Balloon-expandable vs. Self-expandable TAVR for Bicuspid Aortic Valves: When and How?

James D. Flaherty, MD
Bluhm Cardiovascular Institute
Feinberg School of Medicine, Northwestern University
Chicago, Illinois U.S.A.

Disclosure

- None

TAVR and Bicuspid Aortic Valves

- Can TAVR be done safely and effectively in BAV patients?
- What are the unique features of BAV patients for TAVR?
- When is Surgical AVR preferable to TAVR in BAV patients?
- Balloon-expandable or Self-expandable TAVR valve in BAV patients?

About Bicuspid Aortic Valve

- Most common congenital heart defect
- Prevalence is 0.5% to 2.0%
- More common in males

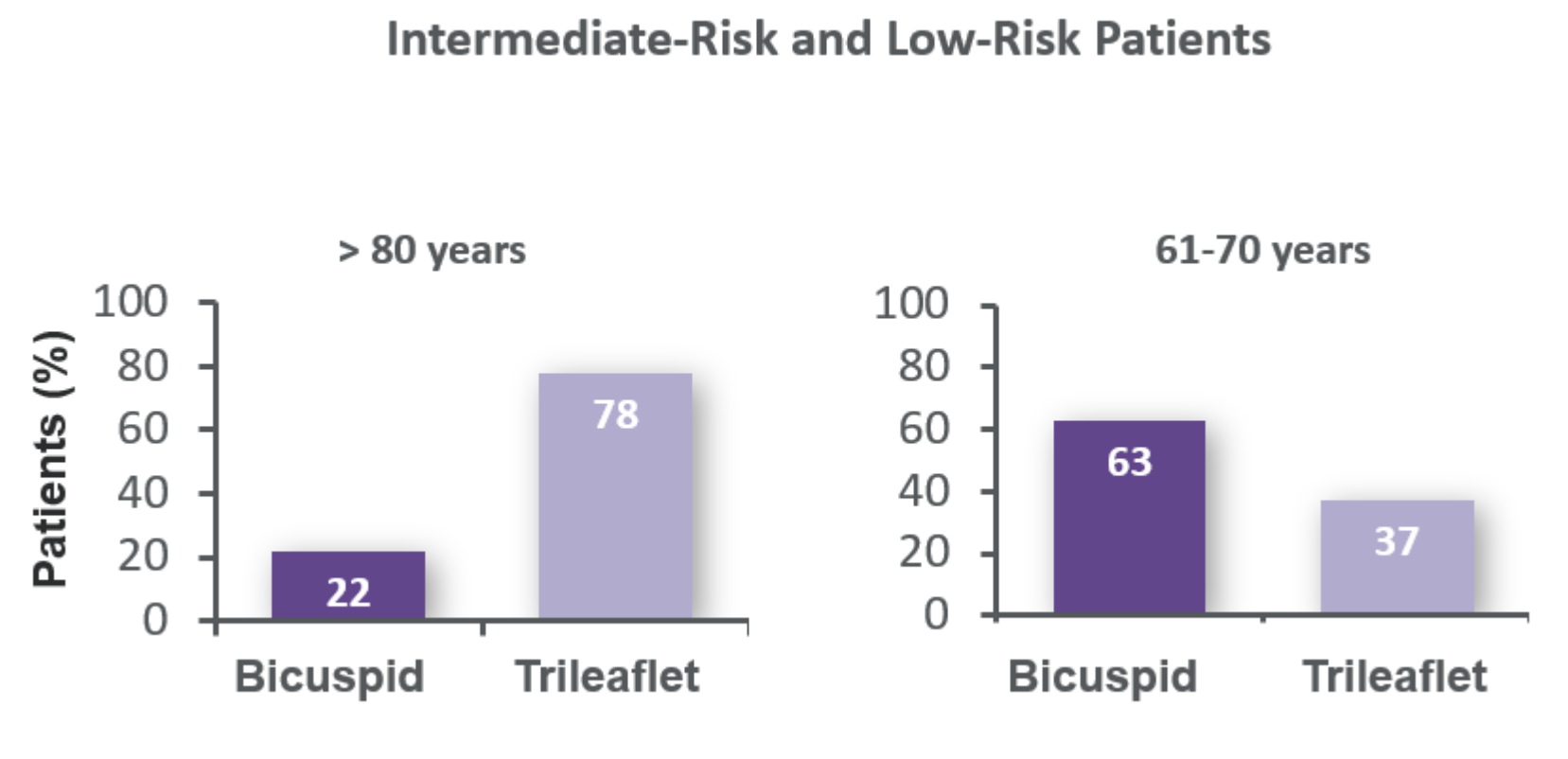
- Up to 50% of patients with BAV have dilated aortic root or ascending aorta
- Up to 20% of patients over age 80 years have evidence of bicuspid valvular anatomy (either congenital or due to fusion of degenerated leaflets)

- About 5% of patients evaluated for TAVR have BAV anatomy

Praz F, et al. JACC Interventions 2015; 8: 1777-96.

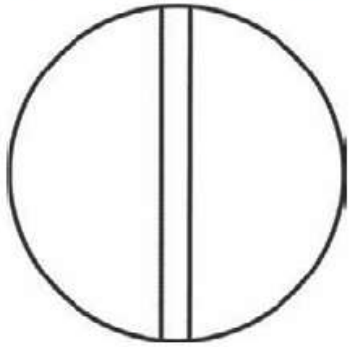
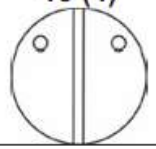
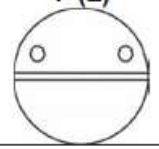
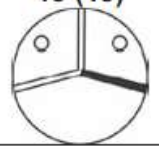
Bicuspid vs. Trileaflet Aortic Stenosis

Baylor University, 923 operatively excised stenotic aortic valves



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

BAV Phenotypes

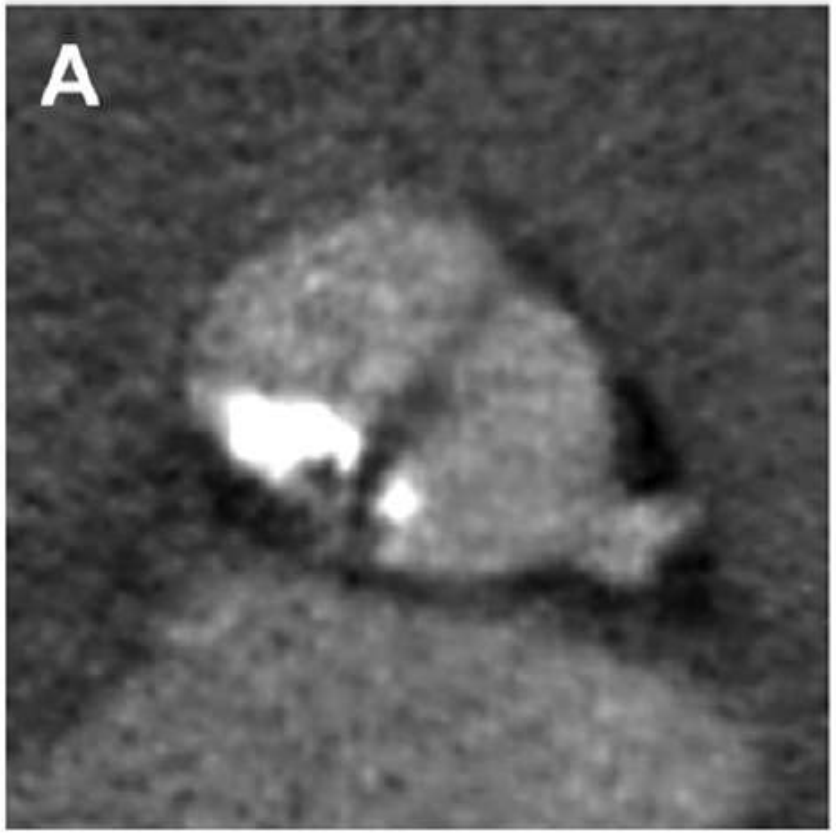
main category: number of raphes	0 raphe - Type 0		1 raphe - Type 1			2 raphes - Type 2
						
	21 (7)		269 (88)			14 (5)
1. subcategory: spatial position of cusps in Type 0 and raphes in Types 1 and 2	lat 13 (4) 	ap 7 (2) 	L – R 216 (71) 	R – N 45 (15) 	N – L 8 (3) 	L – R / R – N 14 (5) 
2. subcategory:						
VALVULAR FUNCTION I	6 (2)	1 (0.3)	79 (26)	22 (7)	3 (1)	6 (2)
VALVULAR FUNCTION S	7 (2)	5 (2)	119 (39)	15 (5)	3 (1)	6 (2)
VALVULAR FUNCTION B (I + S)		1 (0.3)	15 (5)	7 (2)	2 (1)	2 (1)
VALVULAR FUNCTION No			3 (1)	1 (0.3)		

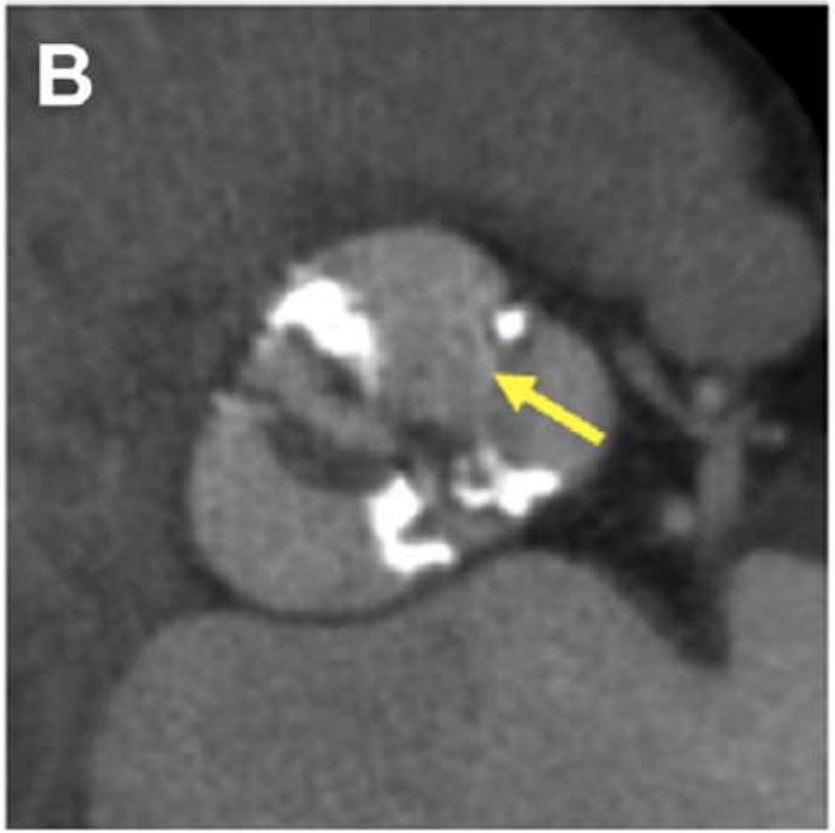
Sievers HH and Schmidtke C. JTCS 2007;133:1226-33.

