TAVI in Bicuspid AV

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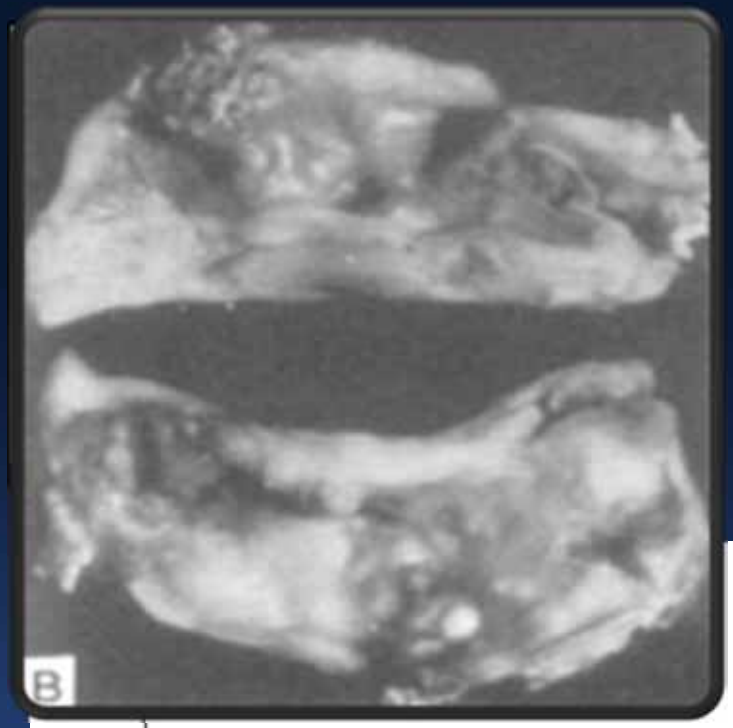
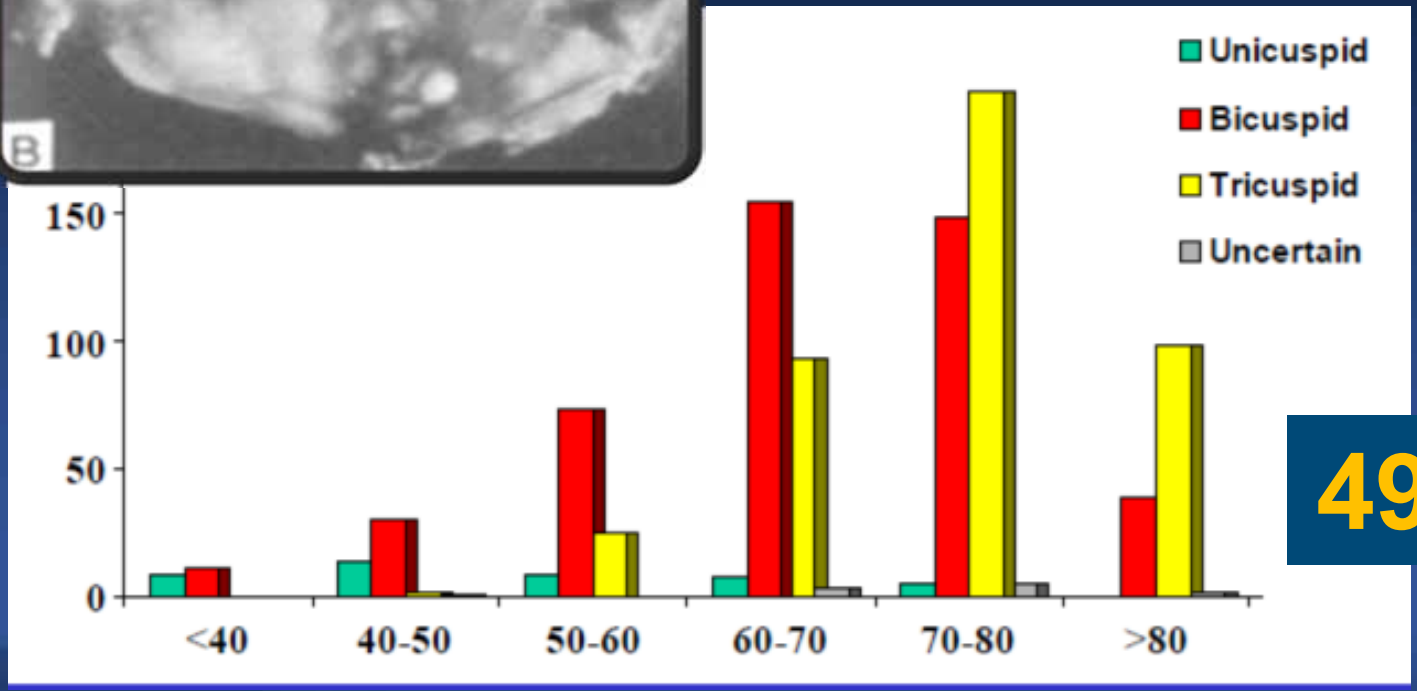
Bicuspid AV is Very Common



