

Bicuspid and Valve-in-Valve; How Different?

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Bicuspid AV is **Very Common**

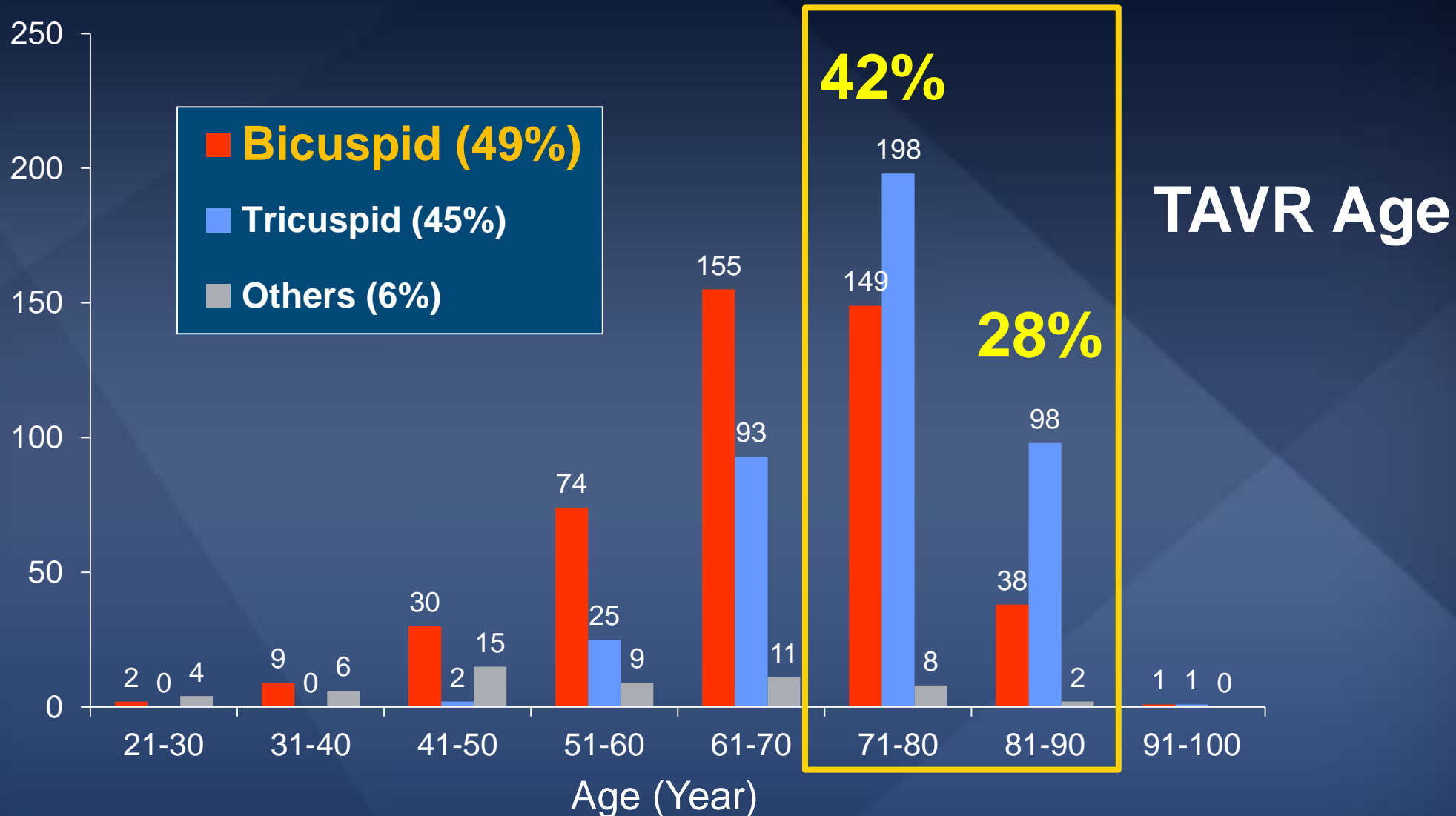
- **1-2%** of the General Population
- **>33%** Have Serious Complications*
- **Aortic Stenosis** Is The Most Frequent Complication

*Valve Complication (AS, AR, infection),
Vascular Complication (Medial Degeneration, Aneurysm, Dissection)

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

Incidence of Bicuspid AV in isolated AVR

584 men and 348 women from USA (Baylor University)



Anatomical Characteristics of BAV

- Annular eccentricity
- Asymmetrical heavy valve calcification
- Unequally-sized leaflets
- Calcified raphe
- Concomitant aortopathy
- Lack of Standardized Annulus Measurement

Lack of Standardized Valve Sizing

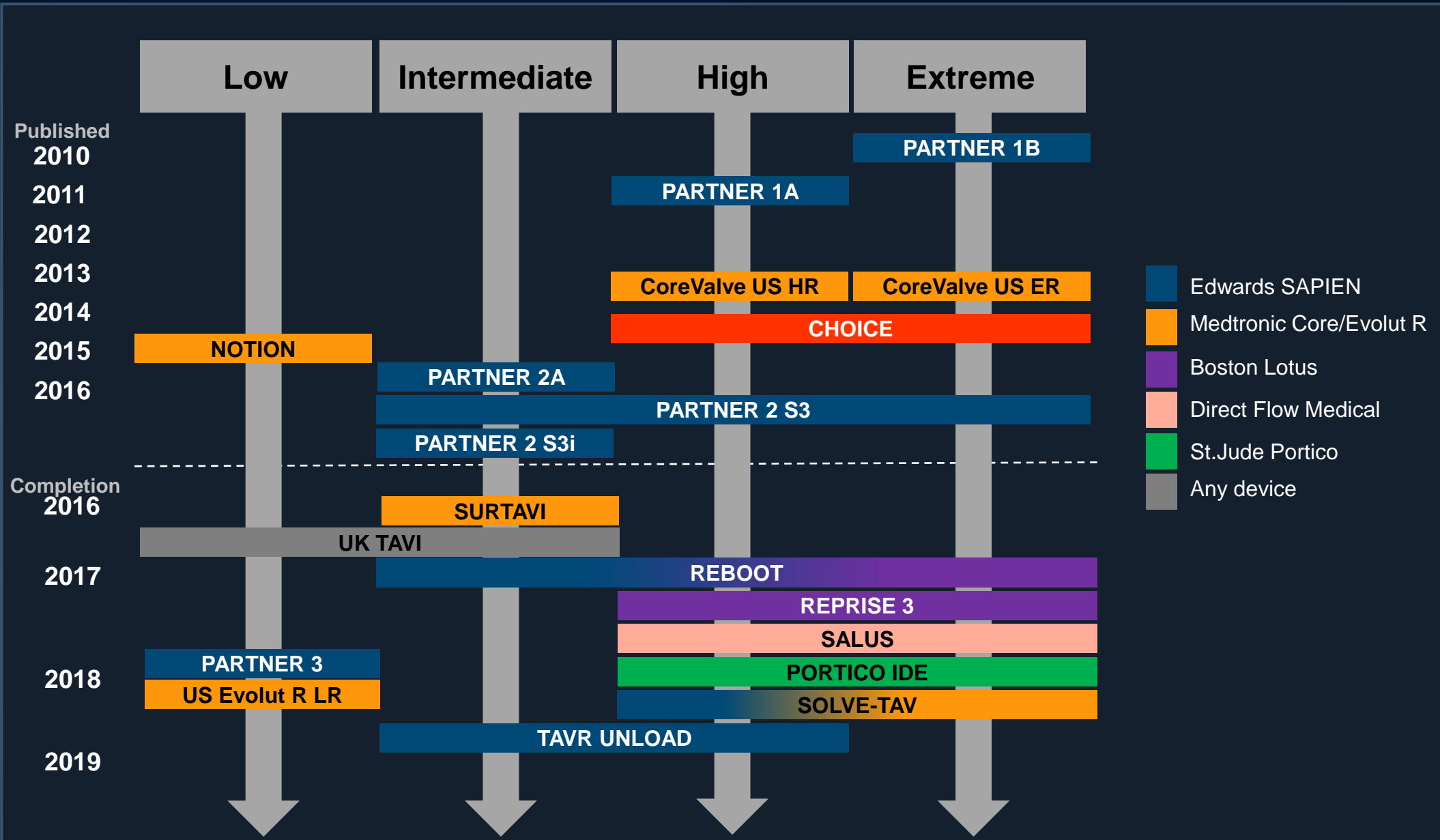
- Annular sizing
- Supra annular sizing
- Under sizing
- Balloon sizing

