# TAVR Technique in Bicuspid Anatomy

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# First-In-Man TAVR was done in **Bicuspid AV By Balloon Expandable Valve**



#### 57 years old

aorto-femoral bypass. Transthoracic echocardiography indicated a severely calcified bicuspid aortic valve with a mean transvalvular gradient of 30 mm Hg, valve area 0.6 cm<sup>2</sup>, and ejection fraction 14%.

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



## **TAVR Trials**

	STS Score	Age
Inoperable Population		
PARTNER IB Trial (2010)	11.6	83
High Risk Population (>8)		
PARTNER IA Trial (2011)	11.8	84
CoreValve US Pivotal Trial (2014)	7.4	83
Intermediate Risk Population (4-8)		
PARTNER II Trial (2016)	5.8	82
Low Risk Population (<4)		
NOTION Trial (2015)	3.0	79
PARTNER III (2019)	1.9	73
Evolut Low Risk Trial (2019)	1.9	74

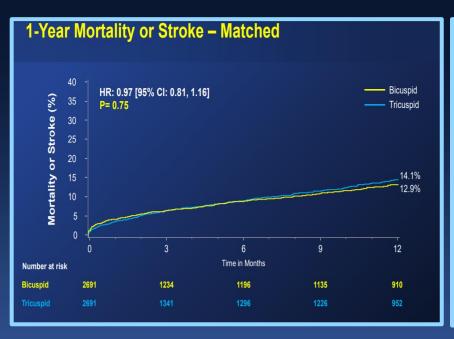


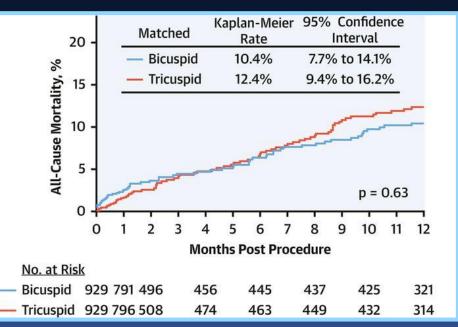


## **STS/ACC TVT Registry**

#### Sapien 3

#### **Evolut R**





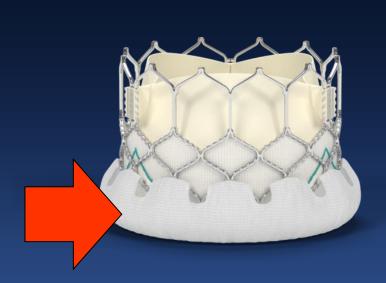
JAMA 2019 Jun 11;321(22):2193-2202

JACC CVI 2020 May 23;S1936-8798(20)30763-9





## Which Device?



**S**3



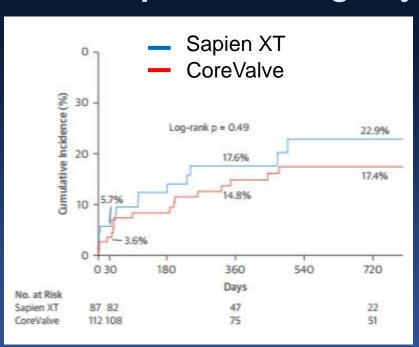
**Evolut R** 



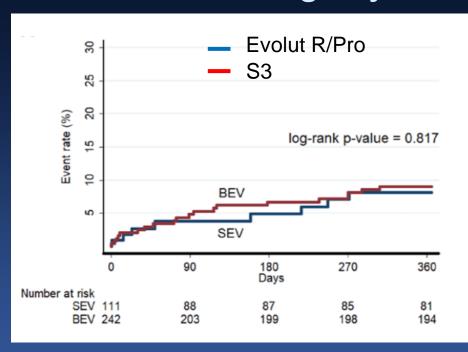
## SEV vs. BEV

#### **All Cause Mortality**

#### The Bicuspid TAVR Registry



#### The BEAT Registry



J Am Coll Cardiol 2016;68:1195–205