- The M/C congenital cardiac malformation (occurring 1% to 2%)
- Serious complications > 1/3:
  AS (M/C) in Adults

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



49% had BAV

Roberts et al. Circulation 2005;111:920-5

Current Guideline for TAVR

Generally Indicated in Tricuspid AS

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)*

2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

BAV was Excluded in Clinical Trials

Exclusion Criteria

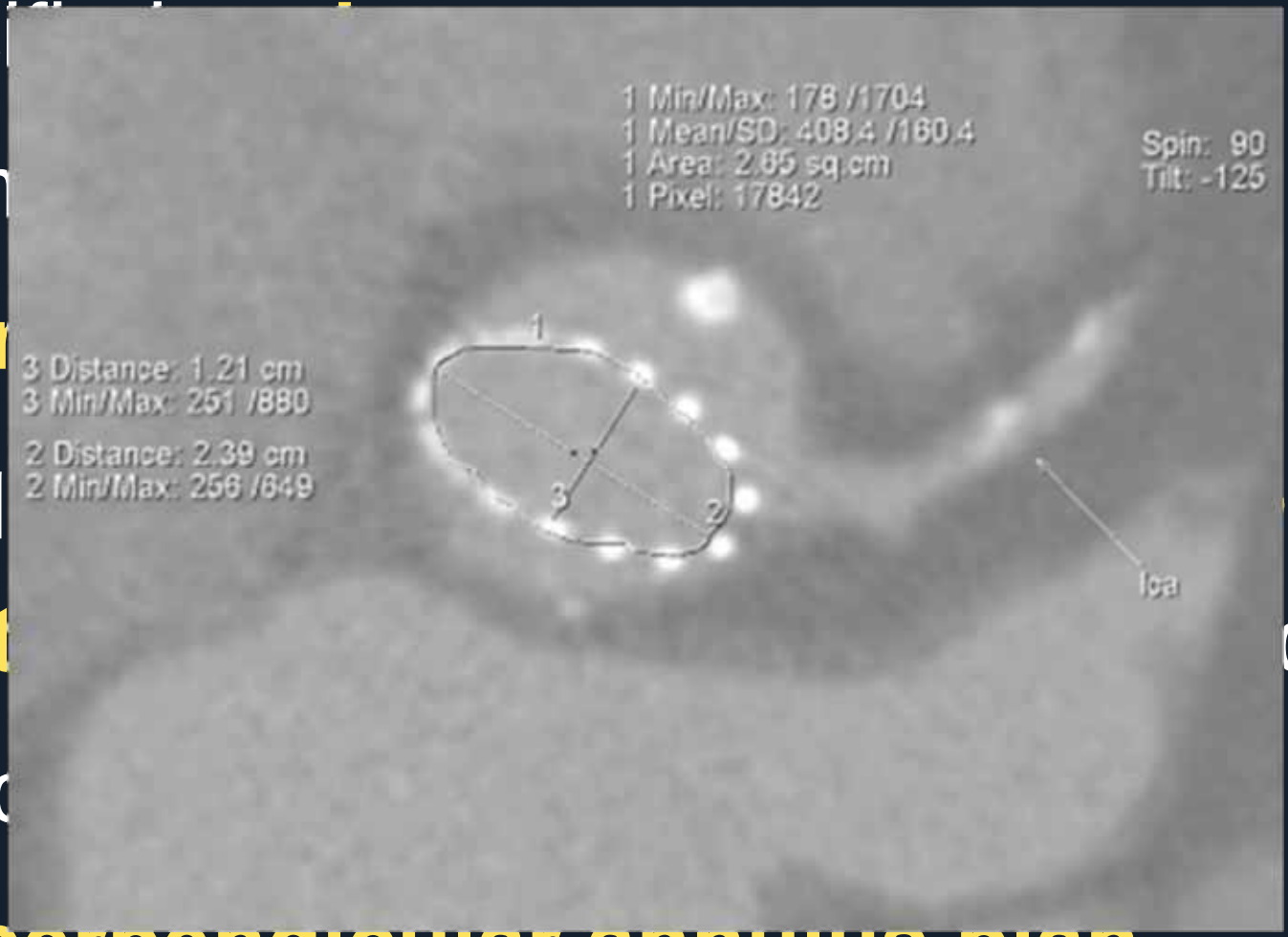
- PARTNER I (NCT00530894)
- Medtronic CoreValve® U.S. Pivotal Trial (NCT01240902)
- PARTNER II (NCT01314313)