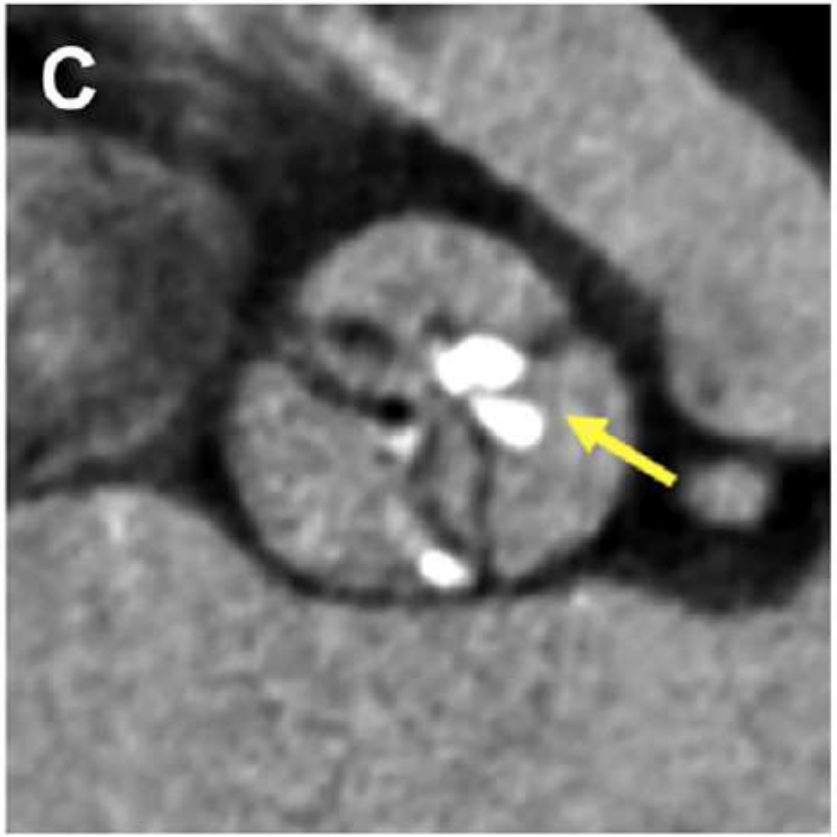
Sievers Type 0 BAV

Sievers Type 1 BAV

Tricuspid valve with fusion



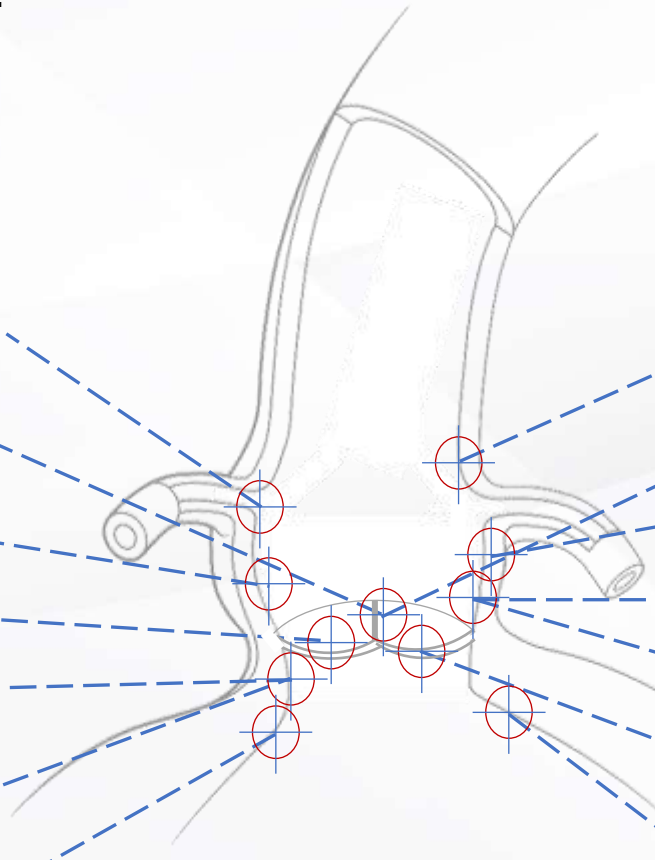




BAV and TAVR – Anatomical Considerations

Are there unfavorable anatomical features on CT?

Will calcium density and location allow for proper THV expansion?



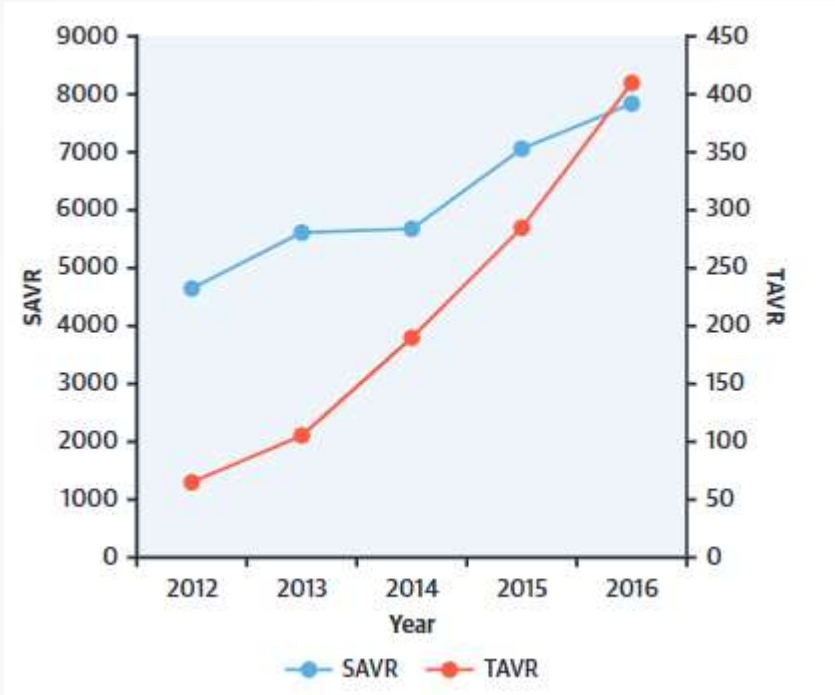
- Coronary height/leaflet interaction
- Raphe/commissure length
- SOV/THV fit, given annular measurement
- Valve morphology
- Annular size and future valve in valve potential
- Risk for annular dissection
- LVOT septal bulge
- Risk associated with aortopathy
- Extent of raphe calcification
- Risk for aortic root dissection
- Dimension/angulation of the aortic root
- SOV calcification
- Extent of commissure calcification
- Extent of LVOT calcification

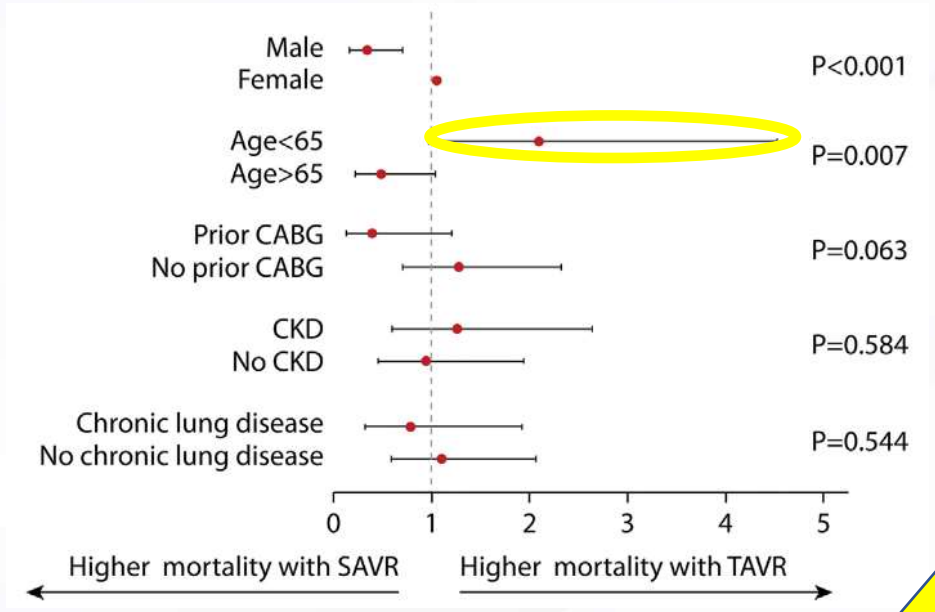
Can TAVR be done safely and effectively in BAV patients?

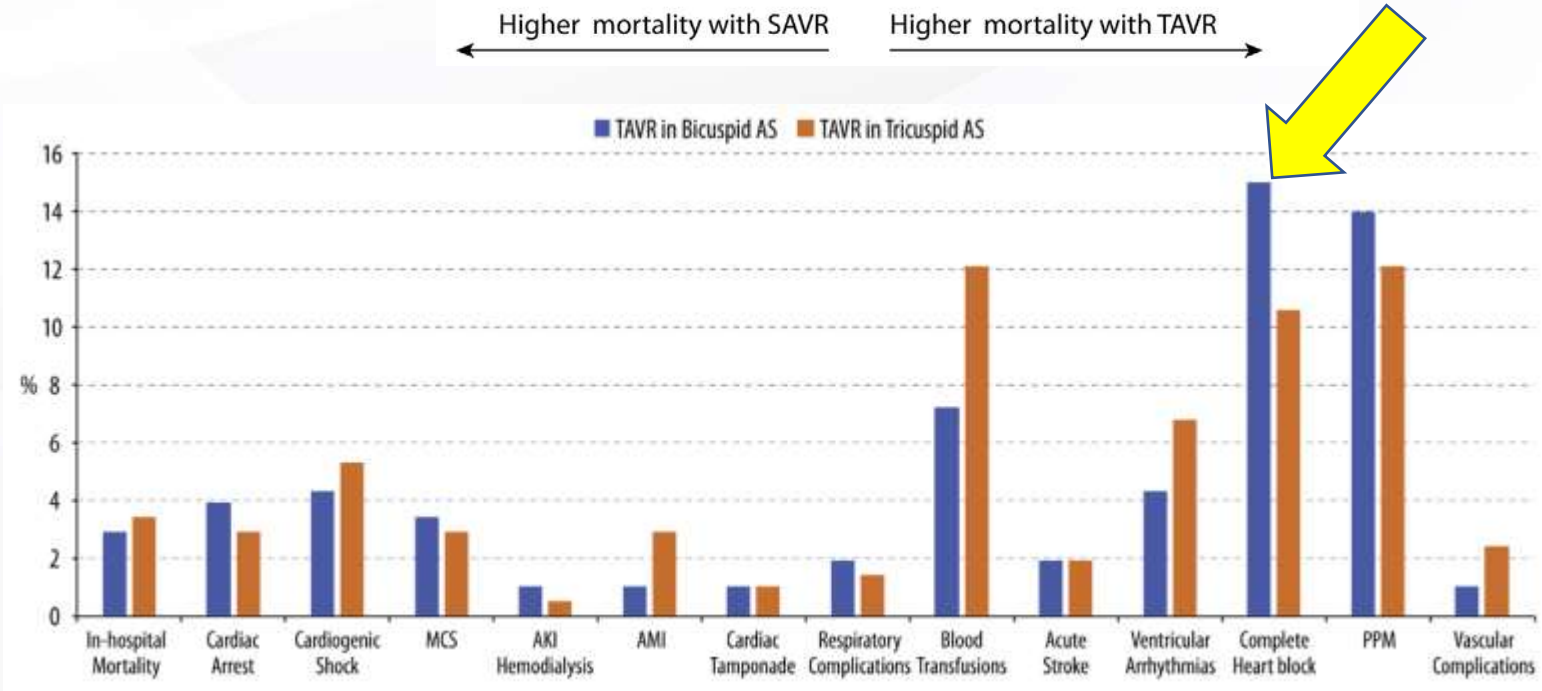
- Is SAVR better than TAVR in BAV patients?
- Pivotal RCT’s excluded BAV patients
- Limited to observational and registry data
- Early TAVR results in BAV may not reflect current practice

