

Mechanisms and Treatment of Paravalvular Aortic Regurgitation

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Potential Conflicts of Interest

Speaker's Name: Alain G. Cribier

I have the following potential conflicts of interest to disclose:

Consultant / Proctor for Edwards Lifesciences

AR post-TAVI: The most common drawback

Mild AR observed in $\geq 70\%$ of patients

Moderate to severe AR remains a serious concern

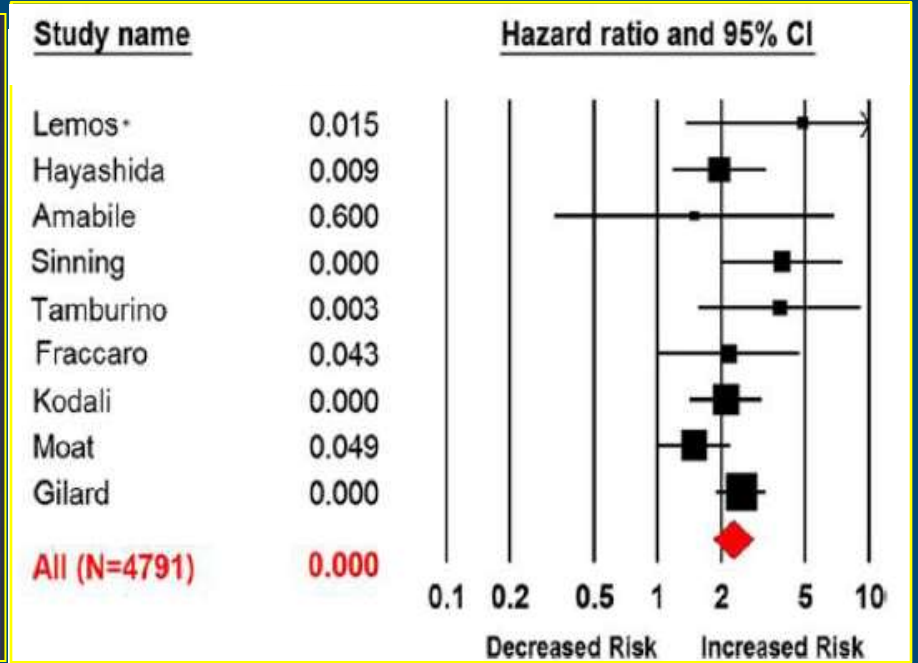
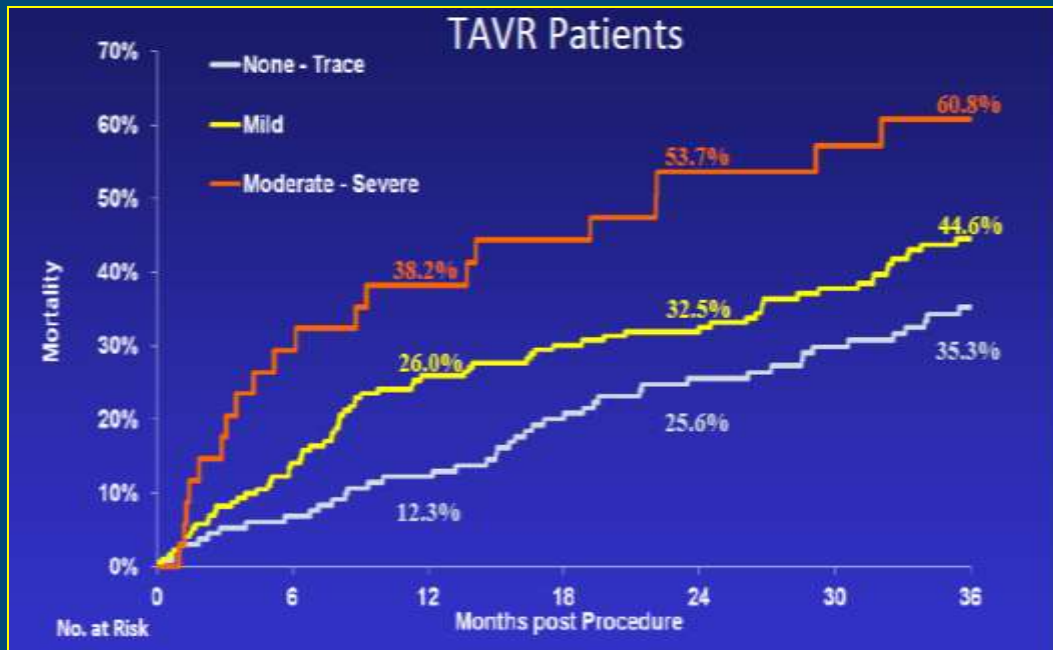


Impact of Post-TAVI / AR on Mortality

Mortality risk is doubled with moderate / severe AR

PARTNER A
Kodali et al NEJM 2012

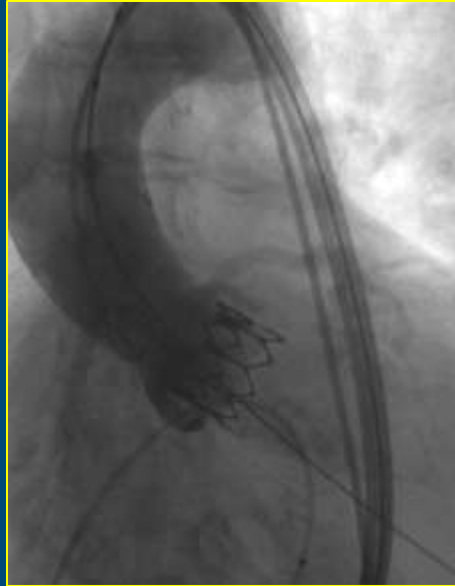
*F. Maisano, Meta-Analysis,
PCR London Valve 2013*



« Even mild AR may have an impact on long term mortality »

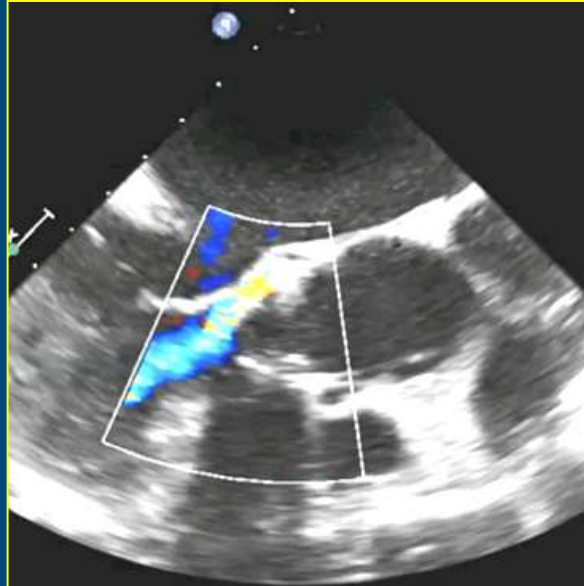
Quantification of AR after TAVI: no gold standard

