# How to Avoid Patient-Prosthesis Mismatch (PPM) and Para-Valvular Leakage (PVL)

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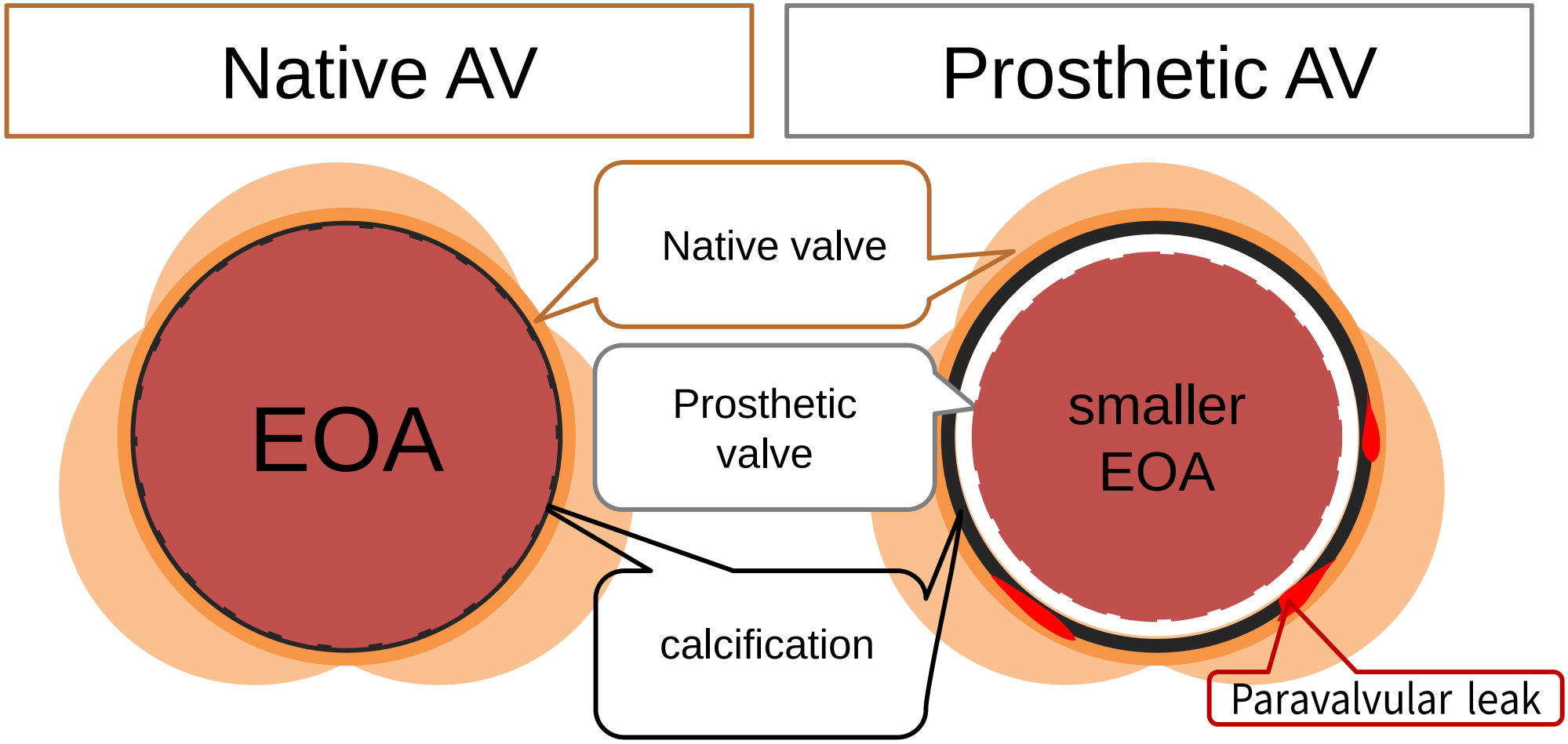
Seoul National University Hospital (SNUH), Seoul, Korea

# Pitfalls of prosthetic valve




1. Stenosis: patient-prosthesis mismatch (PPM)
2. Regurgitation: paravalvular leak (PVL)

# Why we should avoid these complications?

Relation to poor prognosis

To extend the indication of TAVI to younger and lower risk patients

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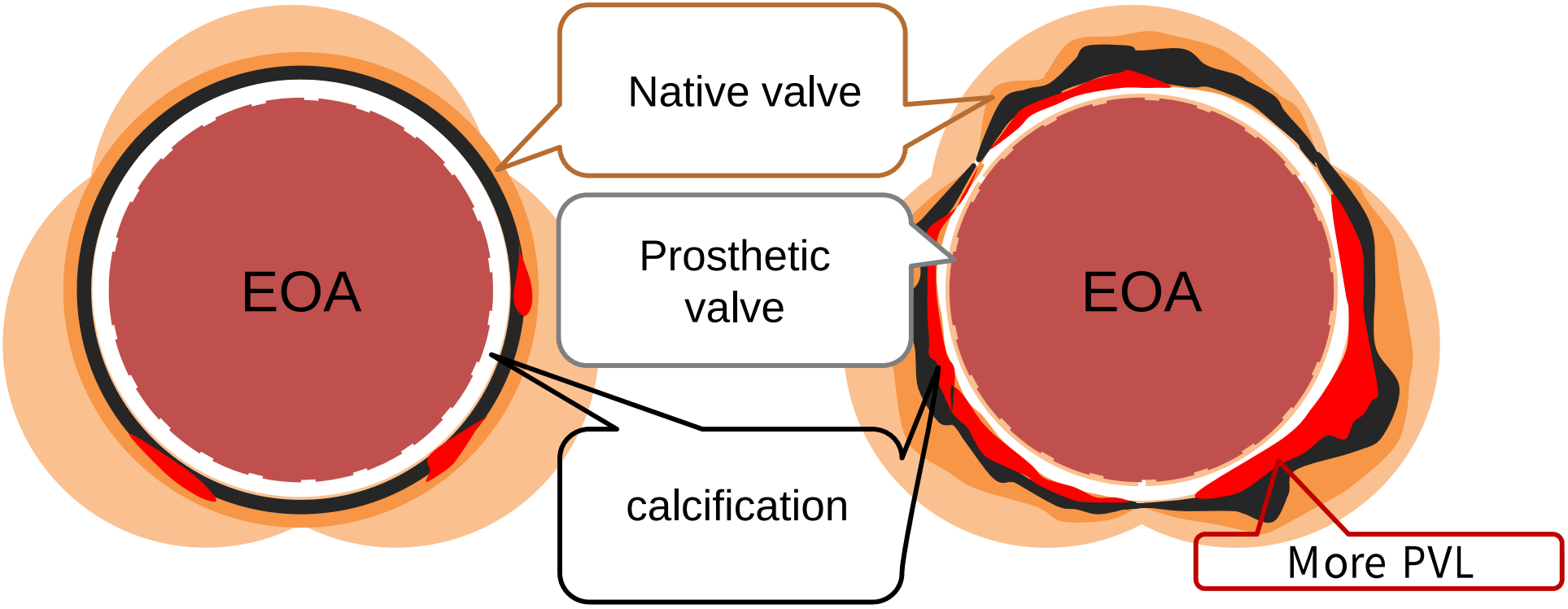
## Surgical AVR