Avoid Oversizing in Heavily Calcified Annulus

Procedural Concern In BAV-TAVR

- Elliptical deployment
- Impaired Bioprosthesis Durability
- Residual Aortic Regurgitation
- Annulus Rupture
- Coronary Obstruction
- Aortic Complication

TimeLine of TAVR Trials



Bicuspid AS was **Excluded** in Major Trials

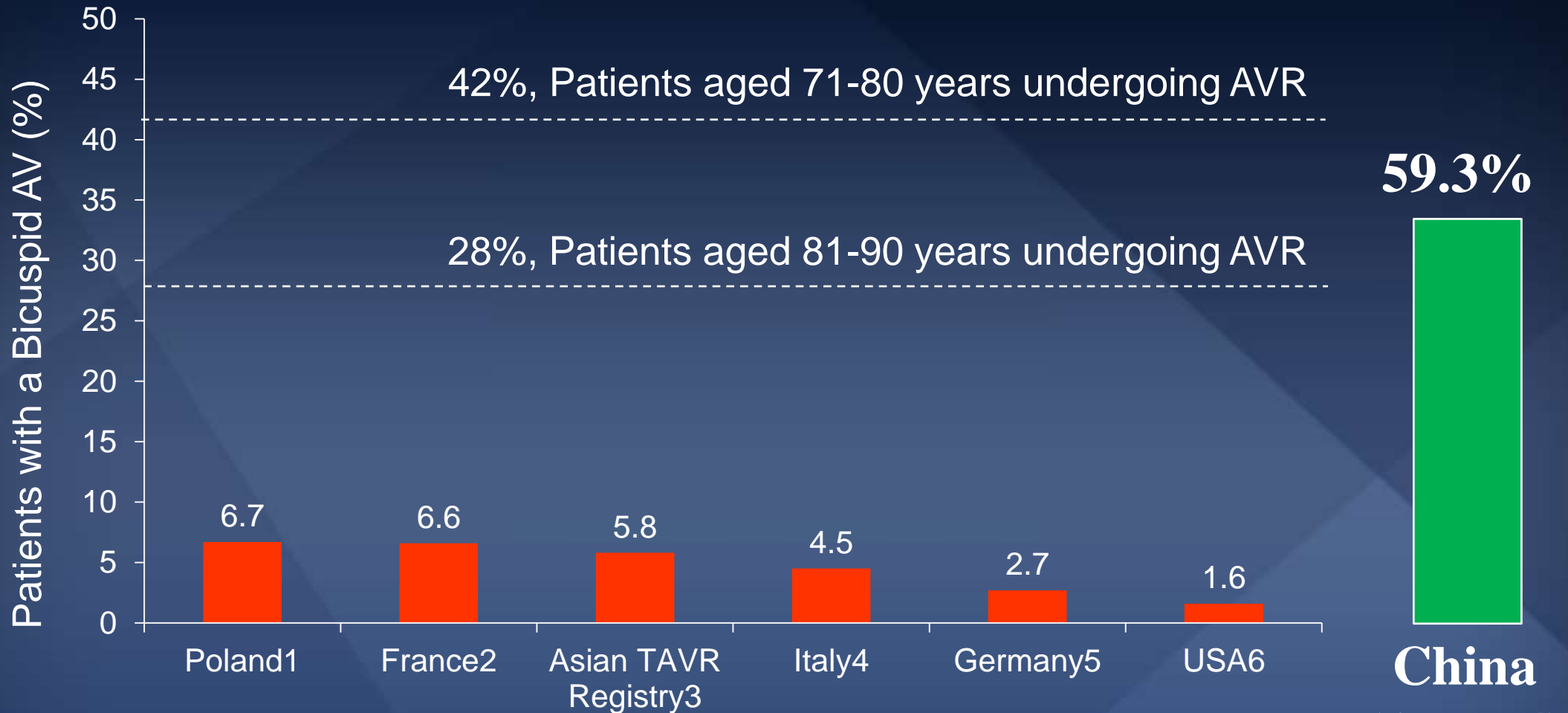
Exclusion Criteria

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

Don't Mention

- NOTION ([NCT01057173](#))
- SURTAVI ([NCT01586910](#))

Frequency of Bicuspid AV in TAVR Registry



1. Am J Cardiol 2014;114:757-762
2. Am J Cardiol 2012;110:877-883
3. JACC Cardiovasc Interv 2016;9:926-33

4. Am J Cardiol 2014;113:1390-1393
5. Am J Cardiol 2014;113:518-521
6. JAMA 2013;310:2069-2077

Outcomes of TAVR in Bicuspid AS

	Bauer (N=38)	Kochman (N=28)	Yousef (N=108)	Mylotte (N=139)	Jilaihawi (N=130)
Age, years	81	78	76	78	77
Mean STS score (%)	-	-	-	4.9	4.7
Type of Valve (%)					
Balloon Expandable	32	18	56	28	54
Self Expandable	68	82	44	72	46
New Pacemaker (%)	17	29	19	23	26
PVL>mild (%)	25	32	31	28	18
30-day Stroke (%)	0	0	2.8	2.2	3.2
30-day Survival (%)	89	96	92	95	96

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

Yousef et al. Int J Cardiol 2015;189:282-8

Jilaihawi et al. JACC:Cardiovascular Imaging 2016;9:1145-58

Kochman et al. Am J Cardiol. 2014;114:757-62

Mylotte al. J Am Coll Cardiol 2014 ;64:2330

AHA/ACC (2014) and ESC (2012) Guideline

COR

LOE

I

B

➤ Inoperable

TAVR was Generally Indicated in **Tricuspid AS**

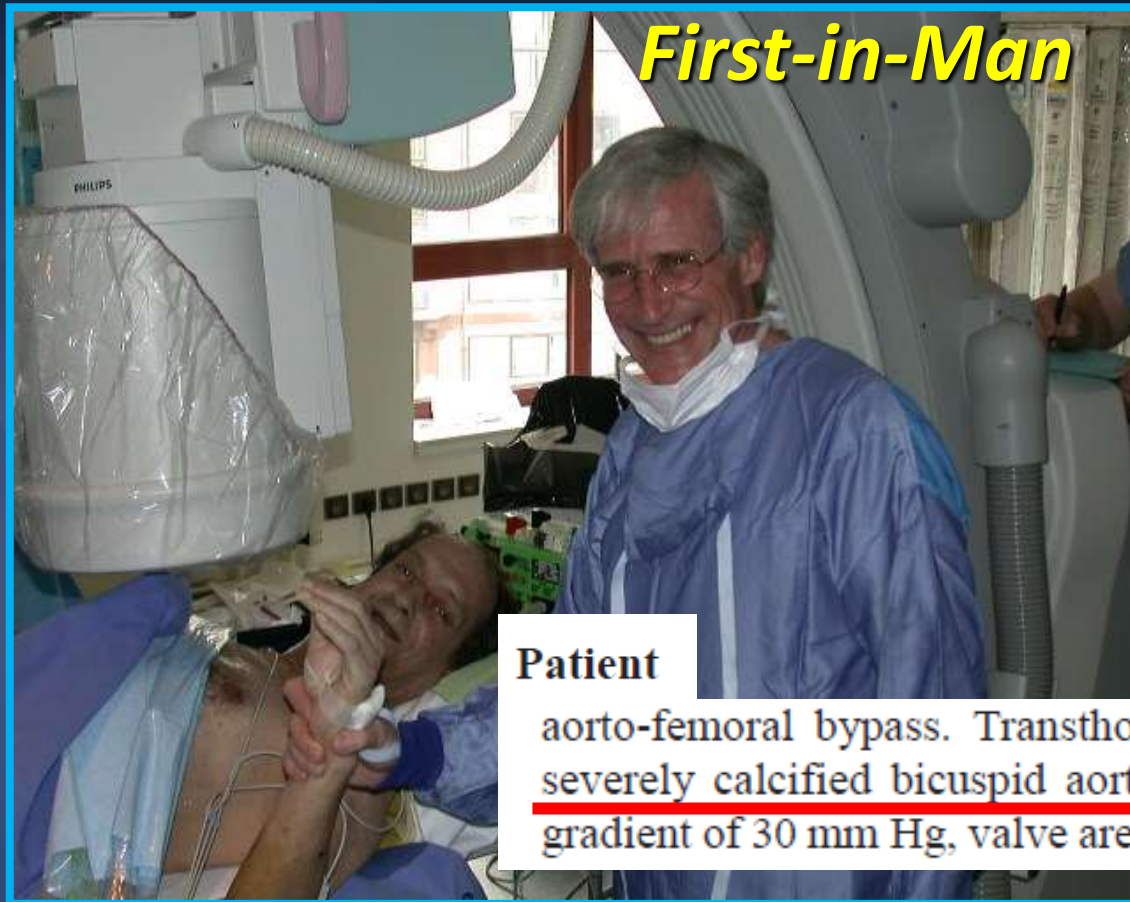
?