Angiography



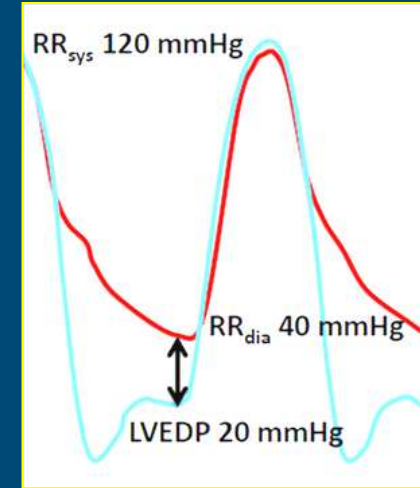
Sellers Classification

TTE / TEE



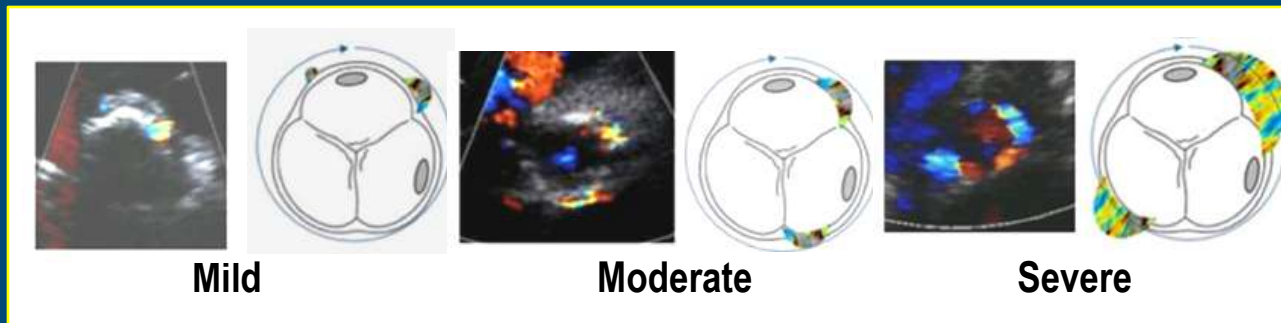
Echocardiography Guidelines

AR Index



$$[(RR_{dia} - LVEDP) / RR_{sys}] \times 100$$

MRI Post-Procedure



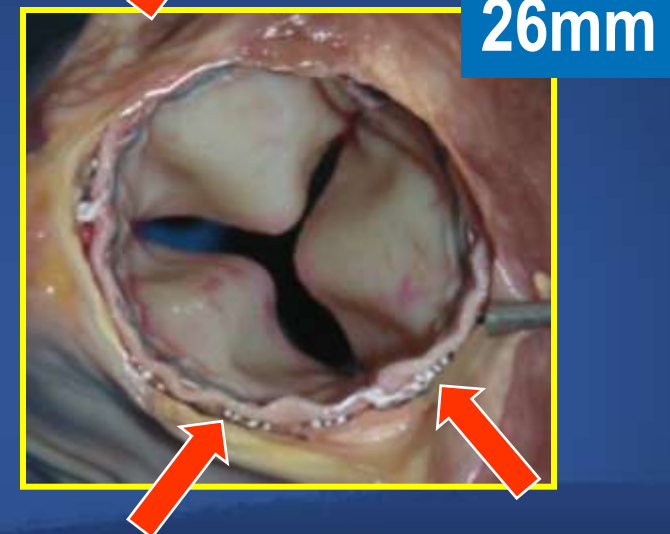
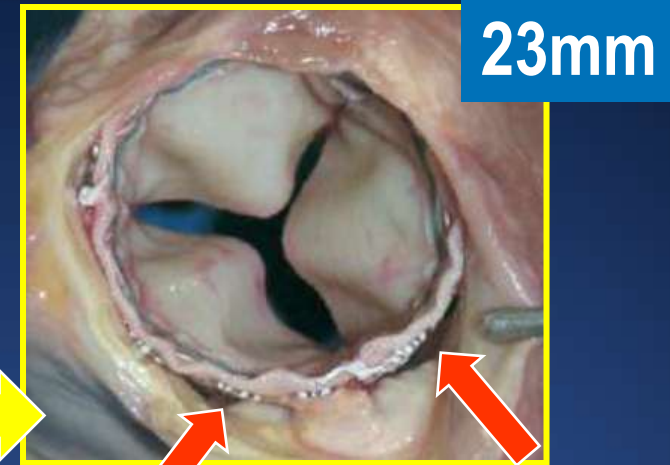
Echocardiography Guidelines

Origin of AR post TAVI : most commonly paravalvular

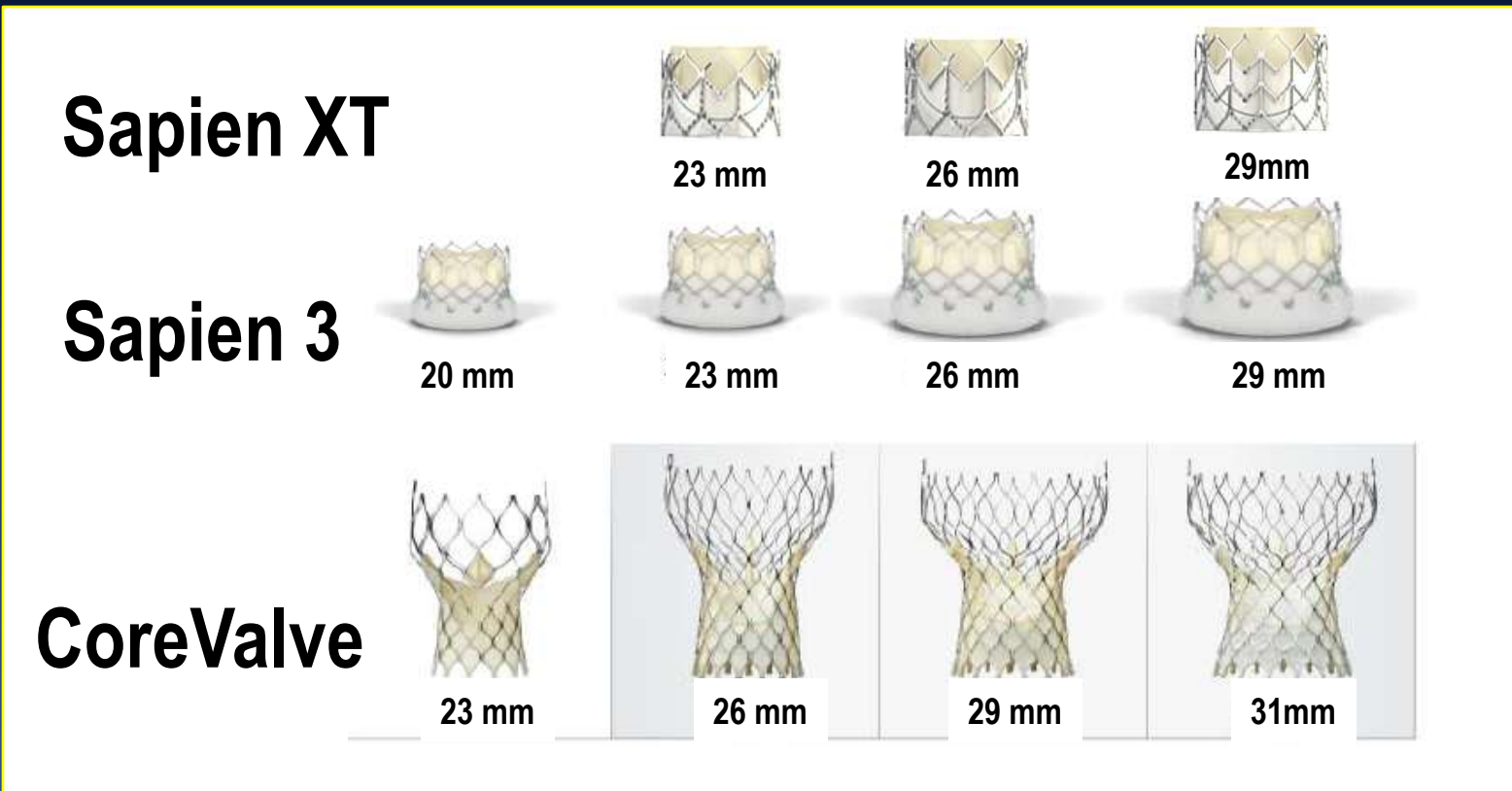
Due to incomplete sealing of the paravalvular space

