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Optimal TAVR Procedure for Bicuspid AV Stenosis: Self-Expanding Devices

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Financial Disclosure

I, Eberhard Grube have the following financial interest/arrangement that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

Speaker Bureau/ SAB: Medtronic, Boston Scientific, HighLife, Jena Valve, Protembis

Equity Interest: Cardiovalve, Claret, Shockwave, Valve medical, CardioMech, Millipede, Imperative Care, Pi-Cardia, Ancora, Laminar, ReNiva Medical

Quote of the late Secretary Rumsfeld:

”…there are “***known-knowns”***; those are things we know we know.
We also know there are “***known-unknowns”***; that is to say we know there are some things we do not know.
But there are also “***unknown-unknowns”.*** the ones we don't know we don’tknow..”

TAVR FOR BICUSPID AORTIC VALVE STENOSIS

"KNOWN-KNOWNS"

- BAV is a frequent disease in the general population and in TAVR patients with some geographic differences
- Bicuspid AS will be encountered with greater frequency as TAVR moves into younger patients
- Bicuspid AS is NOT included in any of the pivotal trials – No randomized data exist
- TAVR is approved for Bicuspid AS in the US and in Europe
- Clinical outcomes are comparable between Tricuspid AS and Bicuspid AS when using second-generation THV's

TAVR FOR BICUSPID AORTIC VALVE STENOSIS

"KNOWN-UNKNOWNS"

- Which are the high risk features of bicuspid AS that preclude TAVR ?
- Sizing methodology in BAV ?
- Which valve is optimal for this anatomy ?
- What would be the result of a RCT ?

TAVR FOR BICUSPID AORTIC STENOSIS

"UNKNOWN-UNKNOWNS"

- How many patients will continue to need surgery if a RCT of TAVR vs SAVR will ever get done?

TAVR FOR BICUSPID AORTIC VALVE STENOSIS
"KNOWN-KNOWNS"

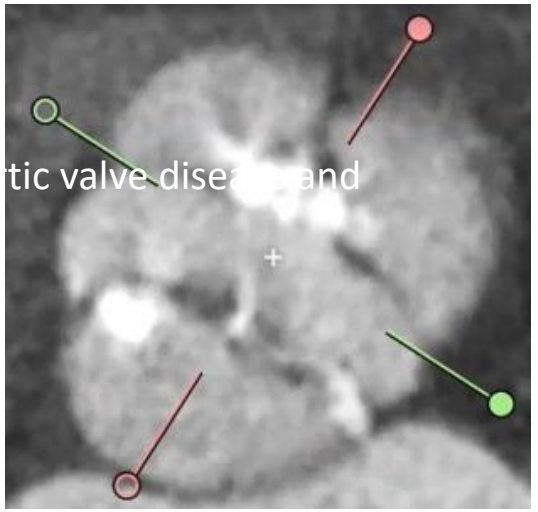
- ***Procedural Considerations (Self Expanding Valves)***

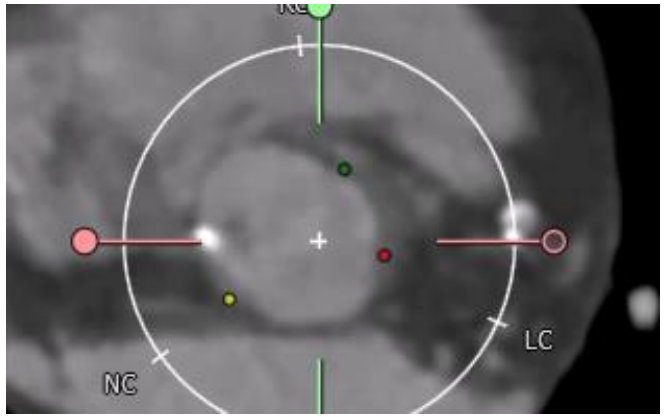
  - Concerns / Role of CT
  - Wire and Pigtail
  - Predilatation Sizing
  - Implantation Technique
  - Post Dilatation
  - Complications

CT SCROLL TECHNIQUE in BAV

- **In mid-systole, identify the basal annular plane** and slowly scroll up and down from the annulus to above the sinuses of valsalva.

- ***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 EOA**

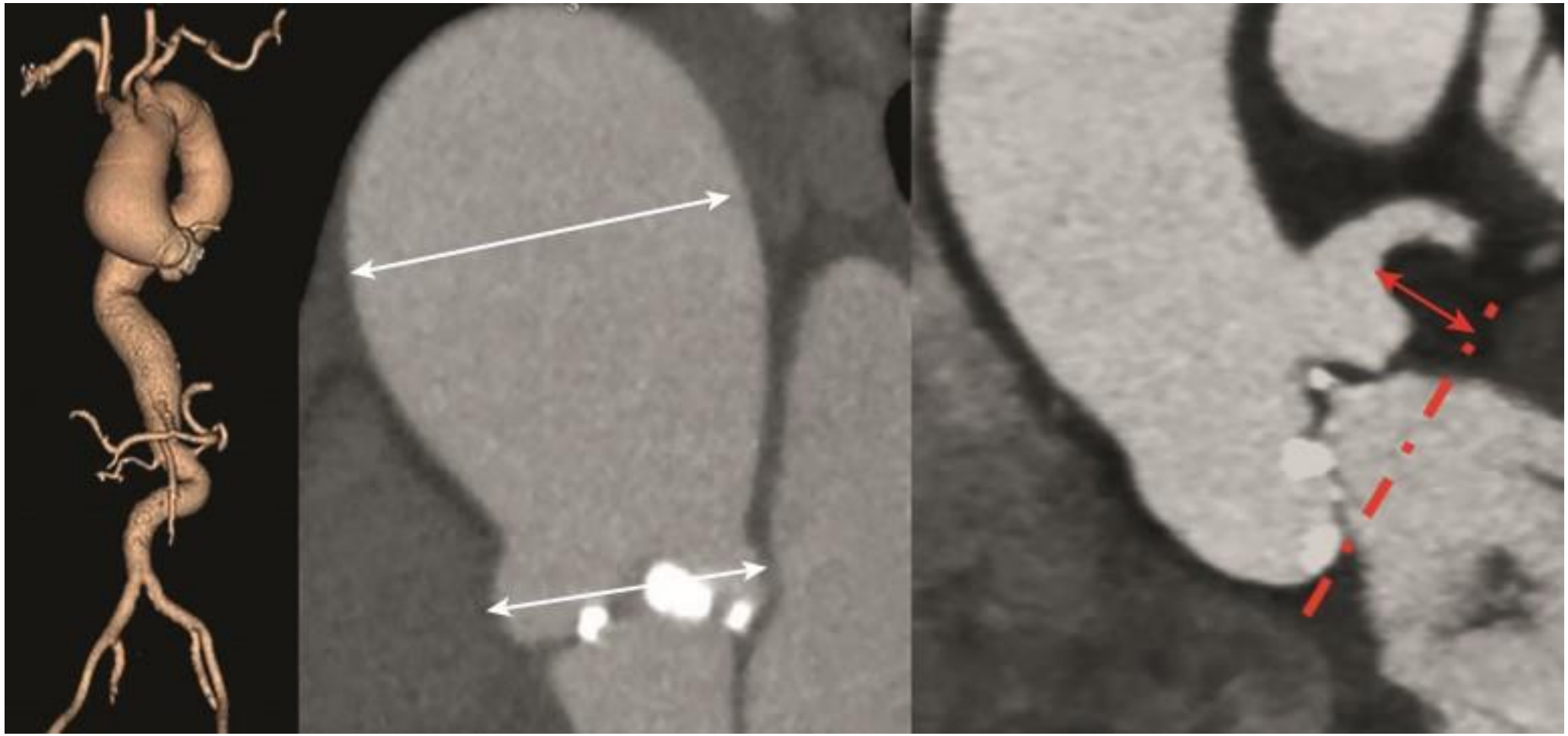




BICUSPID AORTIC VALVE DISEASE

CRITICAL ADDITIONAL CT MEASUREMENTS

Iliofemoral Anatomy **Ascending Aorta/SOV/Annulus** **Coronary Height**



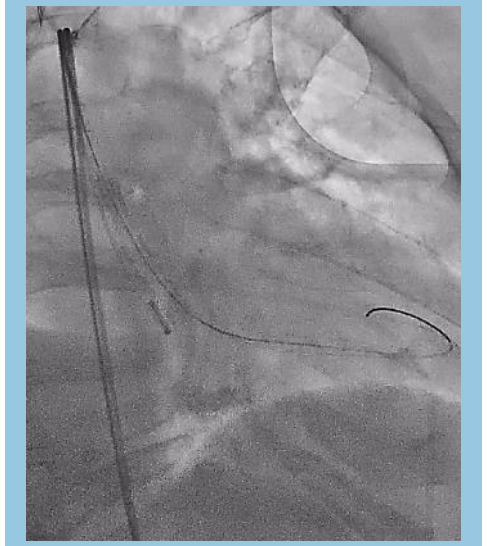
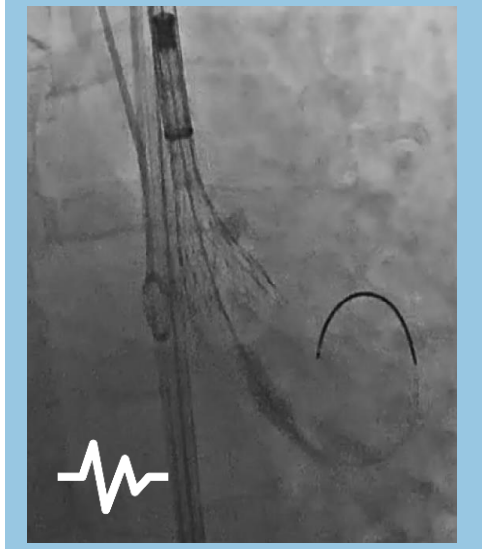
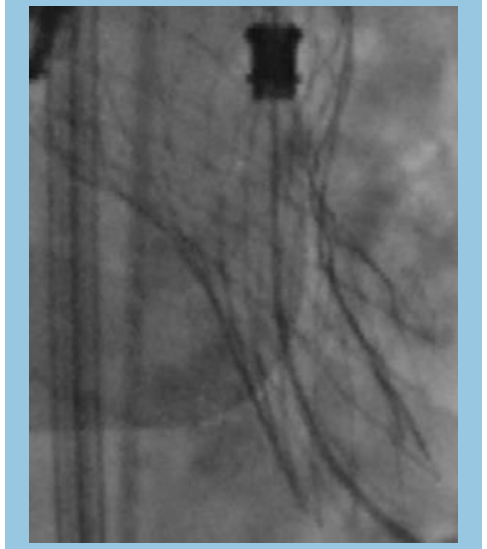
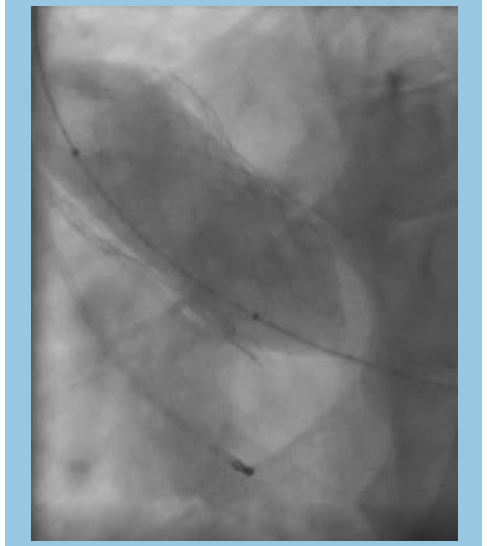
Bax JACC CV Imaging 2019; 13 (1); 124-139

EVOLUT IMPLANT PROCEDURE IN BAV

PROCEDURAL CONSIDERATIONS

Follow standard implantation best practices with…

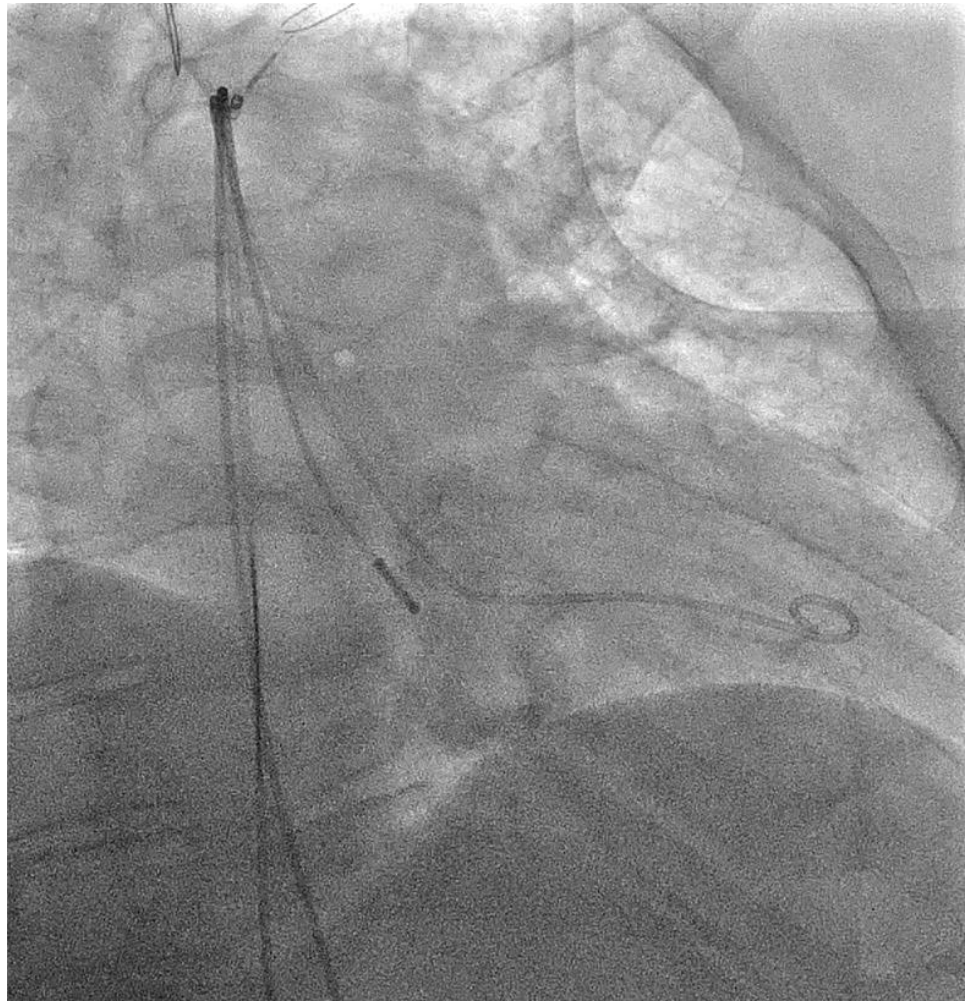
(Minor adaptations to address unique characteristics of a native bicuspid valve)

Pigtail and wire position	Pre-dilatation	Pacing	Frame expansion	Post-dilatation
				

BAV PROCEDURAL CONSIDERATIONS

Pigtail and Wire Considerations

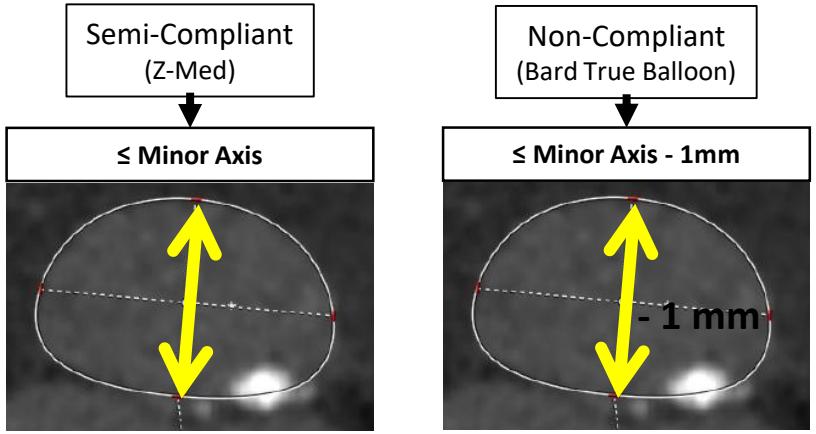
- Place pigtail at the **bottom of the NCC** (or lowest sinus for Type 0 bicuspid valves) with catheter following the greater curvature of the aorta.
- **Bicuspid anatomy may alter wire position** – often displacing the wire posteriorly and resulting in increased device parallax.
    - Consider **pre-dilatation and a stiff wire** to help achieve a more favorable wire position.