1. Direct visualization
2. Suture (+)
3. Removal of own leaflet (+)

## TAVI

1. Estimation
2. Suture (-)
3. Removal of own leaflet (-)




TAVI has 1. Comparable or lower risk of PPM
2. Higher risk of PVL

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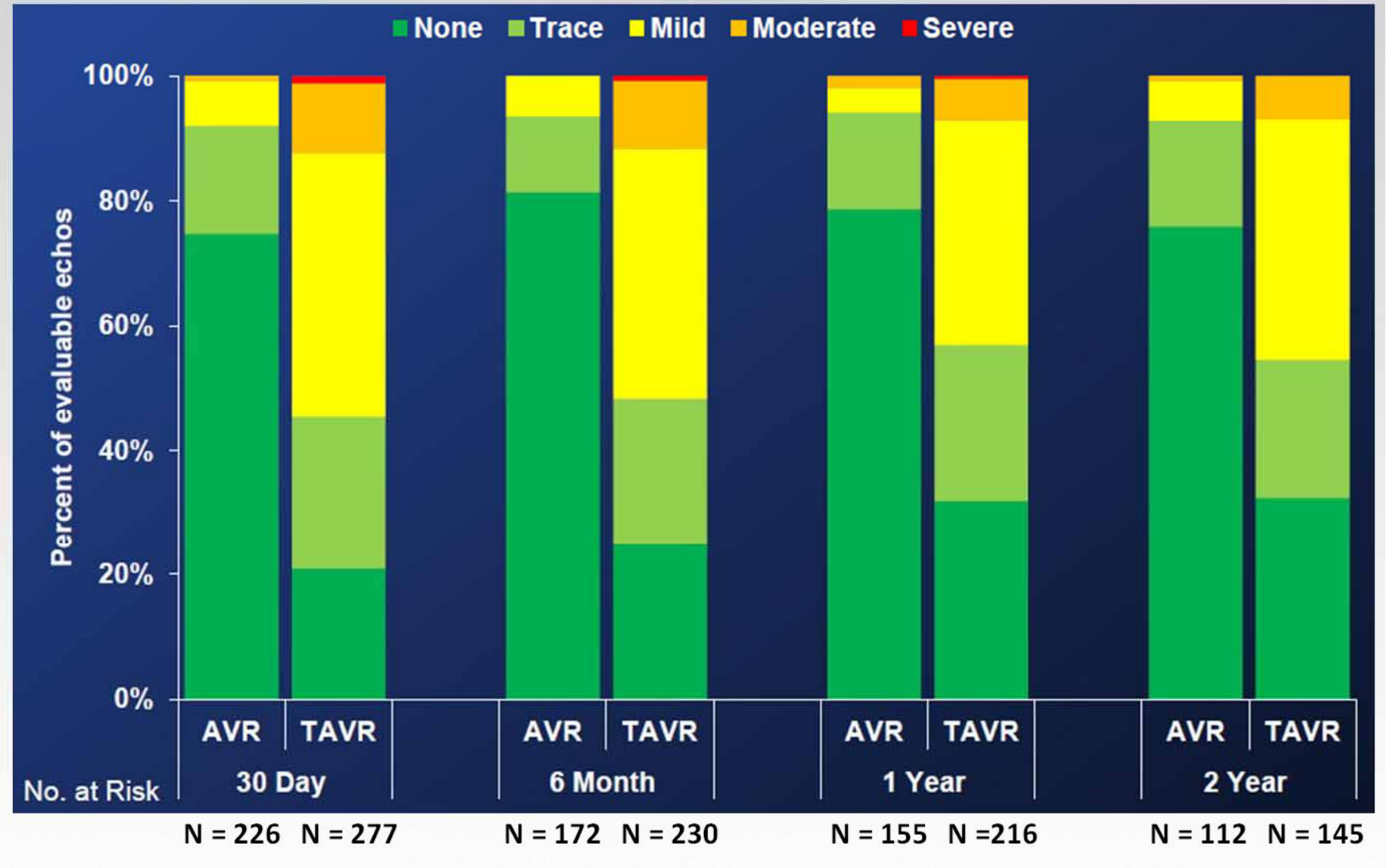
# Paravalvular leak (PVL)

