

Sizing and Treatment of Low Risk Bicuspid Patients



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Conflict of interest

-Consultant for

Abbott/Boston Sci/Edwards/Medtronic/4Tech/ T-Heart

Patient selection for TAVI

Evolut Low Risk Bicuspid Study Summary

- TAVI with Evolut supra-annular self-expanding valve in **low-risk bicuspid patients** (mean age 70.3 ± 5.5 years) achieved excellent early results using consistent annular sizing:
 - 95.3% device success
 - Low mortality and stroke at 30 days (1.3%)
 - Consistent hemodynamics across Sievers Classification: mean EOA 2.3 cm² at 30 days, mean gradient 7.6 mmHg, No moderate/severe AR, severe PPM in 5.3%
- Patients will be followed for 10 years

Transcatheter Aortic Valve Replacement in Low-Risk Bicuspid and Tricuspid Patients: Meta-Analysis

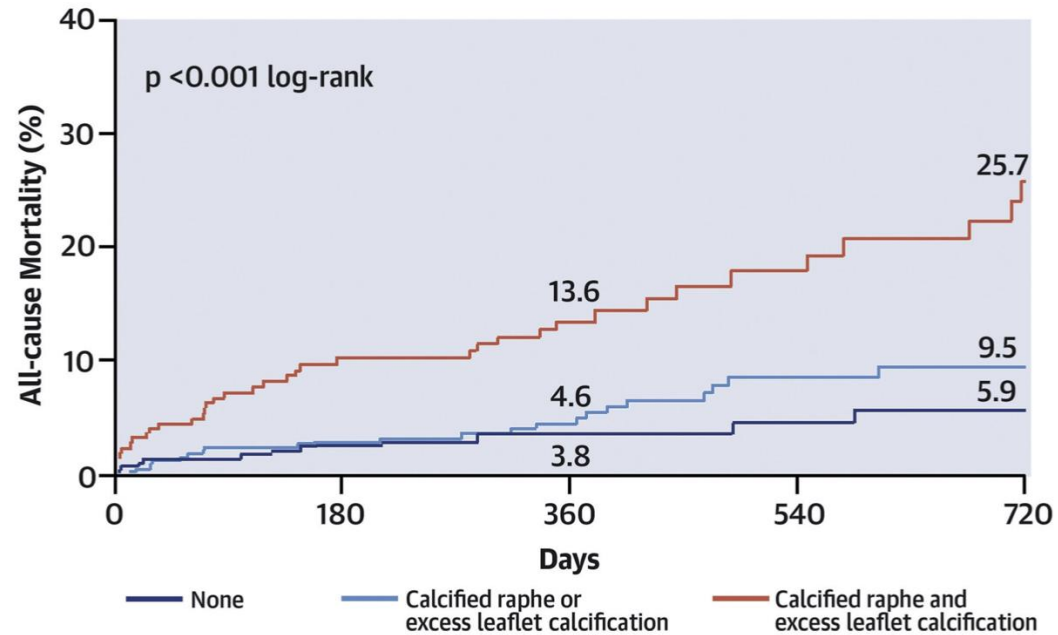
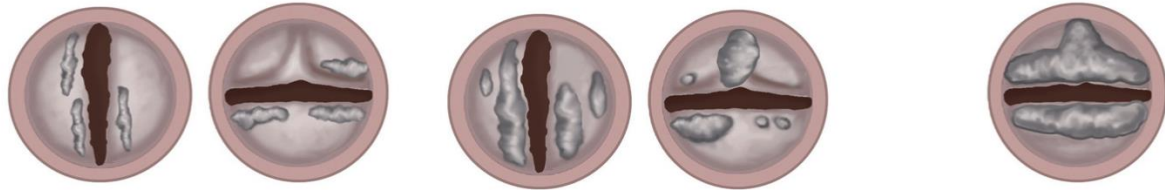
Giorgio A Medranda ¹, Toby Rogers ², Gheorghe Doros ¹, Cheng Zhang ¹, Brian C Case ¹,
Charan Yerasi ¹, Christian C Shults ³, Ron Waksman ⁴

Conclusions: Preliminary data from the FDA-approved IDE trials of low-risk patients with bicuspid AS undergoing TAVR demonstrated 30-day outcomes comparable to low-risk tricuspid patients, except for a trend toward higher stroke in bicuspid patients. Randomized trials are warranted to reassure the safety and long-term outcome of TAVR in patients with severe bicuspid AS.