Multifactorial etiology

- 1) Non optimal valve size / annulus size
Valve sizing is crucial
- 2) Anatomy and amount / distribution of valvular calcification
- 4) Prosthesis positioning
- 3) Valve type effect (BE vs SE vs other valves)



Multiple size options is the key

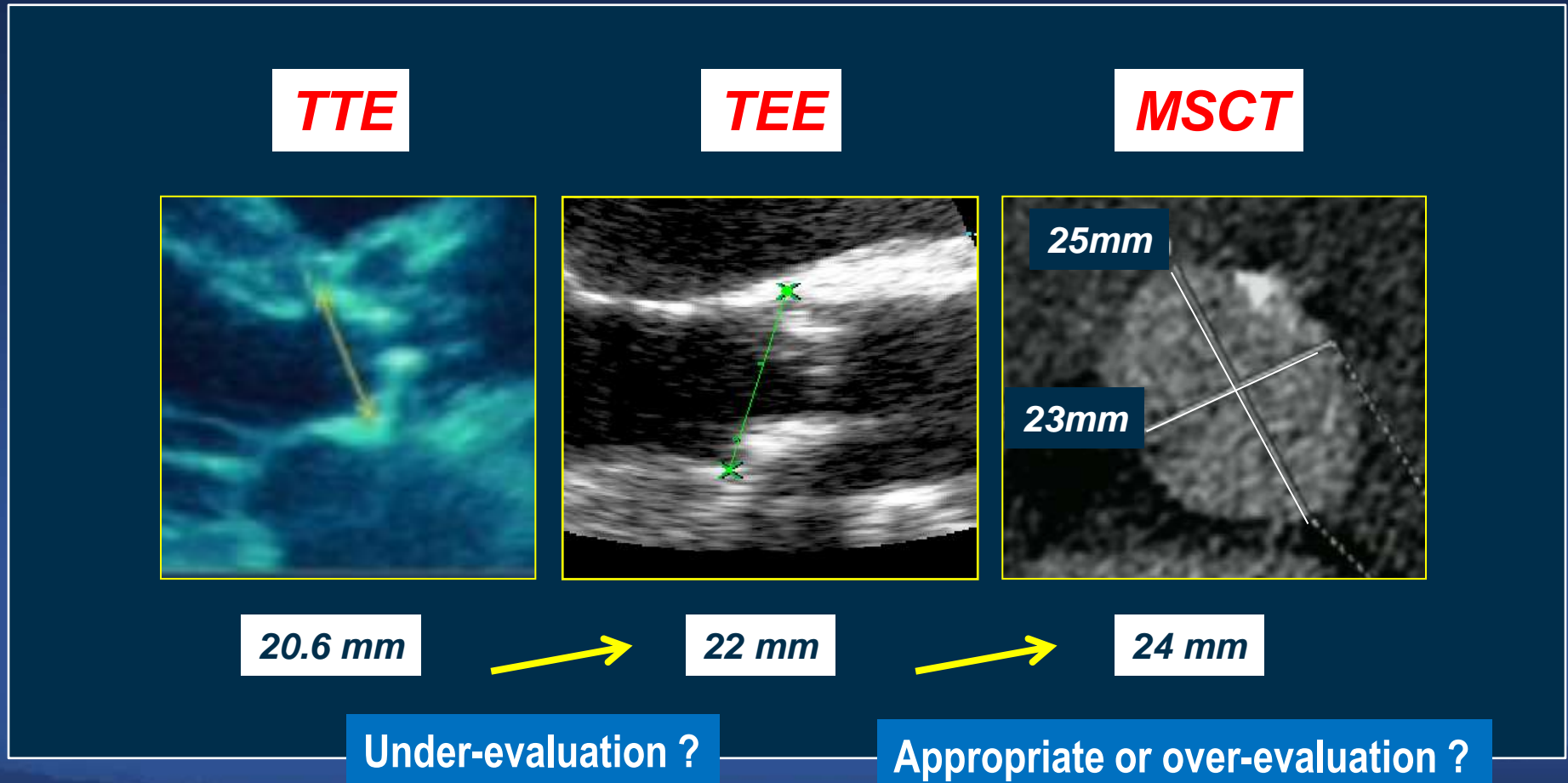


| | | | | |
|---------------------|----|--------------|-------|--------------|
| | | 23 mm | 26 mm | 29 mm |
| Edwards | | ┌──────────┐ | | ┌──────────┐ |
| <i>Annulus (mm)</i> | 18 | 21 | 24 | 27 |
| CoreValve | | ┌──────────┐ | | ┌──────────┐ |
| | | 23 mm | 26 mm | 29 mm |
| | | | | 31 mm |

Annulus size: the key factor for appropriate valve sizing

No gold standard method!

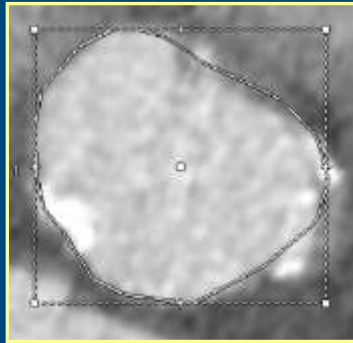
1- Diameters



No gold standard for annulus size measurement

2- Annular cross sectional area: MSCT – most accepted approach

Vancouver sizing Guidelines



Perimeter: 75.7 mm

No oversizing by > 1.3% (J. Webb)

Annular Area: 430.7 mm²

➤ Optimal: oversize by 5-10%

➤ Underfill if > 20% or >10% if high risk features

Valve Area

| Annular area cm ² | 20mm | 23mm | 26mm | 29mm |
|------------------------------|-------------|-------|------|-----------|
| 2.40 | | | | |
| 2.50* | NR (10.9) | | | |
| 2.60* | 25.7* | | | |
| 2.80 | 20.8 | | | |
| 2.70 | 16.4 | | | |
| 2.80 | 12.2 | | | |
| 2.90 | 8.3 | | | |
| 3.00 | 4.7 | | | |
| 3.10 | 1.3 | | | |
| 3.20* | | NR | | |
| 3.30* | NR (-1.9%)* | 29.8* | | |
| 3.40* | | 25.9* | | |
| 3.50* | | 22.2* | | |
| 3.60 | | 18.7 | | |
| 3.70 | | 15.4 | | |
| 3.80 | | 12.3 | | |
| 3.90 | | 9.3 | | |
| 4.00 | | 6.5 | | |
| 4.10 | | 3.9 | | NR |
| 4.20* | | 1.1 | | NR (29.5) |
| 4.30* | | | | 26.4* |
| 4.40 | | | | 23.5* |
| | | | | 20.7 |
| | | | | 18.0 |
| | | | | 15.4 |
| | | | | 13.0 |
| | | | | 10.6 |
| | | | | 8.4 |
| | | | | 6.2 |
| | | | | 4.1 |
| | | | | 2.1 |
| | | | | 0.2* |
| 5.50 | | | | 22.3* |
| 5.20 | | | | 20.1 |
| 5.30* | | | | 17.9 |
| 5.40* | | | | 15.0 |
| 5.60 | | | | 13.9 |
| 5.70 | | | | 12.0 |
| 5.80 | | | | 10.1 |
| 5.90 | | | | 8.3 |
| 6.00 | | | | 6.5 |
| 6.10 | | | | 4.8 |
| 6.20 | | | | 3.2 |
| 6.30 | | | | 1.6 |
| 6.40 | | | | 0.1 |
| 6.50 | | | | NR |
| 6.60 | | | | |
| 6.70 | | | | |