# Higher incidence of PVL after TAVI

## Moderate or severe PVL was more common after TAVI

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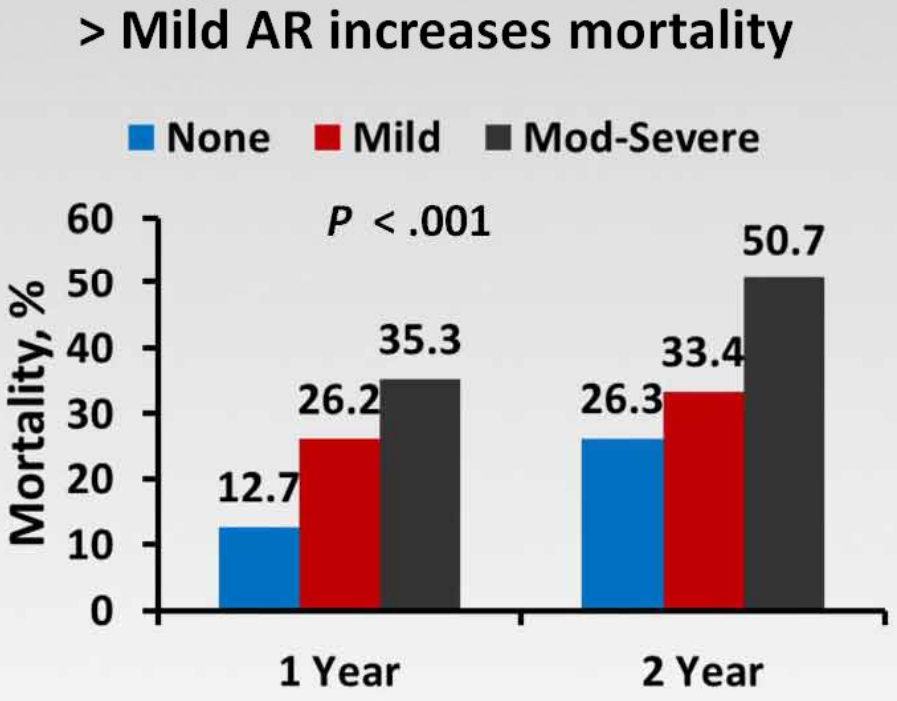
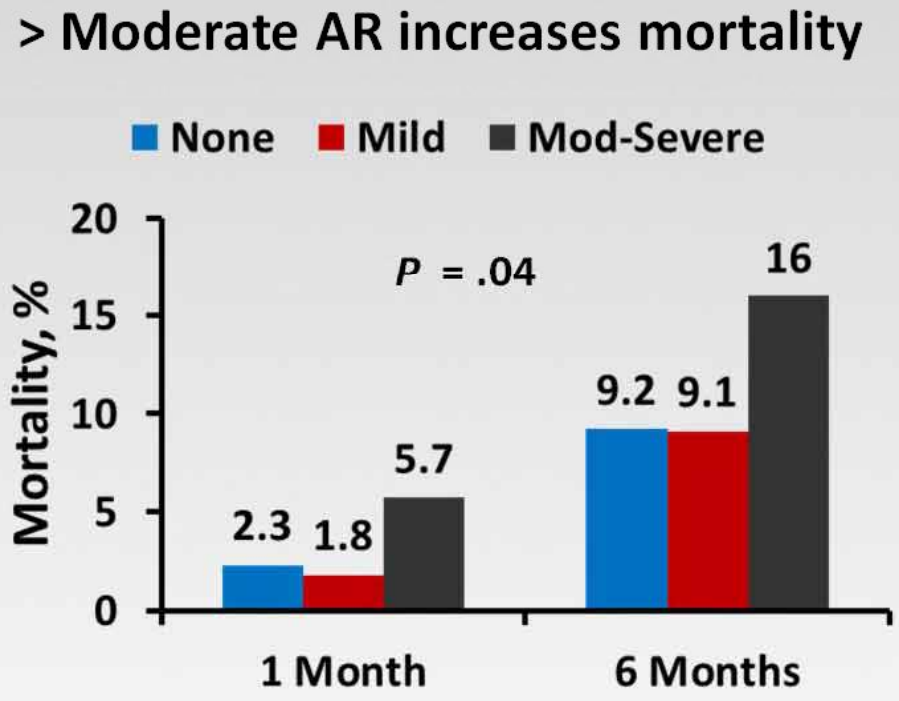
Kodali SK. et al. N Engl J Med 2012;366:1686-95

# PVL, the new Achilles' heel?

## Even mild PVL can increase mortality




PARTNER Cohort A *Sapien valve*
None/Trace (n = 135);
Mild (n = 165);
Moderate-Severe (n=34)

ADVANCE Registry *CoreValve*
None (n = 166);
Mild (n = 551;
Moderate-Severe (n=132)

Kodali SK. et al. N Engl J Med 2012;366:1686-95

Linke A. et al. TCT 2012

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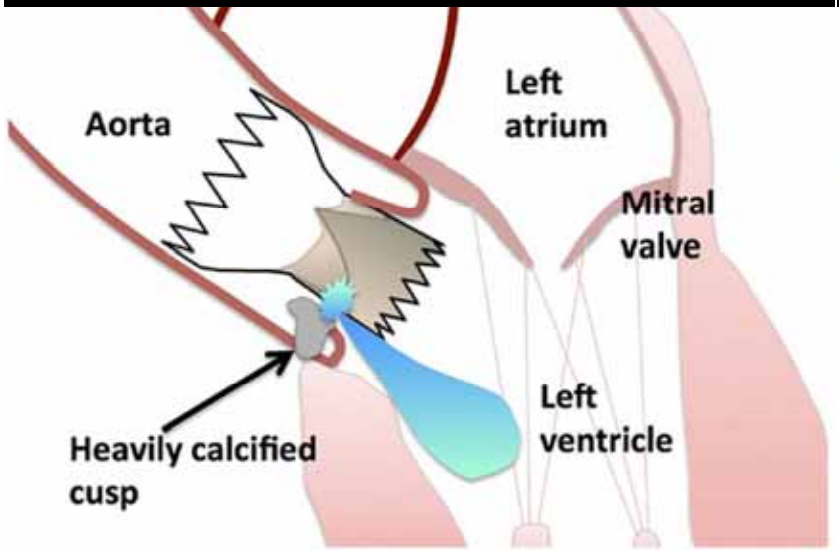
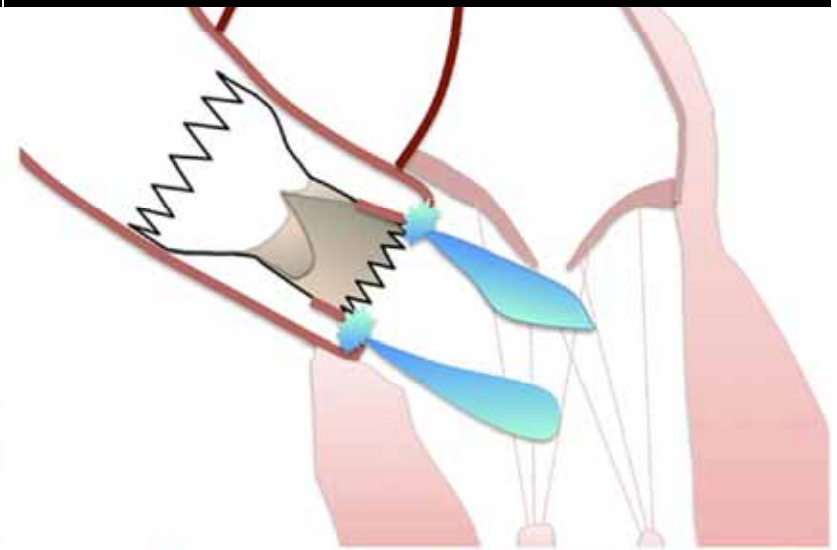
# Mechanisms of PVL