CENTRAL ILLUSTRATION: Death From Any Cause According to Morphological Features

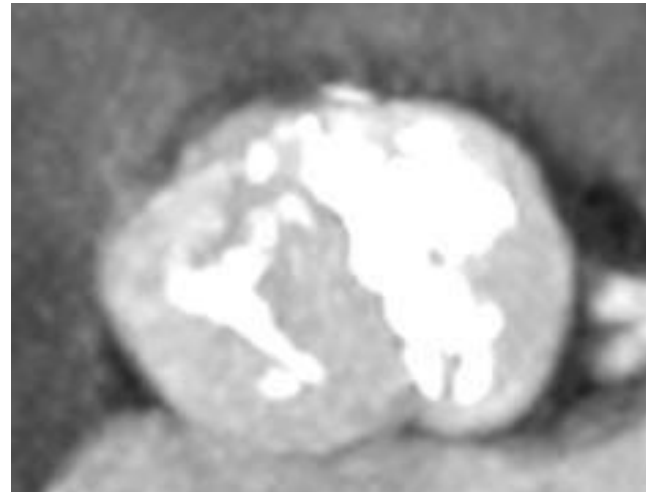
Death From Any Cause, According to Morphological Features

Morphological Feature	Percentage
No Calcified Raphe or Excess Leaflet Calcification	31.3%
Calcified Raphe or Excess Leaflet Calcification	42.6%
Calcified Raphe Plus Excess Leaflet Calcification	26.0%



Anatomical differences with tricuspid aortic valves

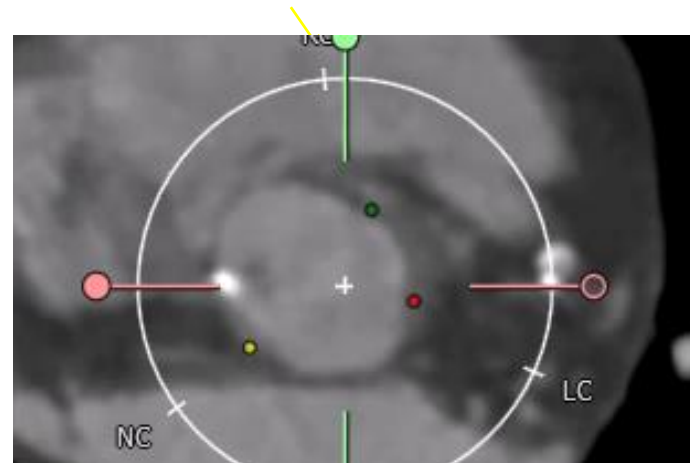
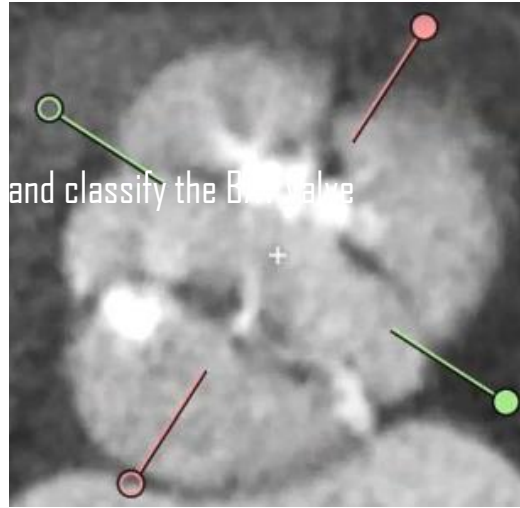
- XL Annulus sizes
- XL Sinus height and width
- Heavy calcifications
- **Widened ascending aorta**
- Higher coronary take-off
- Coronary ostium closer to commissure