430.7

Over expansion 10%

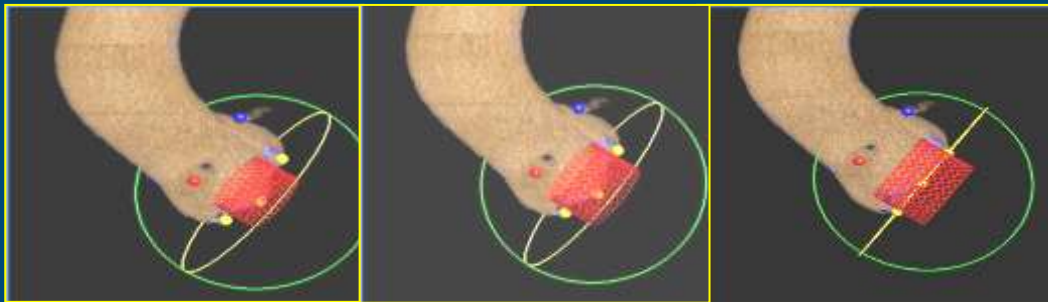
Vancouver Area Sizing Guidelines and underfilling protocole (Sapien XT)

| Annular Area (mm ²) | THV size (mm) | SAPIEN XT | Nominal Balloon Volume | To reduce diameter by ~ 1 mm underfill by ~ 10% |
|---------------------------------|----------------------|-----------|------------------------|-------------------------------------------------|
| 230 to 300 | 20 | | | |
| 310 to 320 | 20 or 23 underfilled | | | |
| 330 to 400 | 23 | | | |
| 410 | 23 or 26 underfilled | 23 mm | 17 ml | 1 ml |
| 420 to 510 | 26 | 26 mm | 22 ml | 2 ml |
| 520 | 26 or 29 underfilled | 29 mm | 33 ml | 3 ml |
| 530 to 660 | 29 | | | |

J. Webb, PCR London Valve 2013

Annulus size measurement: other approaches

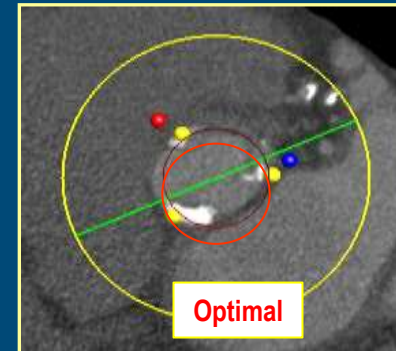
Philips Heart Navigator (pre-procedure)



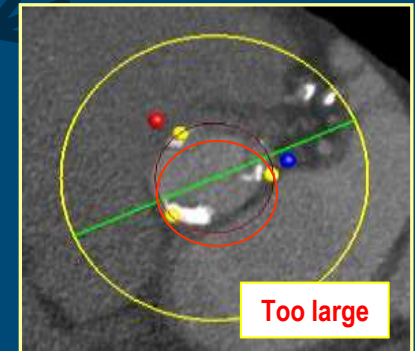
23mm

26mm

29mm

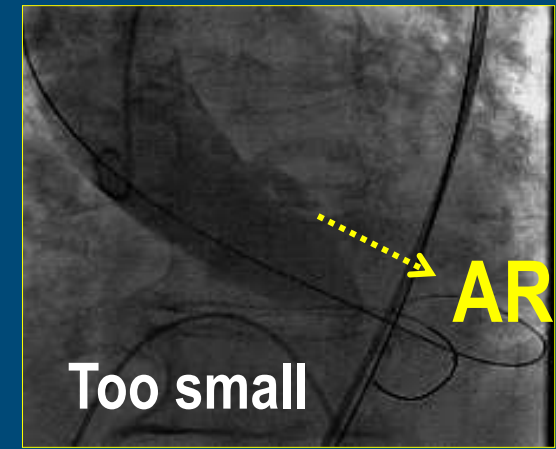
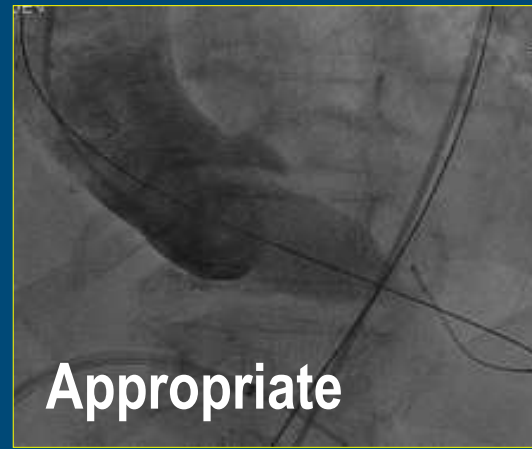


26mm

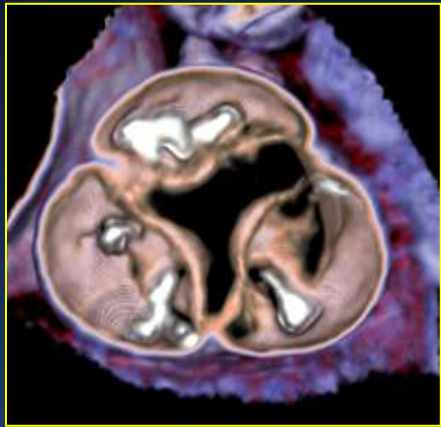


29mm

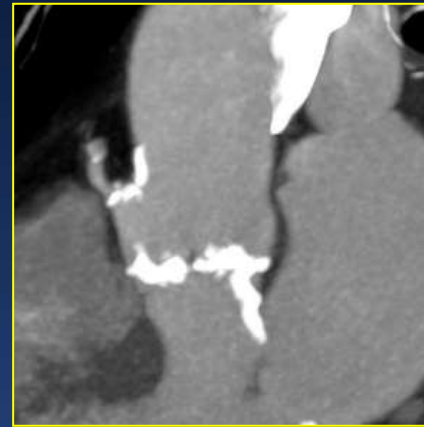
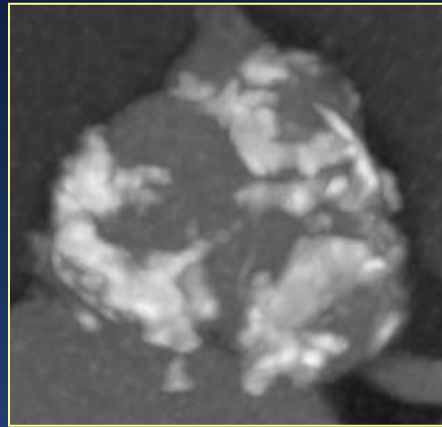
The final touch: Balloon Sizing (per-procedure)



