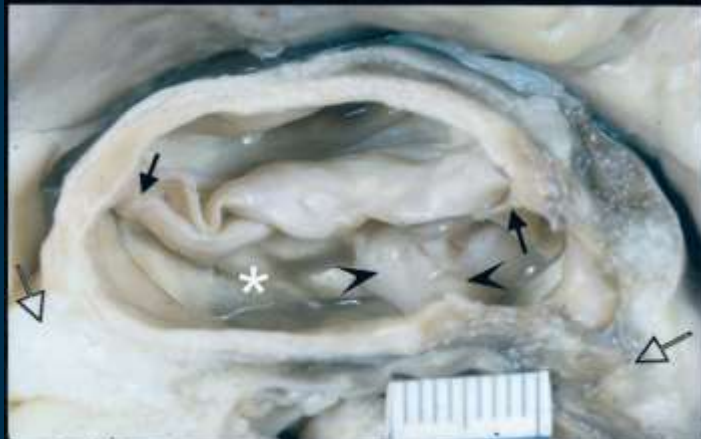# TAVR for Bicuspid Aortic Valve

## Sung-Han Yoon, MD

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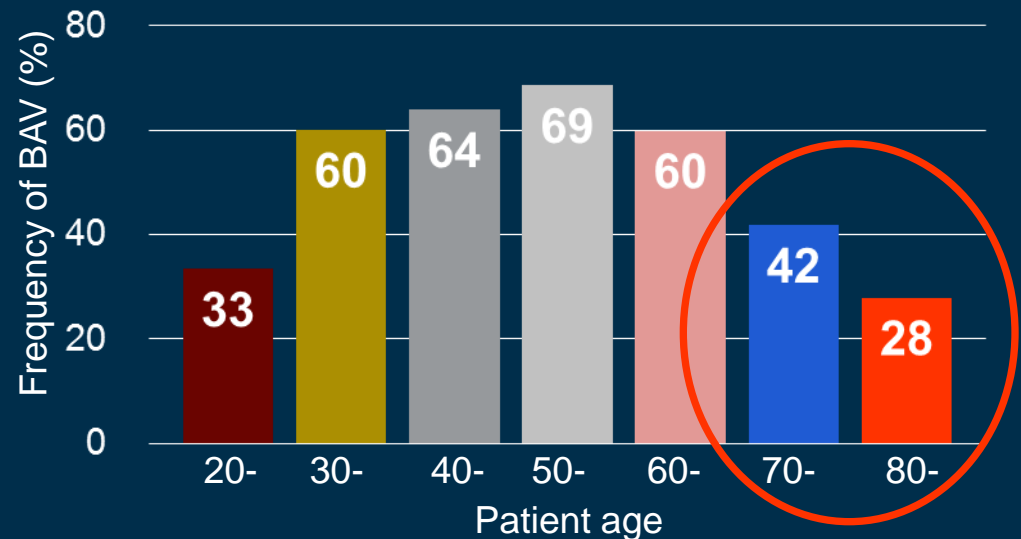
# Bicuspid AS is Common



**Bicuspid aortic valve**

Fedak P W et al. Circulation. 2002;106:900-904

### Frequencies of Bicuspid Aortic Valve



Frequency of BAV (%)

Patient age

20- : 33
30- : 60
40- : 64
50- : 69
60- : 60
70- : 42
80- : 28

Roberts WC et al. Circulation. 2005;111:920-925

- The most common congenital cardiac malformation (1-2%)
- Serious complications occurred > 30%

  **Aortic Stenosis**  (the most common)

  Aortic Regurgitation

  Aortic dilation and dissection

# Current Guideline for TAVR

| Class I |
|---|
| • Patients who meet an indication for AVR with **prohibitive risk** for surgical AVR and a predicted post-TAVR survival > 12 months *(Level of Evidence: B)* |

| Class IIa |
|---|
| • Patients who meet an indication for AVR with **high surgical risk** for surgical AVR *(Level of Evidence: B)* |