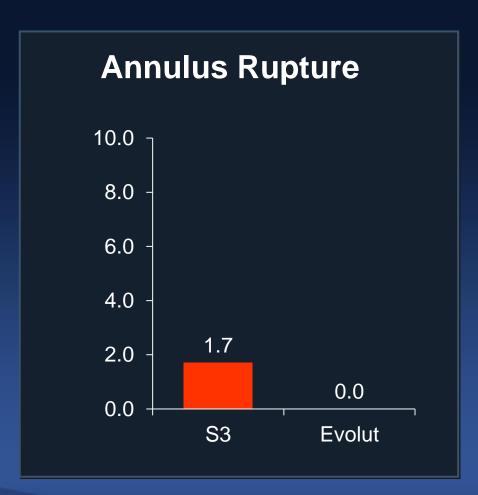
Circ Cardiovasc Interv. 2020;13:e008714

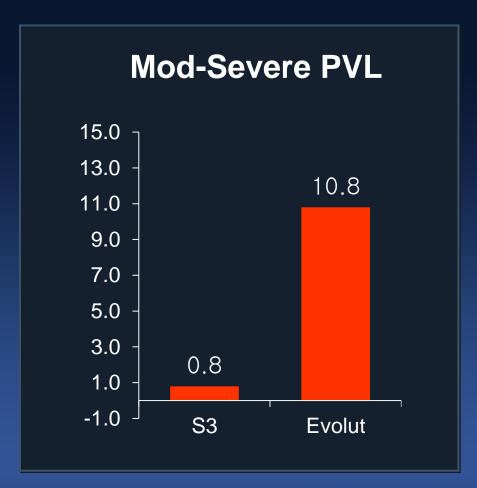




### S3 vs. Evolut R/PRO

#### The BEAT Registry





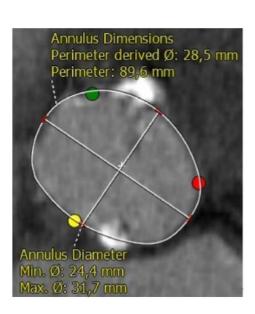


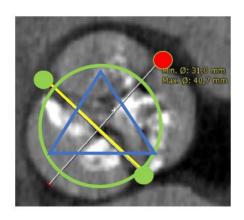


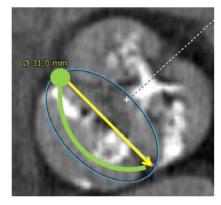
#### **Device Sizing**

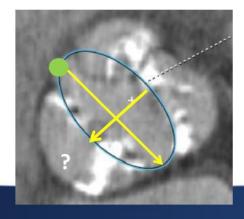
#### Various sizing methodologies are proposed for TAVR in BAV

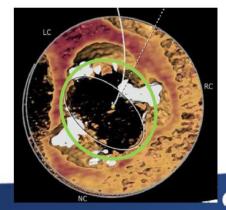












THE STRUCTURAL HEART DISEASE SUMMIT 2018
Transcatheter Valve Therapies (TVT) and LAA/PFO Closure

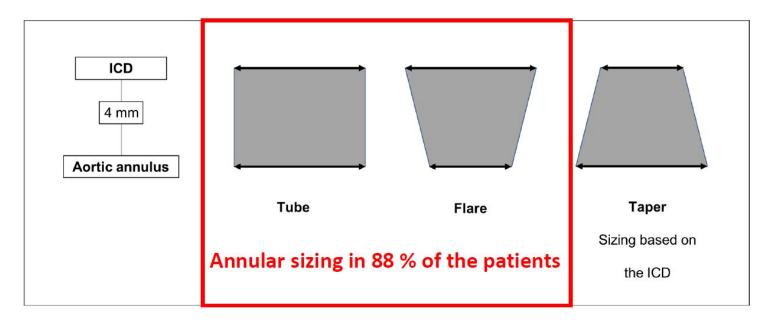




#### **Device Sizing**

#### CP Pasteur

#### Sizing according to the landing zone configuration



BABARD Registry (N=96, S3 65, Lotus 10, Evolut R 21)

THE STRUCTURAL HEART DISEASE SUMMIT 2018
Transcatheter Valve Therapies (TVT) and LAA/PF0 Closure





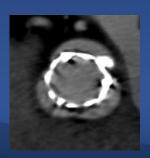
### **Device Sizing**

#### **Annulus Sizing**

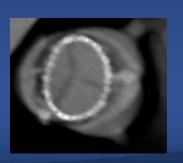
#### **Supra-annulus Sizing**

S3
Don't Do
Oversizing

- Sequential balloon sizing
- : Exolution PRO
- CASPER method



BE "remodels" the annulus

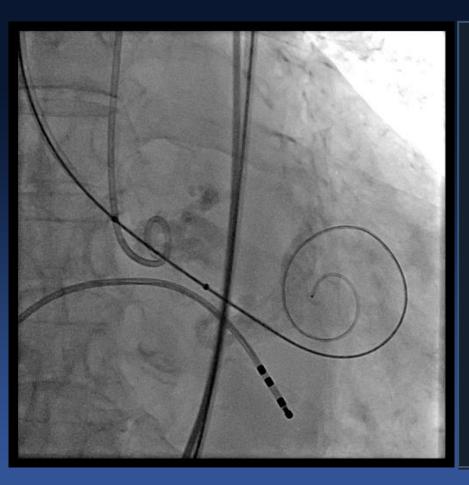


The annulus "remodels" SE





## Balloon Aortic Valvuloplasty More Often in Bicuspid AS



#### Goal

- 1) To facilitate device delivery
- 2) To confirm the device size
- 3) To assess the risk of coronary obstruction