Temporal Trends and Outcomes of Transcatheter Versus Surgical Aortic Valve Replacement for Bicuspid Aortic Valve Stenosis

2012-16 Propensity matched n=975 each group



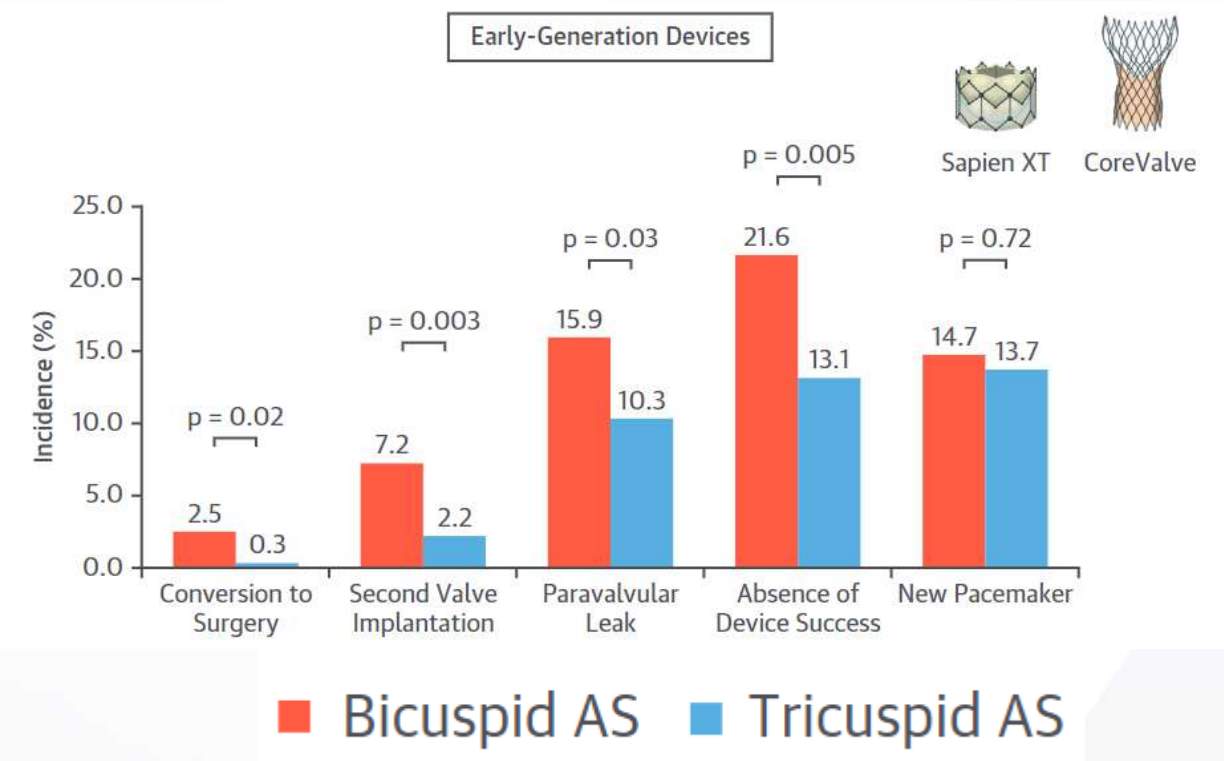




Elbadawi, et al. JACC Interventions 2019; 12: 1811-22.

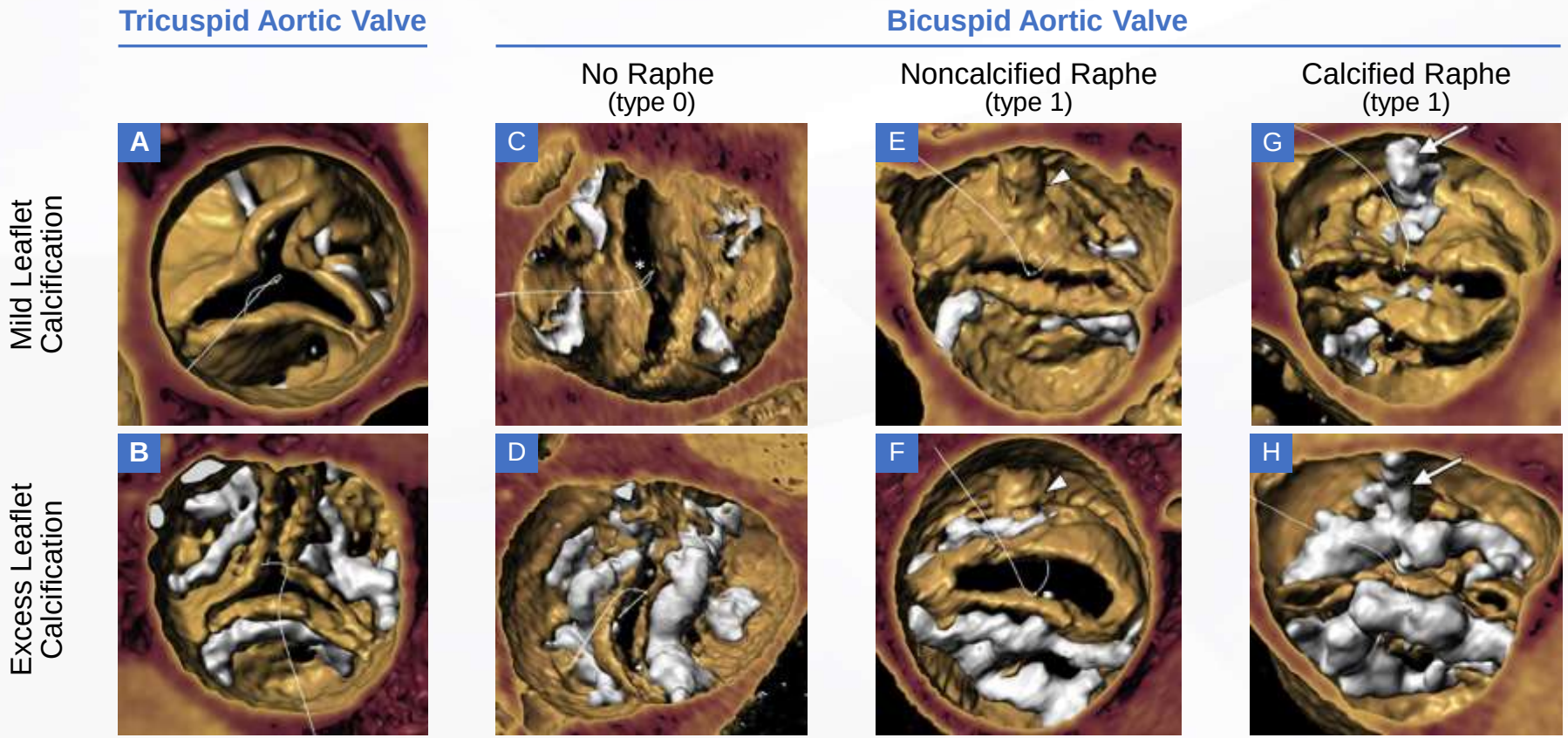
Can TAVR be done safely and effectively in BAV patients?

- The early TAVR experience in BAV:
  - More Annular Injury
    - ↑ Conversions to surgery
  - More Paravalvular leak
    - ↑ 2nd Valve implants
  - More Pacemakers
  - ? Increased Stroke Risk



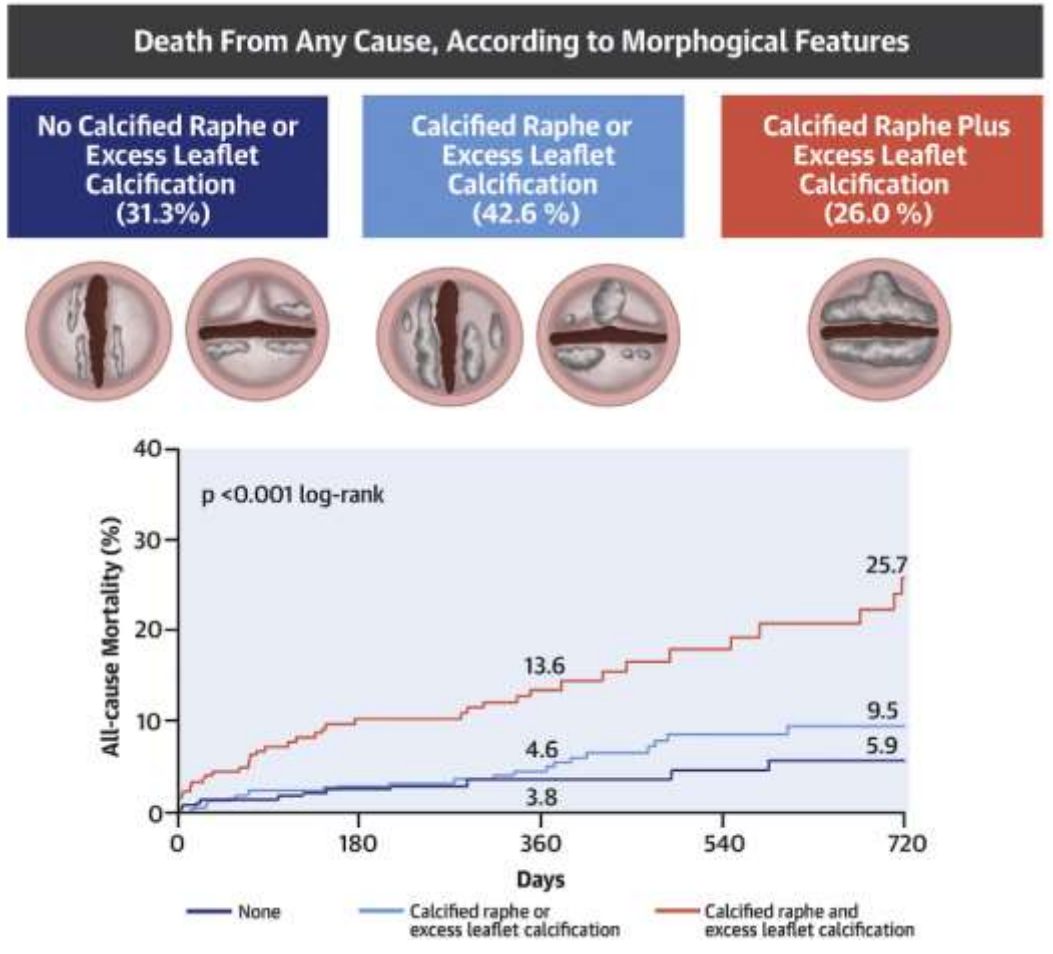
Yoon S-H, et al. *J Am Coll Cardiol* 2017; 69: 2579-89.