Don’t Mention It

- NOTION (NCT01057173)
- SURTAVI (NCT01586910)

Procedural Challenges

- Calci
- Asyn
- **Asyr**
- Freq
- **Dilat** ding Ao
- Conc
- **No perpendicular annulus plan**



Sievers et al. J Thorac Cardiovasc Surg 2007;133:1226-33.

ESC/EACTS Guidelines

Relative contraindications

- ***Bicuspid*** or non-calcified valves
- Untreated CAD requiring revascularization
- Haemodynamic instability
- LVEF <20%
- For transapical approach:
  - Severe pulmonary disease
  - LV apex not accessible

European Heart Journal (2012) 33, 2451–2496

Observational Study in Selected Patients

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

Mylotte D. ACC 2014;Washington, DC

Kochman et al. Am J Cardiol. Epub

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%	57%
Body Mass Index	25	26	-	27	-
Diabetes mellitus	4.8%	37%	39%	29%	25%
Hypertension	57%	-	60%	67%	-
Ejection fraction, %	48%	50%	48%	50%	50%
eGFR < 60ml/min	57%	58%	43%	52%	50%
Logistic EuroSCORE	19.9	18	19	24	-
STS score	-	-	-	7.6	4.9

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Procedural and Clinical Outcome

	Hayashida (N=21)	Bauer (N=38)	Kochman (N=28)	Costopoulus (N = 21)	Mylotte (N=143)
Type of Valve					
CoreValve	**48%**	**68%**	**82%**	**62%**	**64%**
SAPIEN	52%	32%	18%	38%	36%
Bleeding (life threatening or major)	9.5%	-	11%	24%	7%
Major vascular complication	4.4%	-	0	10%	6.3%
Pacemaker implantation	14%	17%	29%	14%	23%
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%	4.9%
1-year mortality	-	13%	18%	32%	16%