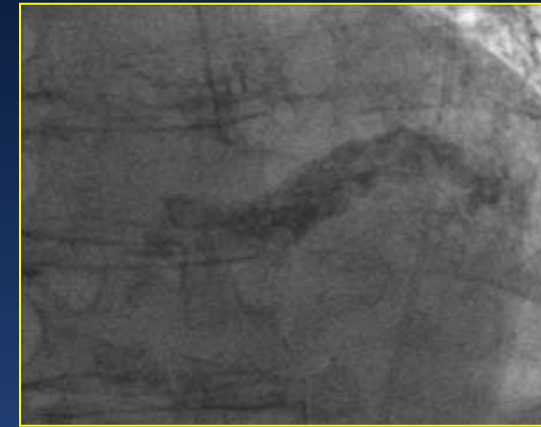
Assessment of aortic valve anatomy and Amount / Distribution of valvular calcification



Degree of calcification, distribution

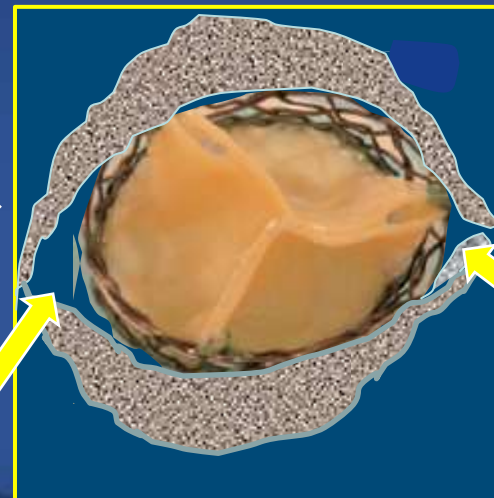
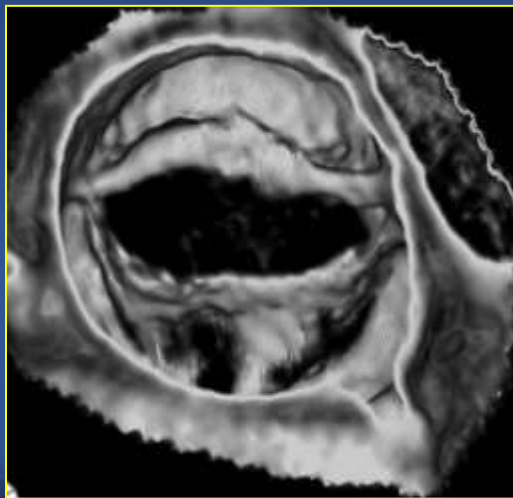


Extensive calcification: septum, mitral valve



Valve anatomy: Echo, MSCT

Bicuspid Valve



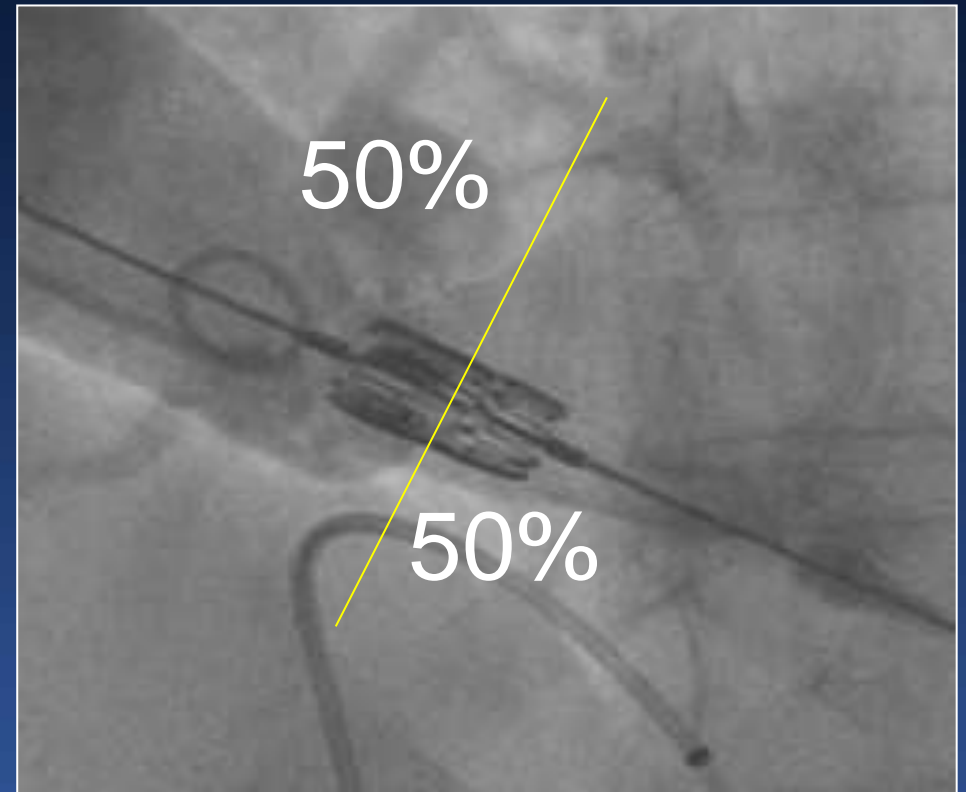
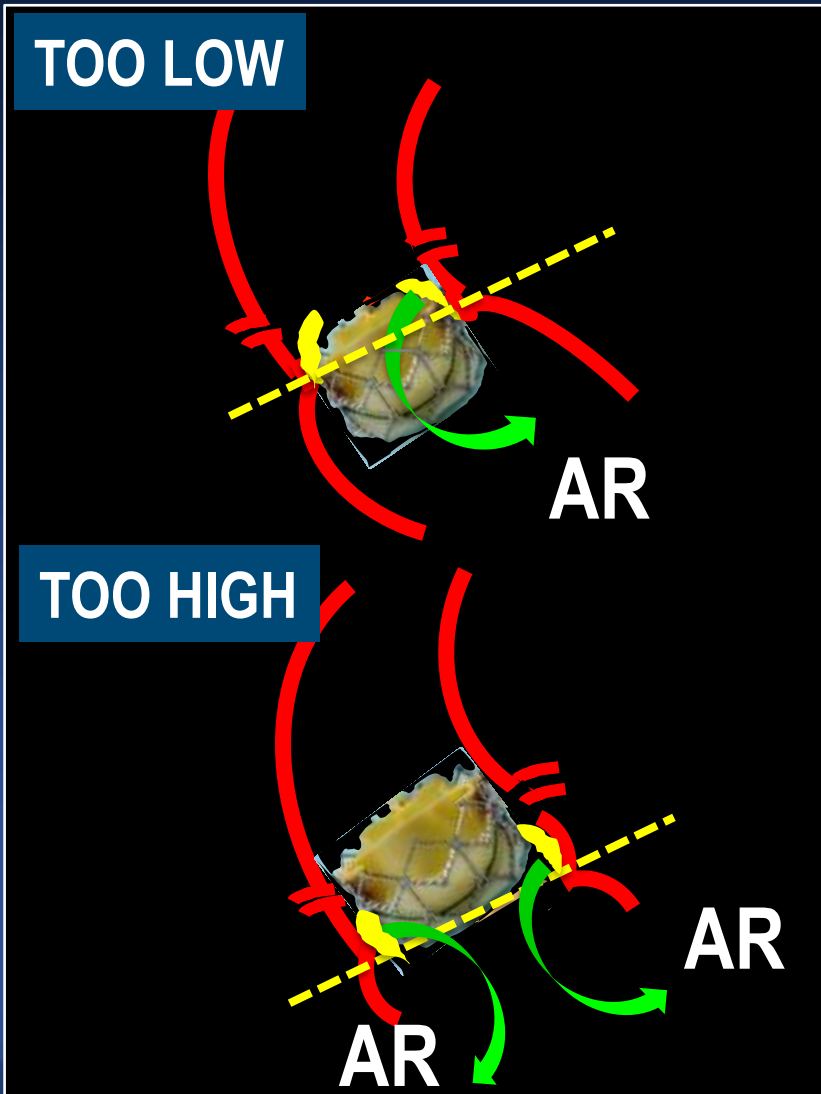
AR