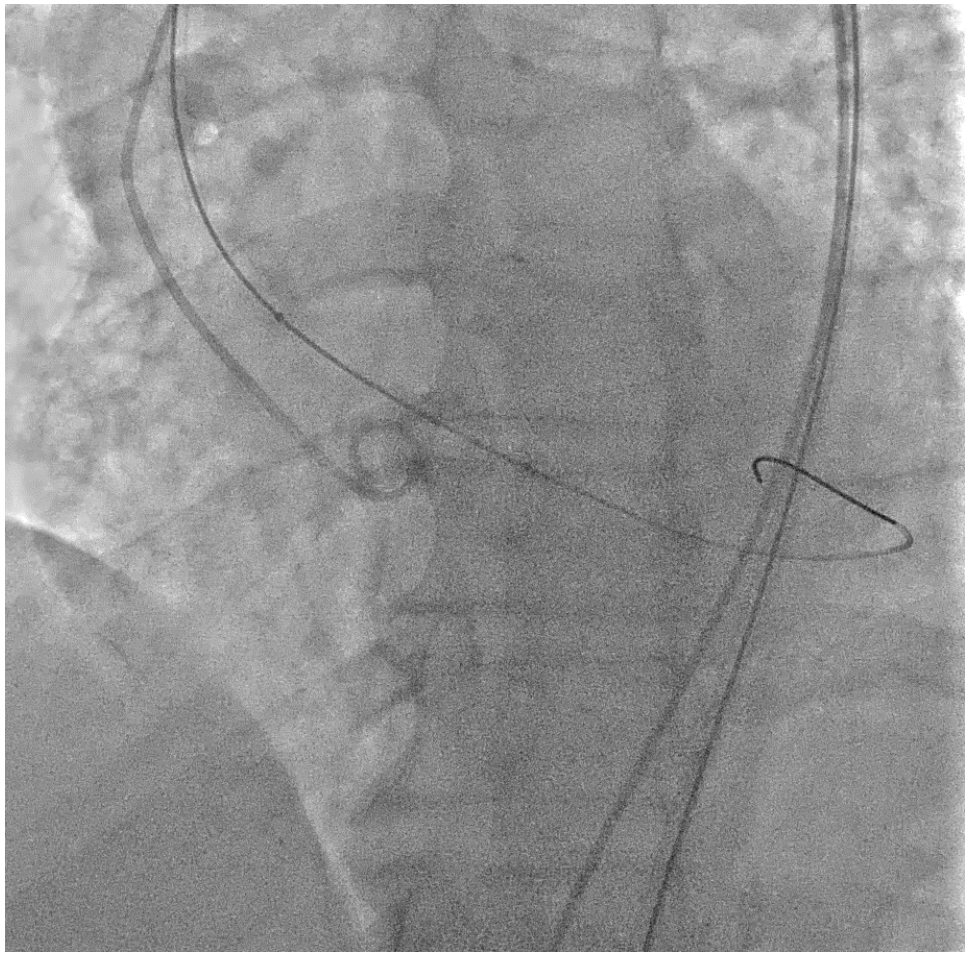


BAV PROCEDURAL CONSIDERATIONS

BALLOON PRE-DILATATION

- Pre-dilatation is **important for BAV** patients to assist with frame expansion as significant leaflet calcification is typically present.[1]
- **Extreme caution must be taken to prevent annular rupture** from balloon inflation -- especially in the presence of dense focal calcification.
- **Balloon should be short (4 – 5 cm), straight, and sized according to the chart below:**



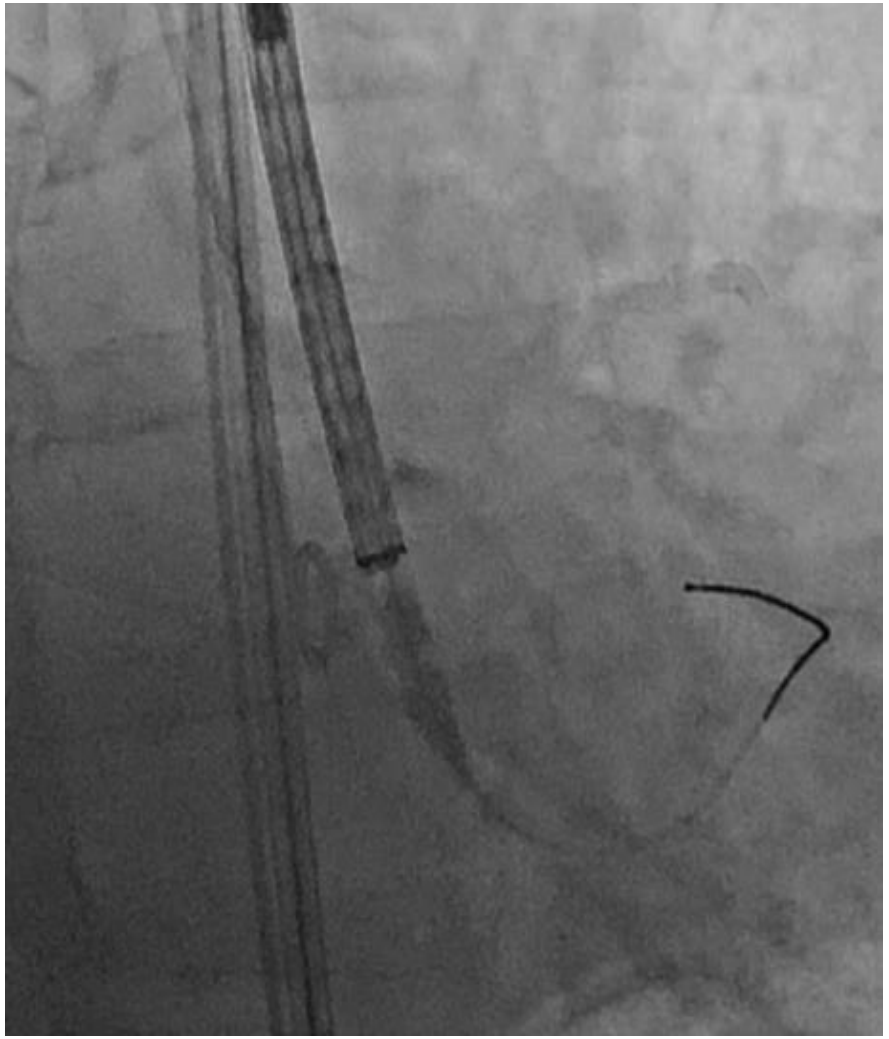


BAV PROCEDURAL CONSIDERATIONS

TEMPORARY PACING

Consider pacing to increase valve stability.

- **Begin pacing when marker band is at 3rd node.**
  - Start pacing at 120 bpm or faster and adjust to achieve desired systolic pressure.*
- **Rapidly deploy from annular contact to before the point of no recapture** as unexpanded bioprosthesis temporarily obstructs cardiac output.
- **Discontinue pacing before reaching the point of no recapture.**
  - ***Consider stepping the pacing rate down incrementally !!!!!***



BAV PROCEDURAL CONSIDERATIONS

Confirm Frame Expansion in Two Views

- **In addition to assessing PVL and hemodynamics, rotate the C-arm on the LAO/RAO axis or obtain a short-axis echo view of the inflow to confirm frame expansion.**
  - **If infolding or under-expansion** is noticed before TAV release, consider **removing the system and performing pre-dilatation** prior to attempting a second deployment with a new valve and delivery system

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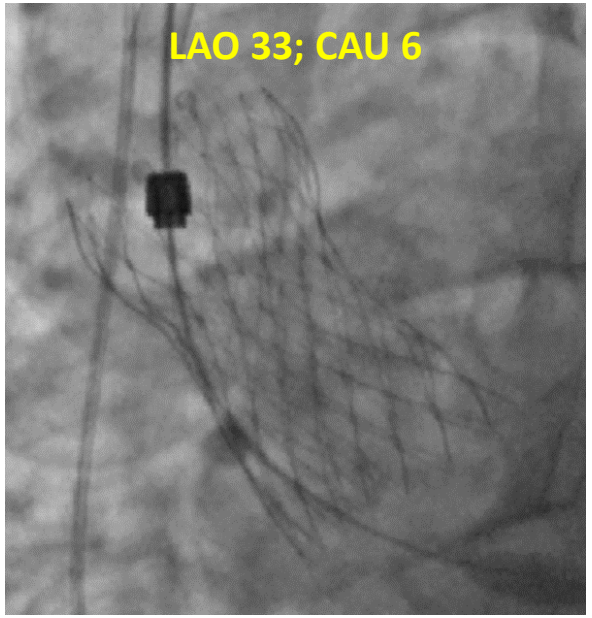
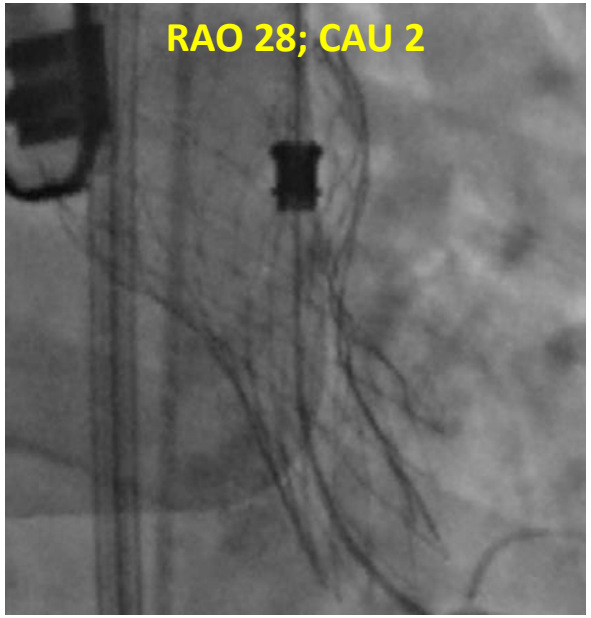




BAV PROCEDURAL CONSIDERATIONS

Balloon Sizing for Post Implation Dilatation (PID)

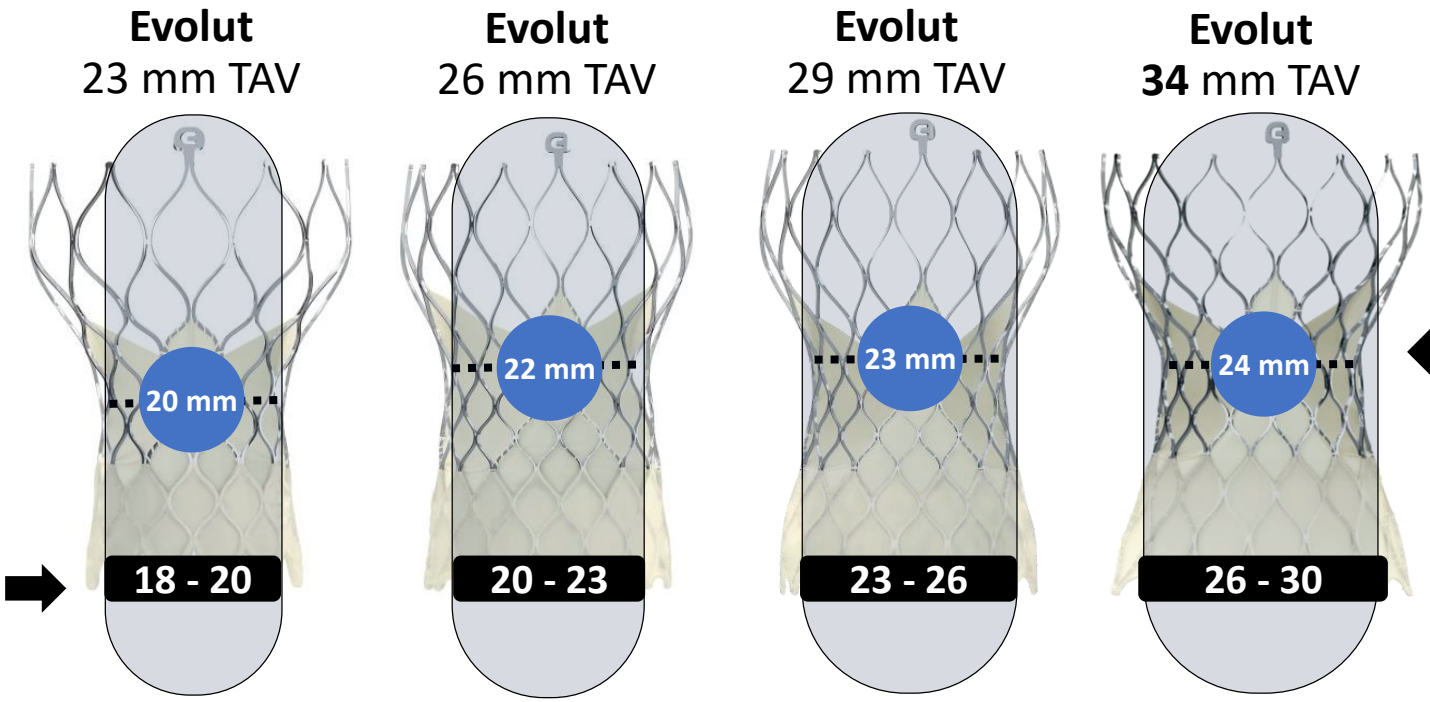
When performing post-implant dilatation (PID) to address valve function or sealing concerns, balloon model, size, position, inflation pressure, and patient anatomy must all be considered to ensure patient safety.