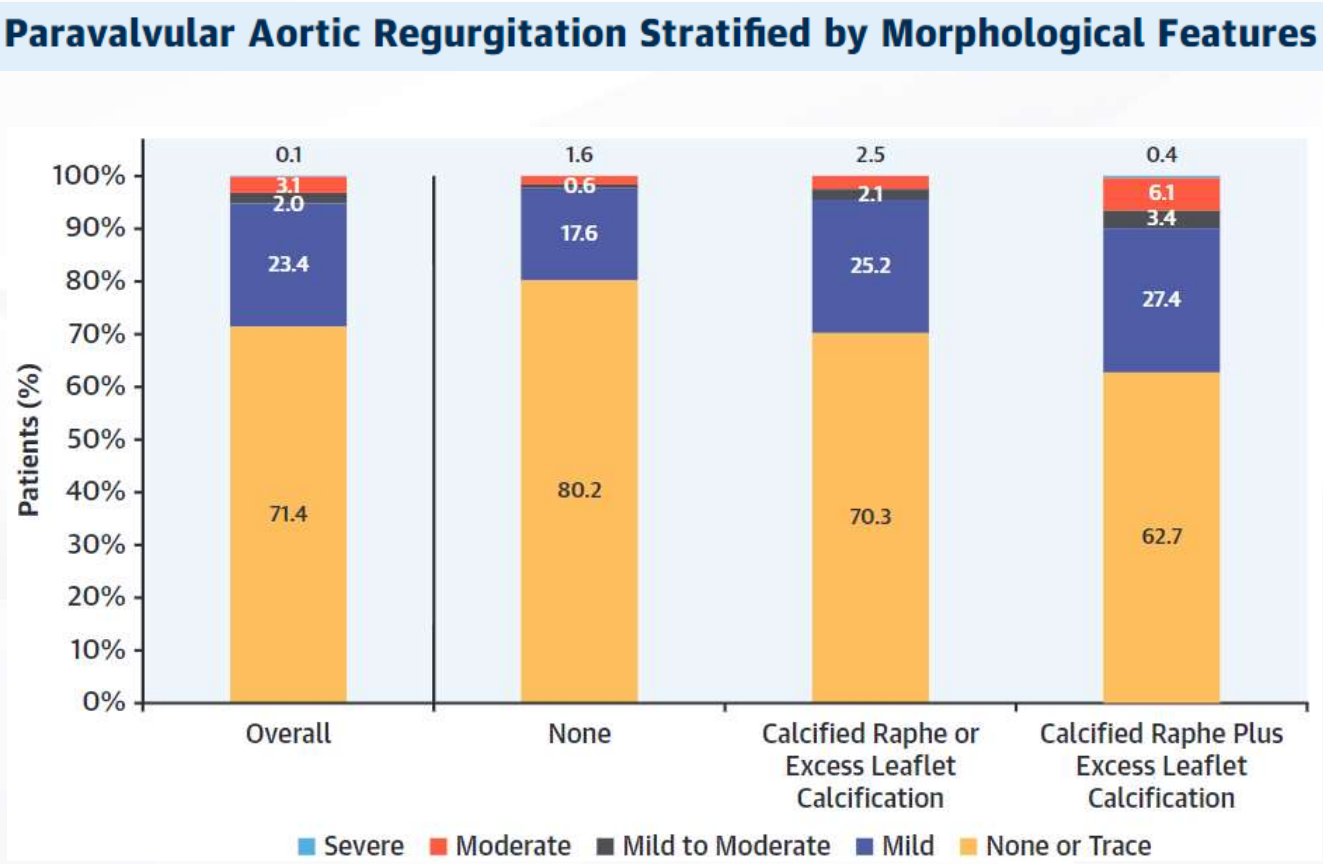
Bicuspid Aortic Valve Morphology and Outcomes After Transcatheter Aortic Valve Replacement



Yoon S-H, et al. *J Am Coll Cardiol*. 2020;76(9):1018-1030.

Bicuspid Aortic Valve Morphology and Outcomes After Transcatheter Aortic Valve Replacement

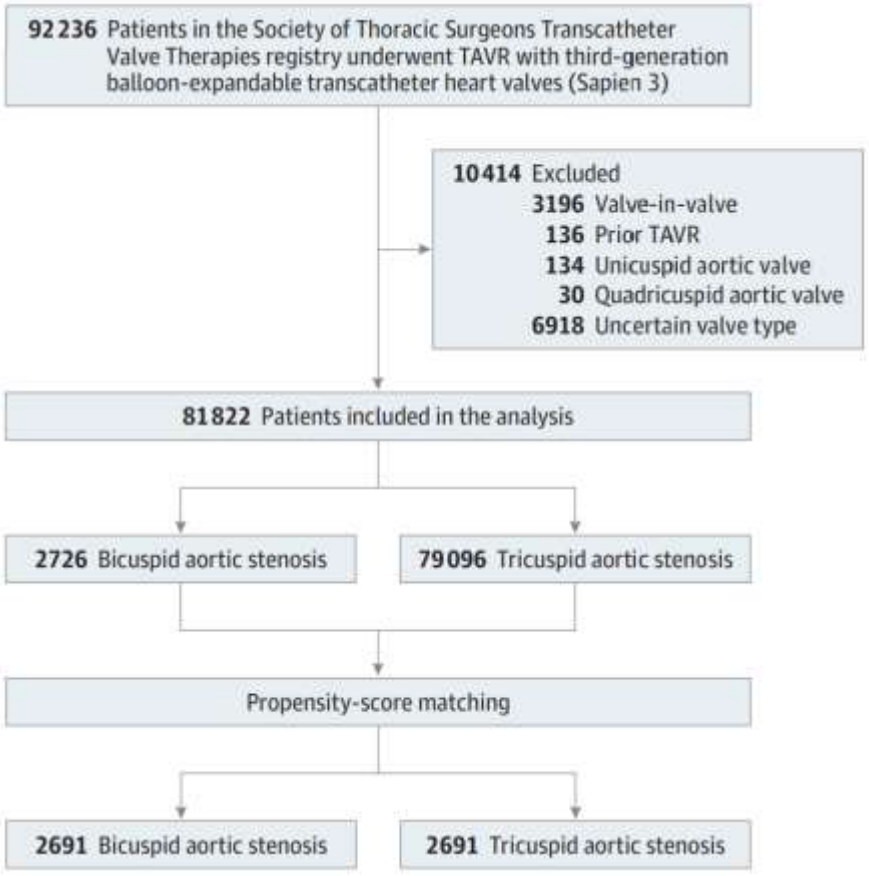




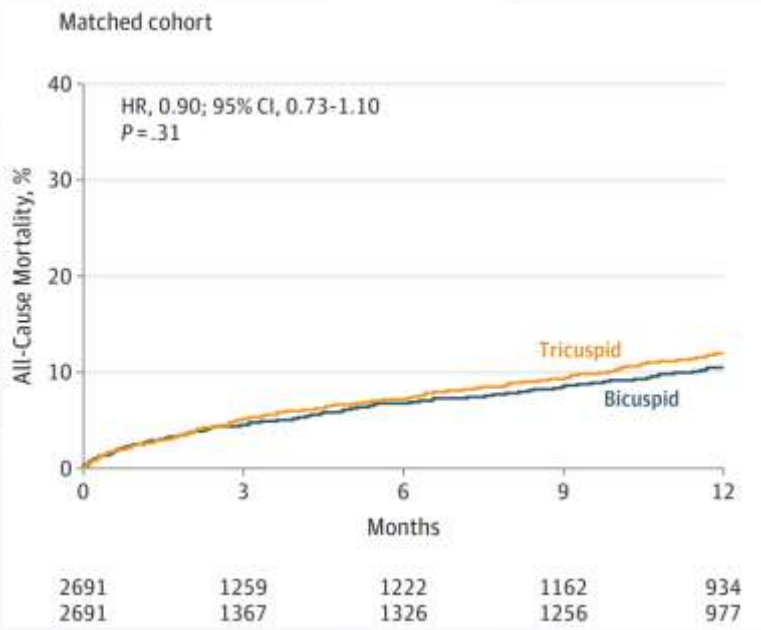
Yoon S-H, et al. *J Am Coll Cardiol*. 2020;76(9):1018-1030.

JAMA | Preliminary Communication

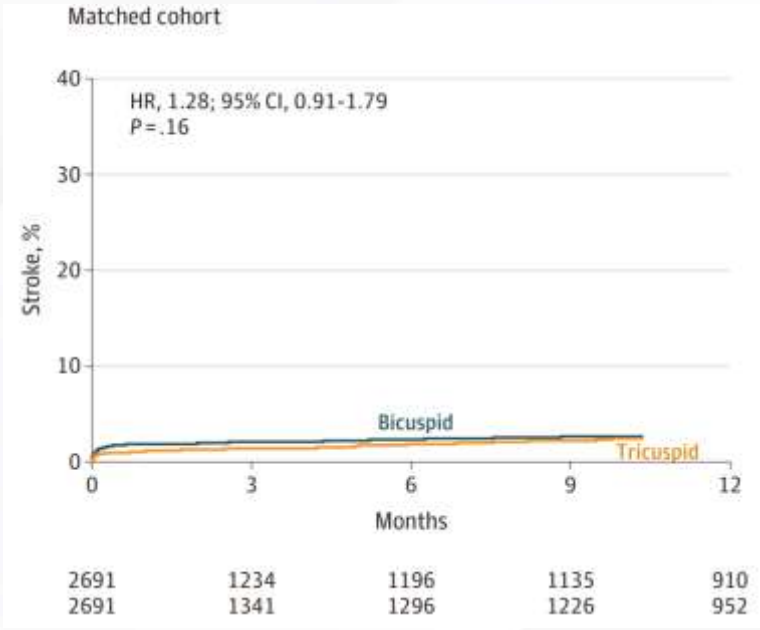
Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid Aortic Stenosis and Mortality or Stroke



All-cause mortality



Stroke



Makkar RR, et al. *JAMA* 2019; 321: 2193-2202.