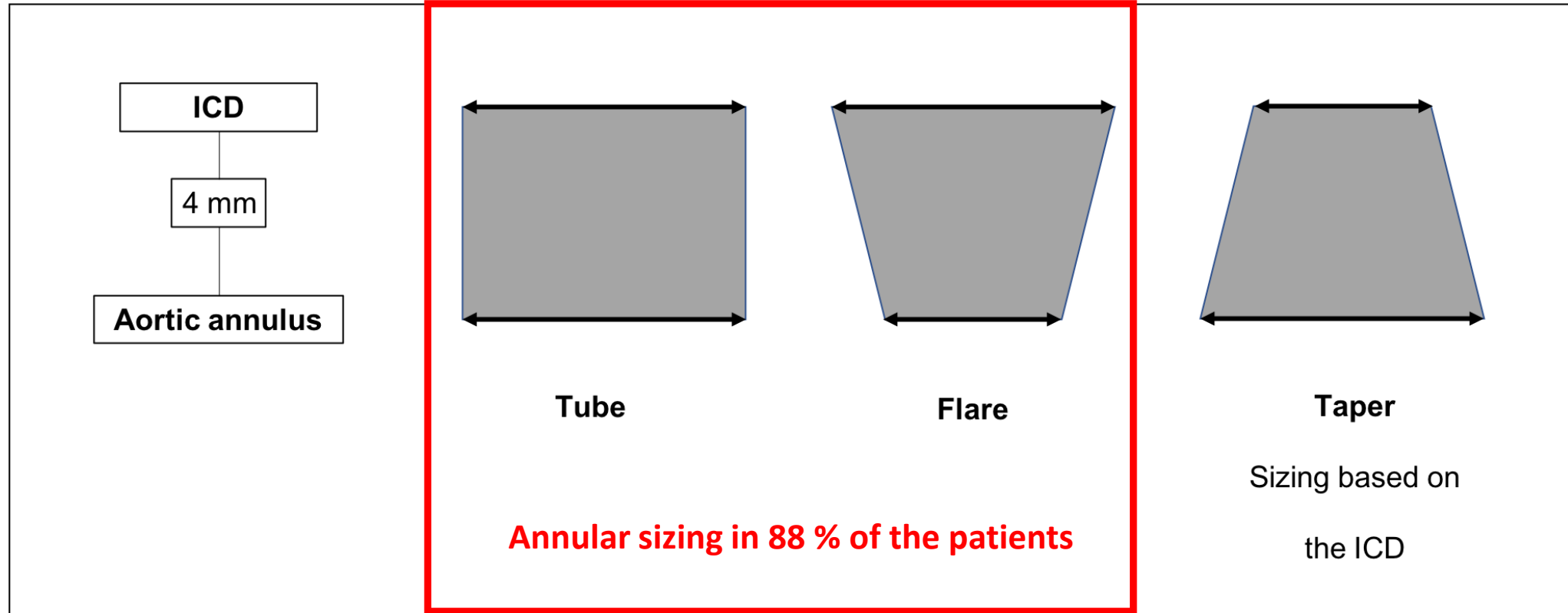
Sizing for BAV

CT scroll technique: the reference

- In mid-systole, identify the basal annular plane and slowly scroll up and down from the annulus to above the sinuses of valsalva.
- Supra-annular measurements standardized at +4 mm (BAVARD registry): ICD and tracing
- Examination of the images can identify the following:
 - Location and morphology of cusps and leaflets
 - Presence of any raphe between leaflets
 - Extent and distribution of calcium
 - Location of coronary arteries
 - Size and shape of supra-annular EDA



BAVARD sizing strategy according to the landing zone configuration



Retrospective and simplified CT Sizing utilized in the BAVARD registry

Mean prosthesis-annulus ratio:

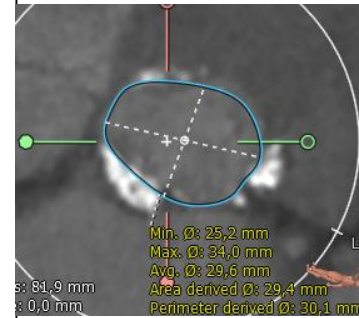
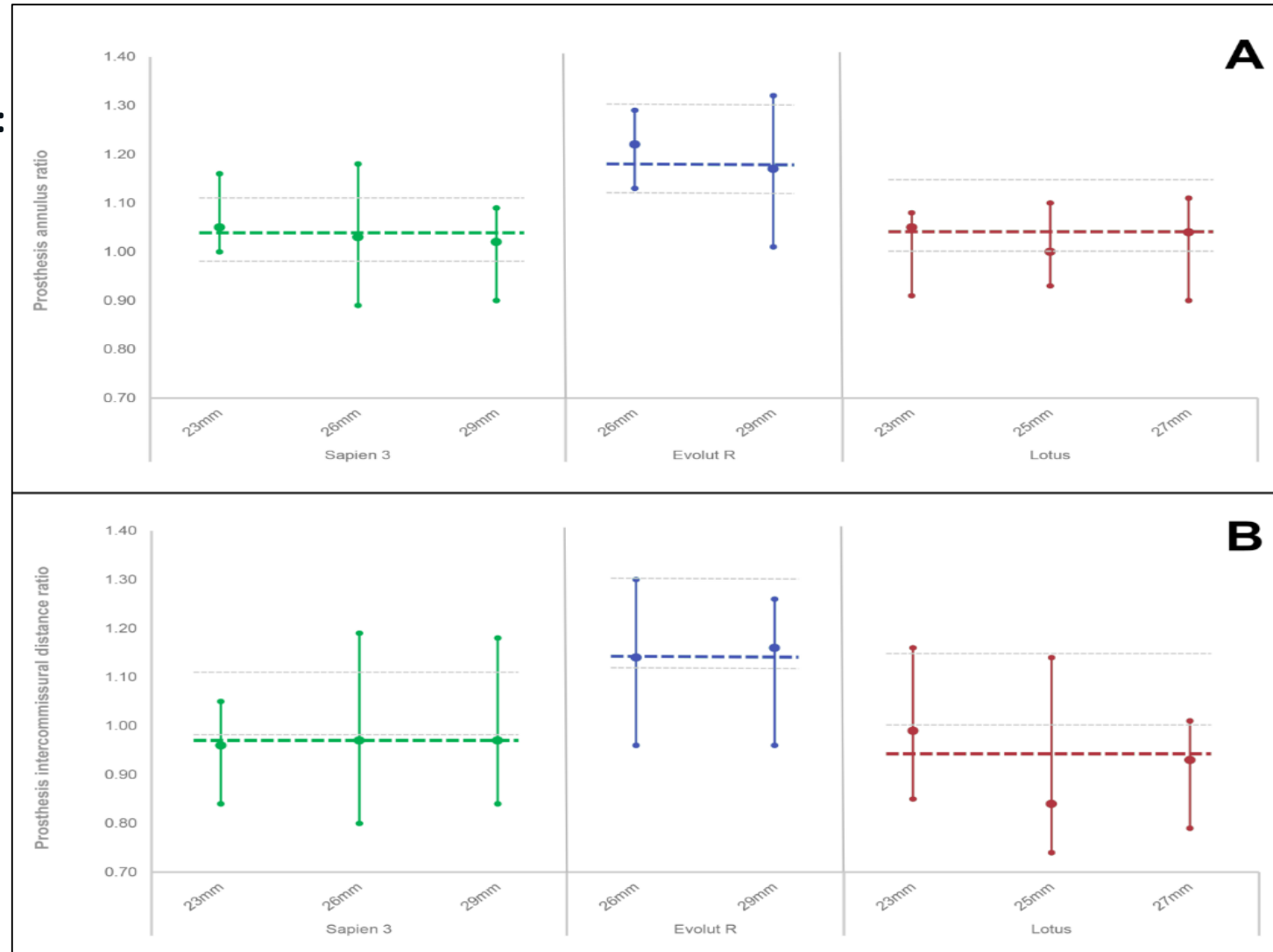
1.037±0.09 (BAV)