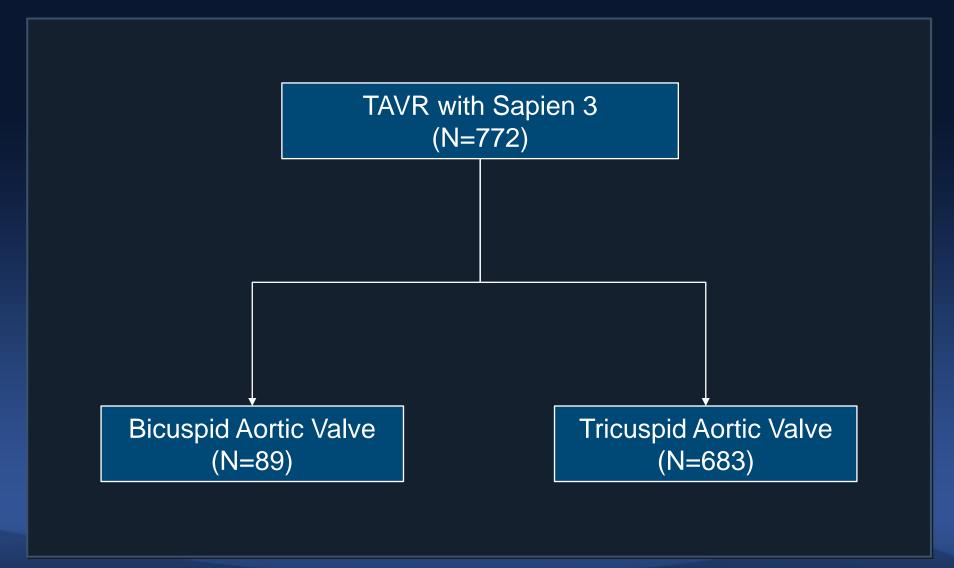
To avoid the risk of aortic complex injury, relatively small balloon should be selected based on the CT measurement of aortic valve complex.