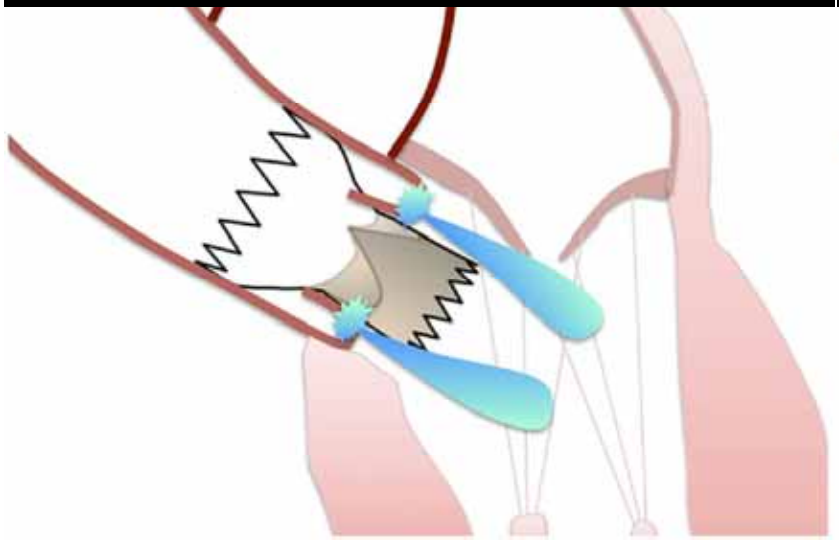
## Calcifications



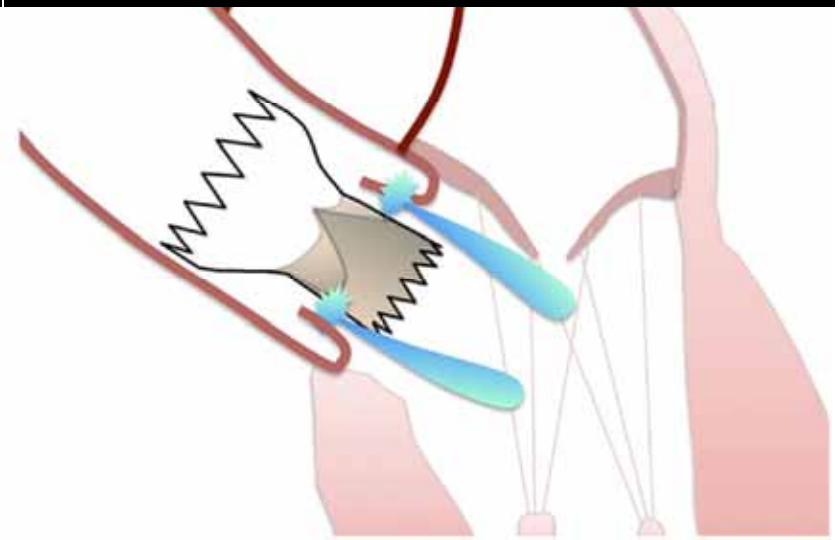

## Malposition – too shallow



## Malposition – too deep



## Size mismatch



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Sinning JM. et al. J Am Coll Cardiol 2012;59:1134–41

# Strategy to avoid PVL

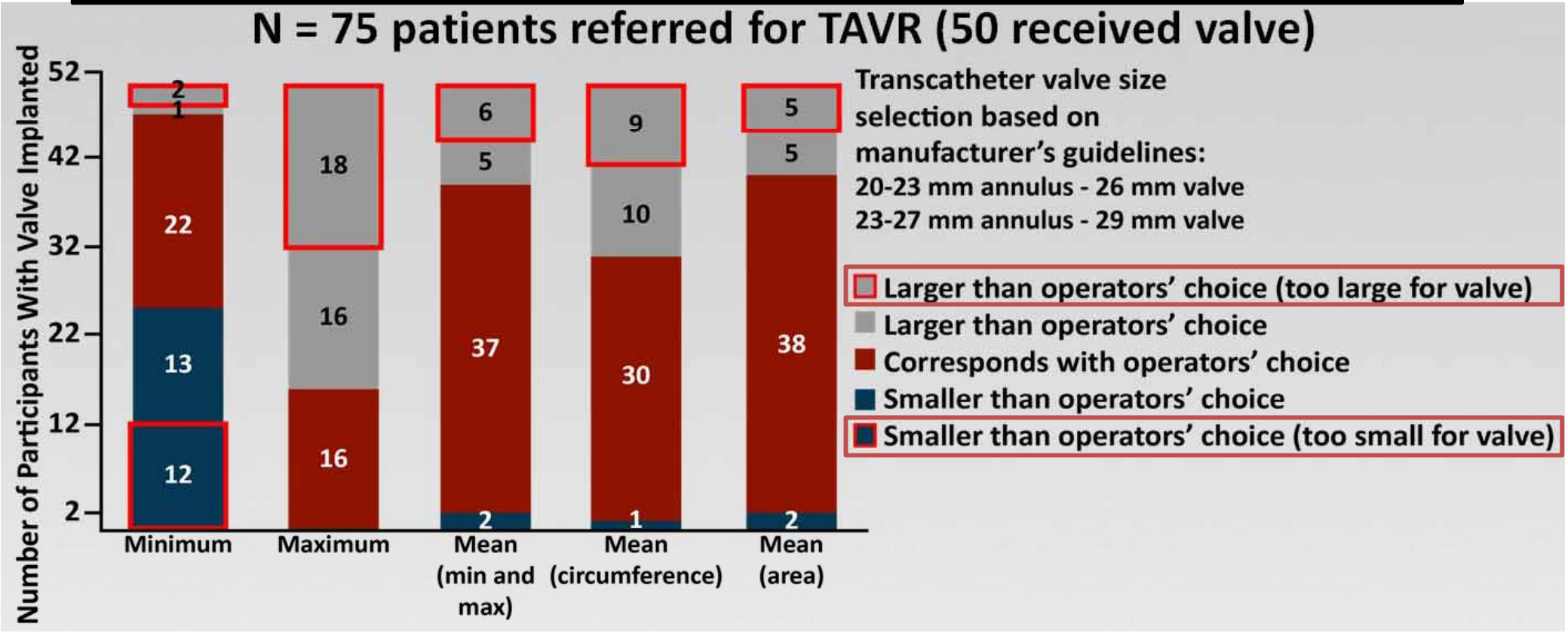
1. Proper preparation for procedure: sizing
2. Optimal procedure: positioning
3. Identification or quantification of PVL
4. Correction