VS

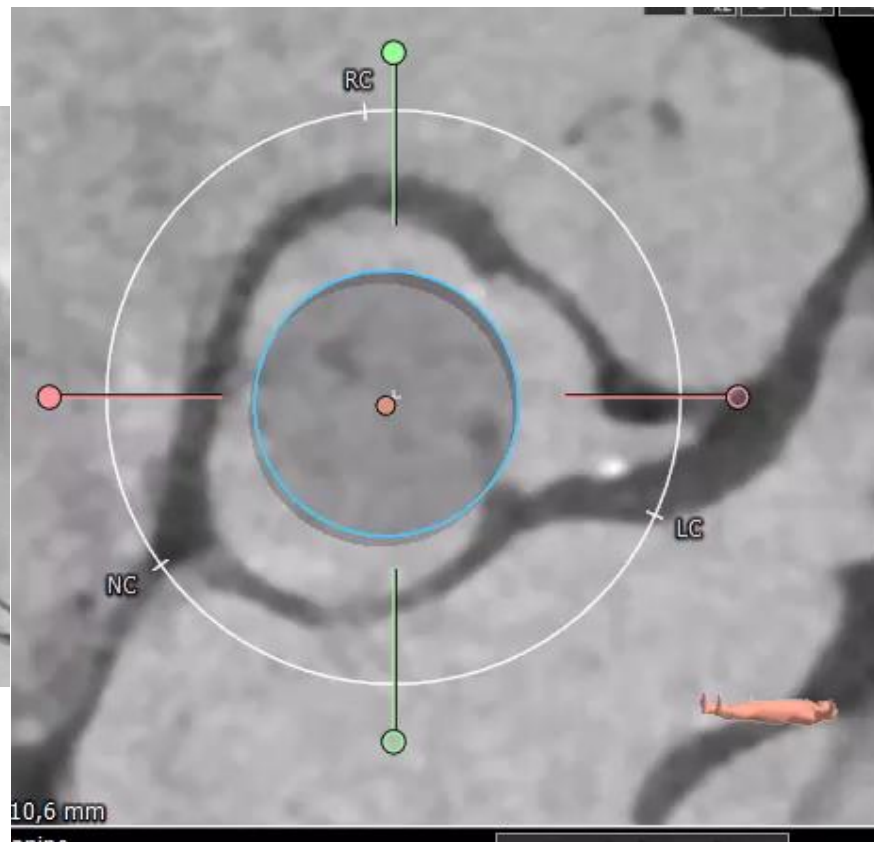
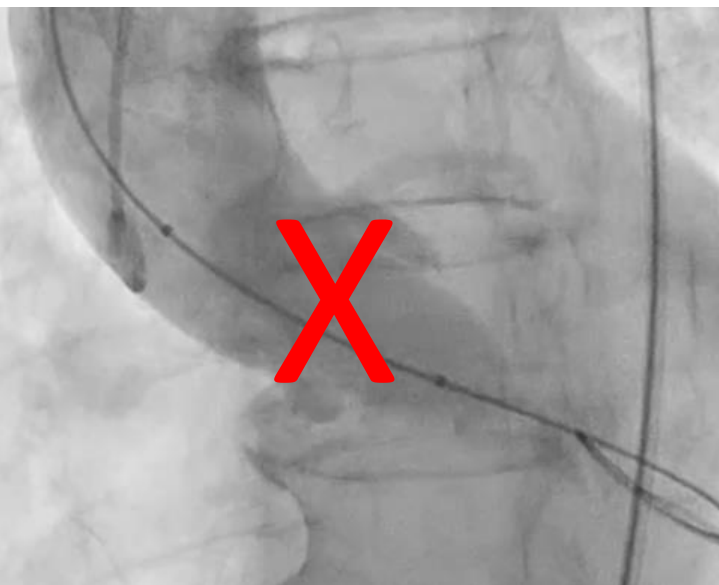
1.14±0.09 (TAV)

Mean prosthesis-ICD ratio:

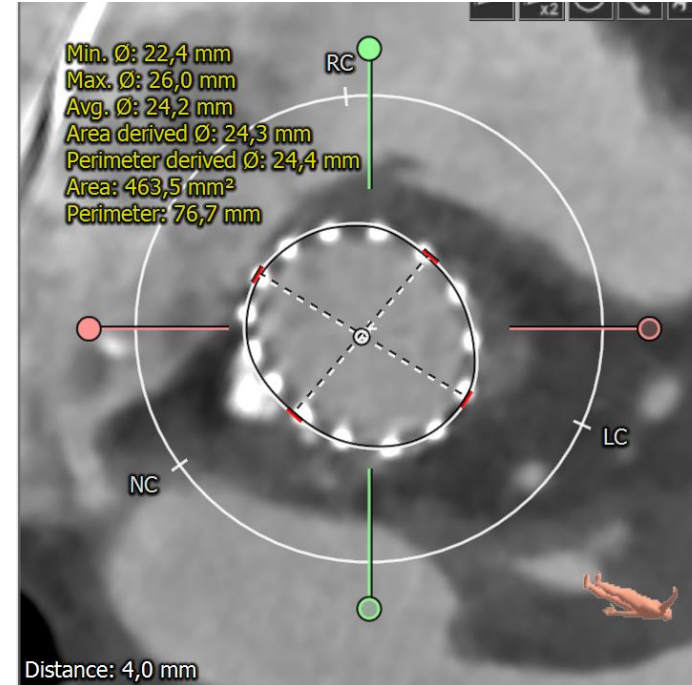
1.032±0.11 (BAV)



CT Assessment: circle method-23 Sapien 3



Supra-annular tracing: anticipating the final THV diameter



Premieter-derived diam at baseline seems to correlate with post implant prosthesis mean diameter

Key messages for sizing in bicuspid anatomies:

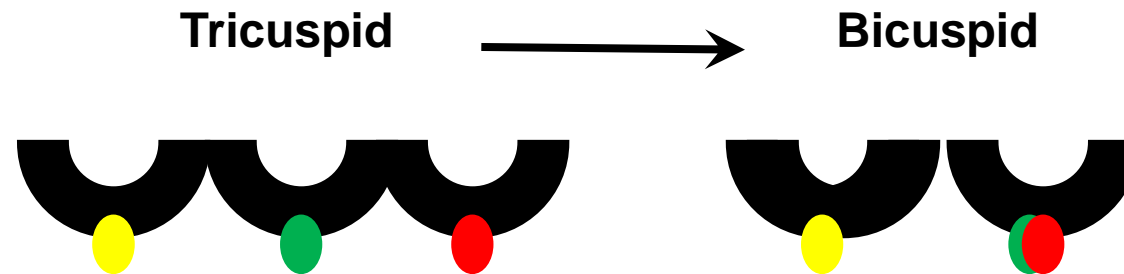
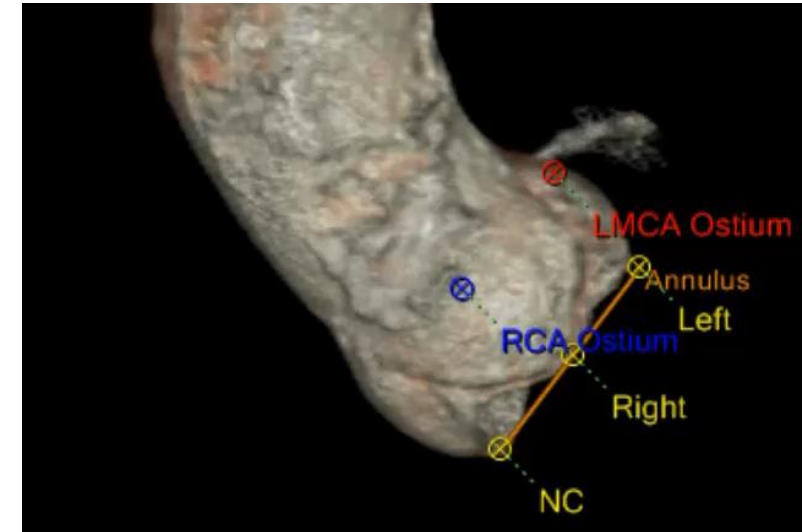
- CT sizing is the gold standard**
- Annulus-based sizing is efficient in about 90% of BAV patients**
- Supra-annular sizing recommended for understanding of the landing zone configuration**
- Circle method for BEV**
- Be cautious in tapered configurations and extremely calcified anatomies**
- Avoid excessive oversizing:**
 - constant underexpansion or devices about 10-15% as compared to annular dimension
 - aggressive oversizing may lead to complications