- ***Two primary factors must be considered in selecting a maximum balloon diameter for PID:***

1

PID balloon must be sized smaller than the annulus perimeter derived diameter to mitigate trauma to the annulus.

Treatable Annulus Range (mm)



2

PID balloon must be sized to mitigate over-expansion of the frame waist which can damage the valve leaflets.

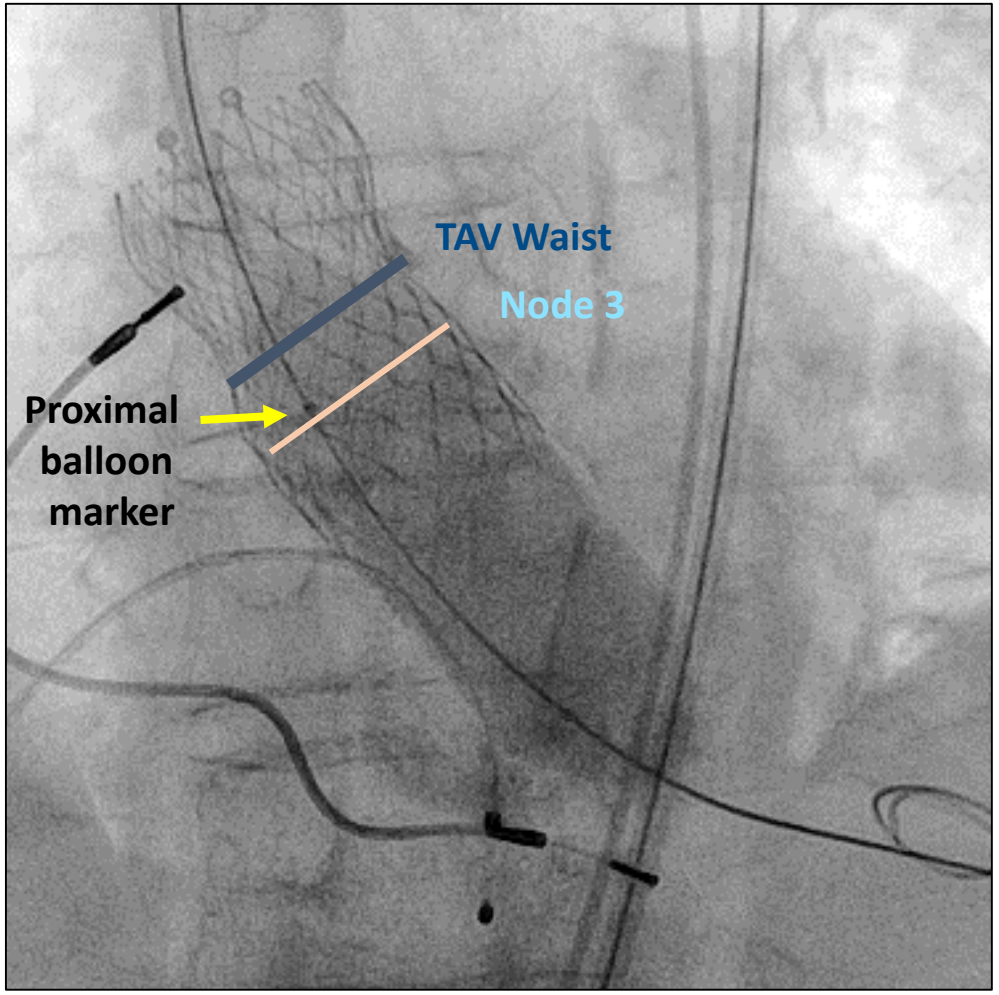
Waist (mm)

BAV PROCEDURAL CONSIDERATIONS

INTRAVENTRICULAR "BAILOUT" BALLOON DILATION

In the event that **larger balloons are required to expand the Evolut frame**, **"bailout" balloon positioning** (i.e., intra-ventricular balloon positioning) **can mitigate the risk of leaflet damage**.

- **Caution:** smaller ventricular cavity, presence of LVOT calcification, or wire positioning (can interfere with mitral valve function)..



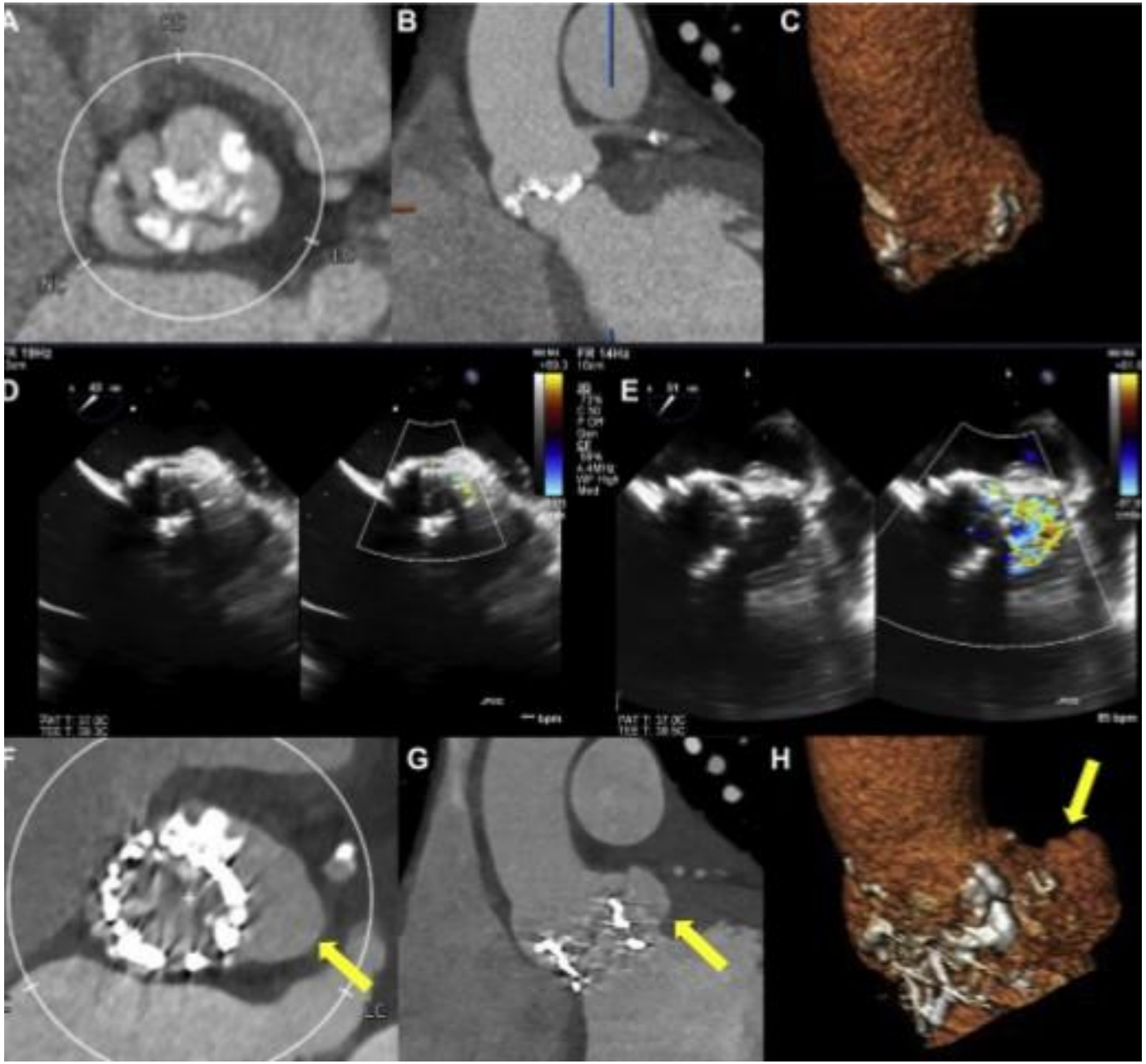
COMPLICATIONS WITH BAV

PVL AND CONTAINED SINUS RUPTURE

- MDCT scans showing **fusion of left and right coronary cusps (Sievers type-1 bicuspid morphology) with severely calcified raphe**.

- **Post-procedural (TEE) showing moderate paravalvular regurgitation.**

- **TEE showing** a **severe paravalvular aneurysmal changes in the left SOV with contained aortic root rupture (yellow arrows).**