# Strategy to avoid PVL

1. Proper preparation for procedure: sizing
2. Optimal procedure: positioning
3. Identification or quantification of PLV
4. Correction

# Sizing based on 3-D CT vs 2-D Echo

## self-expandable valve (Medtronic-Corevalve)




A 2-D image may give a wrong impression of the shape and dimensions of AV

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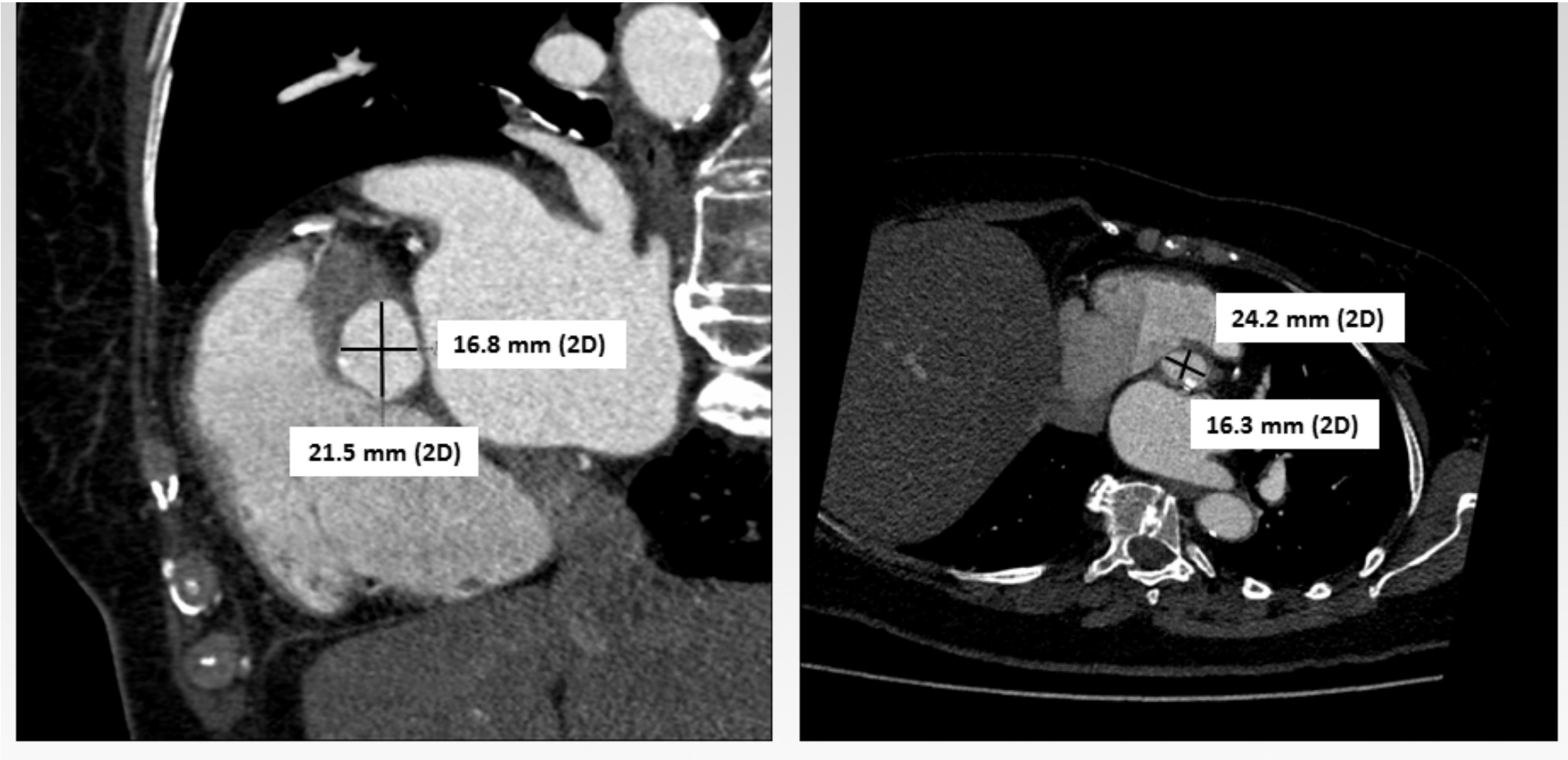
Schultz CJ. et al. Eur Heart J 2010;31,849–856

# Noncircular morphology of aortic annulus




MDCT can offer a 3-D alternative for image reconstruction of the aortic annulus, reproducibly