Procedural considerations

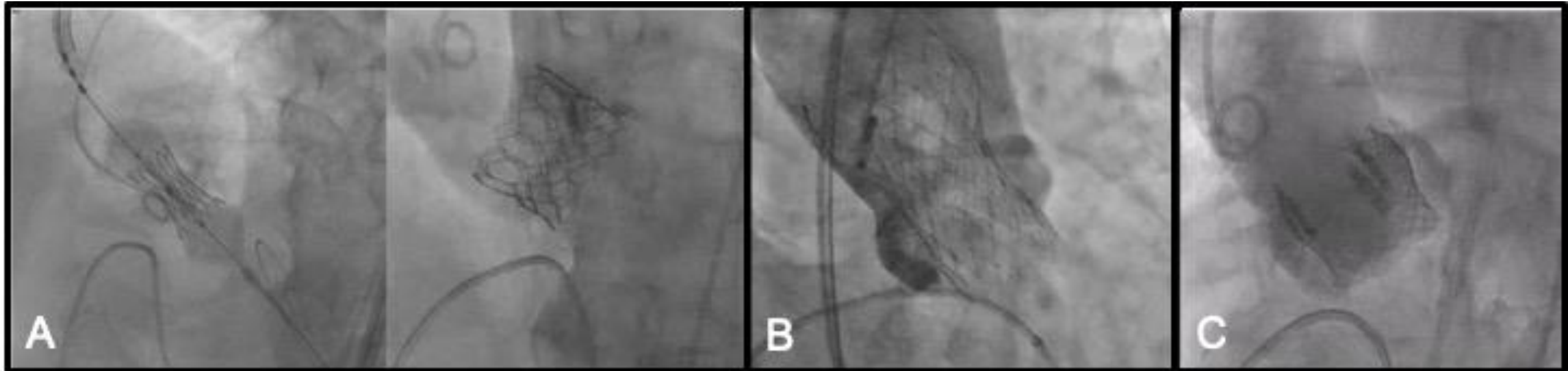
TAVI in Bicuspid

procedural considerations

- Implanter's view – 2 cusp view



Higher implant depth

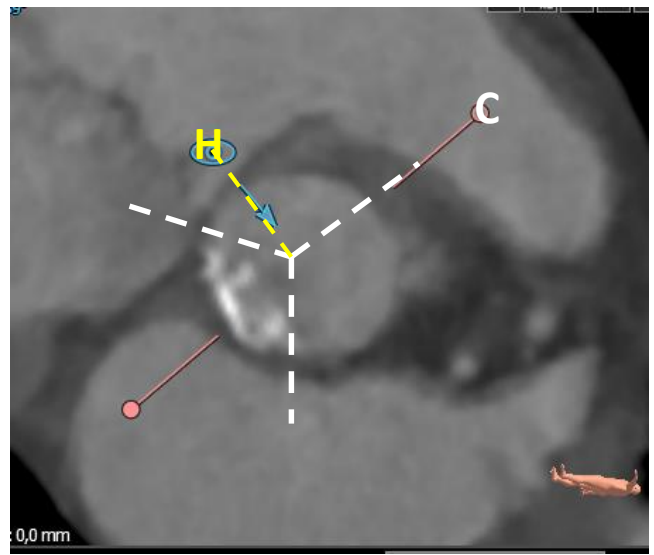
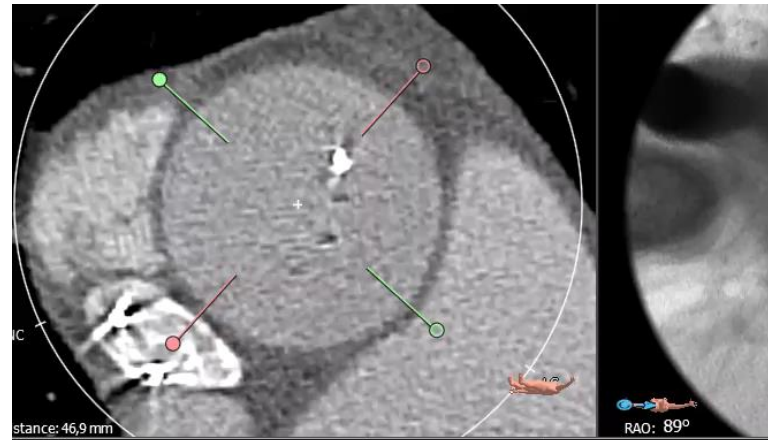
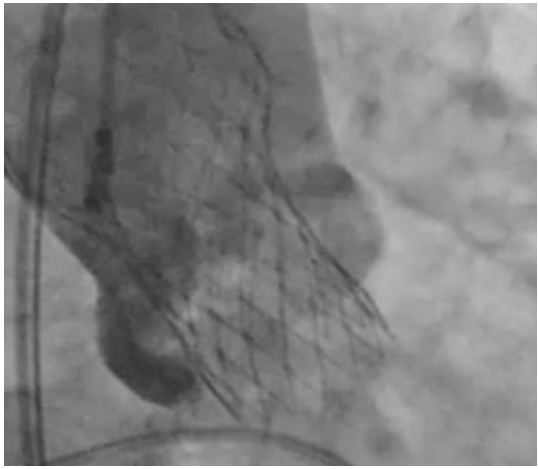
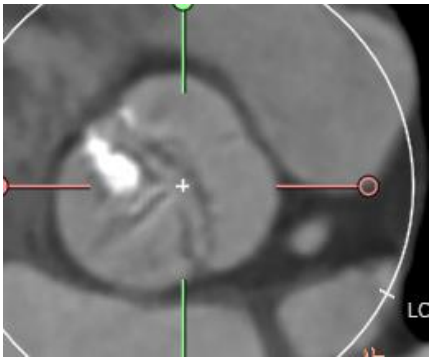