Balloon Size: Smaller Than Minimal Diameter



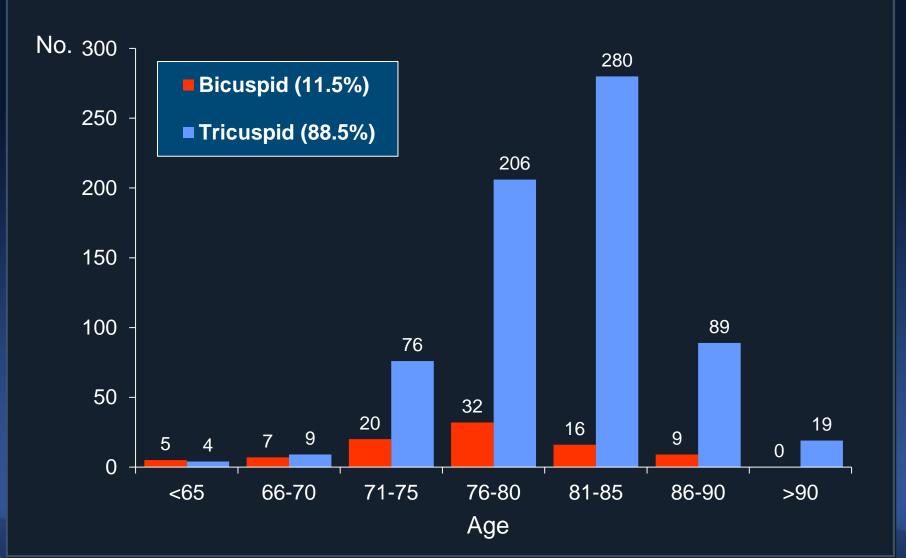


#### ASAN TAVR S3 Registry (2016-2021)

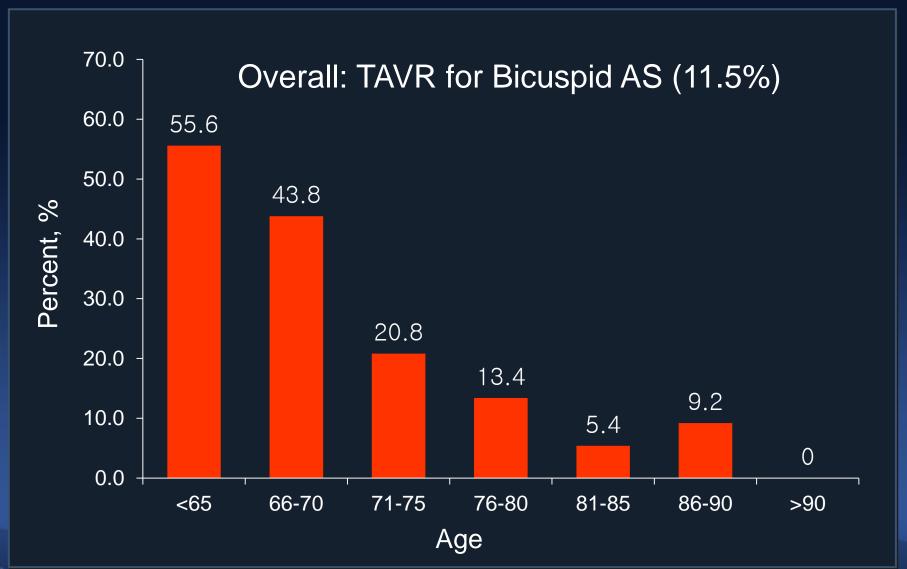




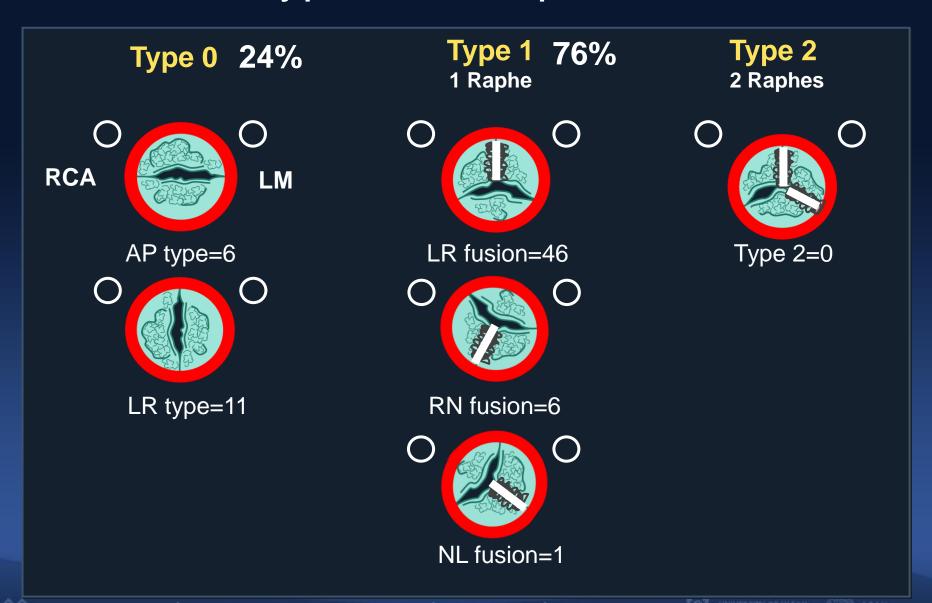
## Age Proportion of TAVR for Bicuspid AS



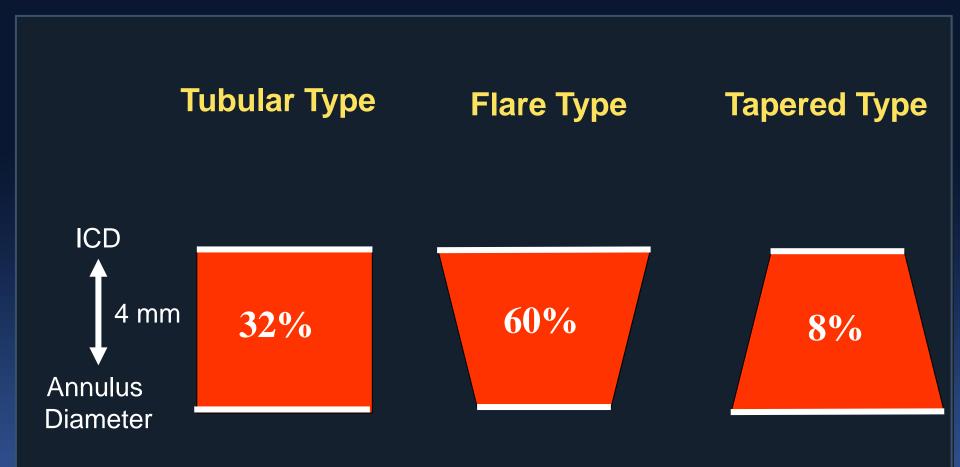
## **Proportion of TAVR for Bicuspid AS**



#### Type of Bicuspid AV\*



#### Type of Bicuspid AV\*



Tubular type: perimeter derived annulus diameter/ICD ratio 0.99-1.1 Tapered type: perimeter derived annulus diameter/ICD ratio >1.1 Flared type: perimeter derived annulus diameter/ICD ratio <0.99