## Basically Bicuspid AV is excluded

# Multicenter MDCT Registry

| |
|---|
| Asan Medical Center, Korea |
| Ferrarotto Hospital, Italy |
| National Taiwan University Hospital, Taiwan |
| Queen Elizabeth Hospital, Hong Kong |

**72 Pts with Bicuspid AV underwent TAVR or SAVR
vs. 302 Pts with Tricuspid AV underwent TAVR**

# Morphologic Features of BAV

| | Bicuspid (n = 72) | Tricuspid (n = 317) | P value |
|---|---|---|---|
| **Aortic Annulus Measurement** | | | |

*Larger Annulus*
*Higher Coronary Height*
*Heavily Calcified*
*Calcified Raphe and Commissure*
*Dilated Aorta*
*Difficulties in Perpendicular Angle*

| | Bicuspid (n = 72) | Tricuspid (n = 317) | P value |
|---|---|---|---|
| RCA height, mm | 20.4 ± 10.6 | 17.0 ± 3.0 | 0.009 |
| LCA height, mm | 15.8 ± 4.5 | 12.7 ± 3.0 | < 0.001 |
| Calcium volume | 722 ± 494 | 365 ± 337 | < 0.001 |

# Reported Clinical Data on TAVR-BAV

*Hayashida et al.* Circulation CI. 2013 ;6:284-291

*Bauer T et al.* Am J Cardiol. 2014 ;113:518-21

*Costopoulos C et al.* Am J Cardiol. 2014 ;113:1390-1393

*Kochman et al.* Am J Cardiol. Epub

*Mylotte et al.* JACC.2014; 64: 2330-39

# Baseline Characteristics

| | Hayashida (N = 21) | Bauer (N=38) | Kochman (N=28) | Costopoulus (N=21) | Mylotte (N=143) |
|---|---|---|---|---|---|
| Age | 82 | 81 | 78 | 77 | 78 |
| Male | 57% | 42% | 46% | 57% | 56% |
| Body Mass Index | 25 | 26 | - | 27 | 26 |
| Diabetes | 48% | 37% | 39% | 29% | 25% |
| LVEF, % | 48% | 50% | 48% | 50% | 50% |
| eGFR < 60ml/min | 57% | 58% | 43% | 52% | 50% |
| Logistic EuroSCORE | 19.9 | 18 | 19 | 24 | 14.8 |
| STS score | | | | 7.6 | 4.9 |

Hayashida et al. Circulation CI. 2013 ;6:284-291
Bauer T et al. Am J Cardiol. 2014 ;113:518-21
Costopoulos C et al. Am J Cardiol. 2014 ;113:1390-1393
Kochman et al. Am J Cardiol. Epub
Mylotte et al. JACC.2014; 64: 2330-39

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# Procedural and Clinical Outcomes

| | Hayashida (N = 21) | Bauer (N=38) | Kochman (N=28) | Costopoulus (N=21) | Mylotte (N=143) |
|---|---|---|---|---|---|
| Type of device | | | | | |
| CoreValve | 48% | 68% | 82% | 62% | 65% |
| SAPIEN | 52% | 32% | 18% | 38% | 35% |
| Bleeding (life-threatening or major) | 9.5% | - | 11% | 24% | 7% |
| Major vascular complication | 4.4% | - | 0 | 10% | 6.3% |
| Stroke | 0 | 0 | 0 | 0 | 2.1% |
| AR ≥ Grade 2 | 19% | - | 32% | 24% | 28% |
| Device success | 100% | 100% | 93% | 86% | 90% |
| 30-day mortality | 4.8% | 11% | 4% | 14% | 5.0% |
| 1-year mortality | - | 13% | 18% | 32% | 18% |