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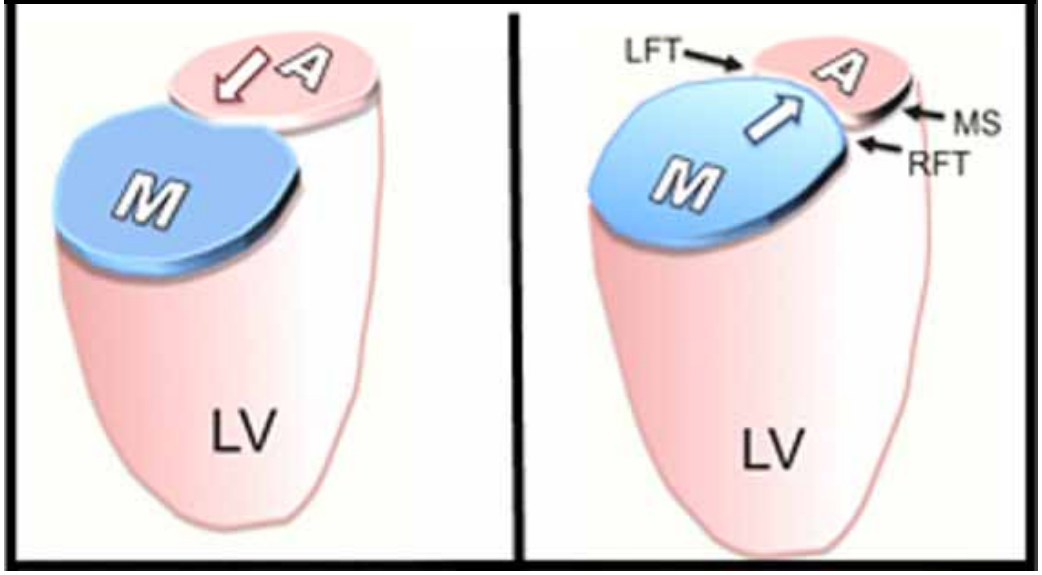
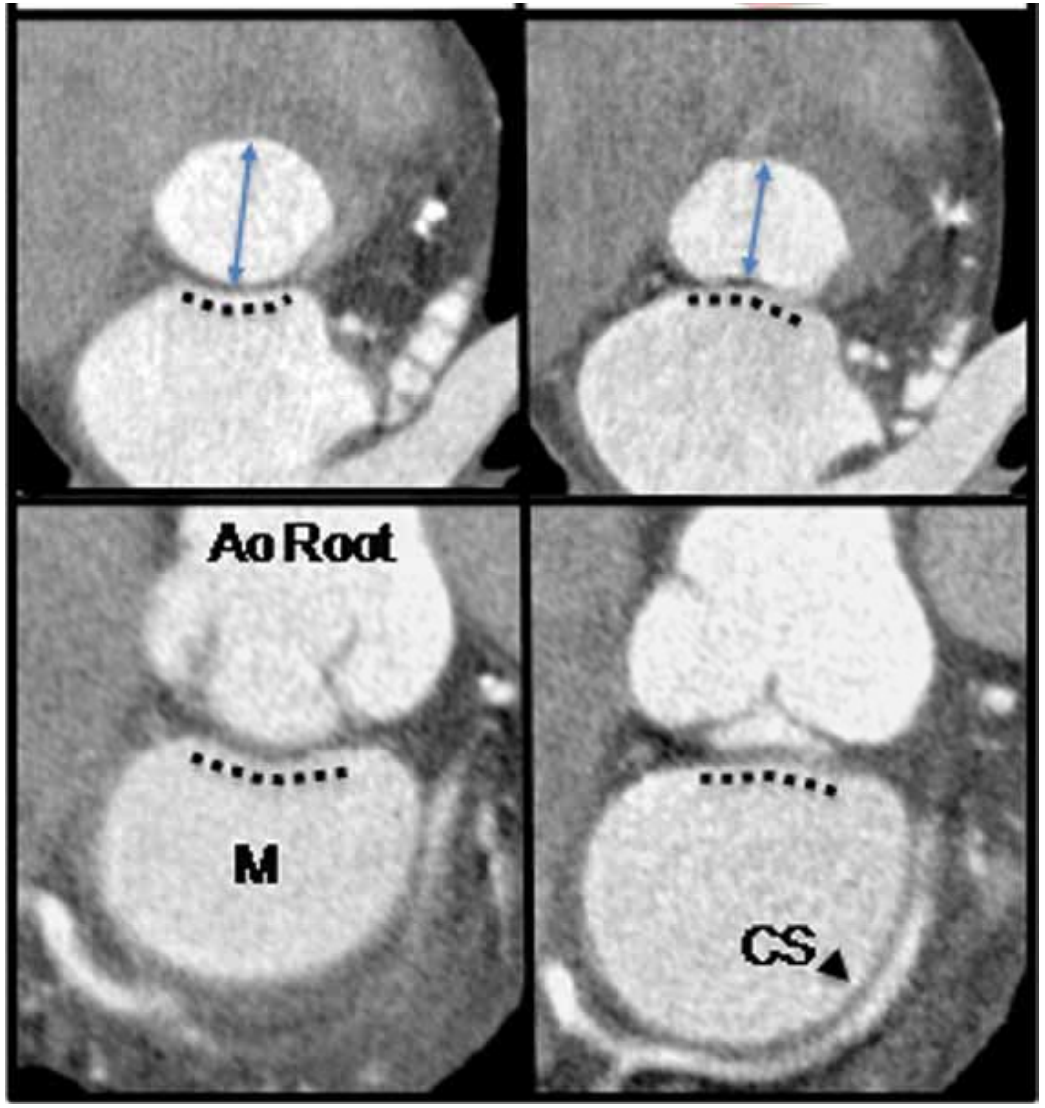
Gurvitch R. et al. J Am Coll Cardiol Intv 2011;4:1235-45