COMPLICATIONS WITH BAV

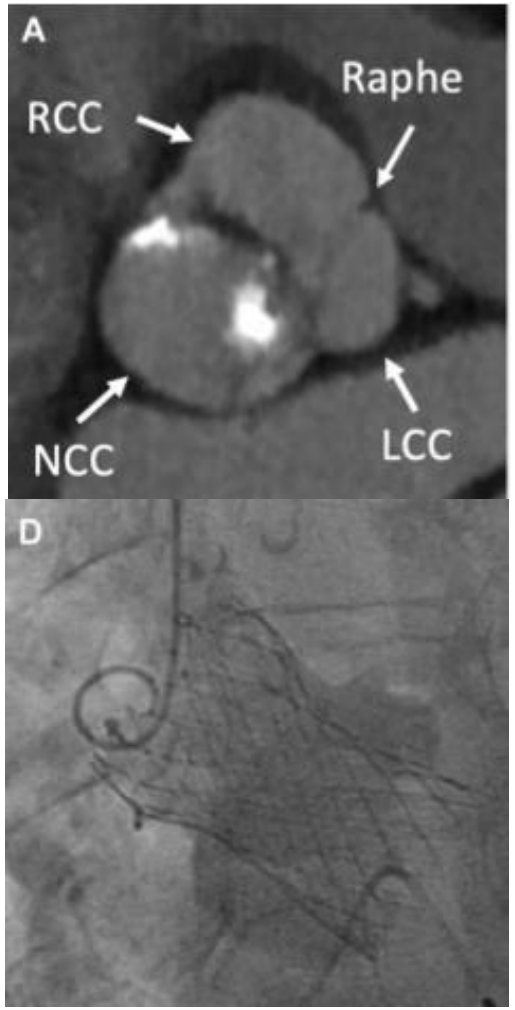
SOV THROMBUS RESOLVED WITH WARFARIN

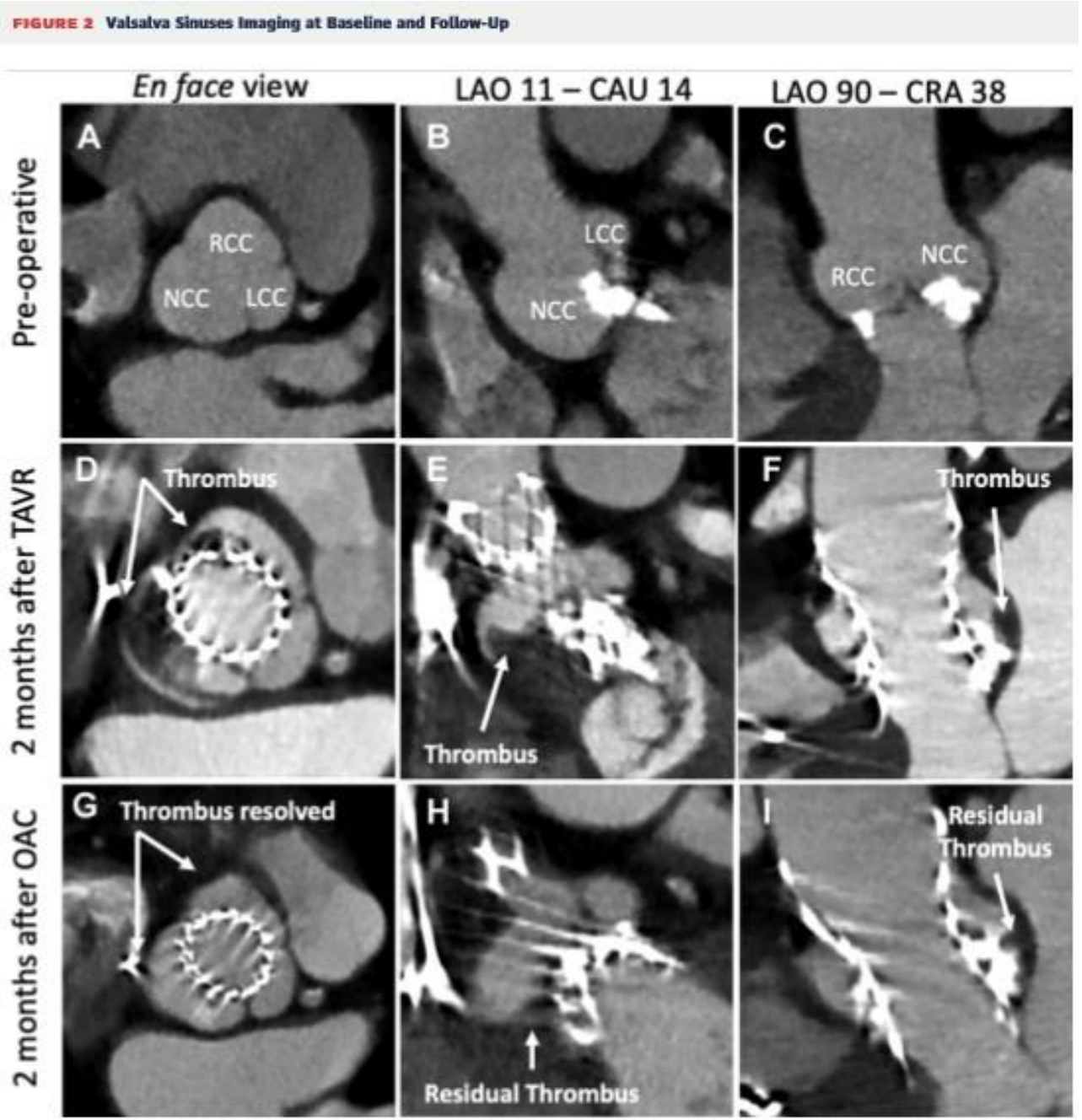
SIEVERS 1

L/R FUSION

NON CALCIFIED

RAPHE

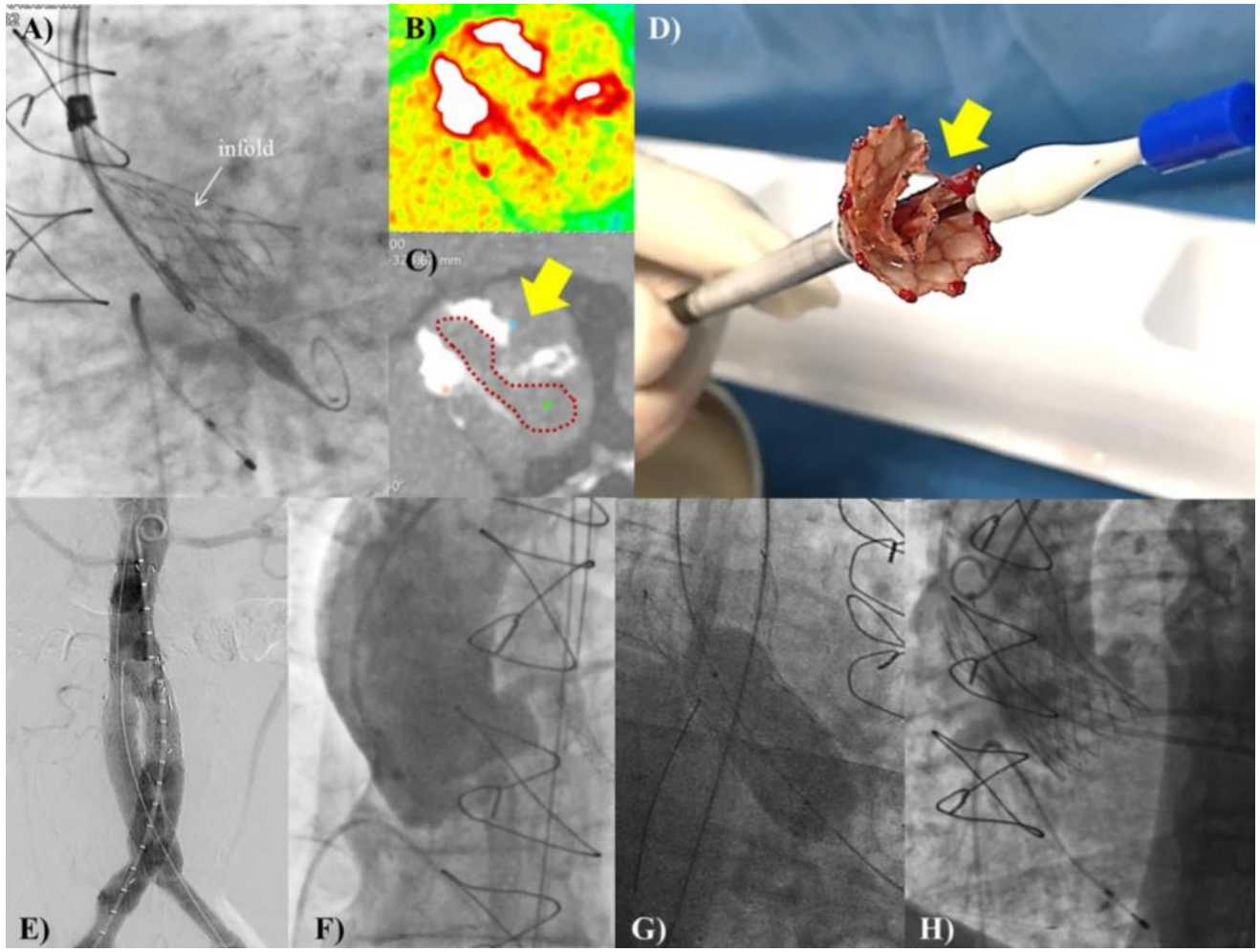




Couture et al JACC Cardiovascular Imaging 2020, epublication prior to print

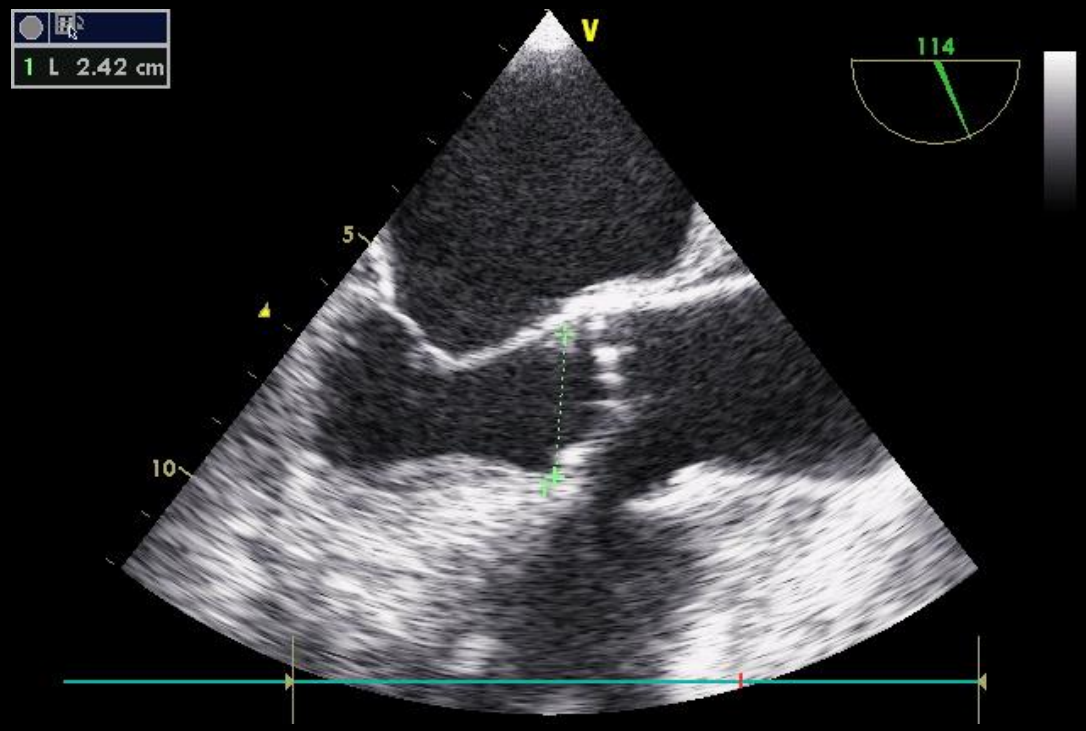
COMPLICATIONS WITH BAV

VALVE INFOLDING

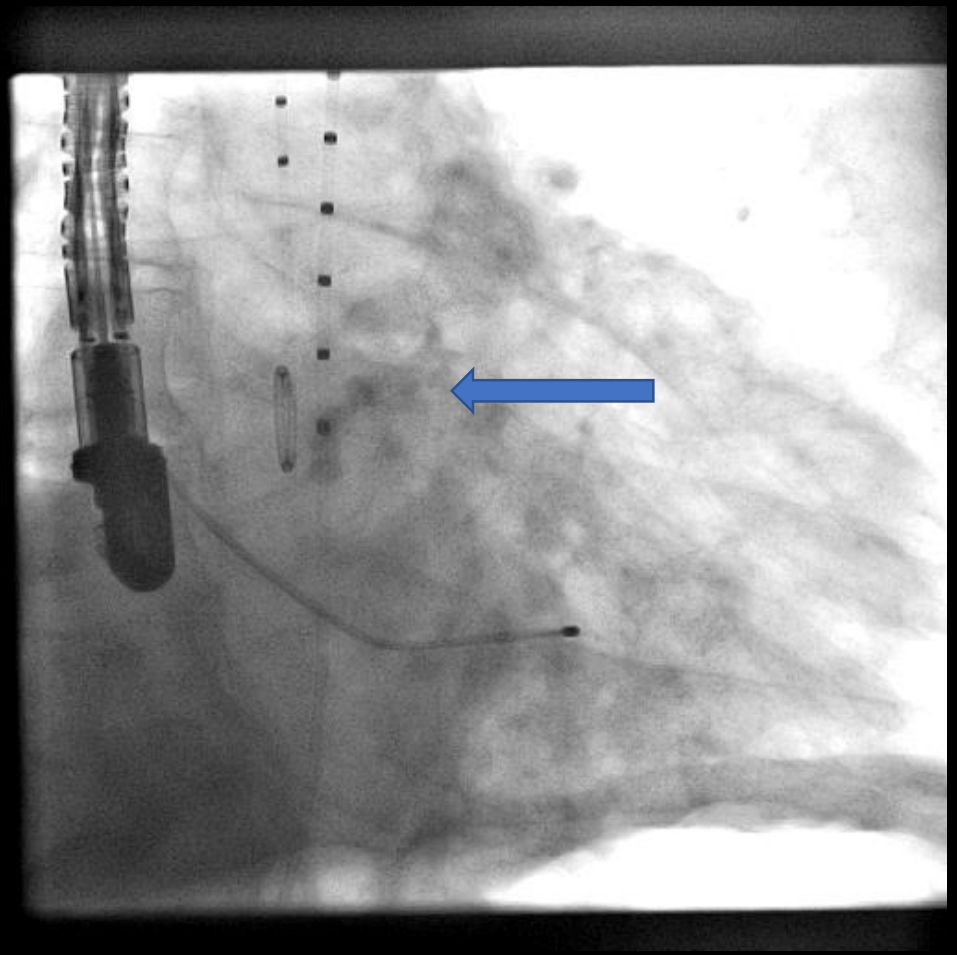


Medda et al Cardiovascular Revascularization Medicine 2019, e publication prior to print