Hayashida et al. Circulation CI. 2013 ;6:284-291
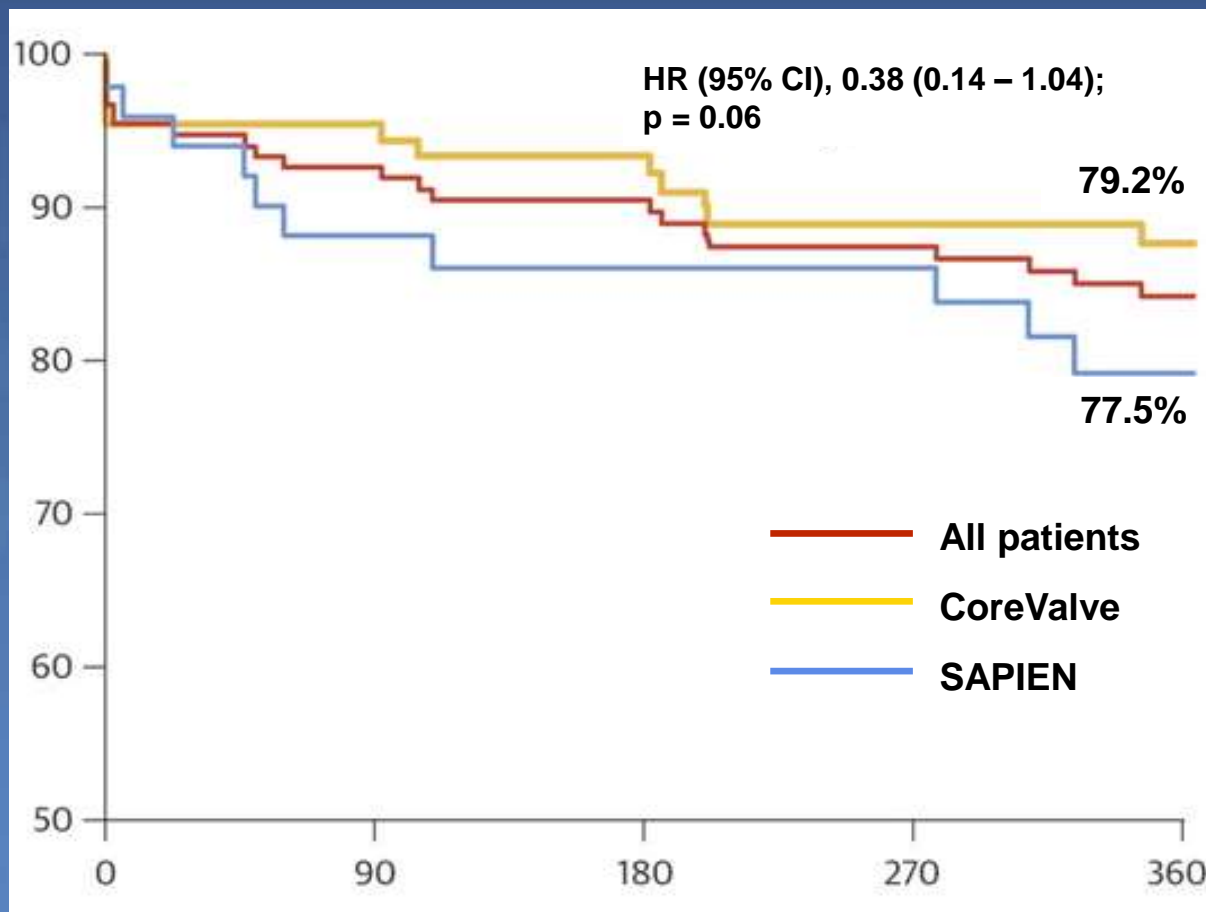Bauer T et al. Am J Cardiol. 2014 ;113:518-21
Costopoulos C et al. Am J Cardiol. 2014 ;113:1390-1393
Kochman et al. Am J Cardiol. Epub
Mylotte et al. JACC.2014; 64: 2330-39

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# TAVR in Bicuspid Aortic Valve