#### **Baseline Characteristics**

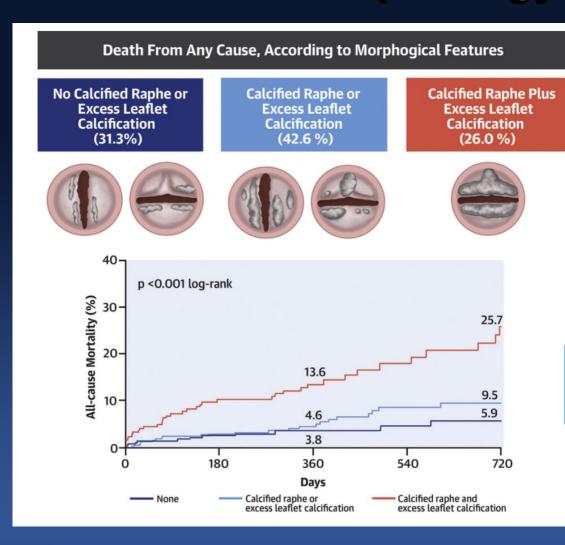
	Bicuspid AS (N = 89)	Tricuspid AS (N = 683)	P value
Age	76.9±6.6	80.9±5.0	0.001
Gender (Male)	69.7%	44.9%	<0.001
NYHA Class III/IV	20.3%	30.2%	0.24
BMI	23.7±3.2	24.1±3.8	<0.001
STS score	2.88±1.6	4.1±2.6	<0.001
Diabetes Mellitus	23.6%	35.9%	0.022
Hypertension	57.3%	79.9%	<0.001
Previous Stroke	14.6%	12.0%	0.48
Peripheral Vascular Disease	2.2%	4.2%	0.37
Previous PCI	10.1%	24.9%	0.002
Previous CABG	0%	3.5%	0.10
LVEF, %	58.3±9.4	59.3±10.3	0.38



## **CT Measurement**

	Bicuspid AS (N = 89)	Tricuspid AS (N = 683)	P value
Annulus Dimensions			
Area, mm²	518±100	428±76	<0.001
Perimeter, mm	81.7±8.1	74.3±7.2	<0.001
Mean diameter, mm			
Maximum	28.7±3.3	26.6±2.6	<0.001
Minimum	22.8±2.5	20.6±2.1	<0.001
STJ area, mm²	856±235	640±140	<0.001
LVOT Area, mm²	505±121	403±99	<0.001
LM Height, mm	16.2±3.9	13.2±2.6	<0.001
RCA Height, mm	18.5±3.4	17.2±2.8	0.001

## Calcification Morphology and Outcomes



Severe AV calcification

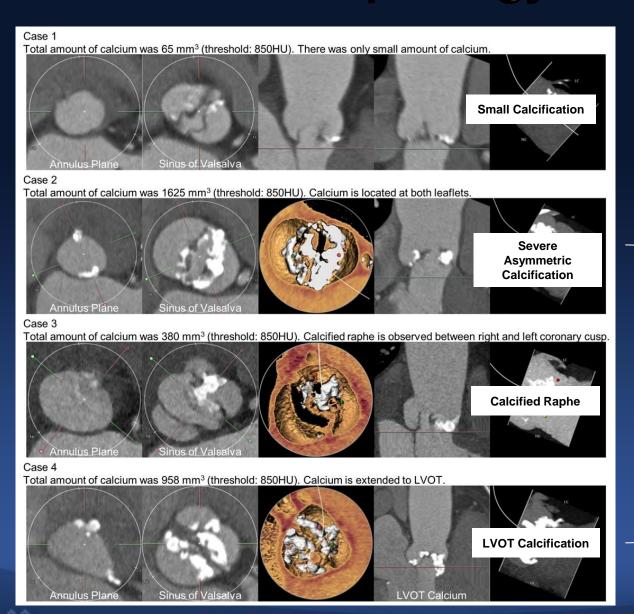


Higher Aortic Root Injury
Higher PVL

J Am Coll Cardiol. 2020;76(9):1018-30



## Mount and Morphology of Calcification



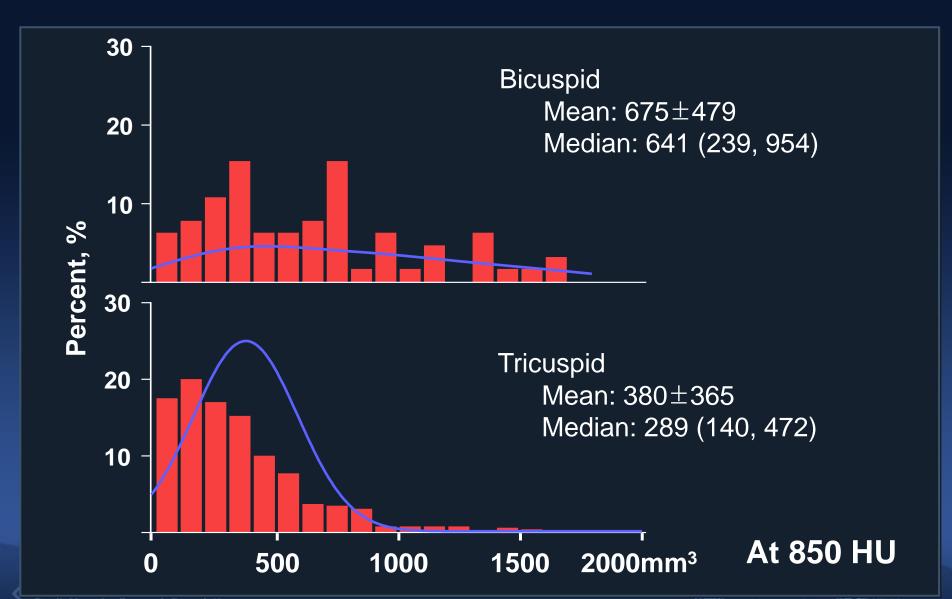
#### **Lower Risk**

### Higher Risk





#### Valve Calcification Volume



# S3 Area Oversizing Based on the CT

10-15%, Cutoff

Mild Calcification (Ca volume < 400 mm³)