- Lower Surgical Risk
Younger Patients
- **Bicuspid AV Stenosis**

Nishimura RA et al. J Am Coll Cardiol 2014;63(22):2438-88

Vahanian A et al. Eur Heart J 2012;33(19):2451-96

First-In-Man TAVR was done in *Bicuspid AV*



57 years old

Cribier A, et al. Circulation. 2002;106:3006-3008

Bicuspid TAVR

To Address Procedural and Clinical Outcomes of TAVR

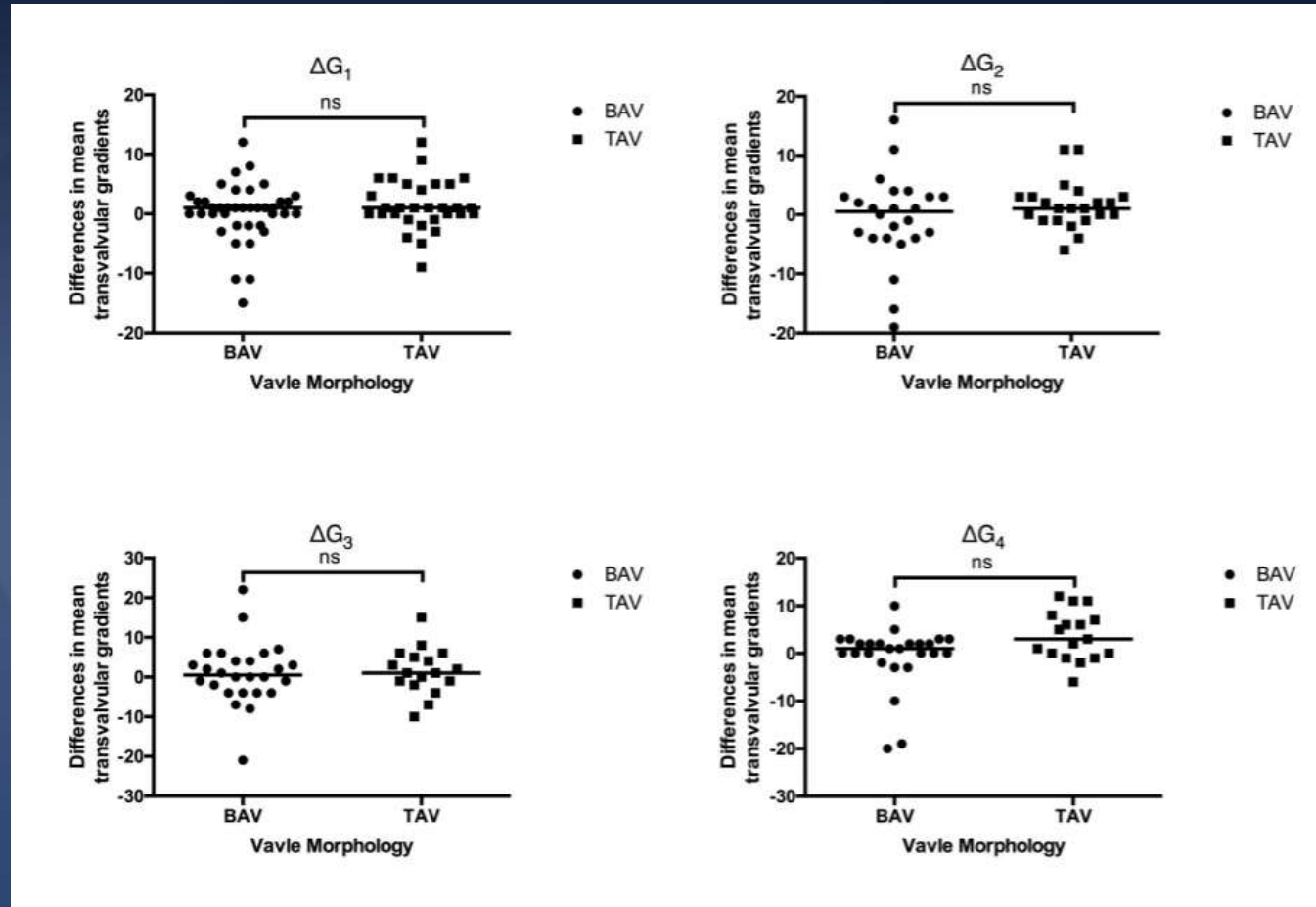
1. Bicuspid vs. Tricuspid AS
2. Early Generation Device vs New-Generation Devices
in Patients with Bicuspid AS

Bicuspid TAVR

To Address Procedural and Clinical Outcomes of TAVR

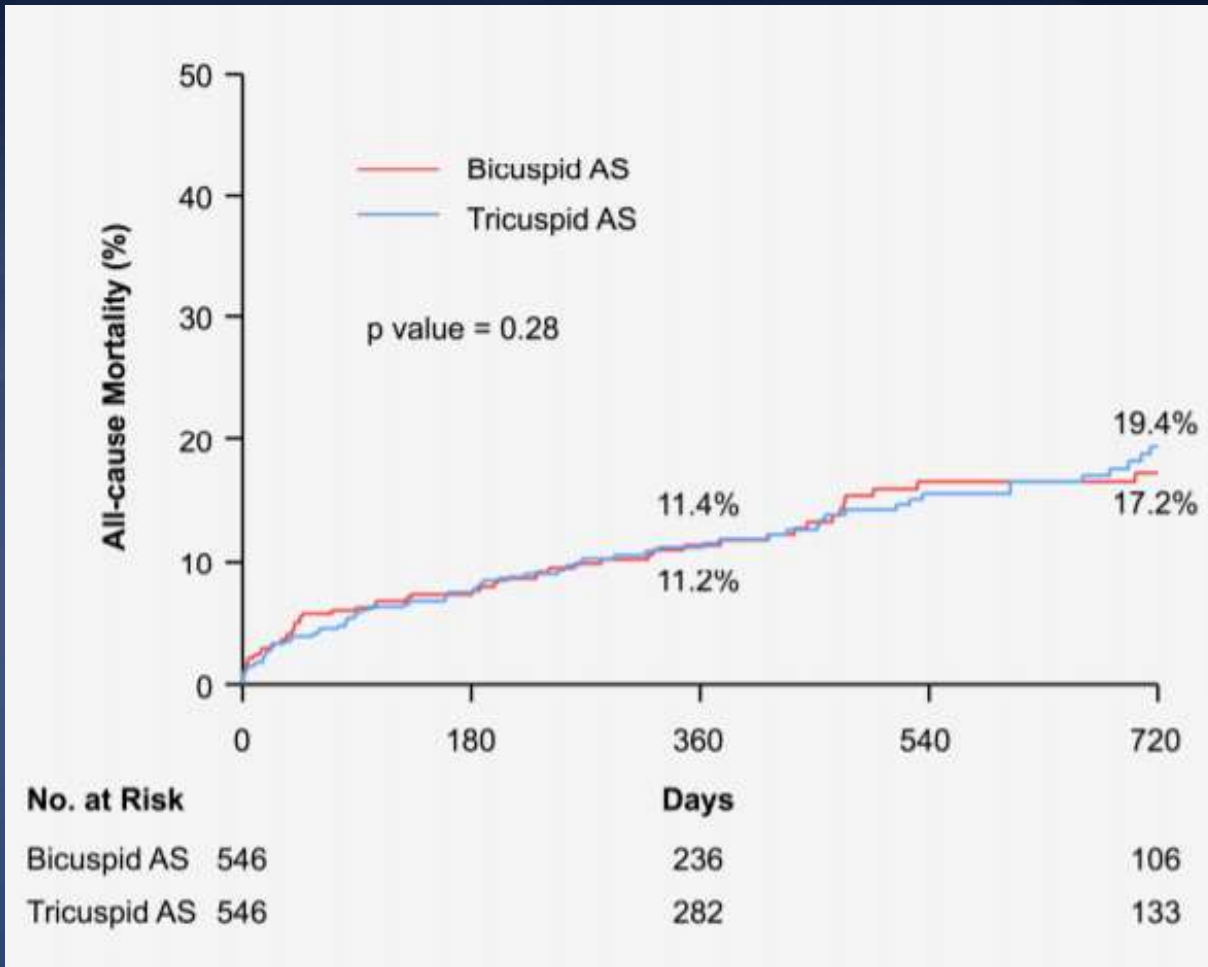
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in Patients with Bicuspid AS