JAMA | Preliminary Communication

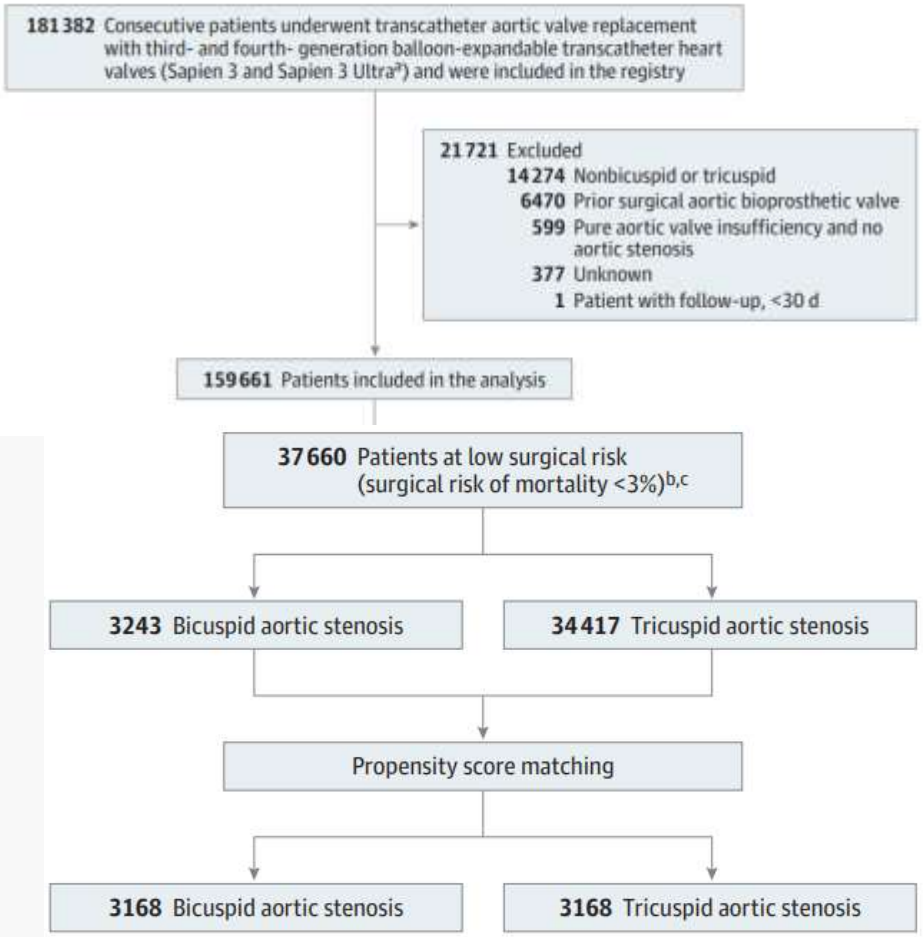
Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid Aortic Stenosis and Mortality or Stroke

	No. (%) of Patients With Aortic Valve Stenosis				
	Bicuspid (n = 2691)	Tricuspid (n = 2691)	Absolute Difference (95% CI), %	Hazard Ratio (95% CI)	Log-Rank *P* Value
Primary Outcomes					
At 30 d					
Mortality	66 (2.6)	63 (2.5)	0.09 (0.08-0.1)	1.04 (0.74-1.47)	.82
Stroke	64 (2.5)	41 (1.6)	0.89 (0.88-0.90)	1.57 (1.06-2.33)	.02
At 1 y					
Mortality	171 (10.5)	200 (12.0)	1.48 (1.45-1.50)	0.90 (0.73-1.10)	.31
Stroke	76 (3.4)	61 (3.1)	0.34 (0.32-0.35)	1.28 (0.91-1.79)	.16

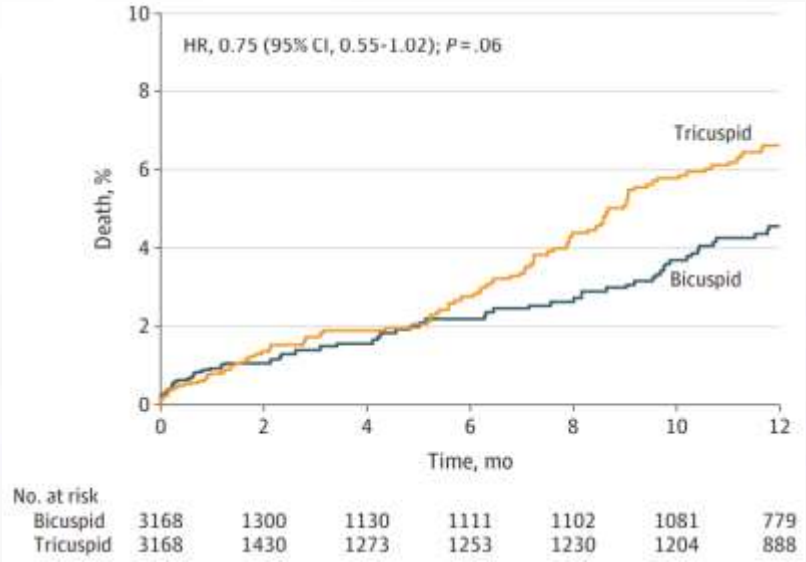
Makkar RR, et al. *JAMA* 2019; 321: 2193-2202.

JAMA | Original Investigation

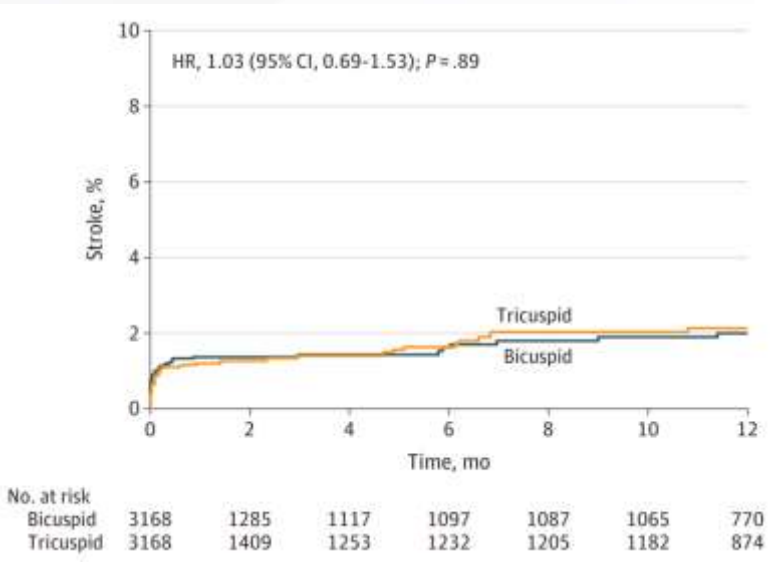
Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid Aortic Stenosis and Mortality or Stroke Among Patients at Low Surgical Risk



All-cause mortality



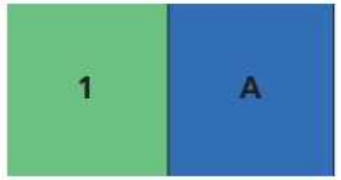
Stroke



Makkar RR, et al. *JAMA* 2021; 326: 1034-1044.

When is Surgical AVR preferable to TAVR in BAV patients?

- Presence of significant aortic aneurysm
  - ≥ 4.5 cm
- Younger patients
  - ? <65 years old
    - Very young (<50 years old) – consider mechanical valve
  - Those who will not have a good TAV-in-TAV option



For symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended.[1–3]

- Predominant Valve Pathology is Aortic Regurgitation
  - Unless there is significant calcium to allow for TAVR valve anchoring

- High procedural risk
  - Severe LVOT calcium
  - Unfavorable valve morphology – bulky/asymmetrical calcium (fused raphe)

JAMA Cardiology | Original Investigation

Transcatheter Aortic Valve Replacement in Low-risk Patients With Bicuspid Aortic Valve Stenosis

150 patients enrolled (out of 222)

Mean age 70.3 years

48.0% Female

90.7% Sievers type I

STS score 1.4%

Forrest JK, et al. *JAMA Cardiol*. 2021;6:50-57.

JACC: Cardiovascular Interventions

The PARTNER 3 Bicuspid Registry for Transcatheter Aortic Valve Replacement in Low-Surgical-Risk Patients

169 patients enrolled (out of 320)

Mean age 71.0 years

45% Female

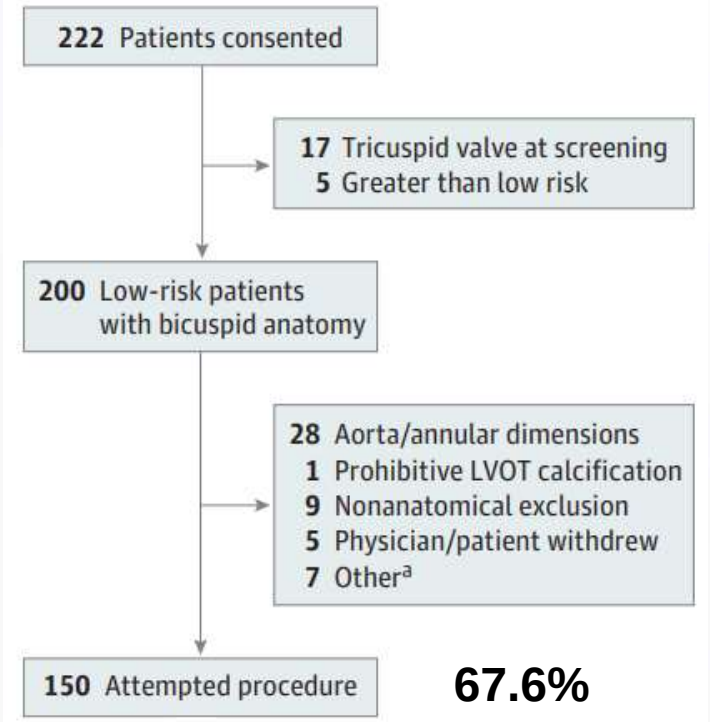
85.8% Sievers type I

STS score 1.4%

Williams MR, et al. *JACC Intv*. 2022;15:523-532.

JAMA Cardiology | Original Investigation

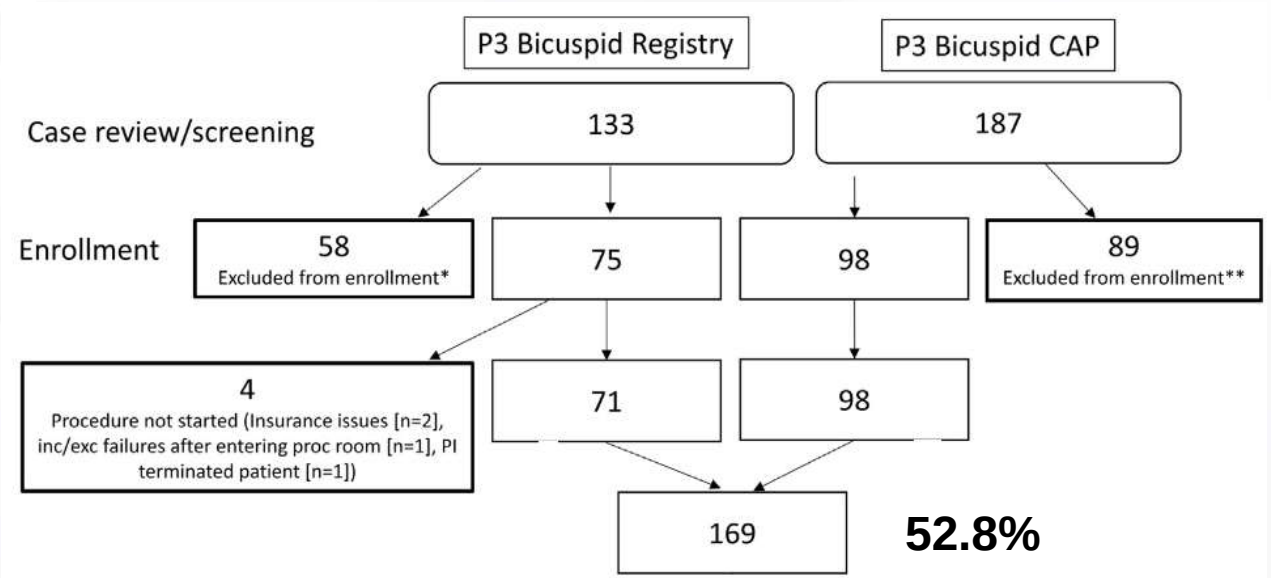
Transcatheter Aortic Valve Replacement in Low-risk Patients With Bicuspid Aortic Valve Stenosis



Forrest JK, et al. *JAMA Cardiol*. 2021;6:50-57.