Frame distortion

AR

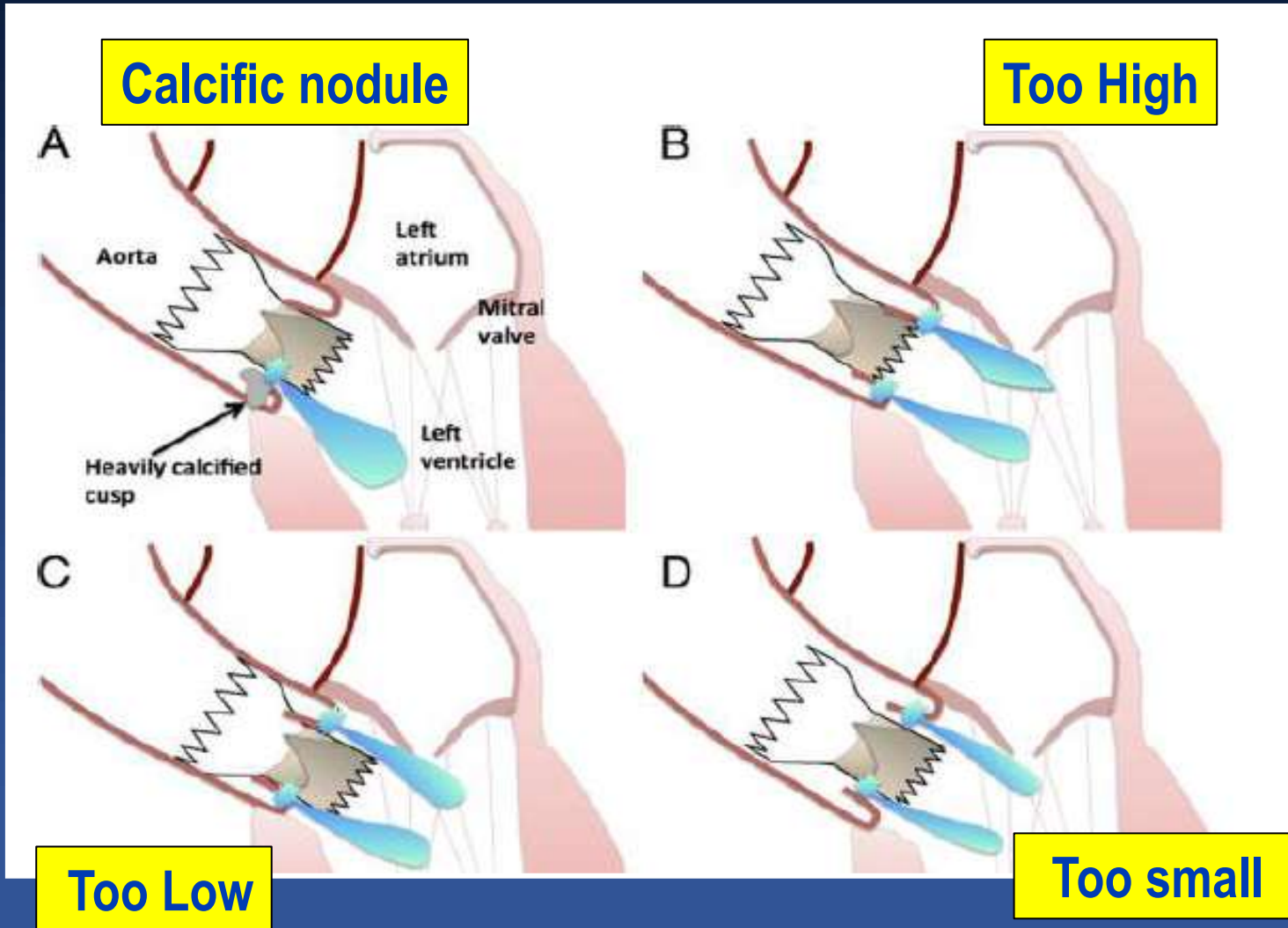
AR

Peri-procedural factors: Valve positioning: Edwards



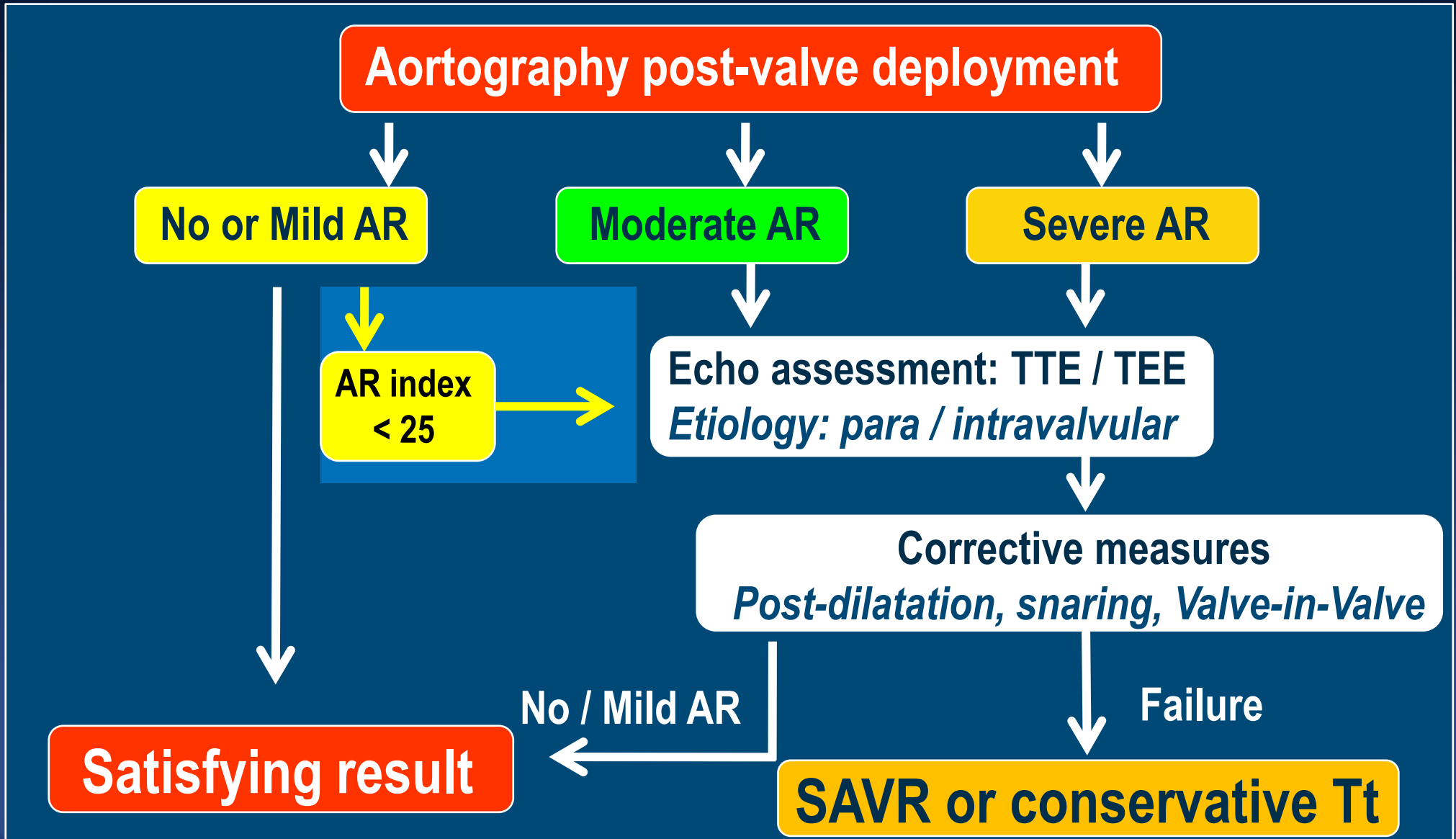
- 1) Be coaxial !
- 2) Final touch of positioning with rapid pacing