Sequential Hemodynamic Changes



Cardiology J 2017 Mar 1. doi: 10.5603/CJ.a2017.0020.

Long-term Mortality



Higher Aortic Root Injury
Higher PVL

Yoon SH, et al. J Am Coll Cardiol. 2017 2017 Mar 15. pii: S0735-1097(17)36041-2

Bicuspid TAVR

To Address Procedural and Clinical Outcomes of TAVR

1. Bicuspid vs. Tricuspid AS
2. Early Generation Device vs New-Generation Devices
in Patients with Bicuspid AS

M/79YO

CC: Chest Pain,

Risk Factors: DM, HT, CKD, AF

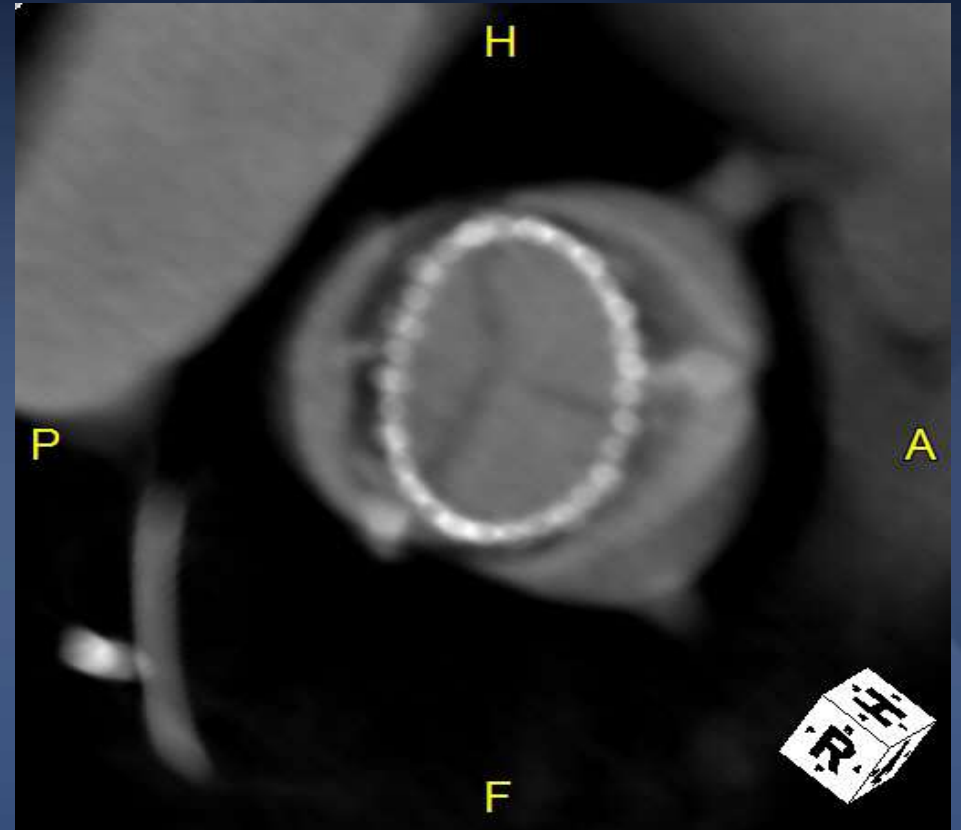
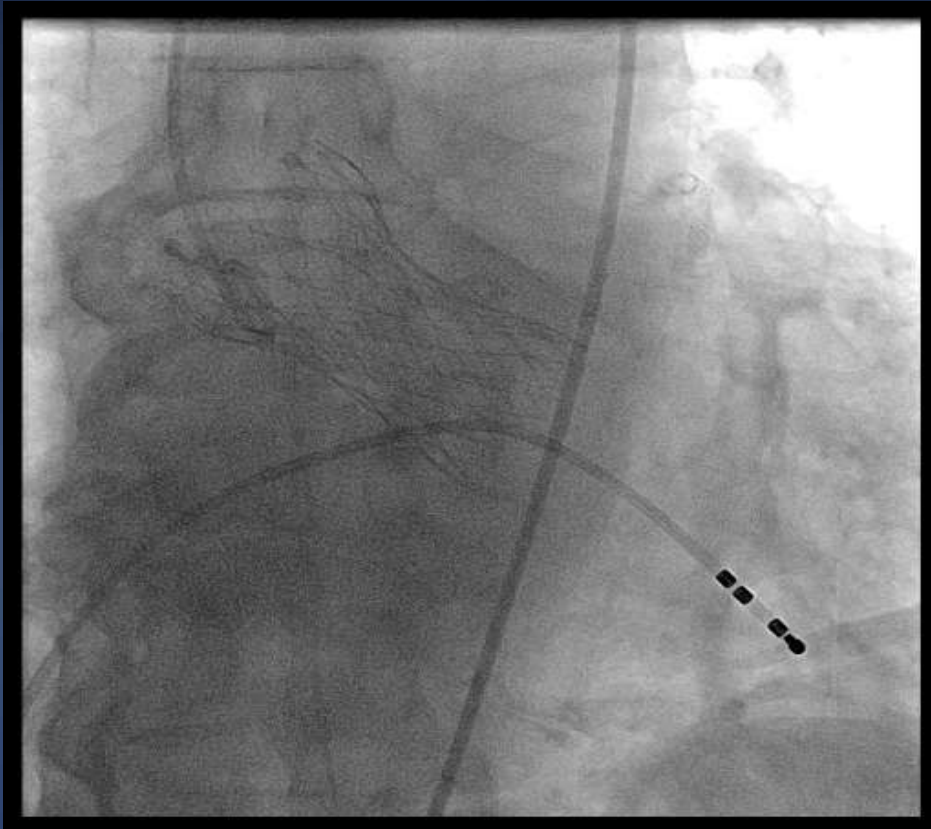
Severe AS with Bicuspid Valve (Type 1, LR fusion)