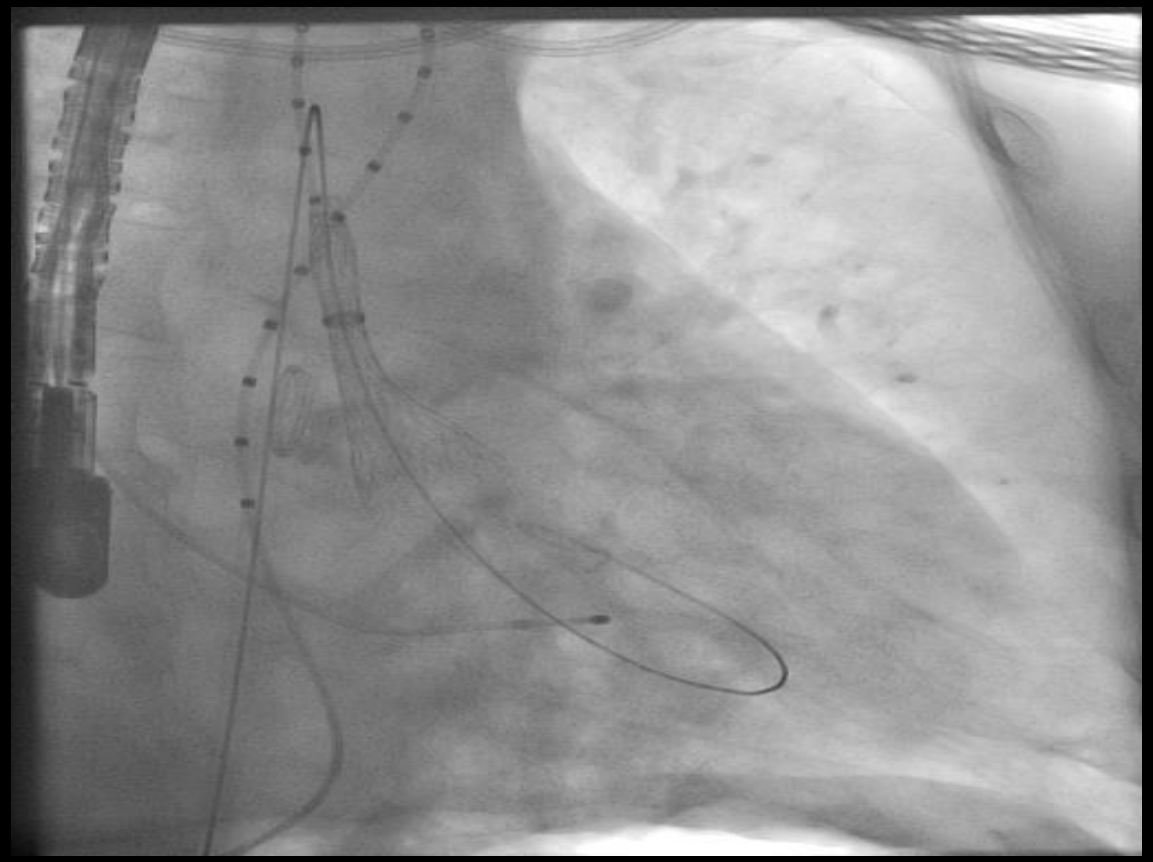
Case Example

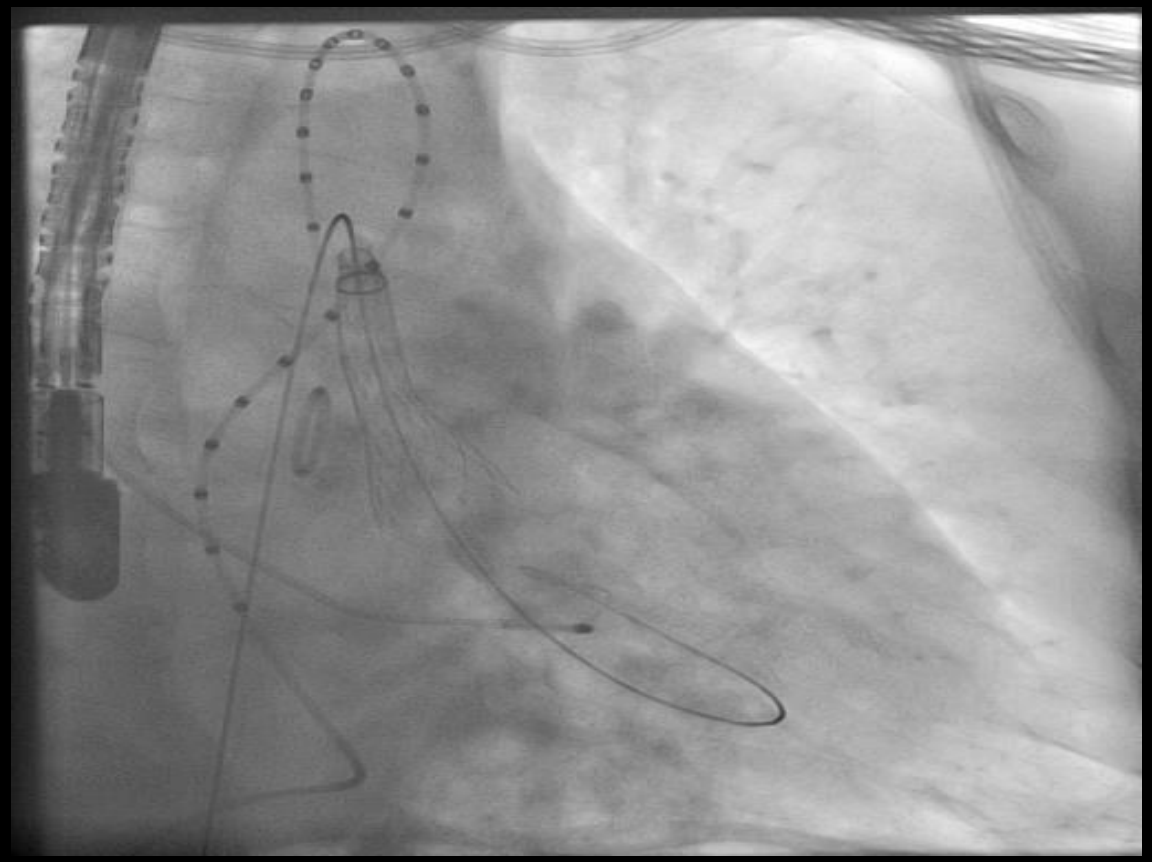


Calcified Annulus 24 mm

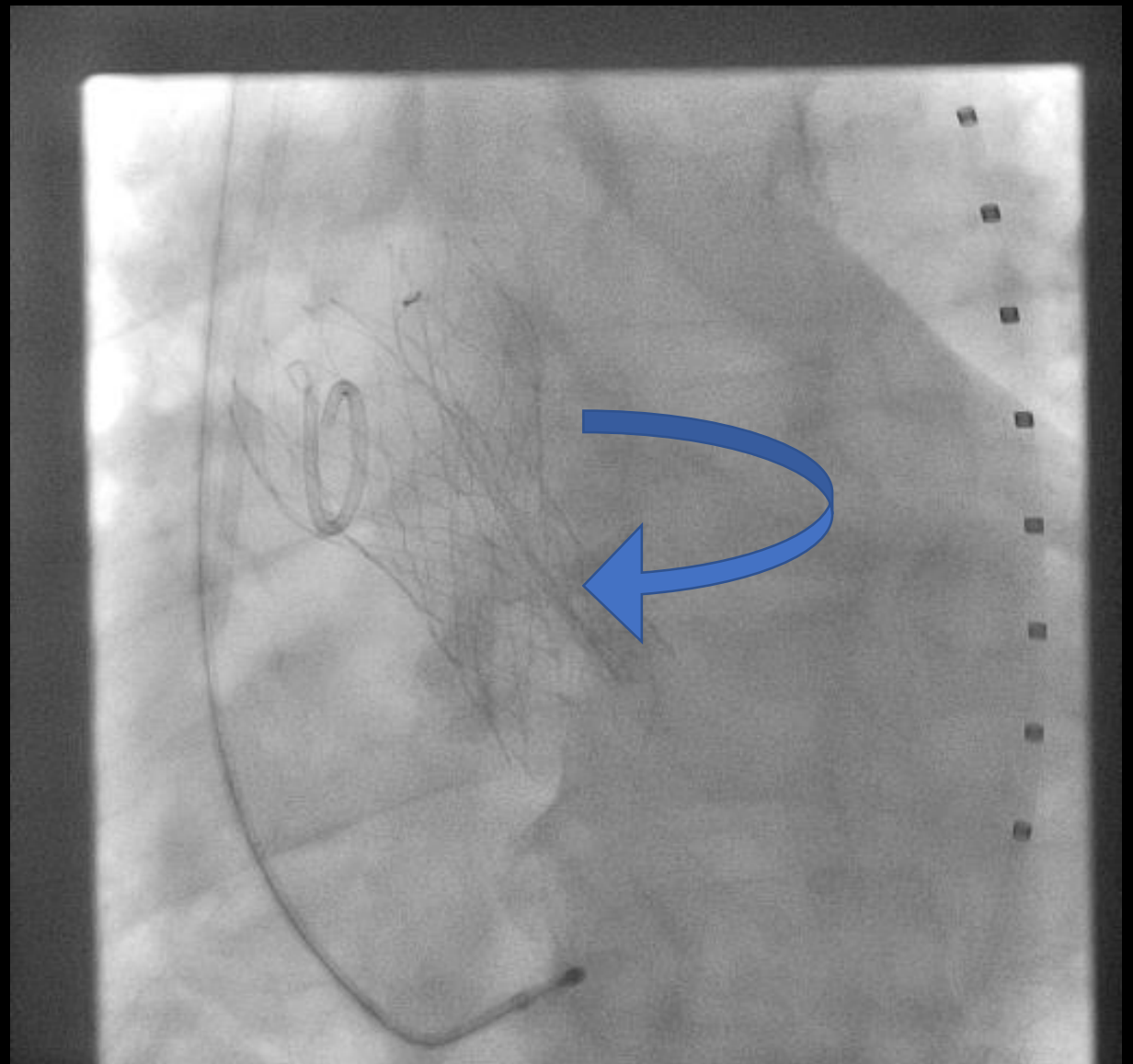


29 CORE VALVE deployed without Pre-Dilatation





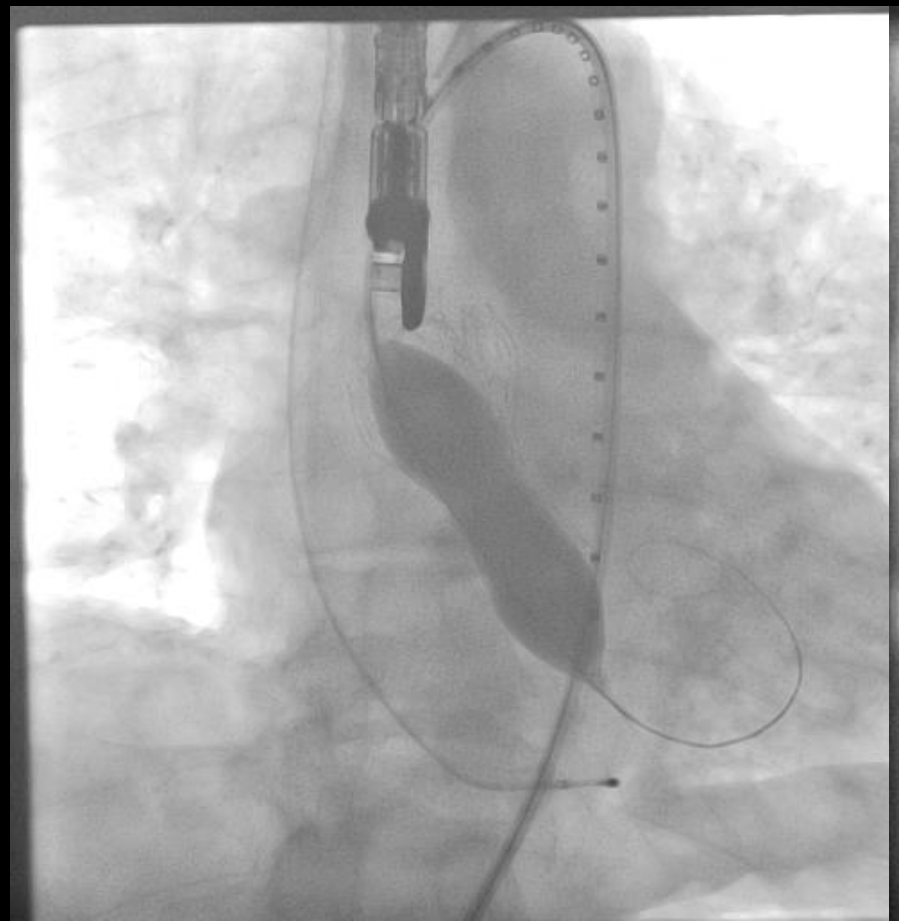
The valve seemed to be well positioned but a closer look revealed…



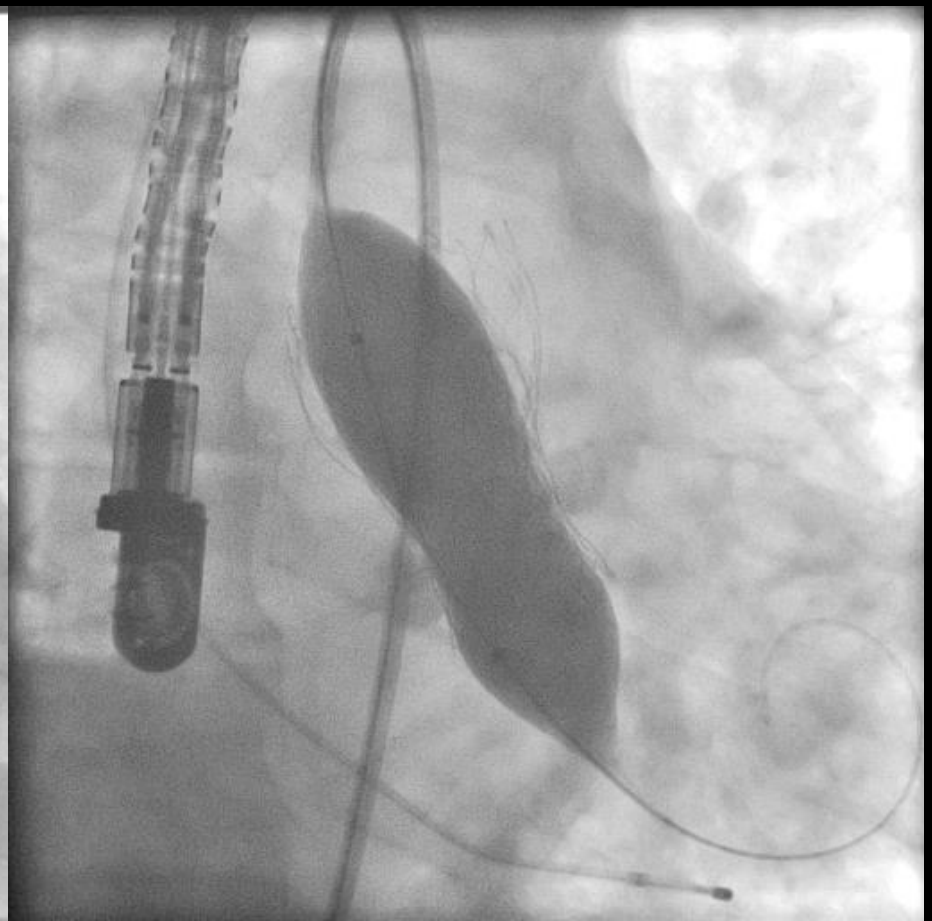
The valve was underexpanded resulting in a significant posterior leak and remaining gradient of 45mmHg