## Device Comparison



A total of 139 patients with bicuspid aortic valve stenosis undergoing TAVR

# International Multicenter Bicuspid AS Registry

58 TAVR-BAV in Asian TAVR Registry

62 TAVR-BAV in Institute Hospitalier Jacques Cartier

**110 TAVR-BAV**
(45 SAPIEN, 63 CoreValve
1 Lotus, 1 Jena)

# The Bicuspid TAVR Registry
## Baseline Characteristics

| | Overall (N = 108) | SAPIEN (N = 45) | CoreValve (N = 63) | p value |
|---|---|---|---|---|
| Age | 78.6±8.4 | 80.3±77.5 | 77.5±8.3 | 0.09 |
| Female | 37.0% | 46.7% | 30.2% | 0.08 |
| BMI, kg/m$^2$ | 24.4±4.5 | 25.0±5.0 | 24.0±4.1 | 0.27 |
| Diabetes mellitus | 16.7% | 20.0% | 14.3% | 0.43 |
| NYHA class III/IV | 73.8% | 90.9% | 61.9% | 0.001 |
| CAD | 36.1% | 35.6% | 36.5% | 0.92 |
| Previous stroke | 8.3% | 6.7% | 9.5% | 0.73 |
| Peripheral vascular disease | 11.1% | 13.3% | 9.5% | 0.54 |
| COPD | 15.7% | 13.3% | 17.5% | 0.56 |

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# The Bicuspid TAVR Registry
## Baseline Characteristics

| | Overall ( N = 108) | SAPIEN (N = 45) | CoreValve (N = 63) | p value |
|---|---|---|---|---|
| Previous PCI | 12.0% | 13.3% | 11.1% | 0.73 |
| Previous CABG | 5.6% | 2.2% | 7.9% | 0.20 |
| eGFR | 63.2±23.5 | 63.8±25.2 | 62.7±22.4 | 0.81 |
| eGFR <60 | 45.2% | 46.7% | 44.1% | 0.79 |
| LVEF, % | 53.2±14.9 | 53.8±13.5 | 52.8±15.9 | 0.74 |
| Mean gradient, mmHg | 54.7±20.8 | 49.4±12.8 | 58.4±24.4 | 0.02 |
| Aortic valve area, $cm^2$ | 0.65±0.16 | 0.69±0.16 | 0.62±0.15 | 0.01 |
| Logistic EuroSCORE | 17.5±12.7 | 16.5±10.9 | 18.3±14.0 | 0.48 |
| STS score | 5.6±5.1 | 5.2±3.2 | 5.8±6.1 | 0.63 |

# The Bicuspid TAVR Registry
## Procedural Data

| | Overall ( N = 108) | SAPIEN (N = 45) | CoreValve (N = 63) | p value |
|---|---|---|---|---|
| **Device size** | | | | |
| 23 mm | 11.1% | 22.2% | 3.2% | < 0.001 |
| 26 mm | 26.9% | 33.3% | 22.2% | |
| 29 mm | 43.5% | 42.2% | 44.4% | |
| 31 mm | 18.5% | 2.2% | 30.2% | |
| **Access site** | | | | |
| Transfemoral | 76.9% | 66.7% | 84.1% | 0.008 |
| Transapical | 5.6% | 13.3% | 0.0% | |
| Subclavian | 1.9% | 0.0% | 3.2% | |
| Transaortic | 15.7% | 20.0% | 12.7% | |

# The Bicuspid AS Registry
## Echocardiographic Outcomes

| | Overall ( N = 108) | SAPIEN (N = 45) | CoreValve (N = 63) | p value |
|---|---|---|---|---|
| LVEF, % | 57.7±11.3 | 57.7±12.5 | 57.8±10.6 | 0.98 |
| Mean gradient, mmHg | 11.5±6.3 | 11.4±8.2 | 11.5±4.9 | 0.93 |
| Aortic valve area, cm$^2$ | 1.69±0.48 | 1.81±1.03 | 1.68±0.42 | 0.84 |
| Paravalvular Regurgitation | | | | |
| None-trace | 61.9% | 84.1% | 45.9% | 0.001 |
| Mild | 29.5% | 13.6% | 41.0% | |
| Moderate | 7.6% | 2.3% | 11.5% | |
| Severe | 1.0% | 0.0% | 1.6% | |
| ≥ mild | 38.1% | 15.9% | 54.1% | < 0.001 |
| ≥ moderate | 8.6% | 2.3% | 13.1% | 0.08 |