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

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

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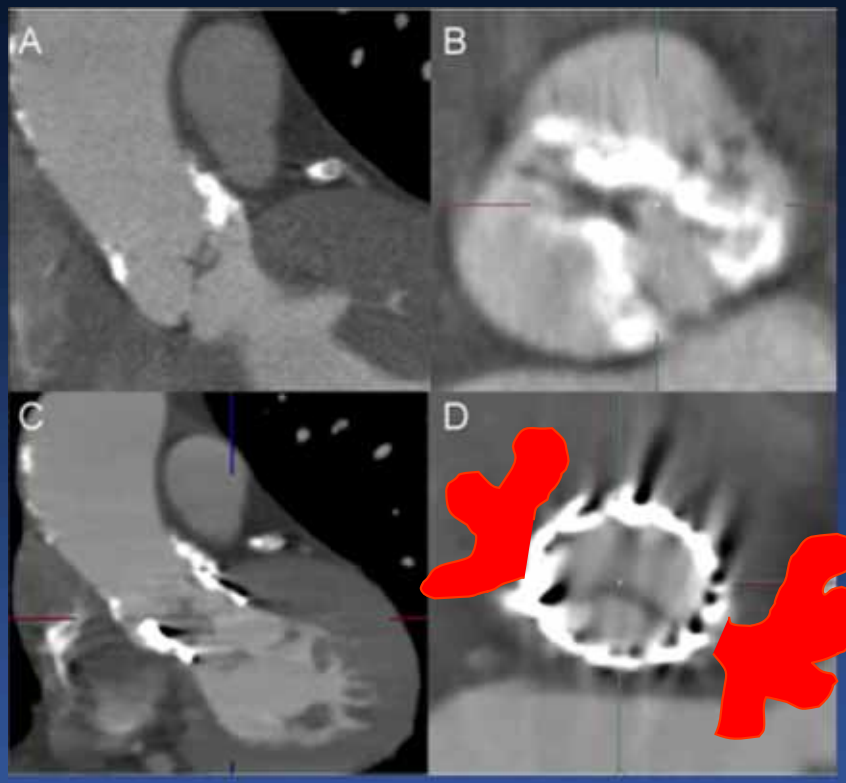
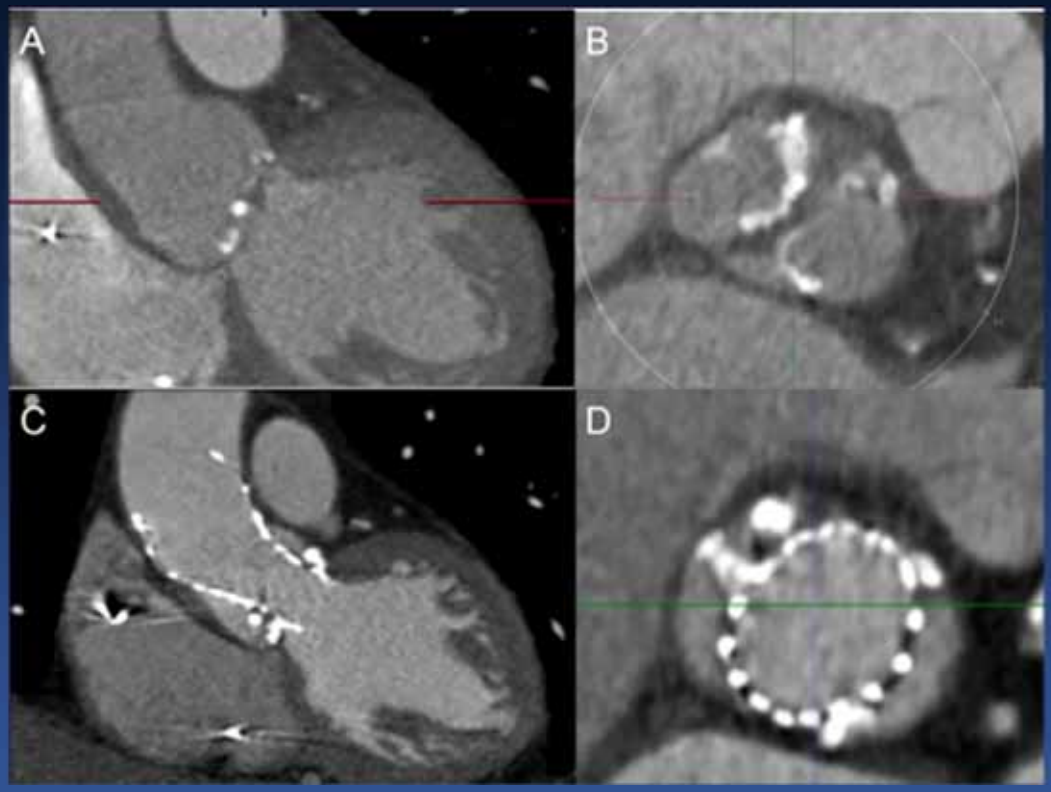
Which Valve?