The issue of valve positioning: Medtronic CoreValve



Sinning et al, JACC Vol 59, 1140

Proposed organigram in AR post-TAVI



From Sinning et al, London PCR 2013

Different valves / Different strategies in AR post-TAVI

Malposition or under-expansion of the prosthesis

Too low

Pull maneuvers

SE

Valve-in Valve

BE

Too High

Pull-out maneuvers
Valve -in-Valve

SE

BE

Under expanded

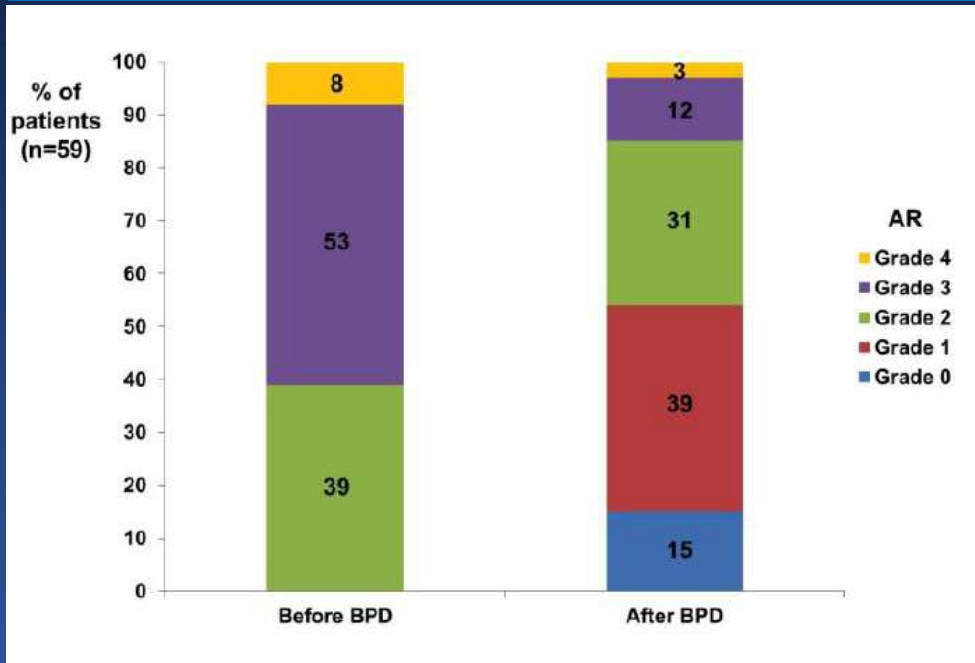
Sapien XT



**Non expansible
external cuff**

Balloon post-dilatation and AR

Decreased AR by one grade



- Increased risk :

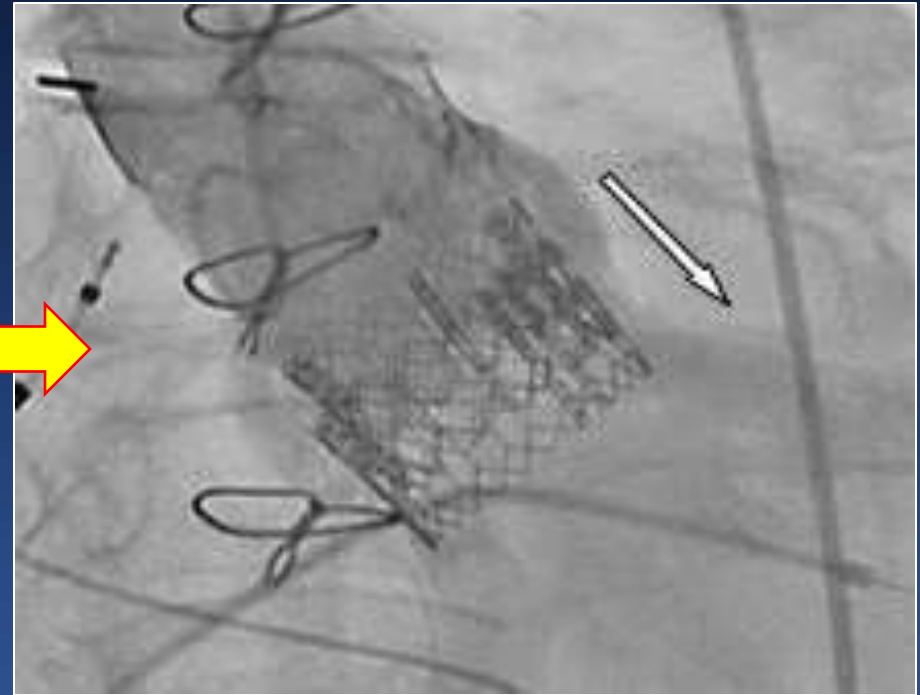
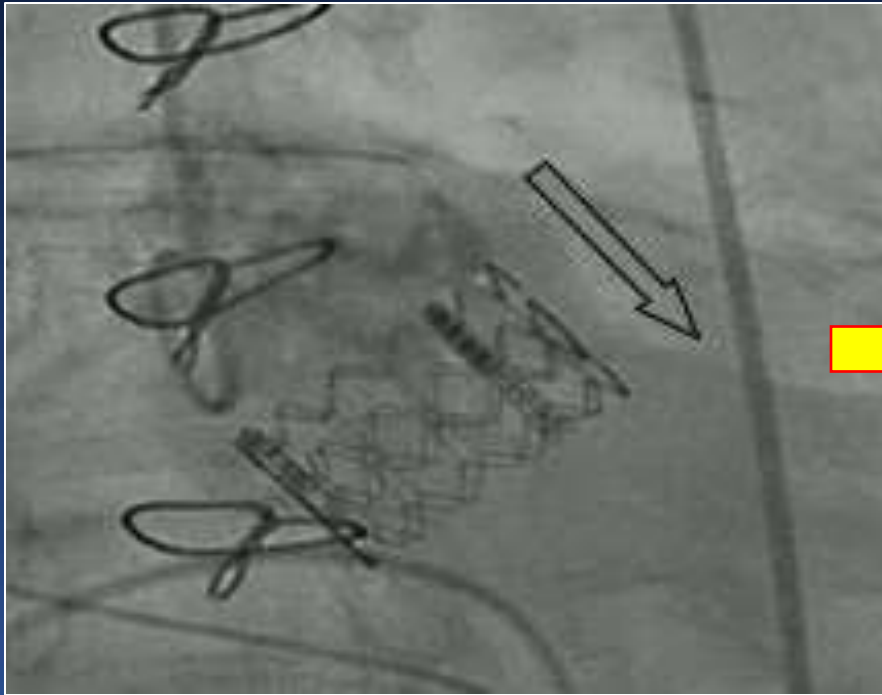
- New LBBB
- *Independent predictor of CV event*