# The Bicuspid AS Registry
## Procedural Outcomes

| | Overall ( N = 108) | SAPIEN (N = 45) | CoreValve (N = 63) | p value |
|---|---|---|---|---|
| Need for 2nd device | 5.7% | 0.0% | 9.7% | 0.08 |
| Coronary obstruction | 1.9% | 2.3% | 1.6% | 0.99 |
| Aortic root rupture | 1.9% | 4.8% | 0.0% | 0.16 |
| Conversion to SAVR | 4.8% | 4.7% | 4.8% | 0.99 |
| Permanent pacemaker | 11.1% | 6.7% | 14.3% | 0.21 |

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# The Bicuspid AS Registry
## Clinical Outcomes

| | Overall (N = 108) | SAPIEN (N = 45) | CoreValve (N = 63) | p value |
|---|---|---|---|---|
| **Mortality** | | | | |
| At Procedure | 1.9% | 2.2% | 1.6% | 0.99 |
| At 30 days | 5.4% | 12.5% | 2.5% | 0.19 |
| At 6 months | 16.1% | 25.0% | 12.5% | 0.26 |

# The Bicuspid AS Registry
## Clinical Outcomes

| | Overall ( N = 108) | SAPIEN (N = 45) | CoreValve (N = 63) | p value |
|---|---|---|---|---|
| **Stroke all** | 2.8% | 2.2% | 3.2% | 0.99 |
| **Vascular complications** | | | | |
| **Major** | 5.6% | 13.3% | 0.0% | 0.009 |
| **Minor** | 0.9% | 0.0% | 1.6% | |
| **Acute kidney injury** | | | | |
| **Stage 1** | 4.6% | 8.9% | 1.6% | 0.13 |
| **Stage 2** | 2.8% | 4.4% | 1.6% | |
| **Stage 3** | 0.9% | 2.2% | 0.0% | |

# The Bicuspid AS Registry
## Clinical Outcomes

| | Overall ( N = 108) | SAPIEN (N = 45) | CoreValve (N = 63) | p value |
|---|---|---|---|---|
| **Bleeding** | | | | |
| Life-threatening | 5.6% | 4.4% | 6.3% | 0.62 |
| Major | 5.6% | 6.7% | 4.8% | |
| Minor | 1.9% | 0.0% | 3.2% | |
| **Device success** | 84.3% | 95.2% | 76.7% | 0.011 |
| **Combined safety endpoint (30 days)** | 66.2% | 43.5% | 78.6% | 0.004 |