Edwards



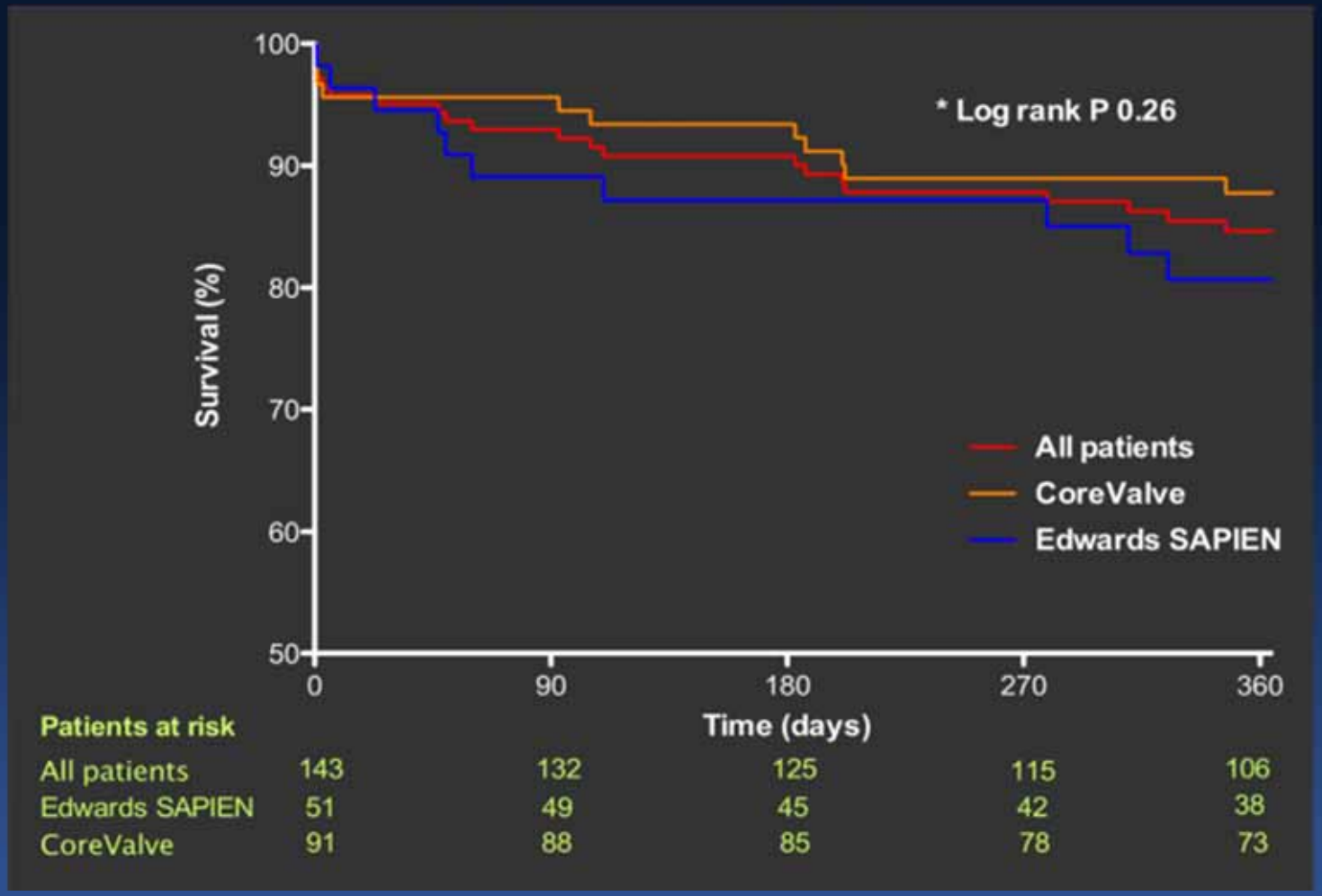
Round

CoreValve



Elliptical

Edwards VS. CoreValve



87.5%
84.1%
76.7%

1 Year Mortality:

CoreValve Implantation HR 0.35 (0.16-0.99), P=0.05

The TAV-in-BAV Group. ACC 2014;Washington, DC

Asian Multicenter Registry

Asan Medical Center
National University Singapore
Queen Elizabeth Hospital, Hong Kong