Annulus Area : 491 mm²

Annulus Perimeter : 81 mm

Evolut R 29mm

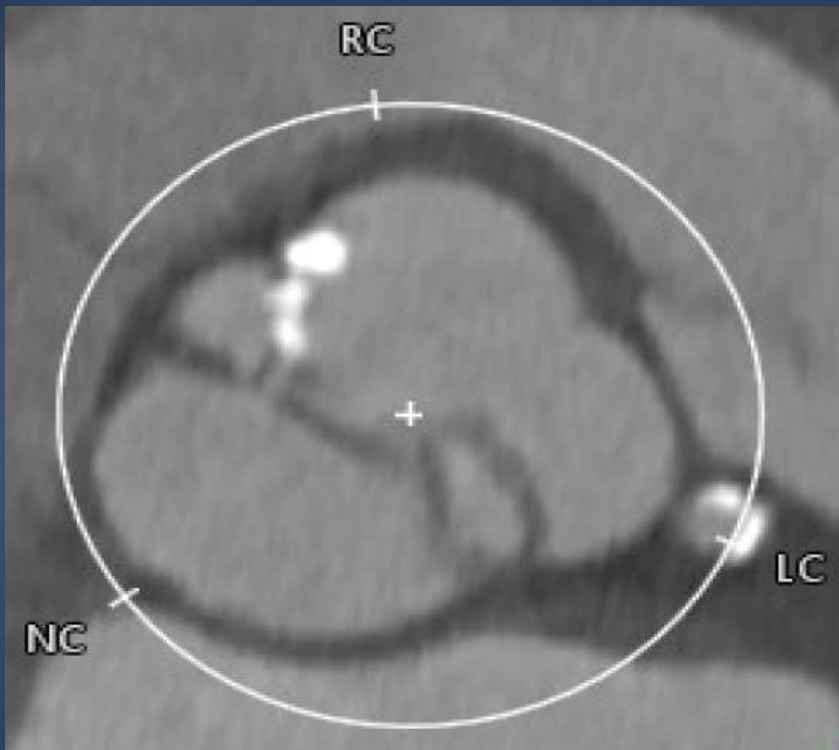


M/78 YO

CC: Dyspnea,

Risk Factors: Interstitial Lung Disease, DM, HT, CKD

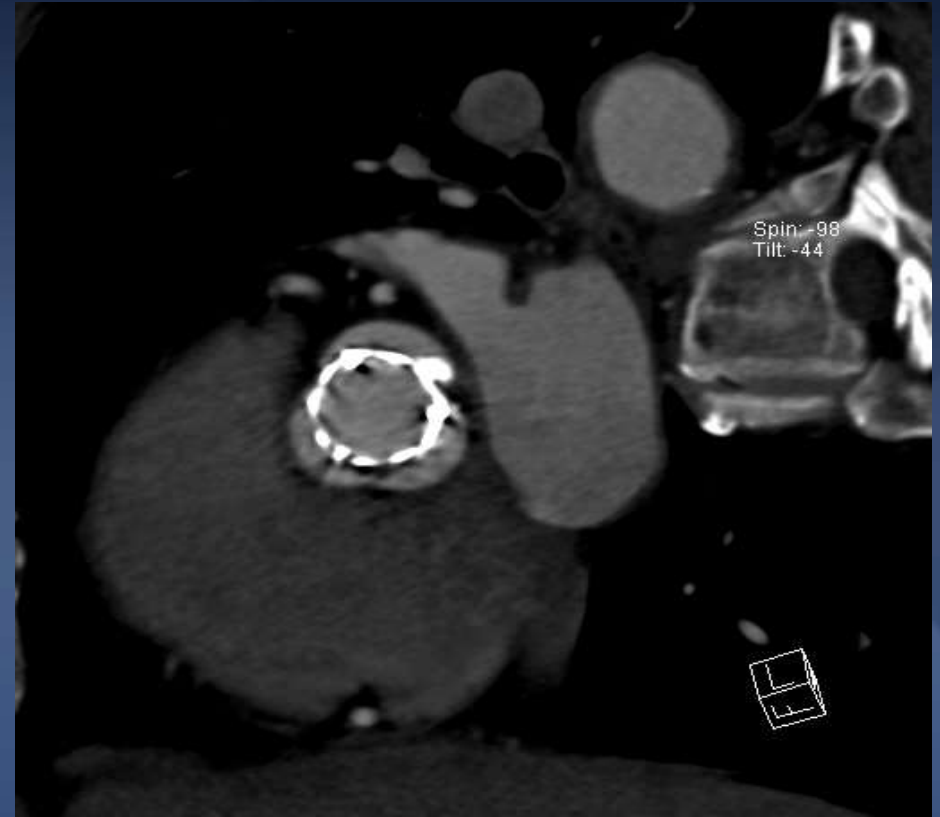
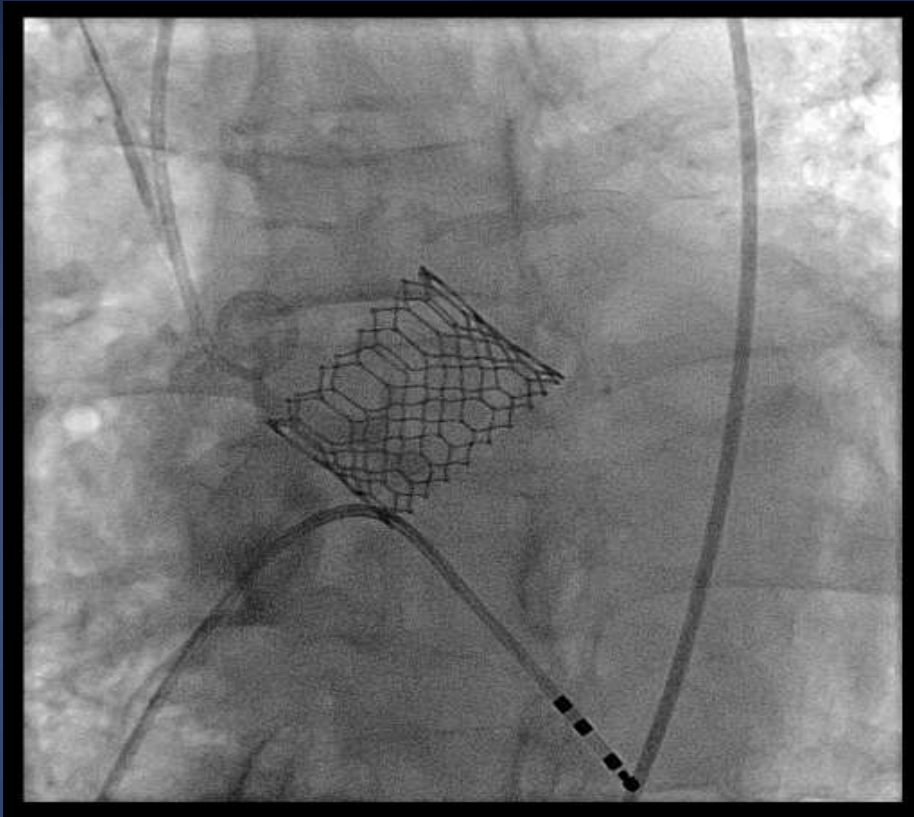
Severe AS with Bicuspid Valve (Type 1, LR fusion)



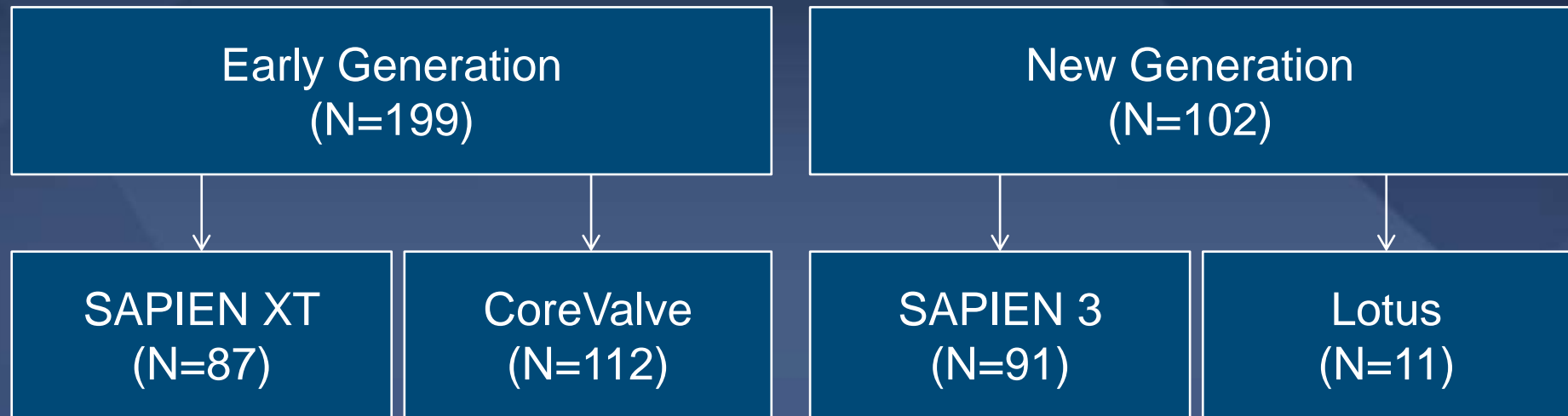
Annulus area : 683 mm²

Annulus perimeter : 95 mm

Sapien 3 29mm (4 cc Overfill)