# Deformation of aortic annulus

| **Systole** : *less* elliptical | **Diastole** : *more* elliptical |
|---|---|

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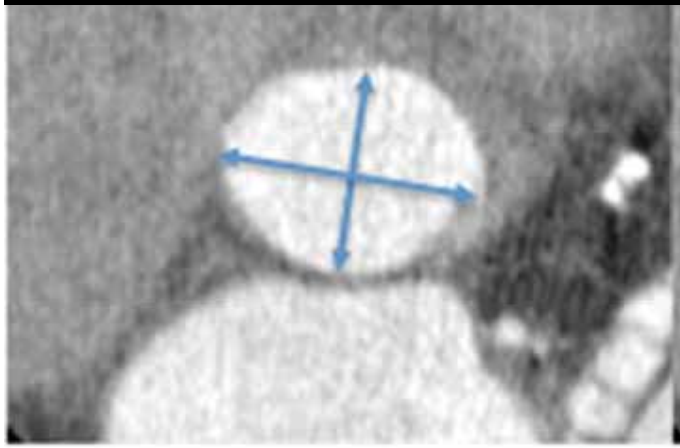
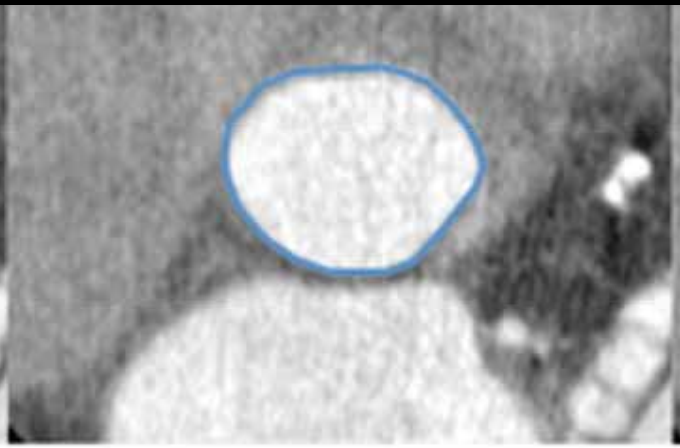
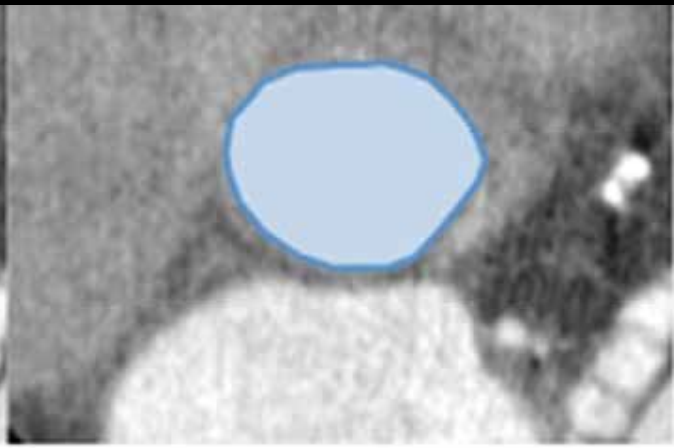
Hamdan A. et al. J Am Coll Cardiol 2012;59:119–27

# Which parameter is better? (1)

| Diameter | Perimeter | Area |
|---|---|---|
|  |  |  |

Calcified tissue properties allow very little expansion

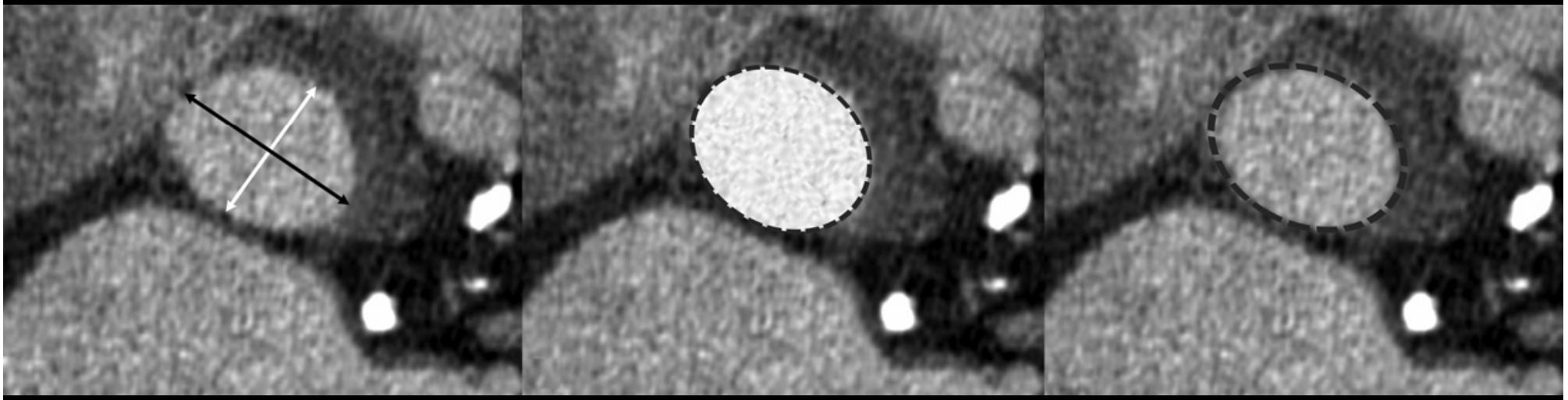
Perimeter changes are negligible
in patients with calcified valves



Hamdan A. et al. J Am Coll Cardiol 2012;59:119–27

# Which parameter is better? (2)

| Diameter | Perimeter | Area |
|---|---|---|
| ICC = 0.84 | ICC = 0.77 | ICC = 0.81 |
| AUC = 0.83 | AUC = 0.79 | AUC = 0.82 |



mean diameter & area =
two most reproducible and predictive
MDCT annular measurements for PVL.

**ICC = interclass coefficiency (index of reproducibility)**
**AUC = area under the curve (index of prediction)**

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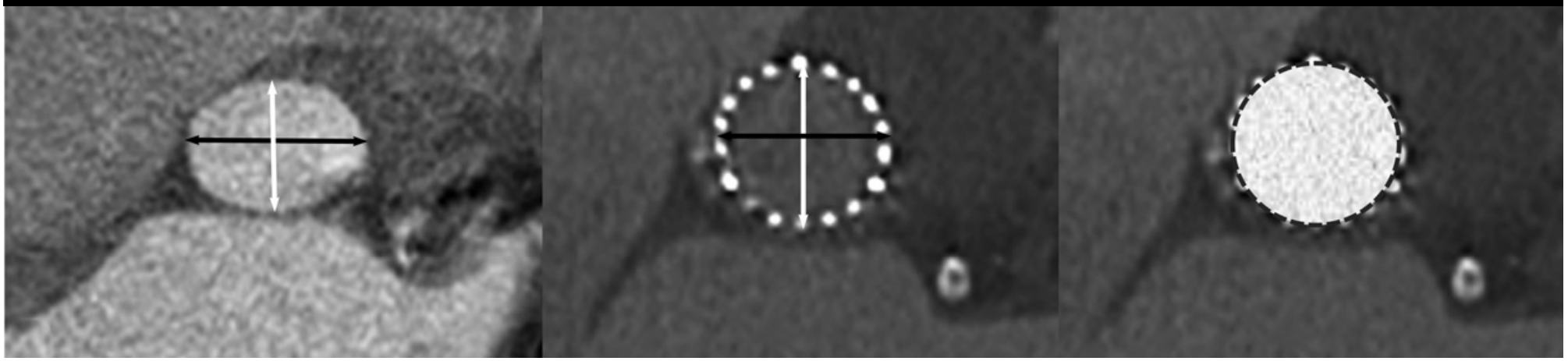
Willson AB. J Am Coll Cardiol 2012;59:1287–94