JACC: Cardiovascular Interventions

The PARTNER 3 Bicuspid Registry for Transcatheter Aortic Valve Replacement in Low-Surgical-Risk Patients



Williams MR, et al. *JACC Intv*. 2022;15:523-532.

JAMA Cardiology | Original Investigation

Transcatheter Aortic Valve Replacement in Low-risk Patients With Bicuspid Aortic Valve Stenosis

30 Day Outcomes

Death		0.7%
Stroke		4.0%
Pacemaker		15.1%
Conversion		0.7%
AI	None/Trace	60.4%
	Mild	39.6%
	>Mild	0.0%

Forrest JK, et al. *JAMA Cardiol*. 2021;6:50-57.

JACC: Cardiovascular Interventions

The PARTNER 3 Bicuspid Registry for Transcatheter Aortic Valve Replacement in Low-Surgical-Risk Patients

30 Day Outcomes

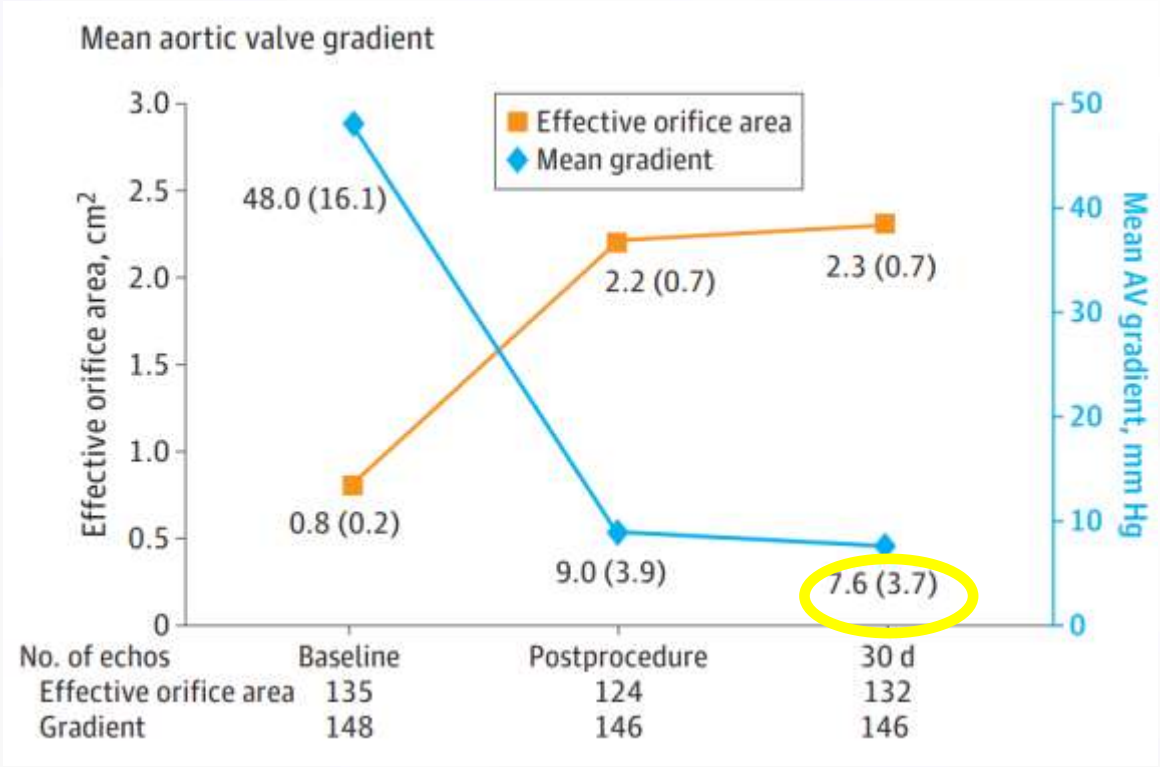
Death		0.0%
Stroke		1.2%
Pacemaker		6.5%
Conversion		0.0%
AI	None/Trace	71.8%
	Mild	26.3%
	>Mild	1.9%

Williams MR, et al. *JACC Intv*. 2022;15:523-532.

JAMA Cardiology | Original Investigation

Transcatheter Aortic Valve Replacement in Low-risk Patients With Bicuspid Aortic Valve Stenosis

Through 30 Days

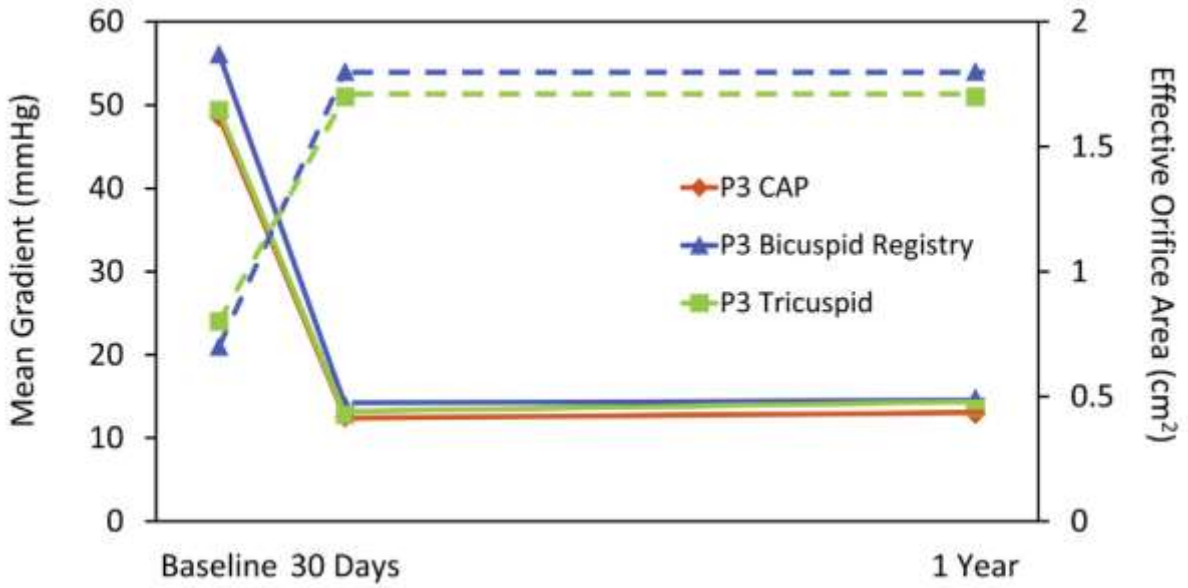


Forrest JK, et al. *JAMA Cardiol*. 2021;6:50-57.

JACC: Cardiovascular Interventions

The PARTNER 3 Bicuspid Registry for Transcatheter Aortic Valve Replacement in Low-Surgical-Risk Patients

Through 1 year



Williams MR, et al. *JACC Intv*. 2022;15:523-532.

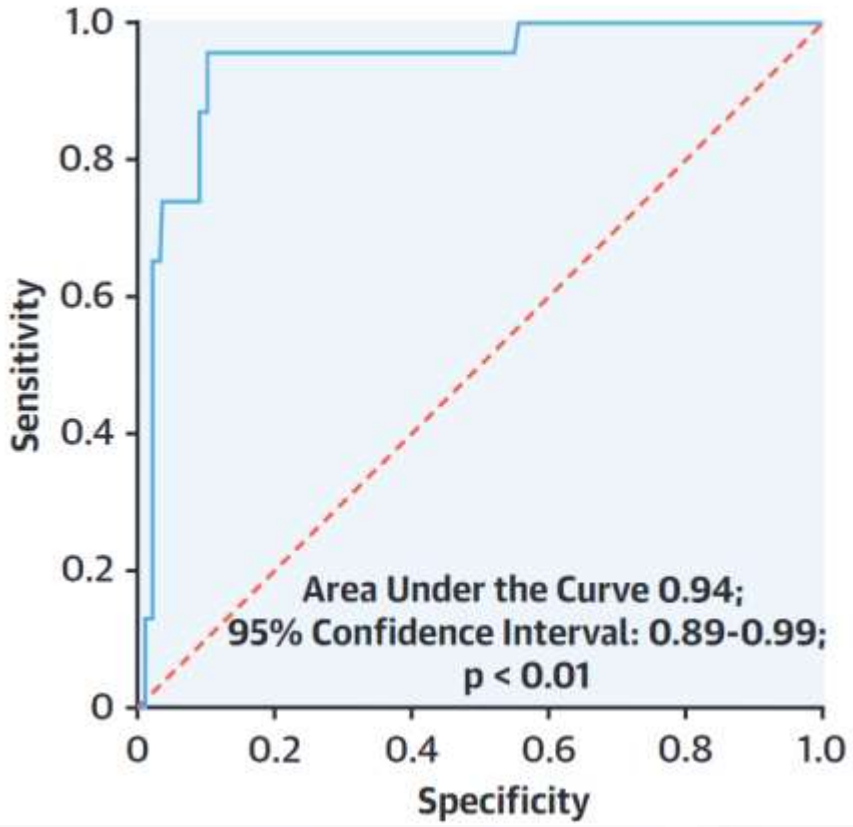
Other Considerations: TAVR in BAV (especially younger patients)

- Risk of Heart Block / need for Pacemaker
- Coronary Artery (Re)Access
- Continued Aortic Surveillance
- Lifetime Management – What is the next valve plan?
  - SAVR after TAVR
  - TAV-in-TAV
  - Valve-in-Valve TAVR

Coronary Cannulation After Transcatheter Aortic Valve Replacement

The RE-ACCESS Study

Predictors of Unsuccessful Coronary Cannulation After Transcatheter Aortic Valve Replacement and Receiver-Operating Characteristic Curve Analysis Applied to Logistic Regression Model



Transcatheter Aortic Valve/ Sinuses of Valsalva Relation
Odds Ratio 1.1;
95% CI: 1.0-1.2; p < 0.01

Transcatheter Aortic Valve Implant Depth
Odds Ratio 1.7;
95% CI: 1.3-2.3; p < 0.01

Evolut Transcatheter Aortic Valve
Odds Ratio 29.6;
95% CI: 2.6-335.0; p < 0.01

Barbanti M, et al. *JACC Invt* 2020;13:2542-55.