Post Dilatation was attempted

- 25 x 5 Cristal balloon



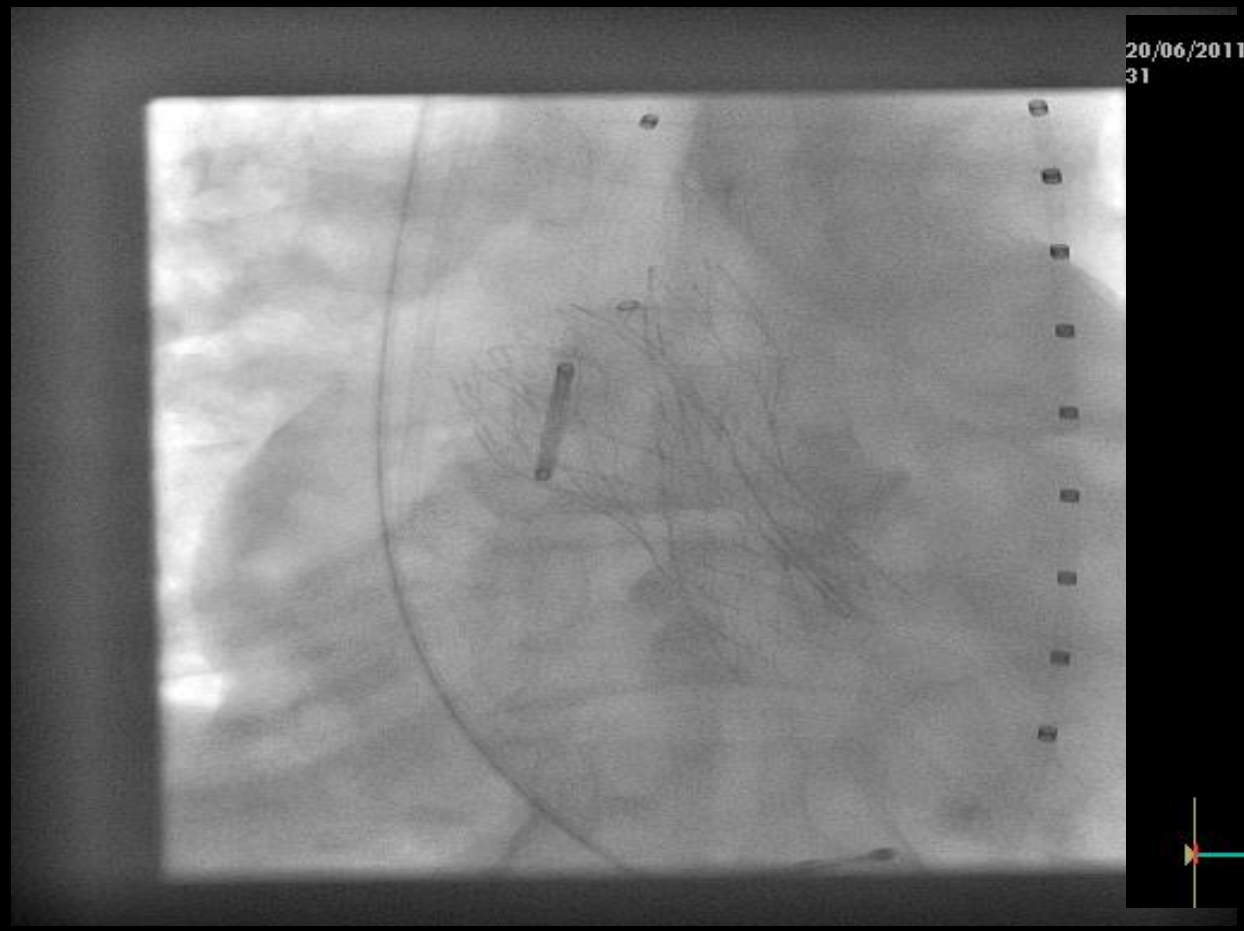
- 28 x 5 Cristal ballon



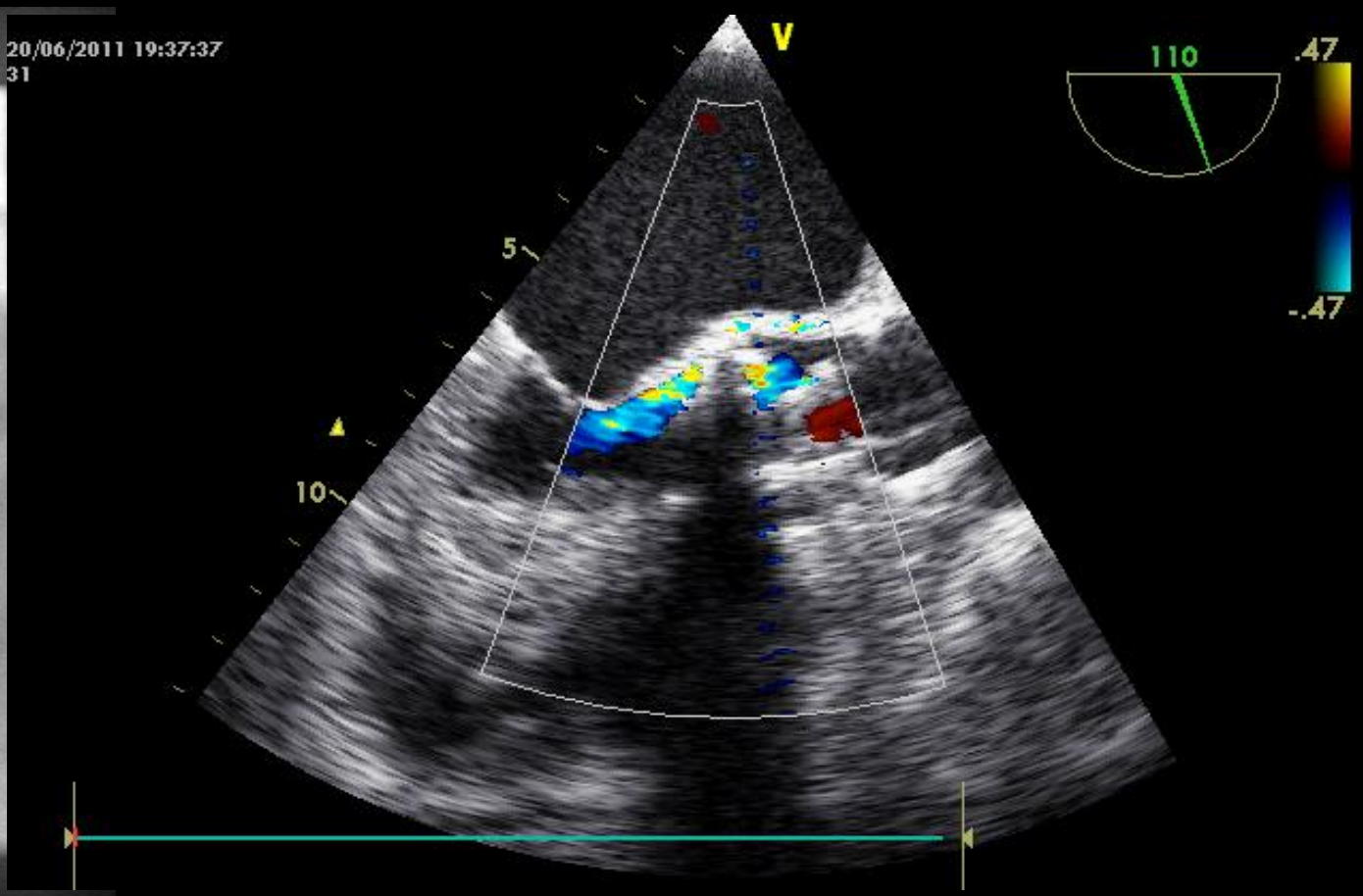
...but nothing changed

Gradient decreasead and Regurgitation increased

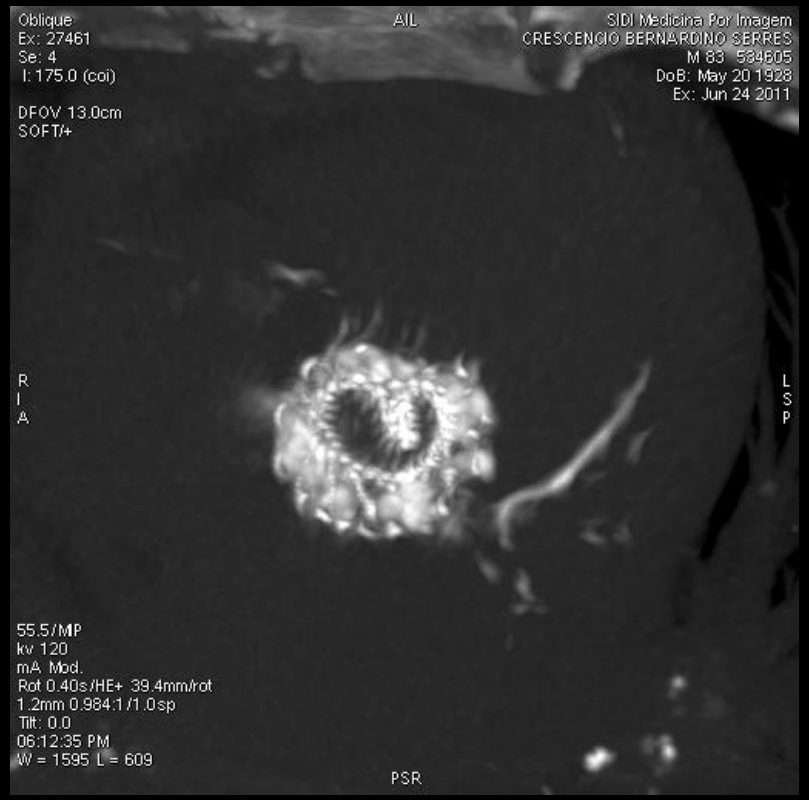
- Angio



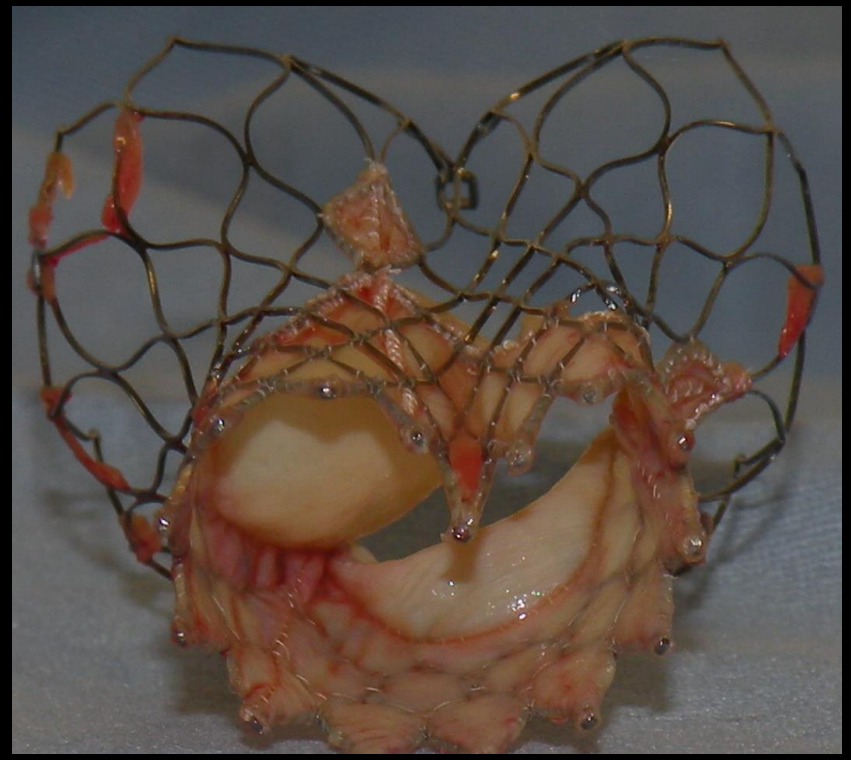
- Echo

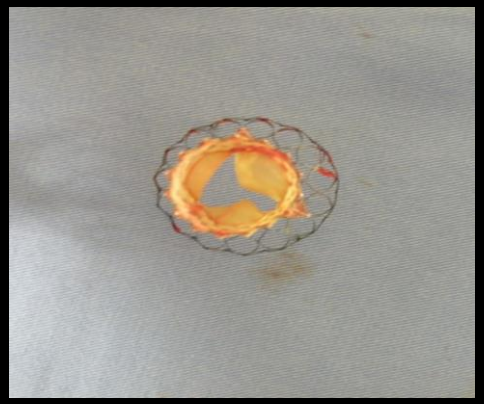


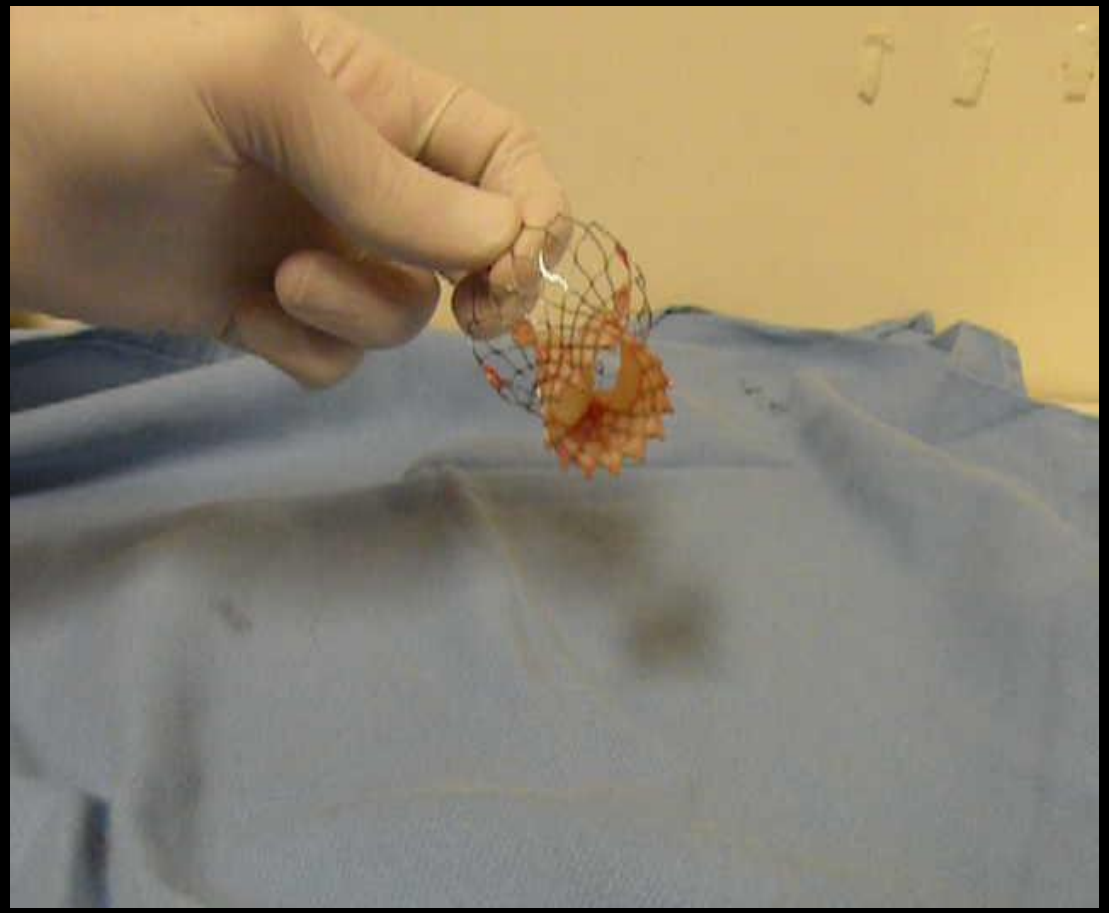
A closer Look…
CT showed an infolded Valve



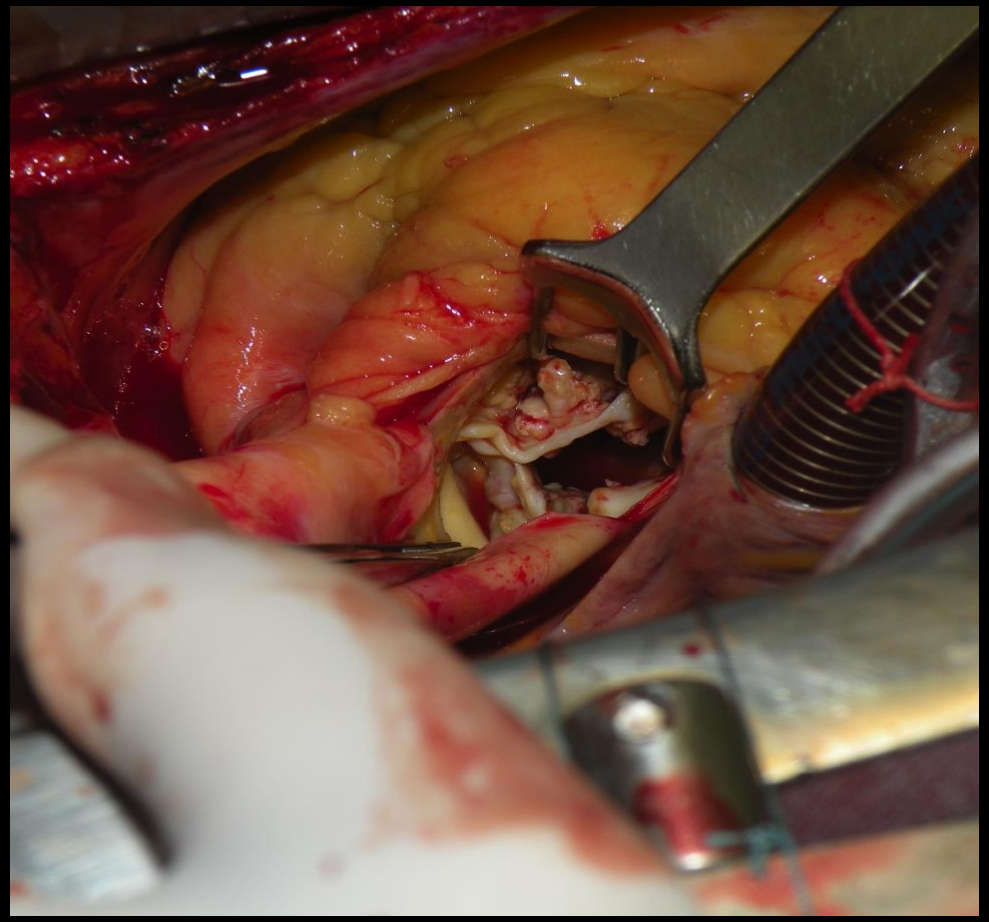
The immediate explant confirmed a “V” shaped valve
A few min later, the valve was back to normal