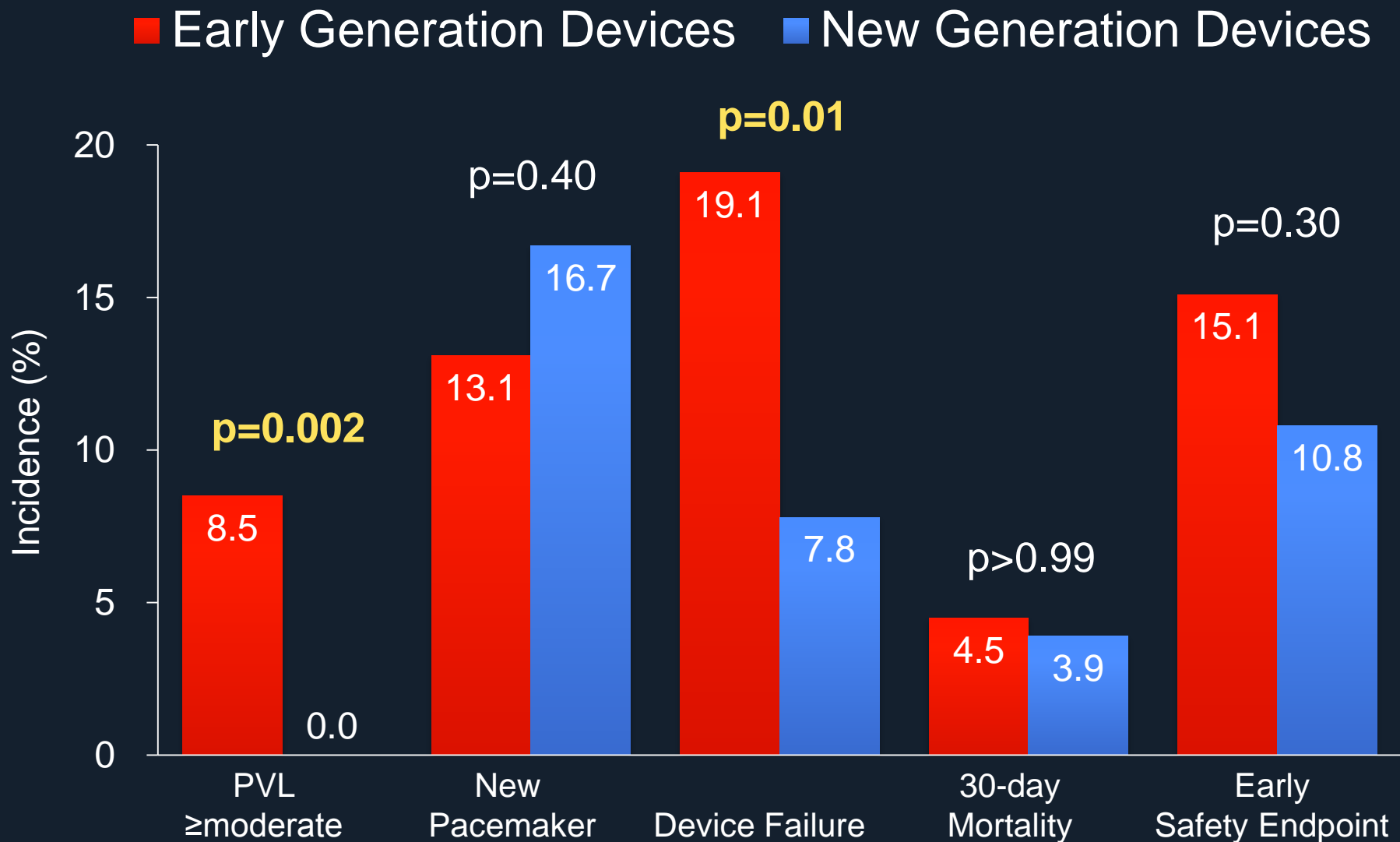


Early vs. New Generation Device



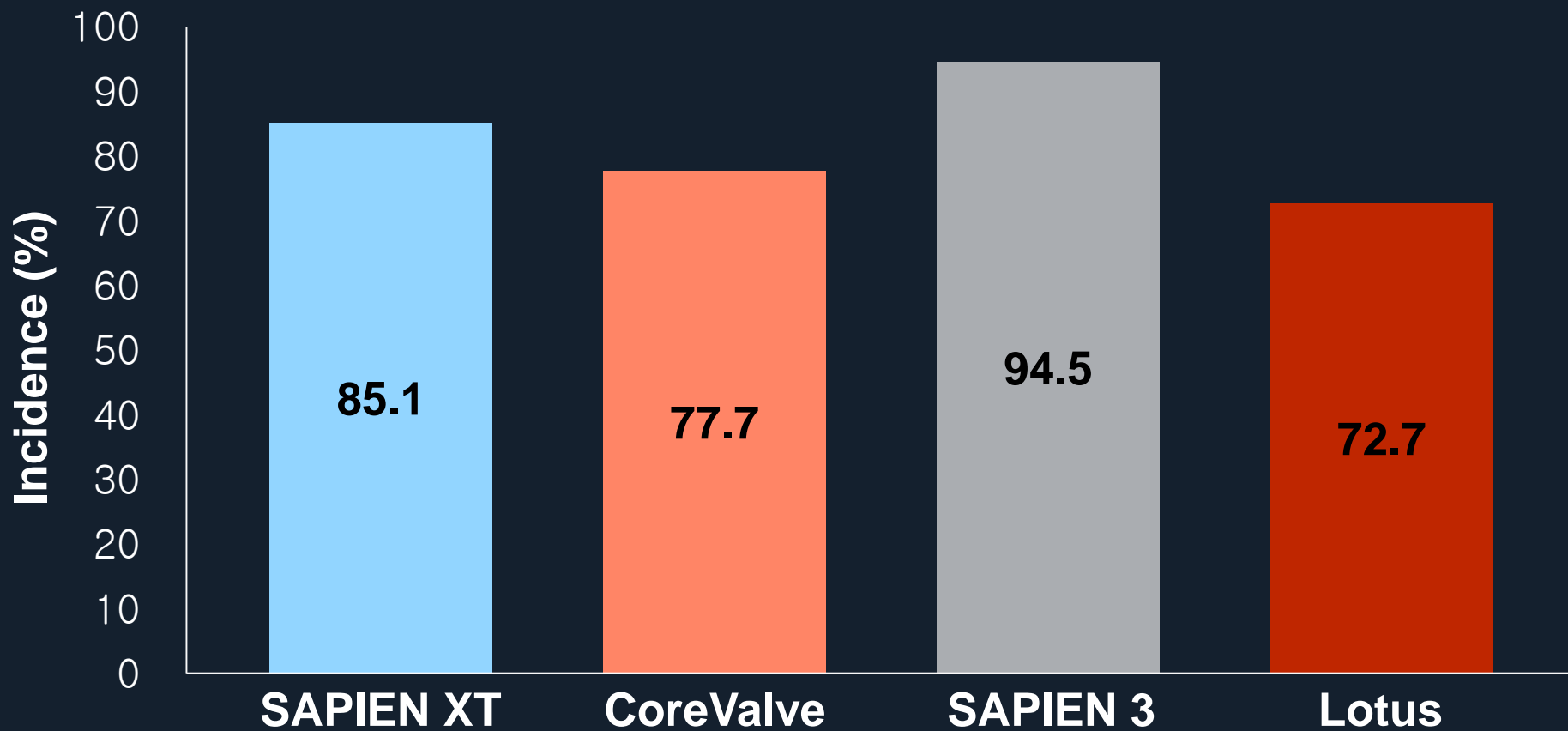
Yoon SH, Ahn JM, Park SJ et al. J Am Coll Cardiol. 2016 Sep 13;68(11):1195-205