# All-cause Mortality
## Overall
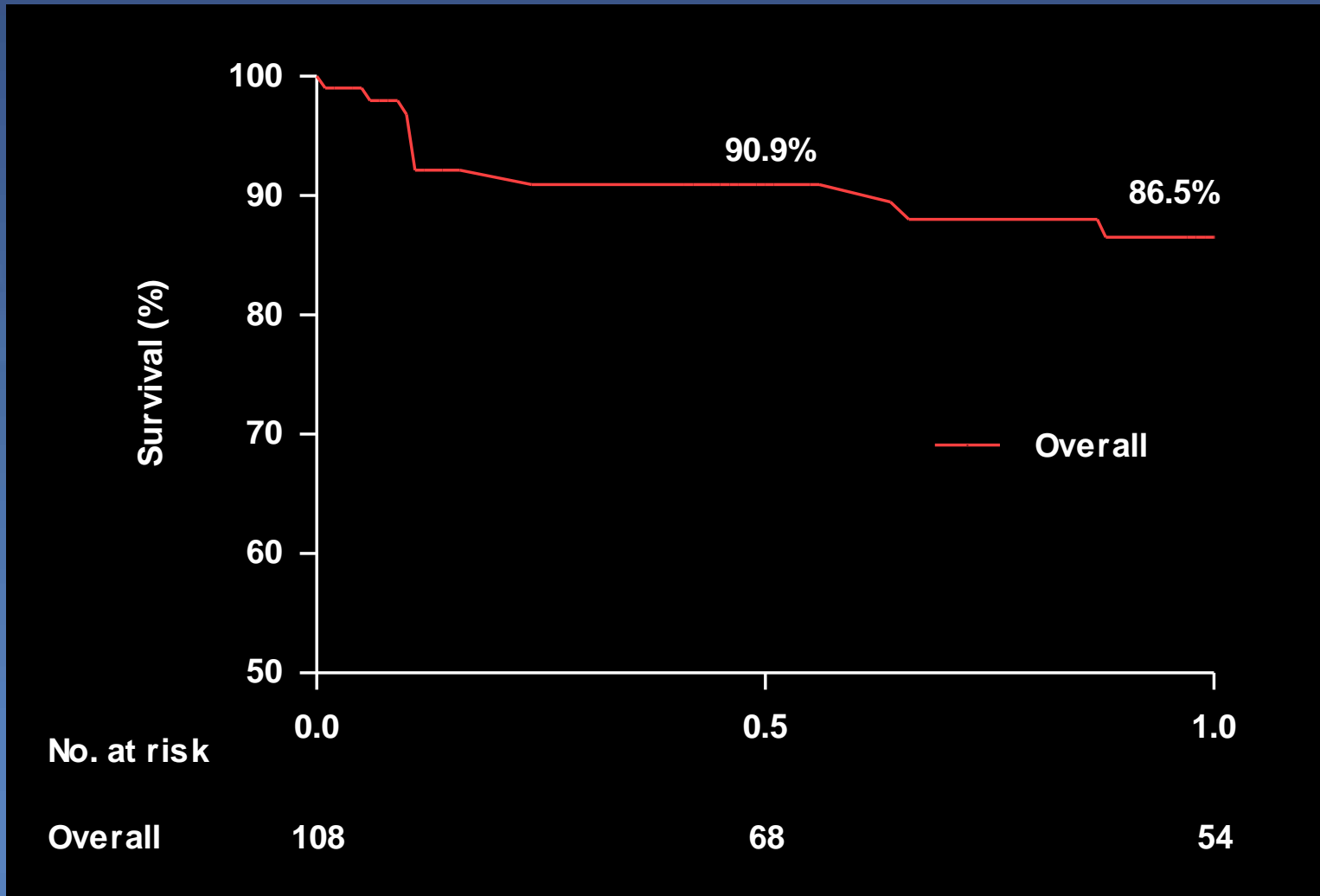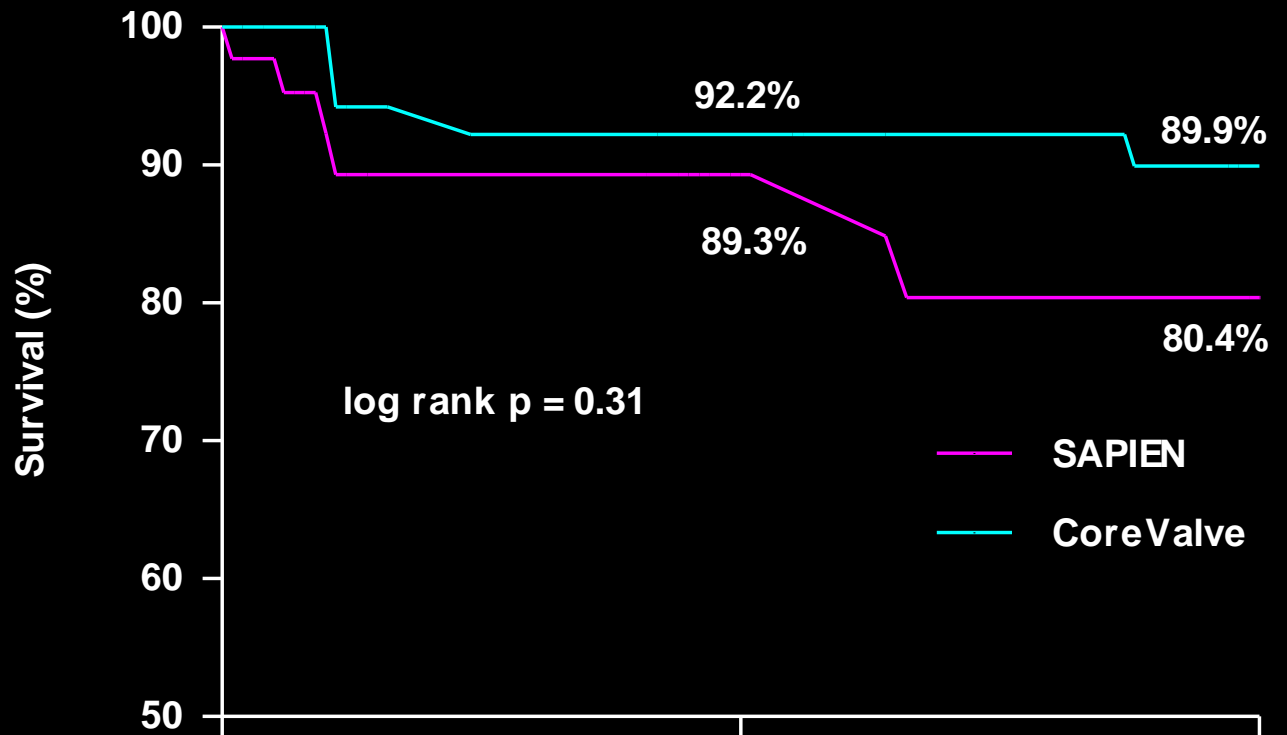
# The Bicuspid AS Registry
## Multivariate Predictors of Mortality