10~15%

Moderate Calcification (Ca volume 400-1000 mm³)

5~10%

Severe Calcification (Ca volume > 1000 mm<sup>3</sup>)

0~5%

Bicuspid AS and Heavy Calcification

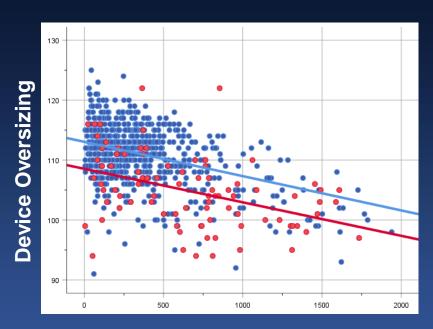
0%



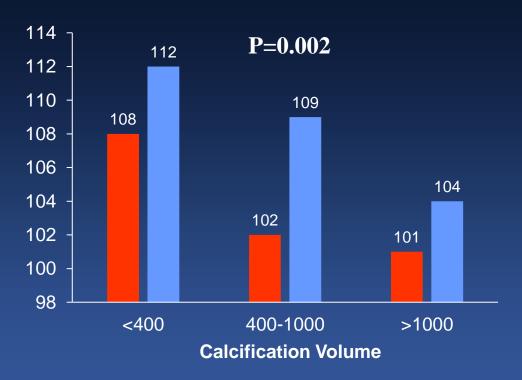
#### Volume Adjusted Device Under-Over Sizing

**Bicuspid: 104.8%** 

**Tricuspid: 110.9%** 



**Calcification Volume** 





# M/79 with Bicuspid AS



#### **Annulus plane**

Aortic Annulus parameters	
Annulus short diameter	26.0 mm
Annulus long diameter	28.6 mm
Annululs mean diameter	27.3 mm
Annulus area	589 mm <sup>2</sup>
Annulus area-driven diameter	27.4 mm
Annulus perimeter	86.5 mm
Annulus perimeter-driven diameter	27.5 mm



## **Calcium Amount**



Calcium volume	
RCC	616 mm <sup>3</sup>
LCC	48 mm <sup>3</sup>
Total	664 mm <sup>3</sup>

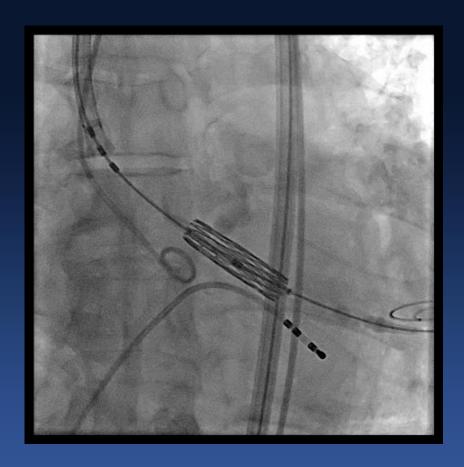


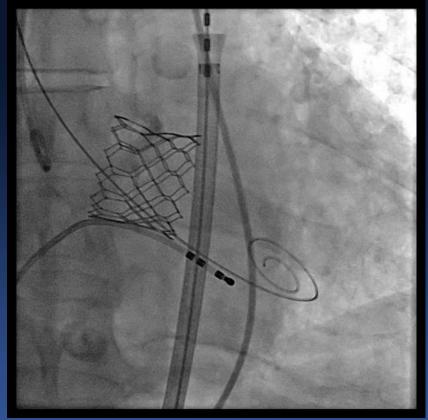
# S3 29mm with -3cc Underfill (2% Oversizing)

Size	Area_oversize (%)	Perimeter_oversize (%)
24	75.6	86.2
25	82.0	89.8
26	88.1	93.3
27	95.0	96.9
28	102.2	100.5
29	110.2	104.4
30	117.9	108.0



# S3 29mm with -3cc Underfill (2% Oversizing)







## M/79 with Bicuspid AS

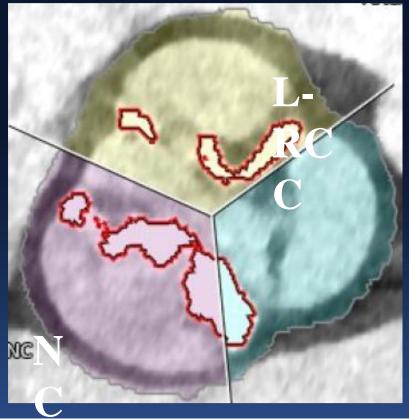


#### Annulus plane\_20%

Aortic Annulus parameters	
Annulus short diameter	21.0 mm
Annulus long diameter	28.8 mm
Annulus mean diameter	24.9 mm
Annulus area	500 mm <sup>2</sup>
Annulus area-driven diameter	25.2 mm
Annulus perimeter	81.1 mm
Annulus perimeter-driven diameter	25.8 mm