19 TAVIs for BAV in 202 TAVIs

Between 2011 and 2014

Baseline Characteristics

	Bicuspid (n = 19)	Tricuspid (n = 183)	P value
Age	76.7 ± 4.1	78.6 ± 6.1	0.17
Male	8 (42.1%)	84 (45.9%)	0.75
BMI, kg/m^2	22.2 ± 3.9	24.3 ± 3.4	0.08
STS score	2.9 ± 1.3	4.7 ± 3.4	< 0.001
Logistic EuroSCORE	18.0 ± 7.2	19.7 ± 9.1	0.34
Hypertension	8 (44.4%)	155 (84.7%)	< 0.001
Diabetes	2 (11.1%)	66 (36.1%)	< 0.009
eGFR, mL/min/1.73m^2	74.4 ± 22.6	61.7 ± 30.7	0.09

Echocardiographic Characteristics

	Bicuspid (n = 19)	Tricuspid (n = 183)	P value
Ejection fraction, %	56.5 ± 13.5	59.0 ± 9.6	0.32
Aortic valve area, cm^2	0.55 ± 0.15	0.66 ± 0.17	0.007
Indexed AVA, cm^2/m^2	0.33 ± 0.06	0.39 ± 0.11	0.051
Mean PG, mmHg	14.2 ± 5.6	12.3 ± 5.8	0.001
AR ≥ moderate	2 (11.8%)	30 (17.0%)	0.74
MR ≥ moderate	2 (10.5%)	24 (13.3%)	> 0.99
PH ≥ moderate	3 (15.8%)	28 (15.5%)	> 0.99

Baseline MDCT characteristics

	Bicuspid (n = 19)	Tricuspid (n = 115)	P value
Aortic Annulus Measurement			
Area, mm^2	502.2 ± 104.9	437.2 ± 77.7	0.004
Perimeter, mm	81.6 ± 8.2	76.1 ± 6.7	0.003
Maximum diameter, mm	28.3 ± 3.2	26.3 ± 2.7	0.004
Minimum diameter, mm	21.9 ± 2.8	20.8 ± 2.1	0.06
RCA height, mm	16.7 ± 4.4	15.0 ± 2.9	0.039
LCA height, mm	15.8 ± 3.0	13.3 ± 2.4	< 0.001
Calcium volume	984 ± 465	474 ± 302	< 0.001

Procedural variables

	Bicuspid (n = 19)	Tricuspid (n = 183)	P value
Type of valve			
Edward Sapien	0	96 (52.5%)	<0.001
Medtronic CoreValve	19 (100.0%)	87 (47.5%)	
Procedure time, min	116.6 ± 47.0	105.3 ± 40.2	0.30
Fluoroscopy time, min	33.1 ± 16.0	29.2 ± 15.9	0.37
Contrast volume, ml	315.4 ± 97.8	308.8 ± 116.5	0.82

30-day Outcomes

	Bicuspid (n = 19)	Tricuspid (n = 183)	P value
All-cause mortality	0	6 (3.3%)	> 0.99
Major Stroke	0	1 (0.5%)	> 0.99
Major Vascular Complication	0	6 (3.3%)	> 0.99
Post AR ≥ Mild	15 (83.3%)	75 (42.9%)	0.001
Post AR ≥ Moderate	3 (16.7%)	18 (10.3%)	0.42
Permanent Pacemaker *	3 (15.8%)	21 (24.4%)	0.55
More than 2 valves used *	3 (15.8%)	12 (14.0%)	> 0.99
Device Success	12 (63.2%)	154 (84.2%)	0.05

* in CoreValve group

1-year Outcomes

	Bicuspid (n = 19)	Tricuspid (n = 183)	P value
Mortality			
All-cause	3 (15.8%)	16 (9.9%)	0.38
Cardiovascular	2 (10.8%)	13 (7.9%)	0.66
Rehospitalization	1 (10.0%)	8 (6.5%)	0.96

1-year All-Cause Mortality for BAV Patients was 13.0% [1], 15.9% [2] and 32% [3].

[1] Bauer T et al. Am J Cardiol. 2014 ;113:518-21
[2] Mylotte D. ACC 2014;Washington, DC
[3] Costopoulos C et al. Am J Cardiol. 2014 ;113:1390-1393

Conclusion

- Despite large size of annulus and severely calcified valves, the incidence of complications and early outcomes of TAVI in Bicuspid AV were acceptable.
- However, the issues about suitable device and long-term clinical outcomes should be addressed in future studies.