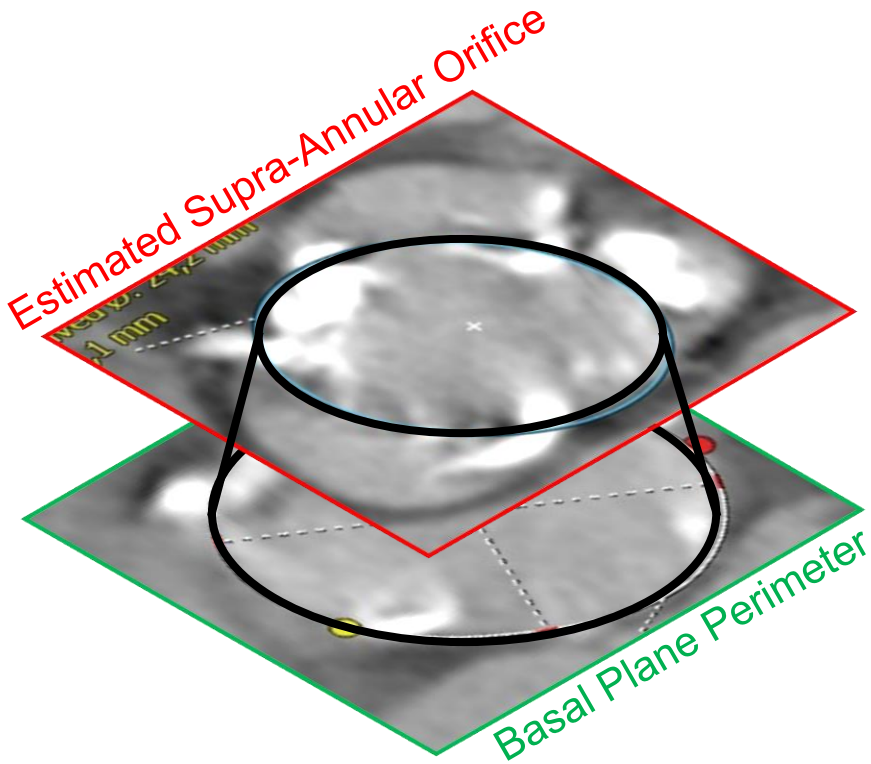
Surgery confirmed BAV with massive Calcifications



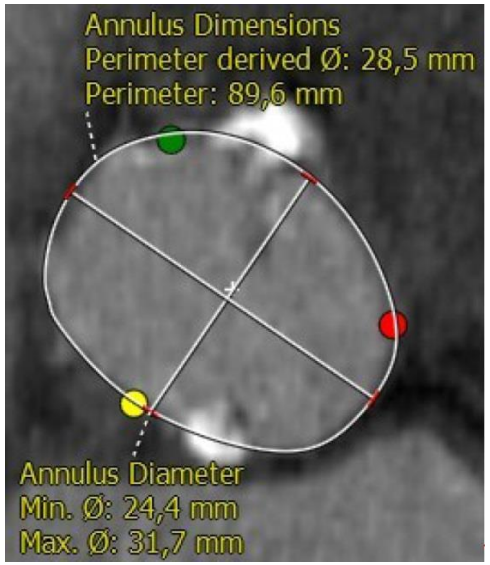
A critical review showed several mistakes have been made
or
Lessons learned…

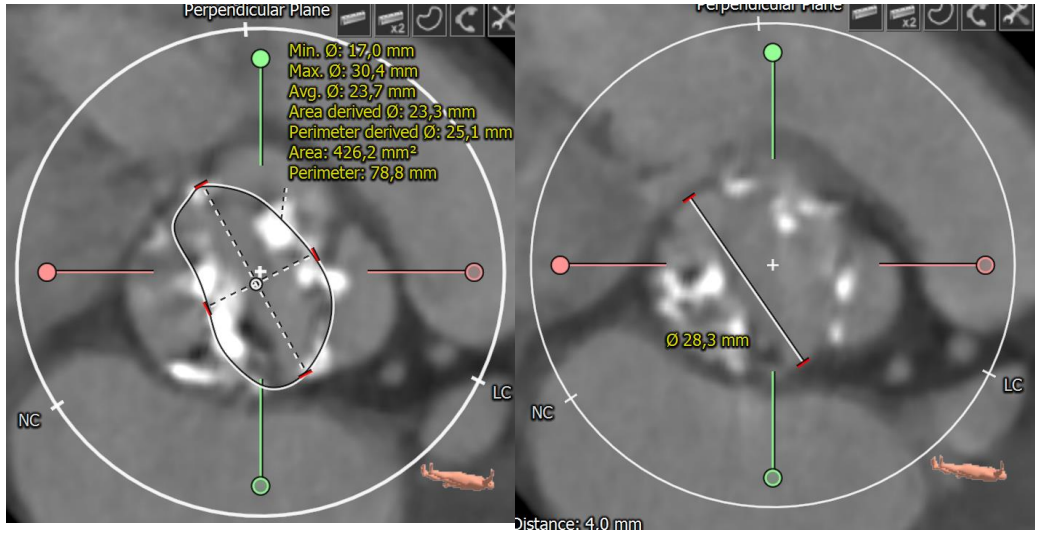
- Careful evaluation of Echo (BAV not diagnosed).
- Evaluation of Calcium (amount and distribution).
- Careful sizing considerations (Core Valve was way oversized).
- Careful inspection of the implanted valve (in the early days „infolding“ was known but rarely seen) Watch for the „fold“.
- Agressive Post Dilatation should only be performed when reasons for gradient and leaks have been identified.
- Not all folds can be unfolded by ballooning
- If after Post-Dilatation the problem persists, consider surgery or implant of a second (smaller) valve..

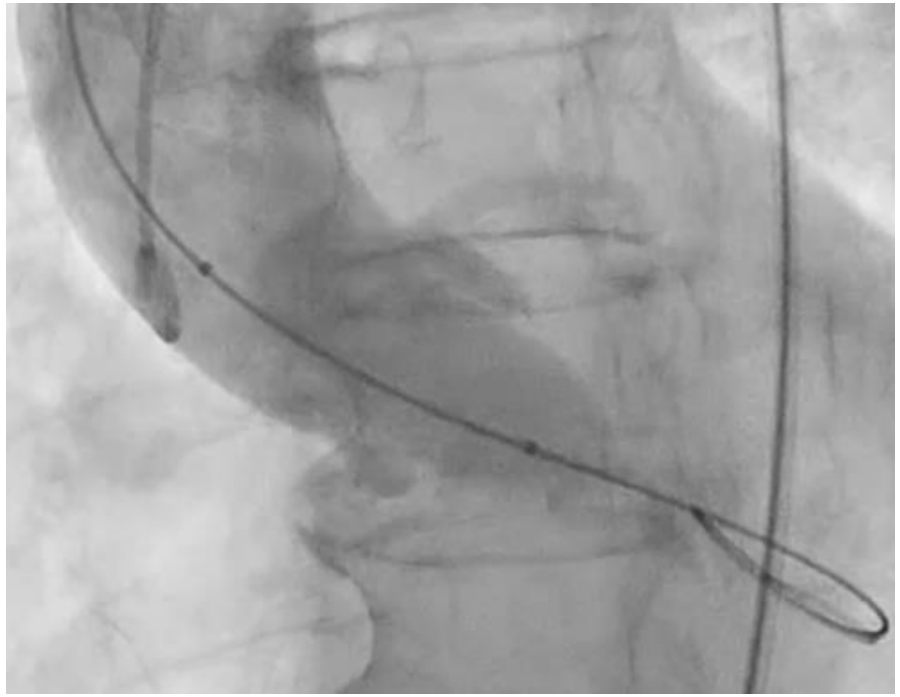
SIZING FOR BICUSPID AV



VARIOUS SIZING METHODOLOGIES ARE PROPOSED FOR TAVR IN BAV





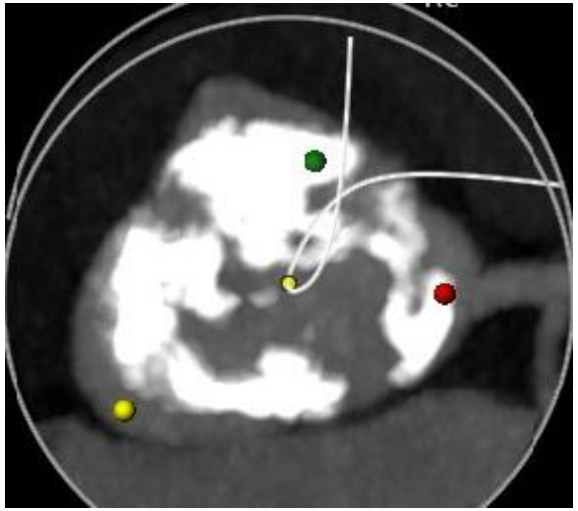


Annular sizing | **Supra-annular sizing** | **Balloon sizing**

BICUSPID SIZING CRITERIA

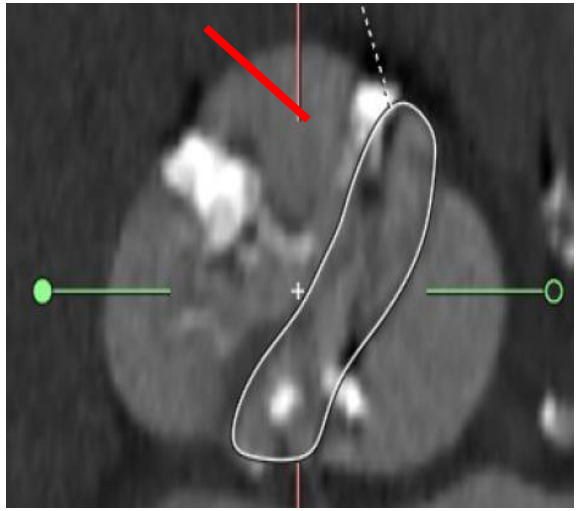
ADDITIONAL CONSIDERATIONS

Additional consideration should be given to the following when determining appropriate TAV sizing for BAV:[1]



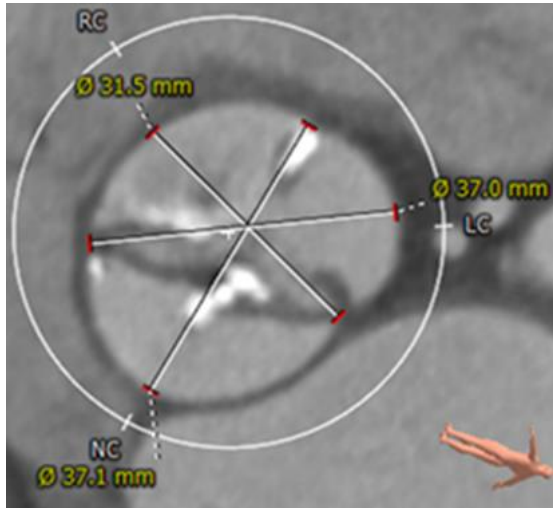
Degree of Calcification

- Will calcium density and location impede TAV frame expansion?



Location and Length of Raphe

- How many leaflets are fused?
- Does the raphe extend the full length of the commissure?



SOV Width and Height

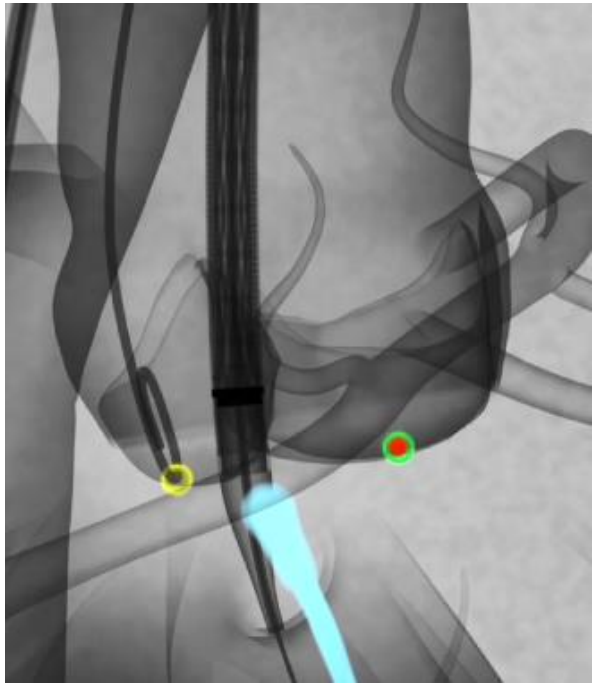
- Can the SOV accommodate the TAV size indicated by the annular measurement?

BAV
IMPLANT VIEW

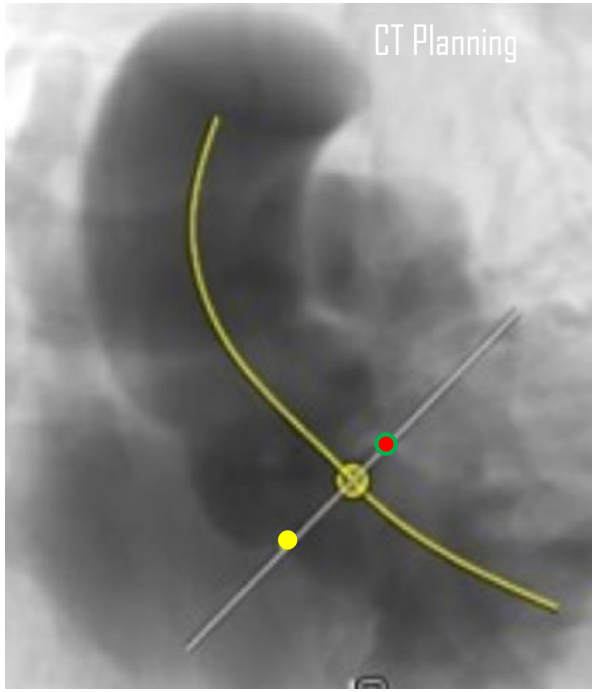
The bicuspid implant view preserves key principles of the standard cusp overlap view for accurate depth assessment during deployment:

- Maintains basal plane alignment of the cusps.
- Elongates the LVOT and centers structures of the conduction system in the visual field.
- Reduces parallax in the delivery system.

