.9
Procedural Outcomes
Sapien XT

Incidence (%)

- Aortic Root Injury
  - Bicuspid AS (n = 155)
    - 4.5 (%)
  - Tricuspid AS (n = 150)
    - 0.0 (%)
  - p = 0.015

- Second Valve Implantation
  - Bicuspid AS (n = 155)
    - 2.6 (%)
  - Tricuspid AS (n = 150)
    - 1.3 (%)
  - p = 0.69

- Paravalvular Leak
  - Bicuspid AS (n = 155)
    - 12.3 (%)
  - Tricuspid AS (n = 150)
    - 10.0 (%)
  - p = 0.53

- New Pacemaker
  - Bicuspid AS (n = 155)
    - 11.0 (%)
  - Tricuspid AS (n = 150)
    - 6.7 (%)
  - p = 0.19
Procedural Outcomes

Sapien XT

Device Success

Incidence (%)

- Bicuspid AS
- Tricuspid AS

p = 0.47

85.2
88.0

Procedural Outcomes
**Procedural Outcomes**

CoreValve

<table>
<thead>
<tr>
<th>Condition</th>
<th>Bicuspid AS (n = 165)</th>
<th>Tricuspid AS (n = 171)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Root Injury</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Second Valve Implantation</td>
<td>11.6</td>
<td>2.9</td>
<td>0.002</td>
</tr>
<tr>
<td>Paravalvular Leak</td>
<td>19.4</td>
<td>10.5</td>
<td>0.02</td>
</tr>
<tr>
<td>New Pacemaker</td>
<td>18.3</td>
<td>19.9</td>
<td>0.71</td>
</tr>
</tbody>
</table>
Procedural Outcomes
CoreValve

- Bicuspid AS: 72.1%
- Tricuspid AS: 86.0%

**p = 0.002**

Device Success

Incidence (%)
New Generation devices
Procedural Outcomes
New Generation Devices

- **Aortic Root Injury**
  - Bicuspoid AS (n = 226): 0.9%
  - Tricuspid AS (n = 225): 0.0%
  - p = 0.50

- **Second Valve Implantation**
  - Bicuspoid AS (n = 226): 1.3%
  - Tricuspid AS (n = 225): 0.4%
  - p = 0.62

- **Paravalvular Leak**
  - Bicuspoid AS (n = 226): 2.7%
  - Tricuspid AS (n = 225): 1.8%
  - p = 0.53

- **New Pacemaker**
  - Bicuspoid AS (n = 226): 16.4%
  - Tricuspid AS (n = 225): 17.8%
  - p = 0.69

*Note: All p-values are statistically insignificant.*
Procedural Outcomes
New Generation Devices

Incidence (%) of Device Success:
- Bicuspid AS: 95.1%
- Tricuspid AS: 97.8%

Statistical Significance:
- p = 0.13
Procedural Outcomes

Sapien 3

- Bicuspid AS (n = 160)
- Tricuspid AS (n = 162)

- Aortic Root Injury: 0.6 % (p = 0.50), 0.0 % (p > 0.99)
- Second Valve Implantation: 1.3 % (p = 0.62), 0.6 % (p > 0.99)
- Paravalvular Leak: 1.9 %, 2.5 % (p = 0.59)
- New Pacemaker: 15.1 %, 17.3 %

Incidence (%) vs. Procedural Outcomes
Procedural Outcomes

Sapien 3

- Bicuspid AS
- Tricuspid AS

Incidence (%)

Device Success

96.2
96.9

p = 0.74
Procedural Outcomes

Lotus

Incidence (%)

Device Success

Bicuspid AS  Tricuspid AS

p = 0.14

95.3  100.0

Procedural Outcomes

Lotus
Mid-term Mortality
1-year All-cause Mortality

- Bicuspid AS: 11.4%
- Tricuspid AS: 11.2%

p value = 0.28

No. at Risk
- Bicuspid AS: 546
- Tricuspid AS: 546

Days
- Bicuspid AS: 308
- Tricuspid AS: 379

No. at Risk
- Bicuspid AS: 235
- Tricuspid AS: 280
1-year All-cause Mortality
Early Generation Devices

Log-rank p = 0.80

<table>
<thead>
<tr>
<th>Days</th>
<th>No. at Risk</th>
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<tbody>
<tr>
<td>0</td>
<td>320</td>
</tr>
<tr>
<td>90</td>
<td>222</td>
</tr>
<tr>
<td>180</td>
<td>236</td>
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<tr>
<td>270</td>
<td>191</td>
</tr>
<tr>
<td>360</td>
<td>191</td>
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</table>

14.5% Bicuspid AS
13.7% Tricuspid AS
1-year All-cause Mortality

New Generation Devices

Log-rank p = 0.64

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>Days</th>
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<tbody>
<tr>
<td>Bicuspid AS</td>
<td>226</td>
</tr>
<tr>
<td>Tricuspid AS</td>
<td>225</td>
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</tbody>
</table>
Conclusions - 1

• TAVR for bicuspid AS was associated with \textit{lower device success rate}

• Among patients receiving \textit{early generation devices}, bicuspid AS had more frequent \textit{aortic root injury} with Sapien XT, and moderate-severe \textit{paravalvular leak} with CoreValve when compared to tricuspid AS

• Among patients receiving \textit{new generation devices}, procedural outcomes were similar between bicuspid and tricuspid AS
Conclusions - 2

- **30-day clinical outcomes** were similar between bicuspid and tricuspid AS

- **All-cause mortality rates at 1-year** were similar between bicuspid and tricuspid AS, across early and new generation devices
Acknowledgement

Columbia University Medical Center
Susheel Kodali, MD
Martin B. Leon

German Heart Center Munich, Germany
Sabine Bleiziffer, MD

Rigshospitalet University Hospital, Denmark
Ole De Backer, MD
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