30-Day Outcomes

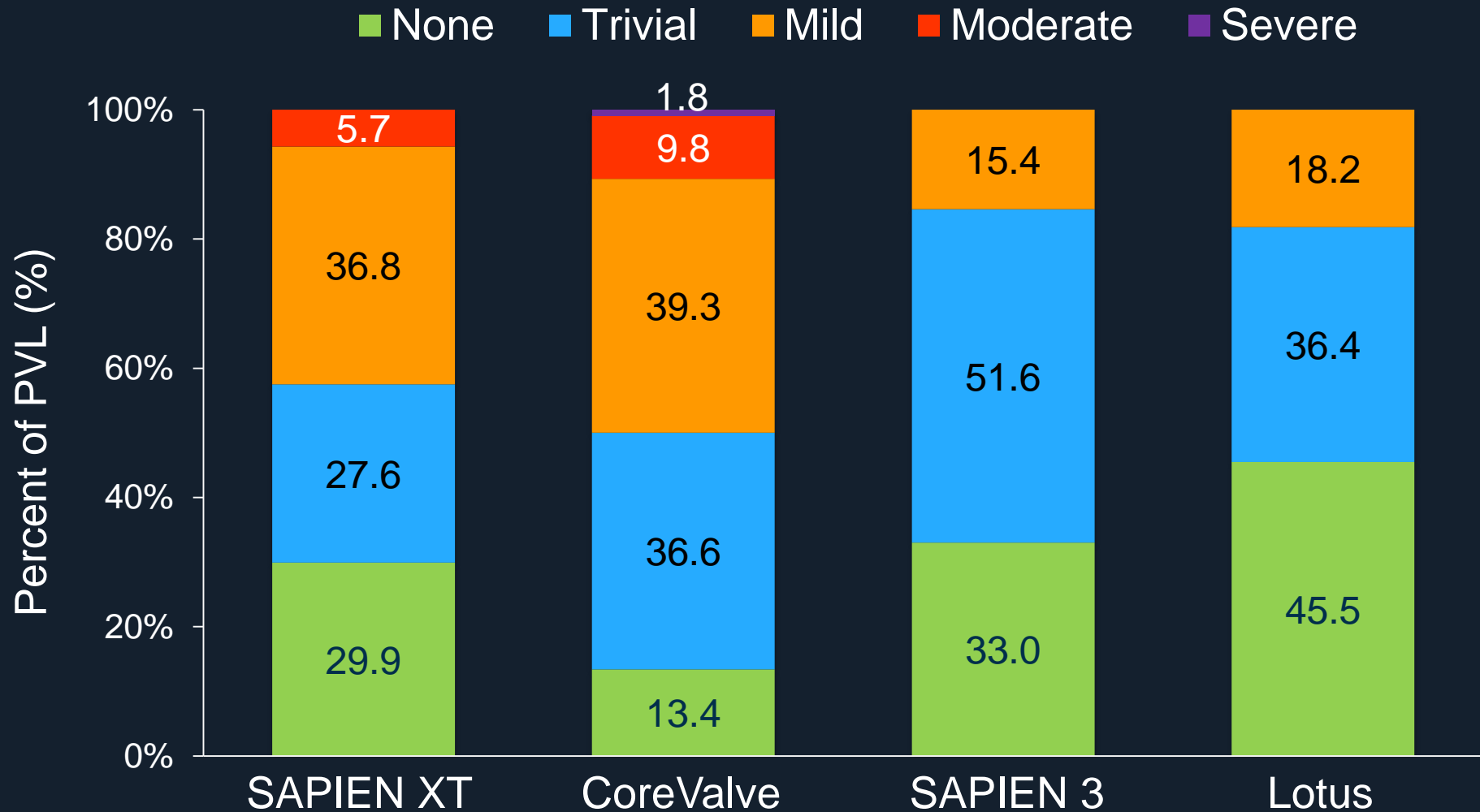


Device success

Overall P=0.07

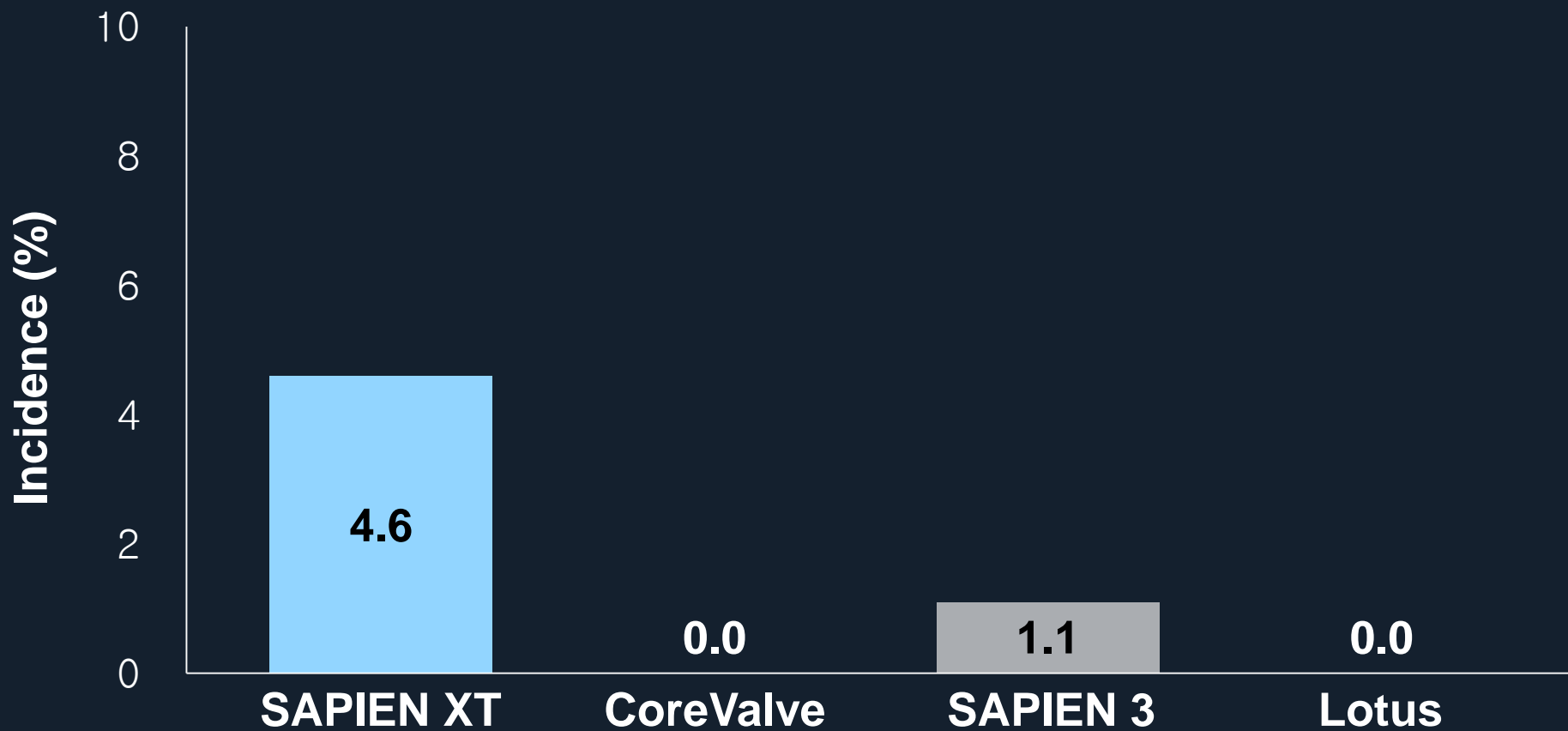


Paravalvular Leakage

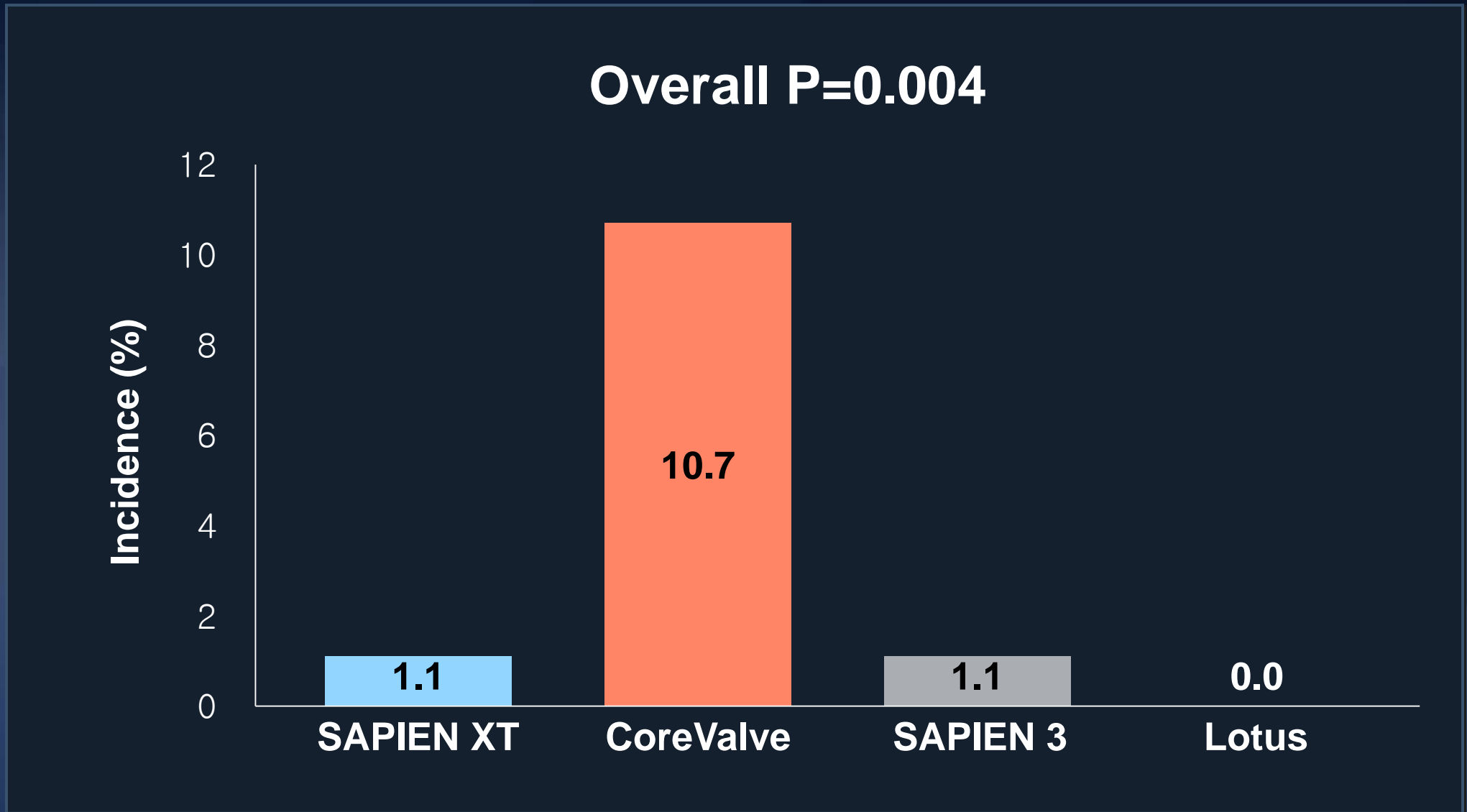


Annular Rupture

Overall P=0.07



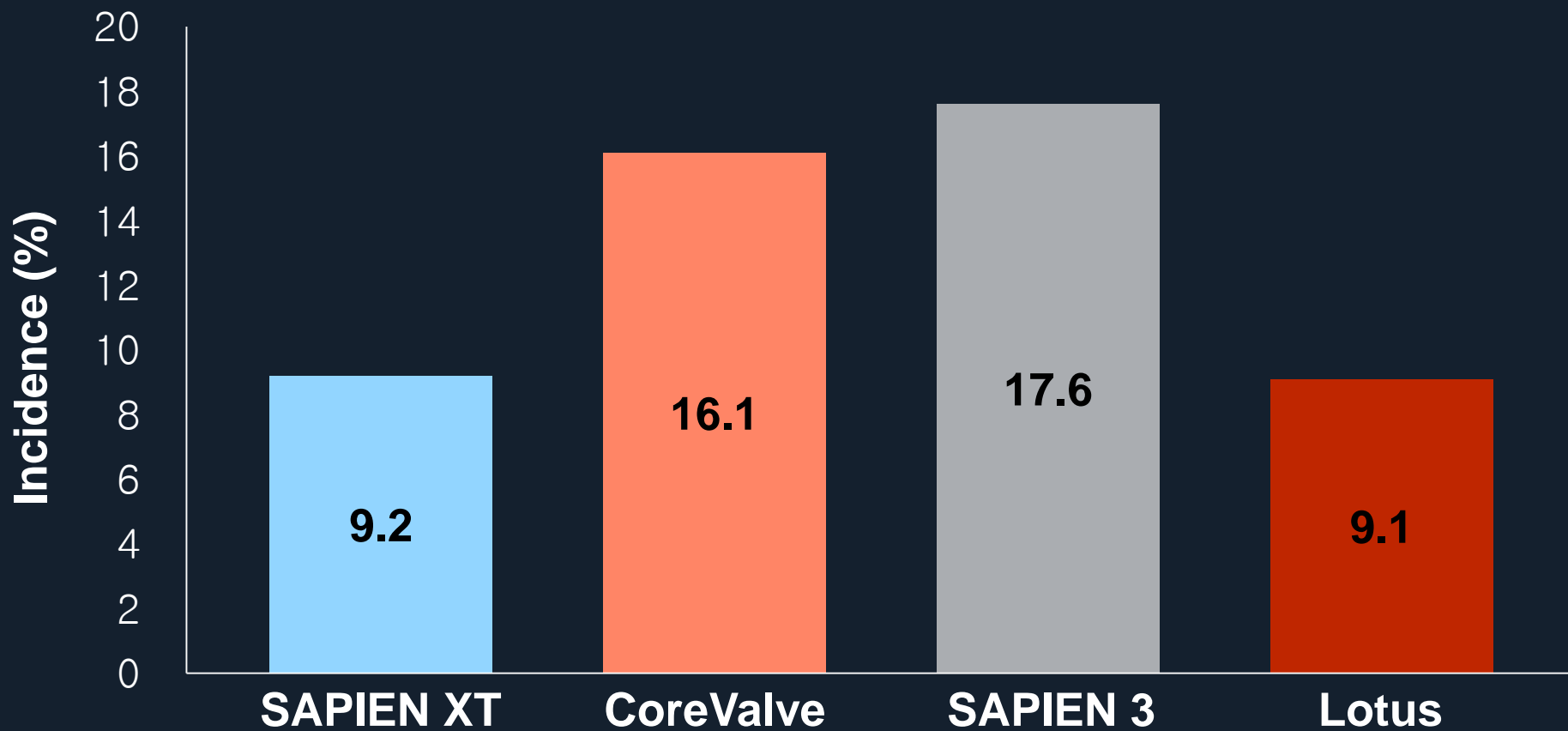
Second Valve Implantation



Yoon SH, Ahn JM, Park SJ et al. J Am Coll Cardiol. 2016 Sep 13;68(11):1195-205

New Permanent Pacemaker

Overall P=0.10



Summary

- TAVR for tricuspid and bicuspid AS showed similar long-term mortality.
- Lower device success rate with early devices
 - Annulus rupture with SAPIEN XT (4.6%)
 - Paravalvular leak with CoreValve
- New devices showed excellent outcomes
 - No moderate or severe paravalvular leakage
 - Improved device success
- This study suggested that the selected patients with bicuspid AV stenosis would be a candidate of TAVR with new devices.