Surgical Explantation After TAVR Failure

Mid-Term Outcomes From the EXPLANT-TAVR International Registry

269 patients

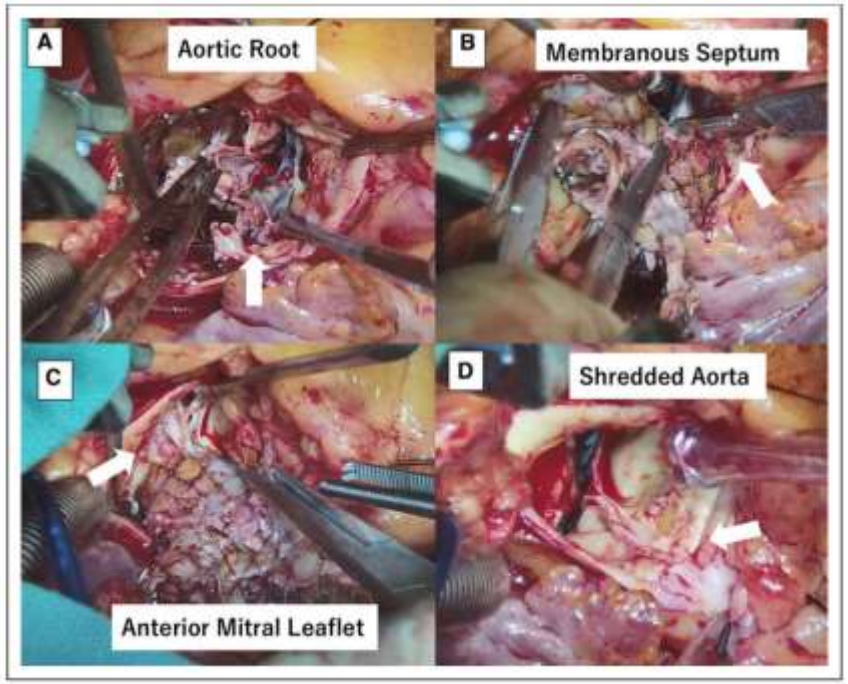
Mean age 72.7 ± 10.4 years

Mean time to failure 11.5 mo

STS score 3.2% at TAVR

STS score 5.0% at explant

11.9% in-hospital mortality



Short- and Mid-Term Outcomes After Transcatheter Aortic Valve Replacement Explantation (N = 269)

Follow-up (mo) post explantation	14.6 ± 20.7
30 d	
Mortality	34 (13.1)
Stroke	18 (8.6)
Readmission	28 (13.7)
Follow-up complete	259 (97.7)
1 y	
Mortality	53 (28.5)
Stroke	23 (18.7)
Follow-up complete	186 (86.1)

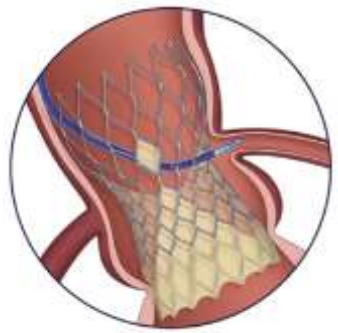
Bapat VN, et al. *JACC Int* 2021;14:1978-1991.

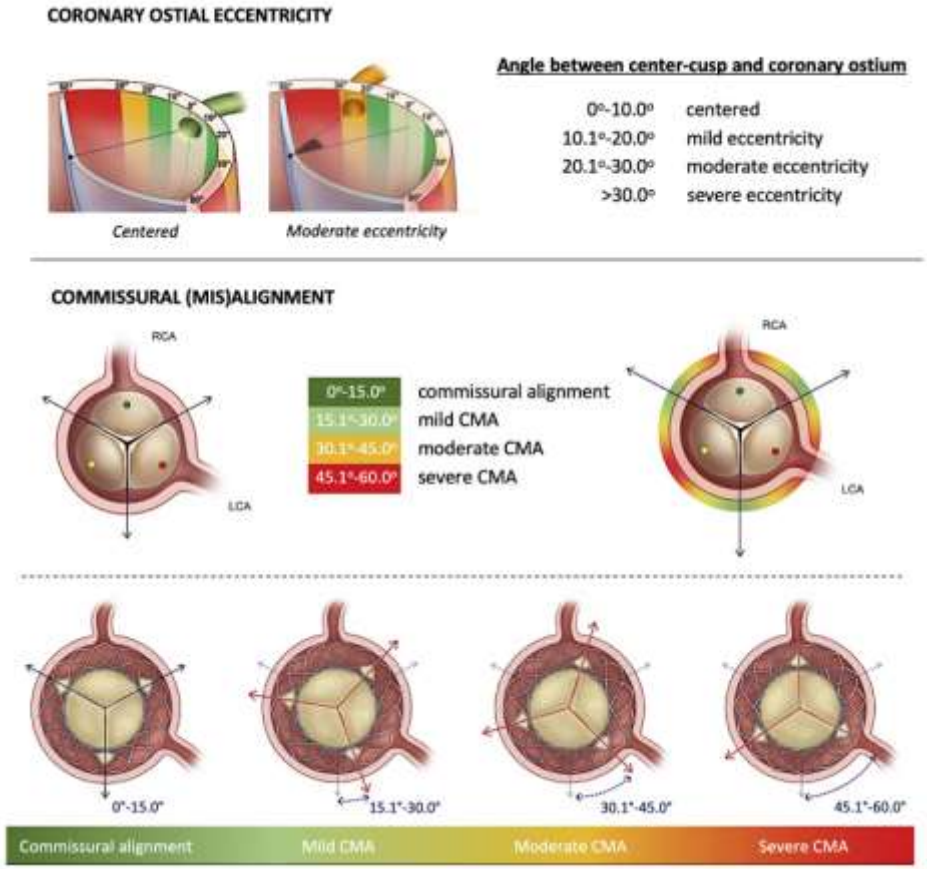
Brescia BA, et al. *Cirv CV Invt* 2021;14:e009927.

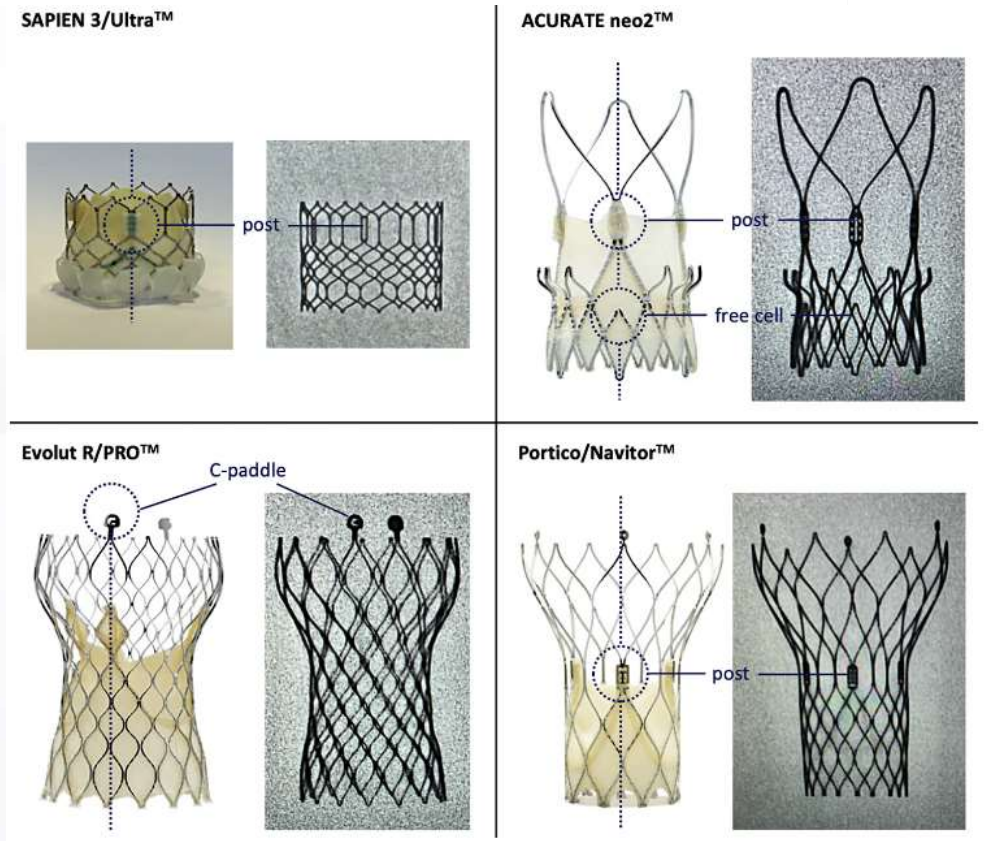
Rationale, Definitions, Techniques, and Outcomes of Commissural Alignment in TAVR

From the ALIGN-TAVR Consortium

- Commissural alignment impacts coronary access, THV hemodynamics, and the feasibility of redo-TAVR.