# CT findings – Aortic Valve Complex



Calcium volume	
NCC	875 mm <sup>3</sup>
L-RCC	436 mm <sup>3</sup>
Total	1316 mm <sup>3</sup>

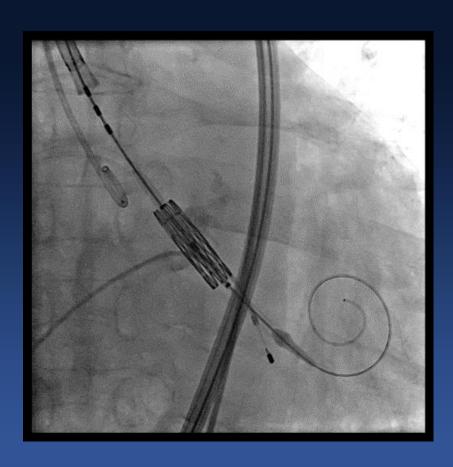


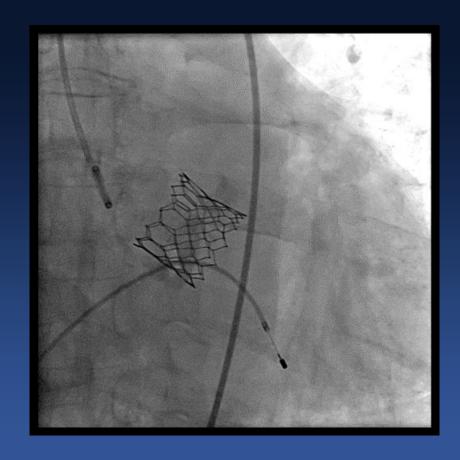
# S3 26mm with 2 cc underfilling (4% Undersizing)

Size	Area Oversize (%)	Perimeter Oversize (%)
23	81.8	88.1
24	89.1	91.9
25	96.6	95.8
26	103.8	99.5
27	111.9	103.3
28	120.4	107.2
29	129.8	111.3



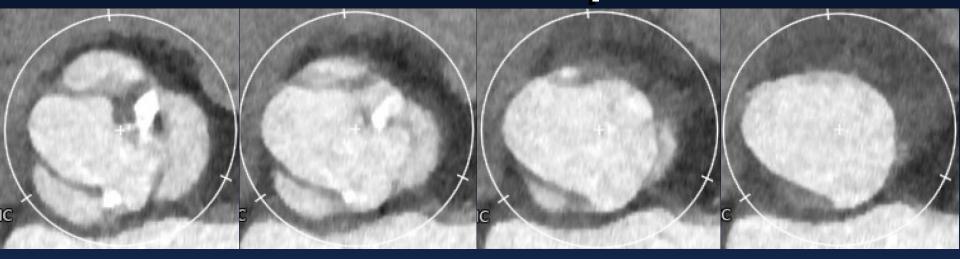
# S3 26mm with 2 cc underfilling (4% Undersizing)







# M/83 with Bicuspid AS

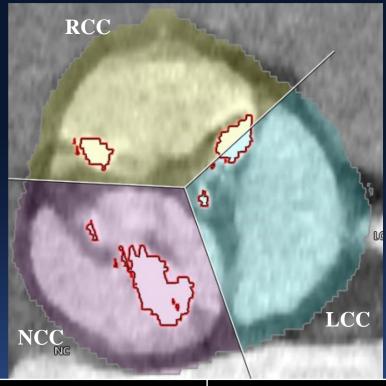


#### **Annulus plane**

Aortic Annulus parameters	
Annulus short diameter	25.3 mm
Annulus long diameter	34.1 mm
Annulus mean diameter	29.7 mm
Annulus area	710 mm <sup>2</sup>
Annulus area-driven diameter	30.1 mm
Annulus perimeter	97.0 mm
Annulus perimeter-driven diameter	30.9 mm



## CT findings – Aortic Valve Complex



Calcium volume	
NCC	366 mm <sup>3</sup>
RCC	295 mm <sup>3</sup>
LCC	166 mm <sup>3</sup>
Total	828 mm <sup>3</sup>