| | Univariate HR (95% CI) | p value | Multivariate HR (95% CI) | p value |
|---|---|---|---|---|
| **Age** | **1.09 (0.99 – 1.18)** | **0.054** | **1.10 (1.01 – 1.20)** | **0.038** |
| **Female** | **0.61 (0.45 – 3.97)** | **0.61** | | |
| **eGFR** | **0.97 (0.95 – 1.00)** | **0.049** | | |
| **COPD** | **1.21 (0.16 – 9.35)** | **0.85** | | |
| **Previous stroke** | **1.23 (0.33 – 4.60)** | **0.76** | | |
| **Mean pressure gradient** 10mmHg | **1.02 (0.80 – 1.30)** | **0.86** | | |
| **LVEF** | **1.03 (0.70 – 1.52)** | **0.89** | | |
| **Transfemoral access** | **0.61 (0.19 – 1.98)** | **0.61** | | |
| **Device (CoreValve)** | **0.64 (0.22 – 1.83)** | **0.41** | | |
| **Paravalvular leak ≥ mild** | **0.87 (0.27 – 2.76)** | **0.81** | | |
| **AKI stage 2-3** | **7.78 (1.70 – 35.71)** | **0.008** | **10.01 (2.00-50.00)** | **0.005** |
| **Major vascular complication** | **3.17 (0.40 – 24.91)** | **0.27** | | |

# Conclusions

1.  Despite limited evidence, patients with Bicuspid AS have been already treated with TAVR in Europe and Asia.
2.  Overall clinical outcomes is comparable to reported studies of TAVR for Tricuspid AS.
3.  However, Bicuspid AS morphology highlights advantages and disadvantages for SAPIEN and CoreValve (higher risk of annulus rupture with SAPIEN and higher risk of paravalvular leak with CoreValve).
4.  Further studies will have to clarify the impact of Bicuspid type, long-term durability, hemodynamics and suitable devices for TAVR in Bicuspid AS.

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