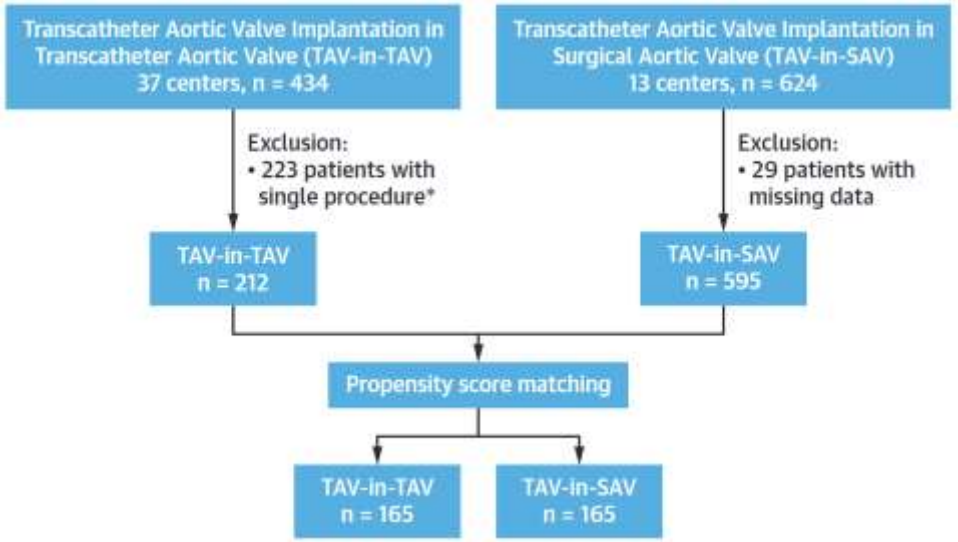


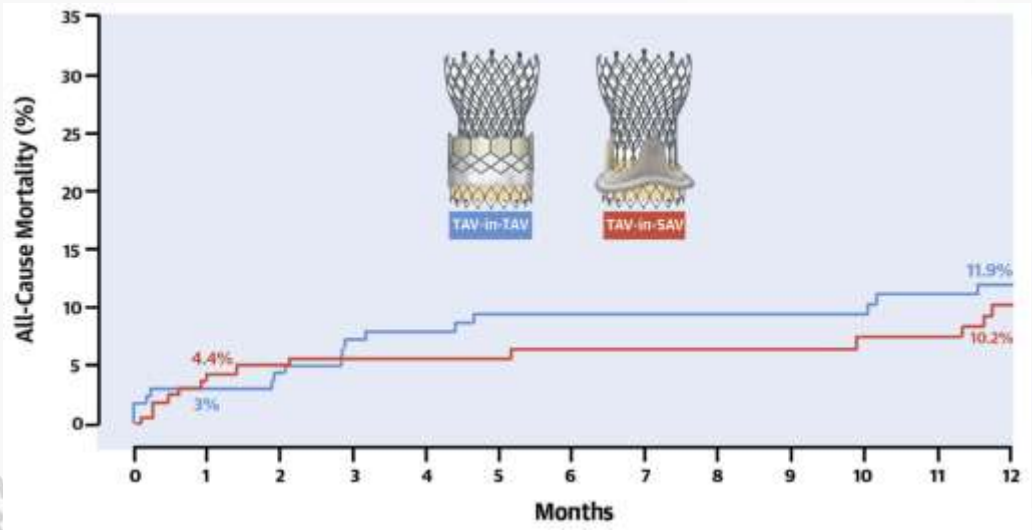


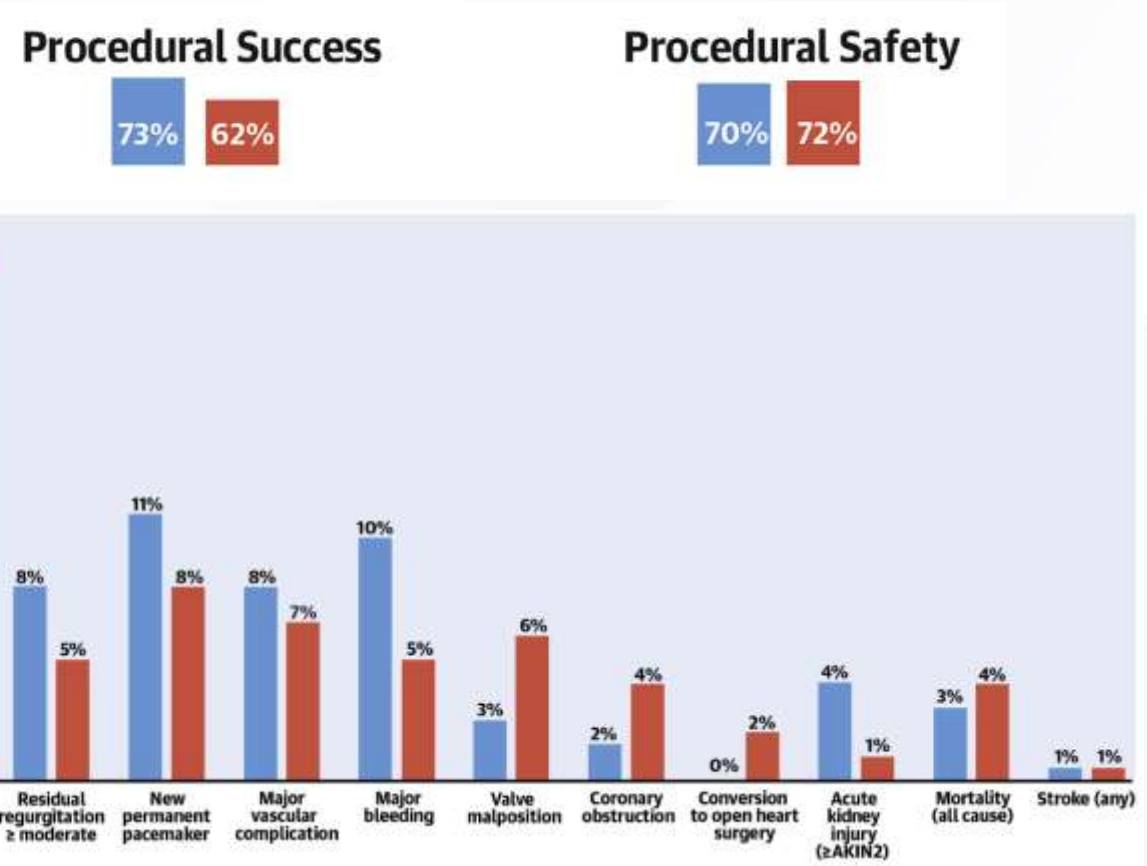
Gilbert HL, et al. *JACC Invt* 2022;15:1497-1518.

Transcatheter Replacement of Transcatheter Versus Surgically Implanted Aortic Valve Bioprostheses

Redo-TAVR international registry

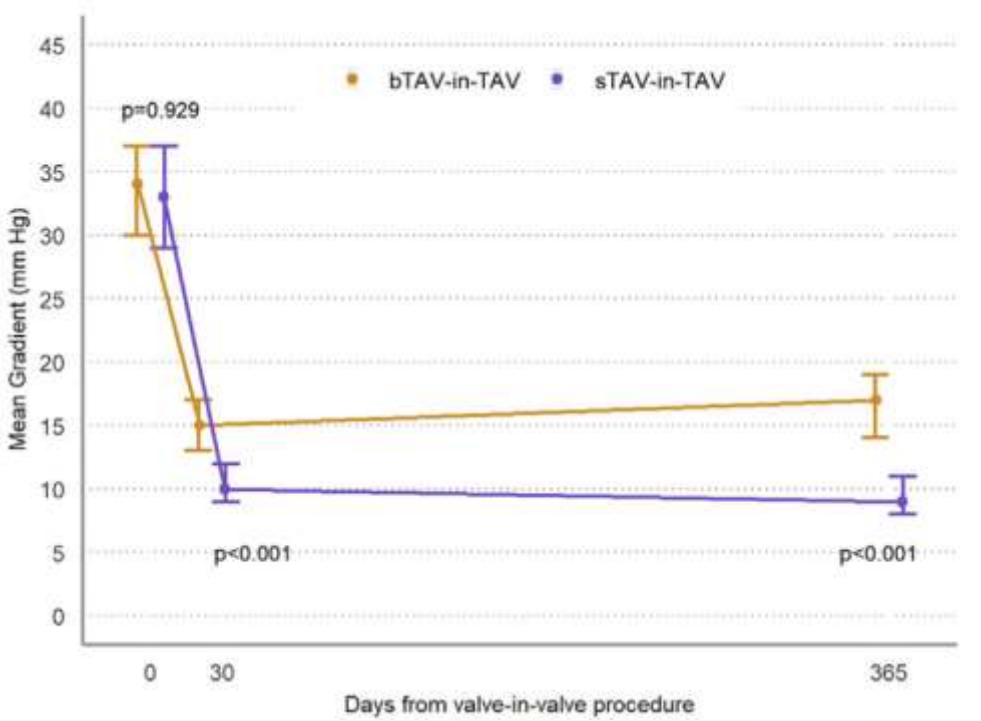


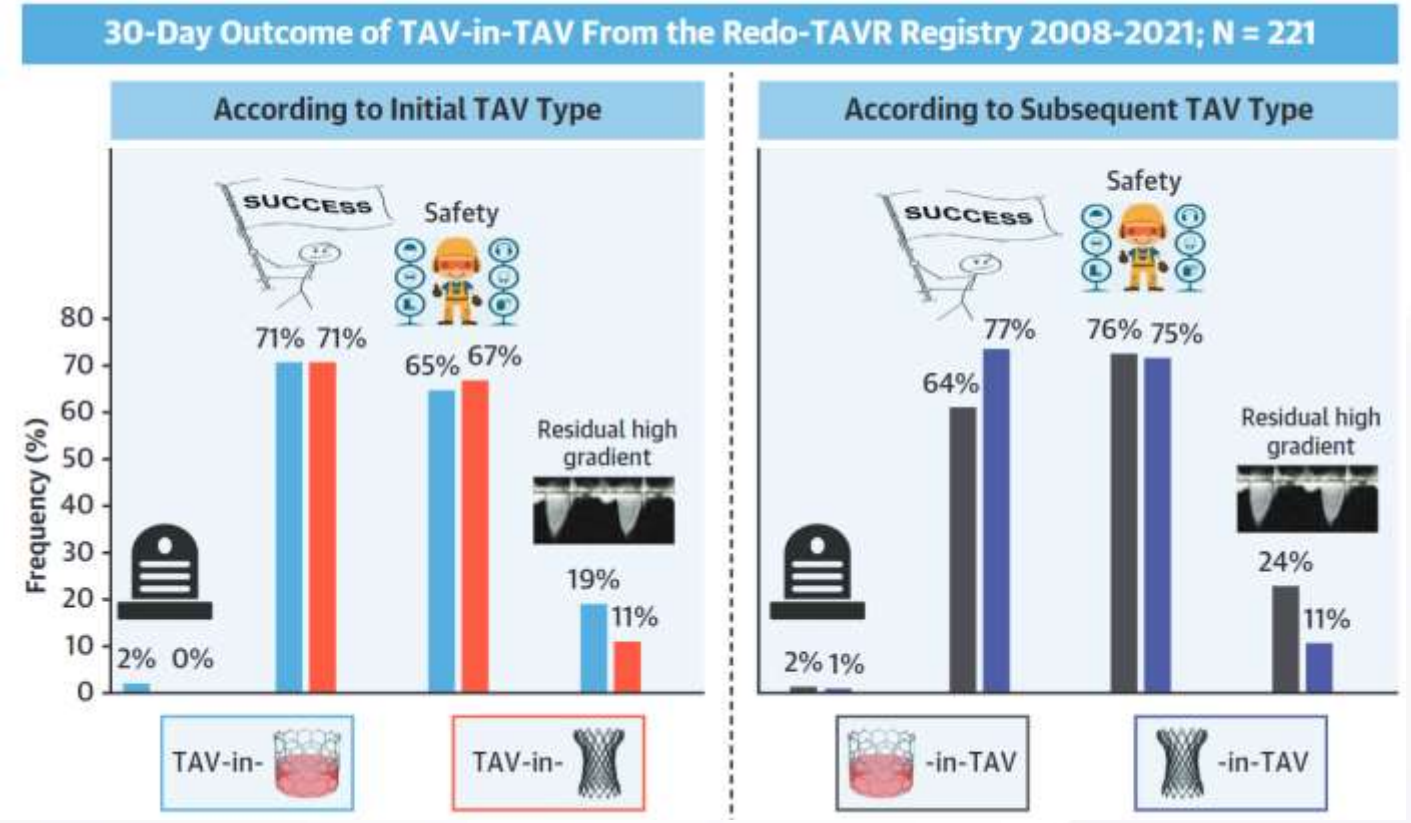




Landes U, et al. *J Am Coll Cardiol* 2021;77:1-14.

Outcomes of Redo Transcatheter Aortic Valve Replacement According to the Initial and Subsequent Valve Type





Landes U, et al. *JACC Invt* 2022;15:1543-1554.

Conclusion

- TAVR with current generation valves has emerged as a viable treatment options for selective patients with severe bicuspid aortic stenosis.
- Prior to TAVR in BAV, careful attention must be paid to specific anatomical risks, including aortic dilation and patterns of calcification.
- In choosing between TAVR and SAVR in BAV patients, life expectancy and anticipated subsequent valve replacement must be considered.
- Both balloon-expandable and self-expanding TAVR valves are safe and effective in most anatomies. The choice of valve may depend on downstream issues, including coronary re-access and TAV-in-TAV.