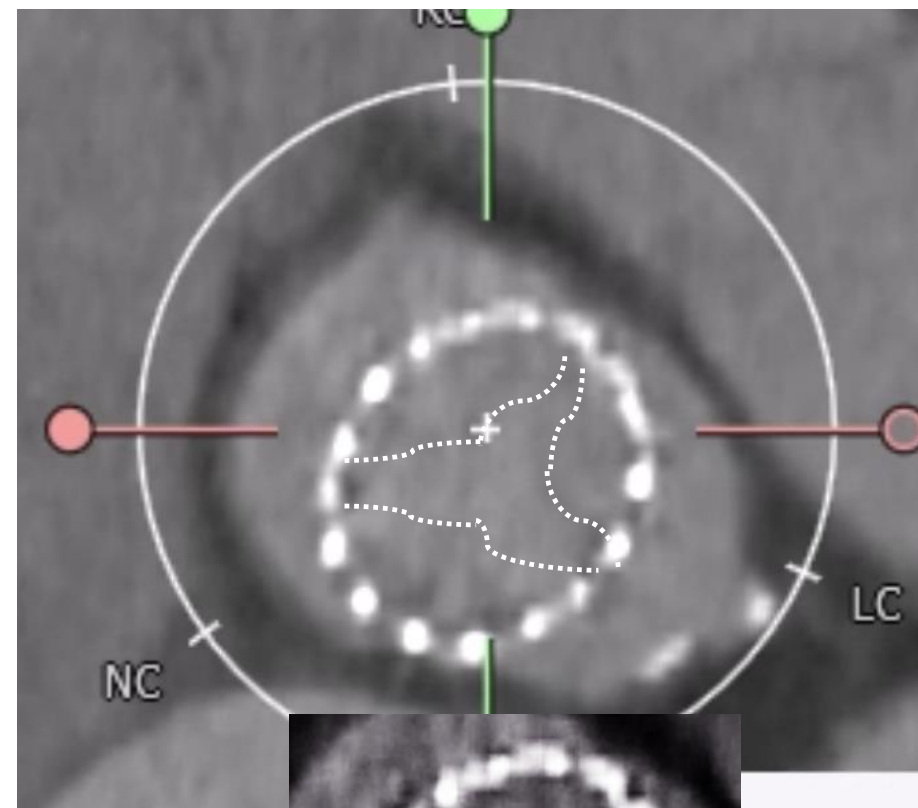
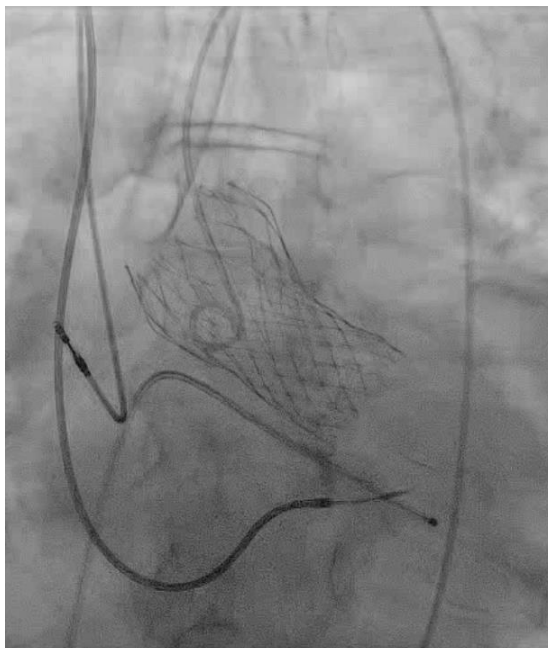
Procedural data	N = 151	Annular sizing N = 78	Combined sizing N = 73	P value
Valve size				
Evolut PRO 26, n (%)	20 (13.2)	10 (13.2)	10 (13.7)	0.7
Evolut PRO 29, n (%)	70 (46.4)	33 (43.4)	35 (47.9)	
Evolut R XL 34, n (%)	54 (35.8)	28 (36.8)	26 (35.6)	
Number of valve used				
1, n (%)	145 (97)	72 (94.7)	71 (98.6)	0.2
2, n (%)	3 (2.0)	3 (3.9)	0 (0)	
Repositioning, n (%)	45 (29.8)	20 (26.3)	25 (34.2)	0.4
Predilatation, n (%)	131 (86.8)	66 (86.8)	65 (89)	0.8
Size of balloon, median (IQR)	23 (22-24)	23 (22-24)	23 (21-24)	-
Postdilatation, n (%)	83 (55)	42 (55.3)	40 (54.8)	1
Size of balloon, median (IQR)	25 (23-28)	25 (23-27)	25 (23-28)	-
Procedural mortality, n (%)	1 (0.7)	0 (0)	1 (1.4)	0.5