- No deleterious effect on valvular structure

5 studies (2 SE, 3 BE), 1000 pts

Numbela-Franco, JACC 2012

Valve in Valve for malpositioning and severe AR



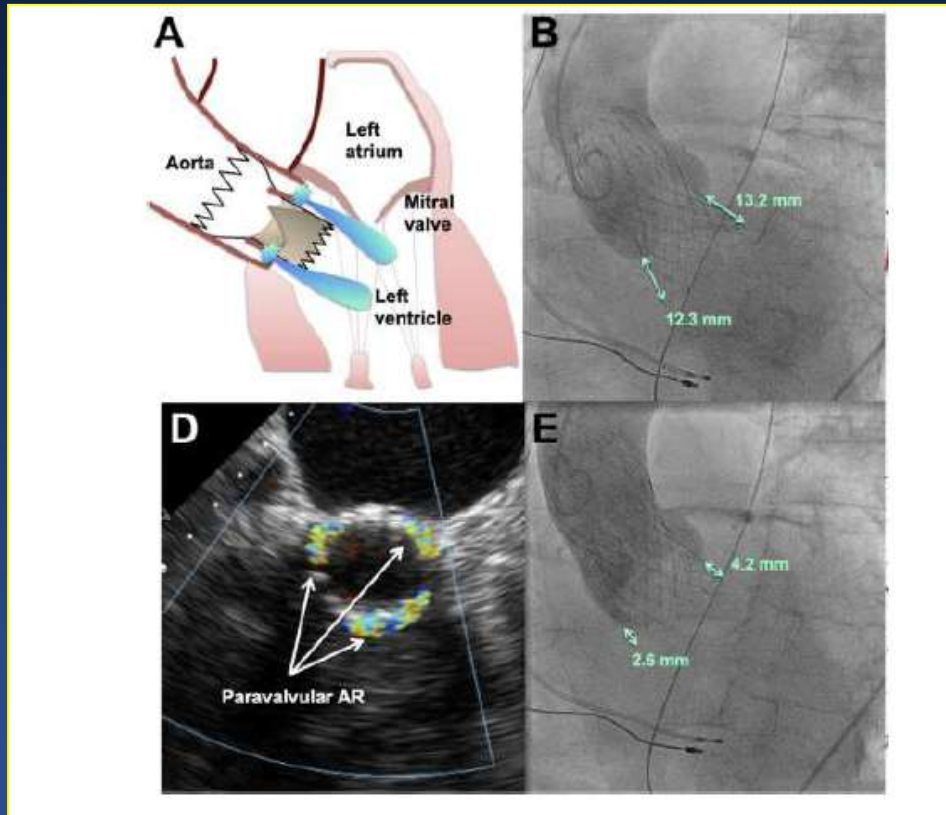
Too low: severe AR

V-in-V: mild AR

High risk of prosthesis migration in LV !

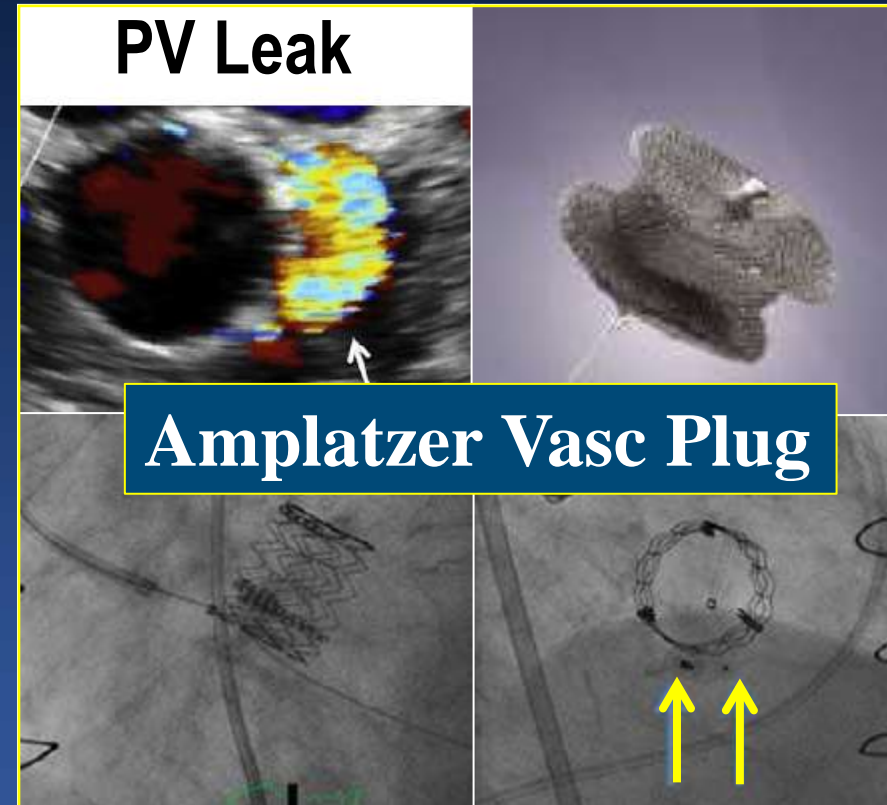
Other strategies for AR post-TAVI

Snaring



J. Webb
PCR London Valve 2013

Device closure ?



Whisenant B et al,
Cath and Cardiovasc Interv 2013

AR post-TAVI: any valve type effect?

J Am Coll Cardiol. 2013 Apr 16;61(15):1585-95. doi: 10.1016/j.jacc.2013.01.047.

Incidence, predictors, and outcomes of aortic regurgitation after transcatheter aortic valve replacement: meta-analysis and systematic review of literature.

Athappan G¹, Patvardhan E, Tuzcu EM, Svensson LG, Lemos PA, Fraccaro C, Tarantini G, Sinning JM, Nickenig G, Capodanno D, Tamburino C, Latib A, Colombo A, Kapadia SR.

45 studies - 12 926 patients 2002-2012

Moderate to severe AR

Medtronic CoreValve 16.0% vs Edwards 9.1% (p=0.005)

E. Van Belle et al, Circulation 2014

From FRANCE 2 registry

AR \geq Grade 2 (Echo)

CV (n= 897) vs Ed (n= 1872)

21.5 % vs 13.0% (p=0.0001)

Abdel-Wahab et al, JAMA 2014

CHOICE Randomized Trial

More than mild AR (Angio)

CV (n= 120) vs Ed (n= 121)

18.3 % vs 4.1% (p=0.01)

New prosthesis design should limit this complication



Edw Sapien 3
External cuff



DF medical



BS Sadra



SJ Portico

Repositionable, retrievable



Edw Centera



Accurate

Self seating features



Jena Valve



Engager

Native leaflets incorporated

CONCLUSIONS

- **Post-TAVI paravalvular AR is common with first generation devices**
- **Moderate to severe AR is associated with excessive mortality**
- **Efforts should be made to minimize AR by careful valve sizing and meticulous procedural execution. The importance of multi-imaging modalities at the time of screening must be emphasized**
- **Improved device design and implantation techniques should considerably help limiting this complication in the next future**