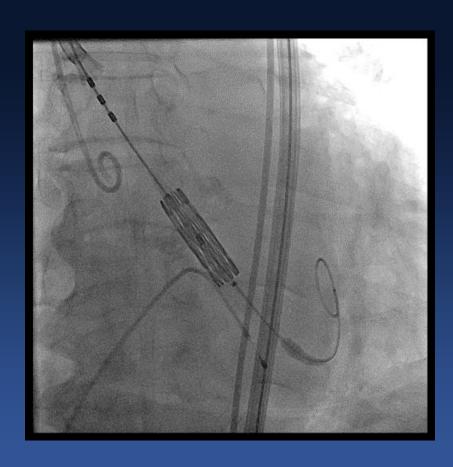


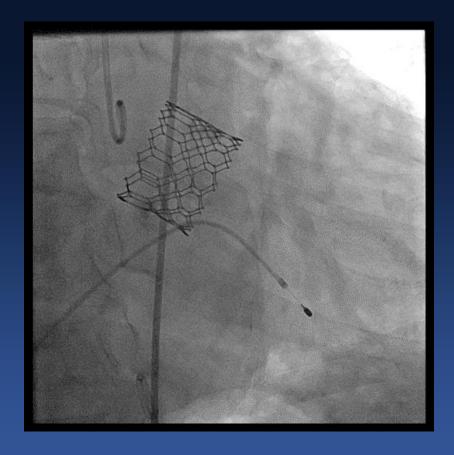
# S3 29mm (-9% Undersizing)

Size	Area Oversize (%)	Perimeter Oversize (%)
26	73.1	83.2
27	78.8	86.4
28	84.8	89.6
29	91.4	93.1
30	97.8	96.3
31	104.4	99.5



# S3 29mm (9% Undersizing)



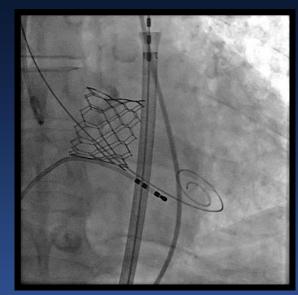




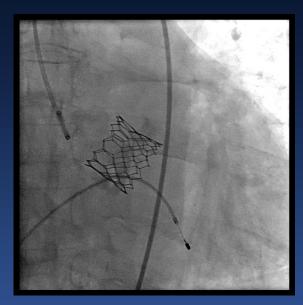
#### Undersizing is Effective and Safe

S3 29mm with -3cc Underfill (2% Oversizing) S3 26mm with 2 cc underfilling (4% Undersizing)

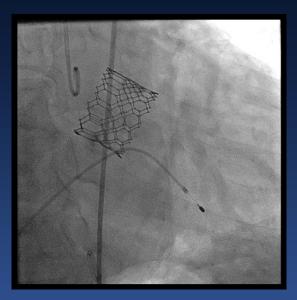
S3 29mm (9% Undersizing)



Calcium 664



Calcium 1316



Calcium 828

Don't Do Oversizing in S3



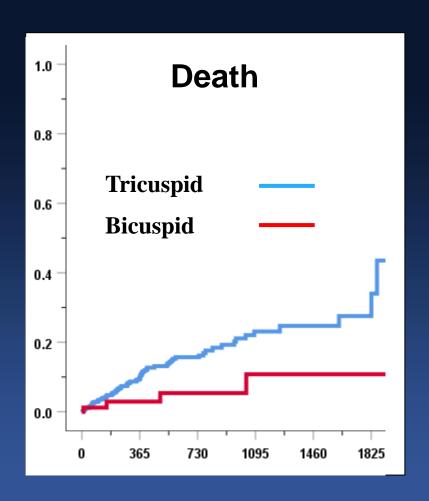


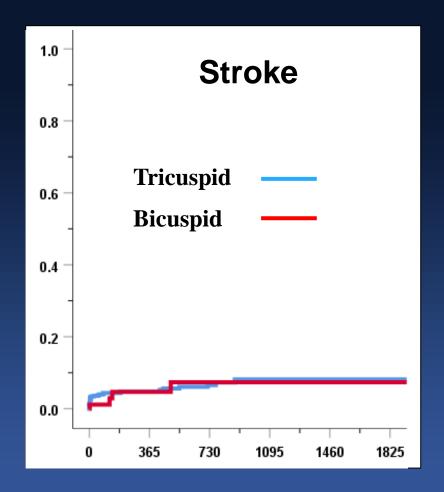
## **Procedural Outcomes**

	Bicuspid AS (N = 89)	Tricuspid AS (N = 493)	P value
Pre-Balloon Valvuloplasty	66 (74.2%)	288 (42.2%)	<0.001
Post-Balloon Valvuloplasty	14 (15.7%)	89 (13.0%)	0.48
Annular Root Injury	0	1 (0.1%)	0.24
New Permanent Pacemaker	4 (4.5%)	50 (7.3%)	0.33
PVL ≥ Moderate	4 (4.5%)	8 (1.2%)	0.017



## **Death and Stroke**







### Optimal TAVR by BEV for Bicuspid AV

- We need more experiences.
- Case selection is important
- The incidence of paravalvular leakage is increased compared to tricuspid aortic valve cohorts undergoing TAVR.
- Aortic injury should be cautious.
- TAVR for bicuspid AS is not associated with excess risk of mortality and stroke.
- S3 implantation on bicuspid AV is not generally different from S3 implantation on tricuspid AV.
- Don't Do Oversizing, Undersizing is Safe and Effective in Bicuspid AS