Tchetche et al,
presented #e-PCR 2020

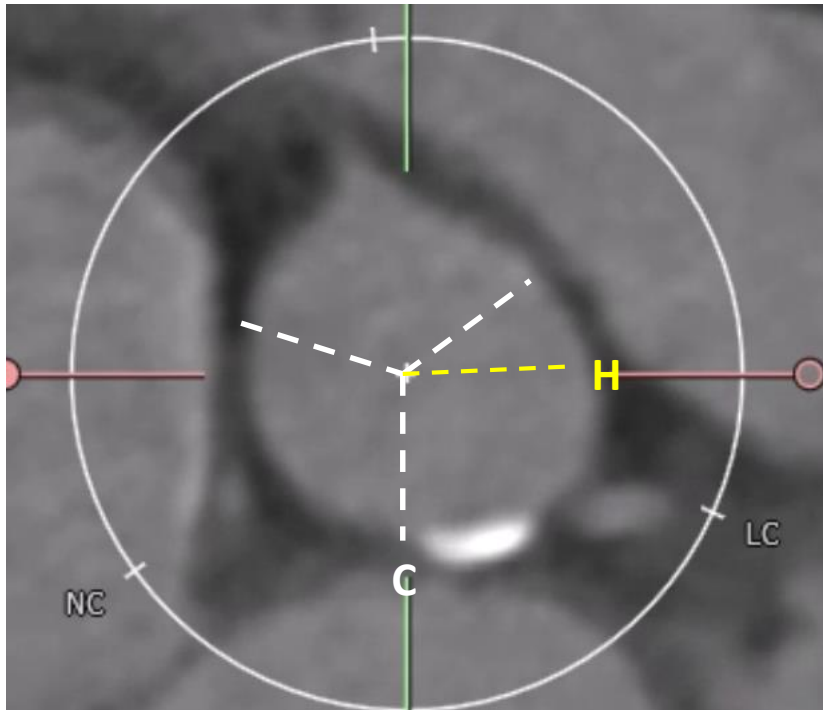
Type 1 LR bicuspid: commissure aligned with raphe



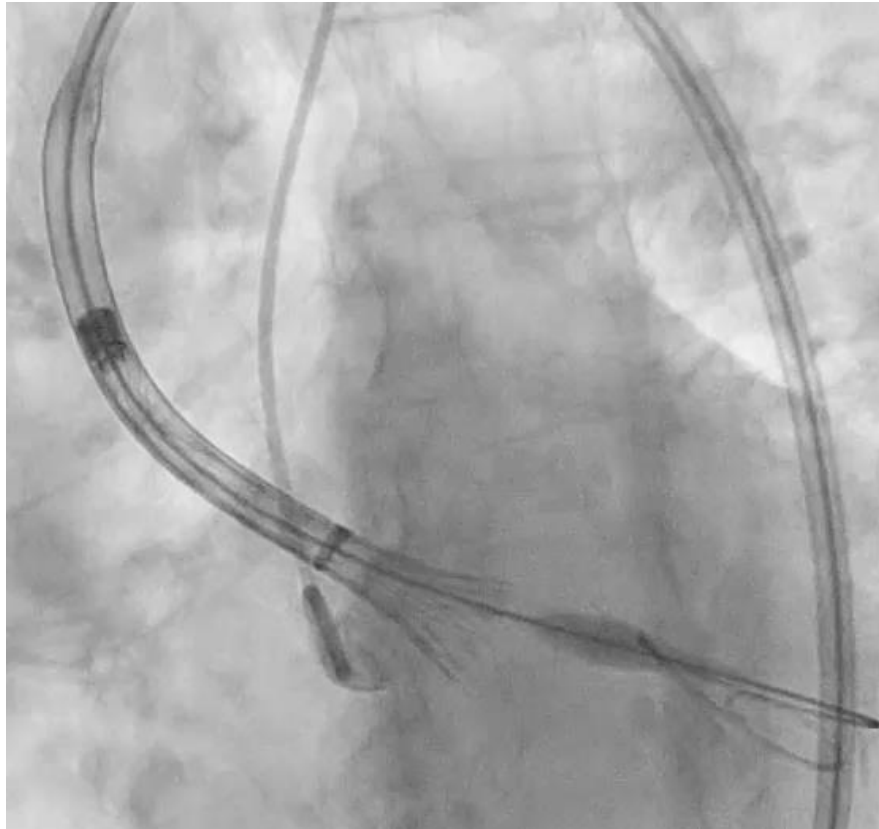
Non type I LR bicuspid: higher risk of misalignment



Evolut Pro in type 1 RN



Evolut Pro in type 1 RN: flush port at 8-9 O'clock



Key messages about TAVI techniques for bicuspid valves

- **2 cusps view**
- **Predilate: minor diameter of the annulus**
- **Commissural alignment**
- **High implants, remaining across the annulus (reposition SEV if necessary)**
- **Assess stent frame expansion in two orthogonal views**
- **Postdilate if necessary: frame optimization**

MERCI

THANK YOU

DANKE

どうもありがとう

GRACIAS

谢x谢

OBRIGADO

GRAZIE

BEDANKT

DEKUJI

Спасибо

ΕΦΗΑRΙΣΤΟ