Cusp Overlap View
(tricuspid aorta))



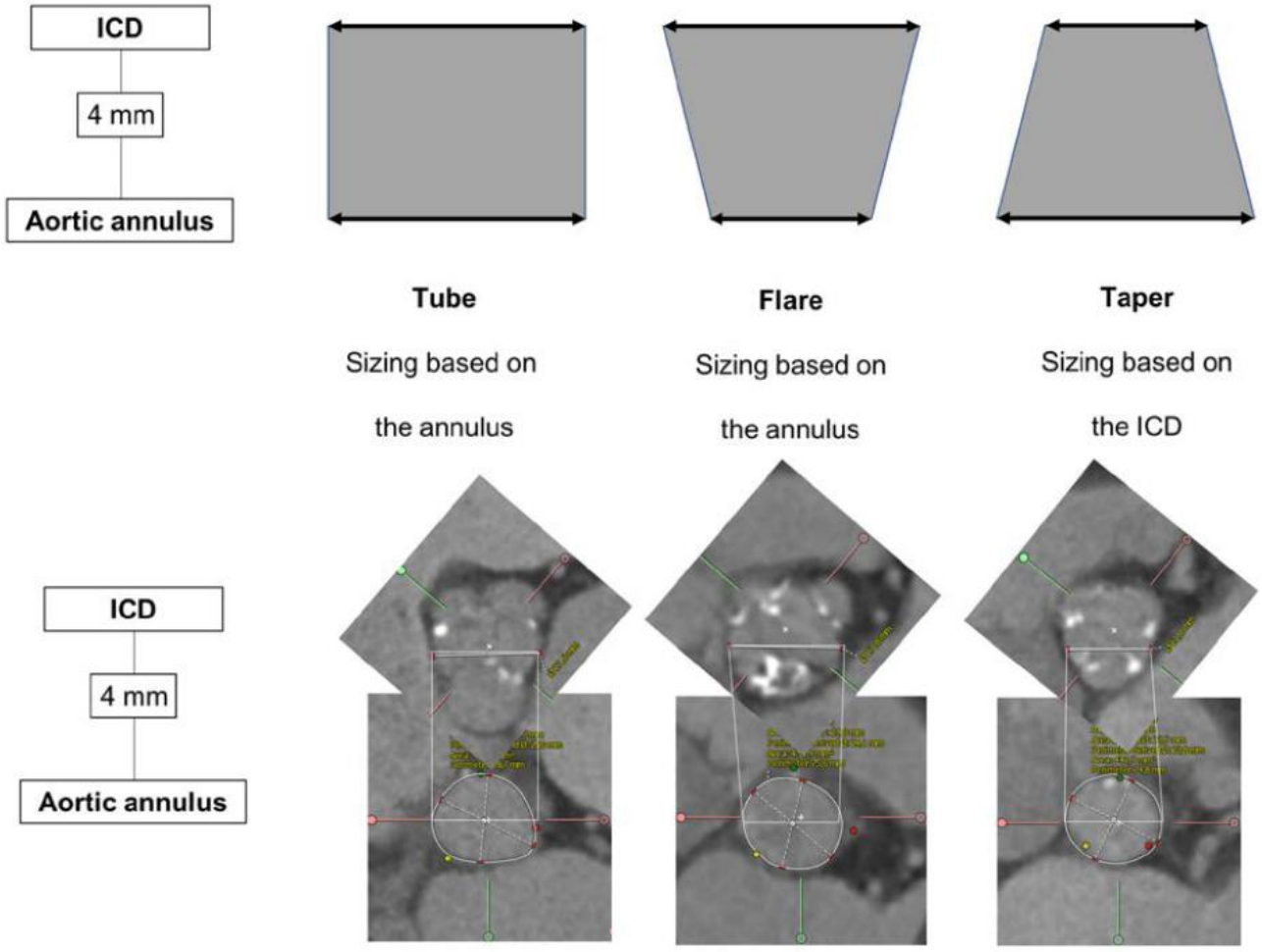
Bicuspid Implant View
(Type 0 Case Example)



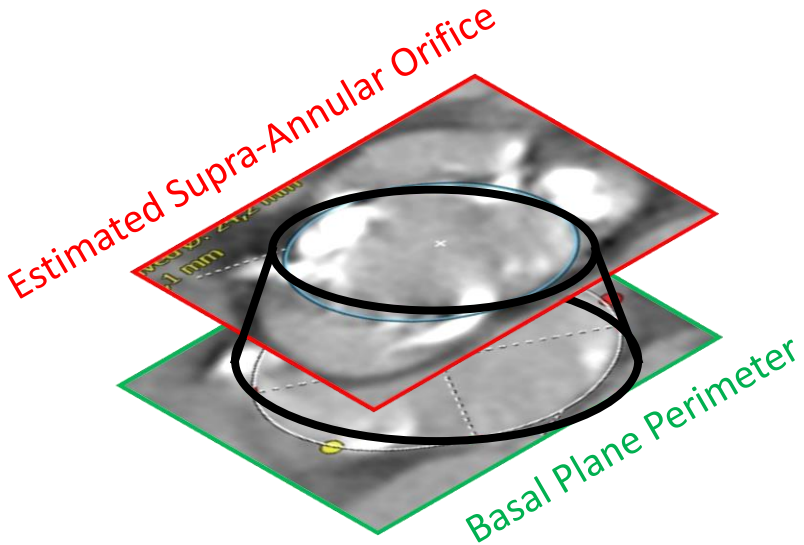
TAVR CHALLENGES IN BICUSPID AORTIC VALVES

SIZING METHOD/BAVARD STUDAY

TAV sizing is also an ongoing challenge in bicuspid patients.

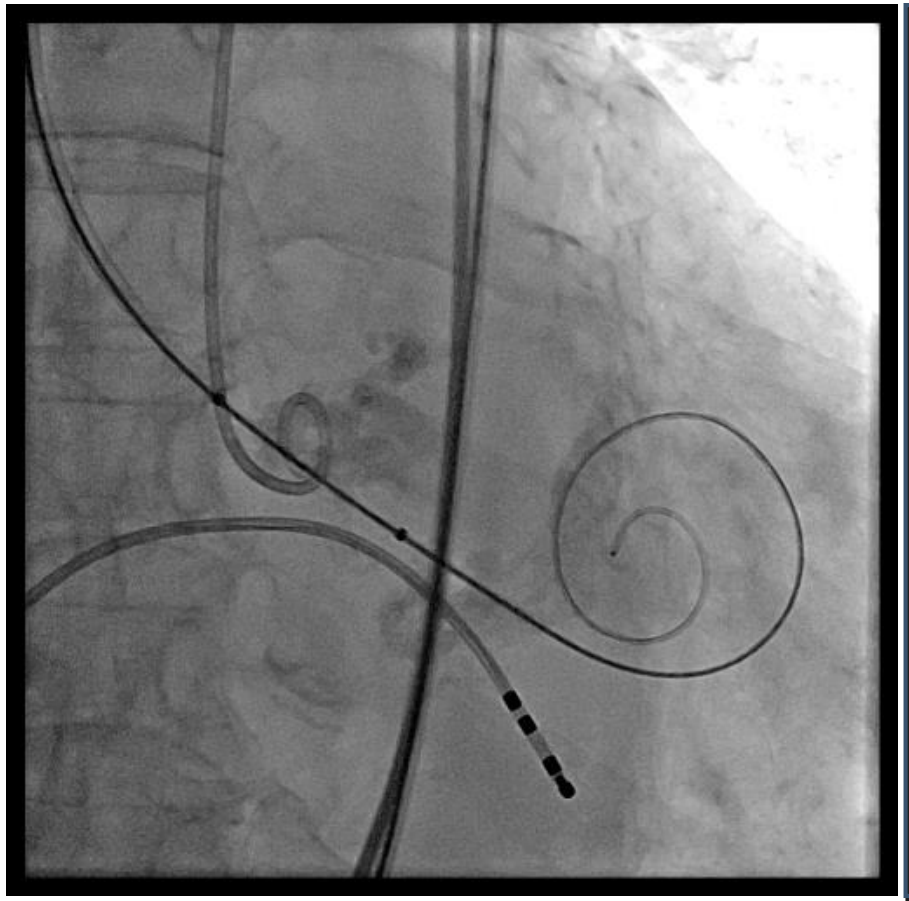


The BAVARD study found that annulus-based sizing was applicable to 88% of BAV patients, and that a "tapered" anatomy may need to take the intercommissural distance (ICD) into account.



FINALLY …

BALLOON AORTIC VALVULOPLASTY MORE OFTEN USED IN BICUSPID AS



Goal

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

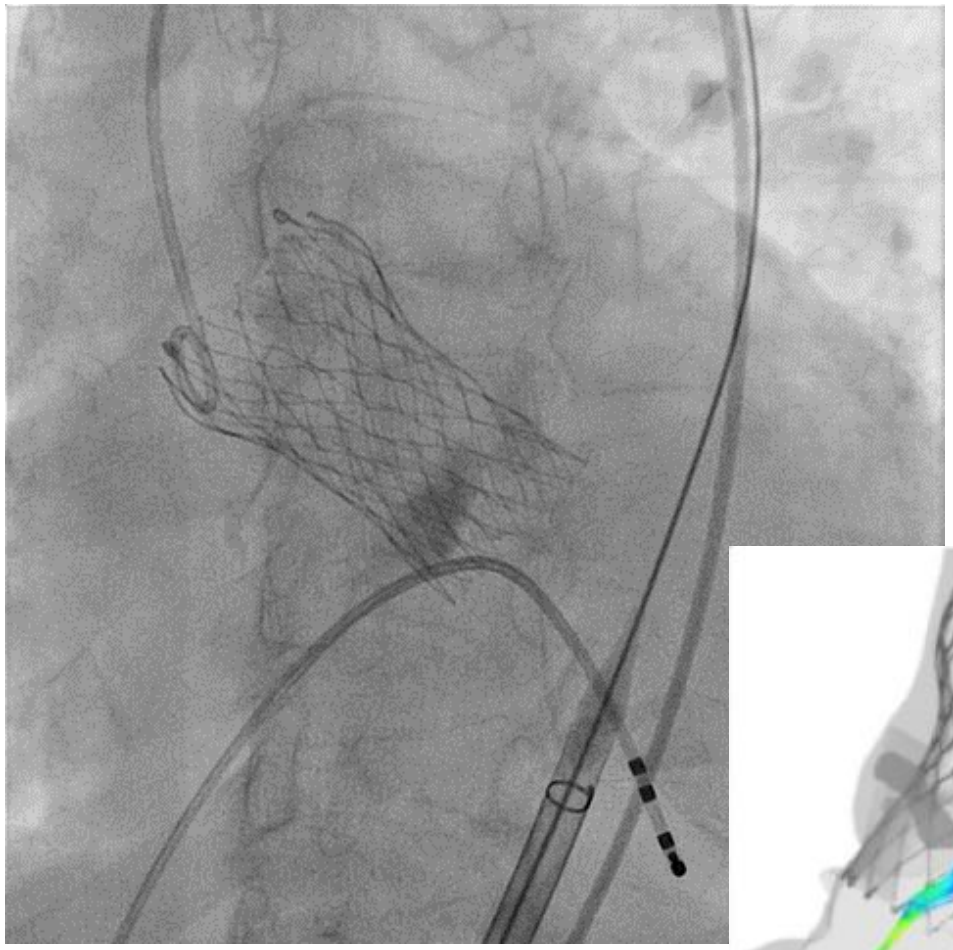
NOTE:

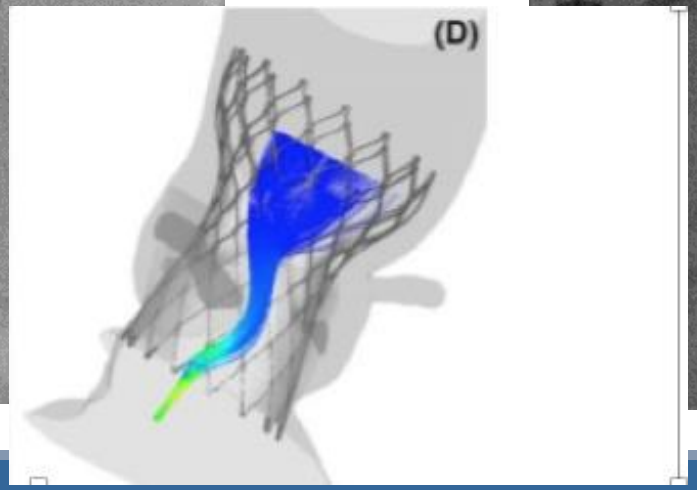
Relatively small balloons should be selected based on the CT measurement to avoid injury of the aortic complex.

NEVER FORGET!

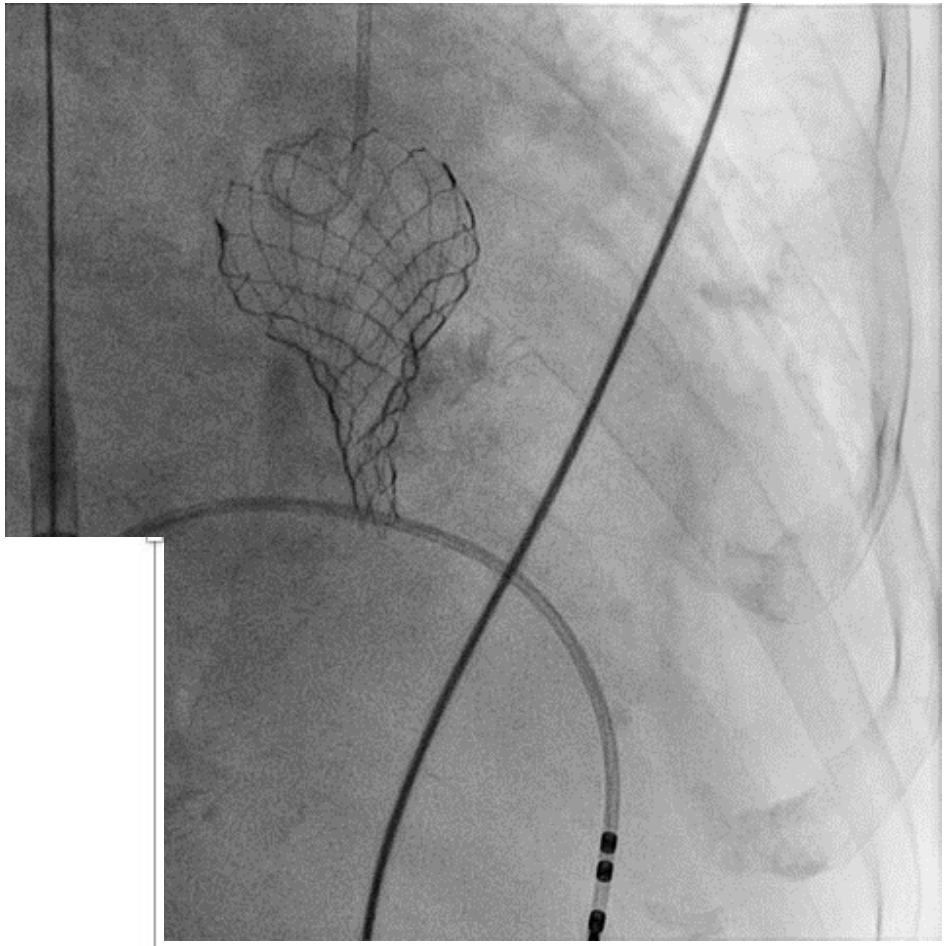
POST-IMPLANTATION VIEWS IN LAO AND RAO

RAO





LAO



TAKE HOME MESSAGE:
TAVR TECHNIQUES FOR BICUSPID VALVES

- CT Sizing is Gold Standard but still empiric
- Predilate: use minor diameter of the annulus as reference
- Consider controlled pacing during deployment
- High implants, (anchoring in BAV not annulus but leaflets)
- Assess stent frame expansion in two orthogonal views
- Post-dilate if necessary: minor annular diameter/mean derived diameter again as reference
- Consider use of cerebral protection devices

THANK YOU FOR YOUR KIND ATTENTION!