# Over-sizing can be effective and safe?

eccentricity = 29% → eccentricity = 1.3%

area = 3.45cm$^2$
d = 20.5 mm
→ Increase of area = 20%
expansion ratio = 103.6%

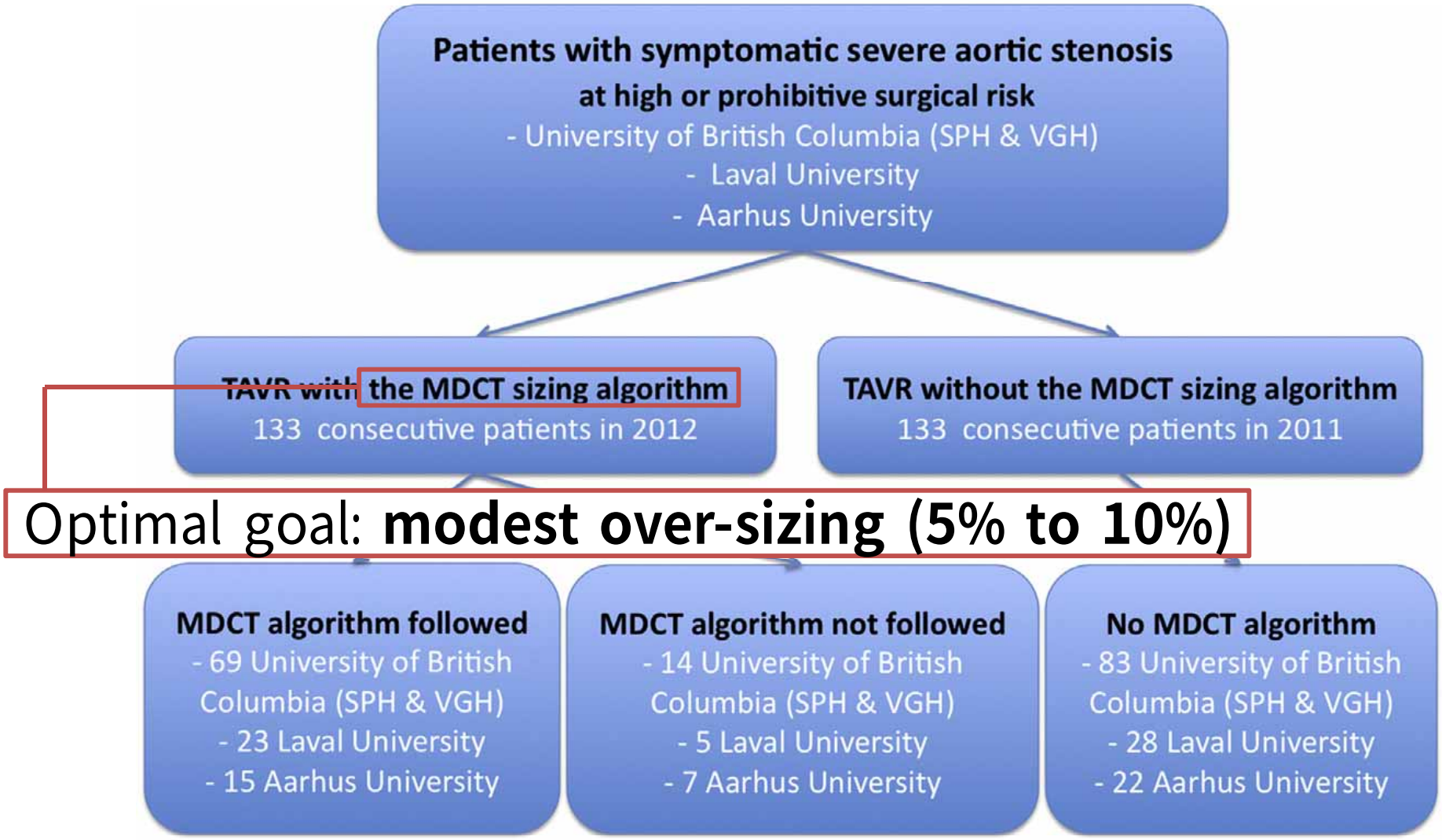


Over-sizing may reduce the risk of moderate or severe PVL
→ The implanted valve size should be greater than the 3-D annular size by MDCT (1mm of diameter or 10% of area)



Willson AB. J Am Coll Cardiol 2012;59:1287–94

# The impact of modest over-sizing by MDCT




| | MDCT (+) | MDCT (-) | p value |
|---|---|---|---|
| > mild PVL | 5.3% | 12.8% | 0.032 |
| death + annulus rupture + severe PVL | 3.8% | 11.3% | 0.02 |

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Binder RK. J Am Coll Cardiol 2013;62:431–8

# Strategy to avoid PVL

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# Optimal positioning depends on Height of Sealed Skirt

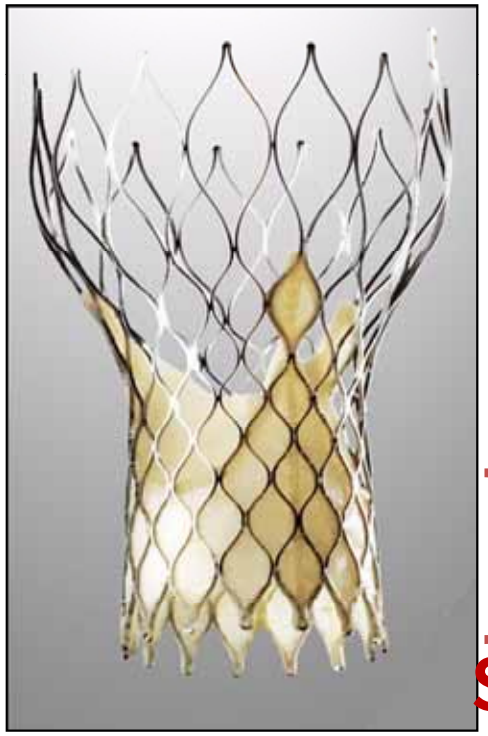
## Edwards SAPIEN valve

14 MM

6~7 MM

Sealed skirt

## CoreValve ReValving System



55 MM

12 MM

Sealed skirt

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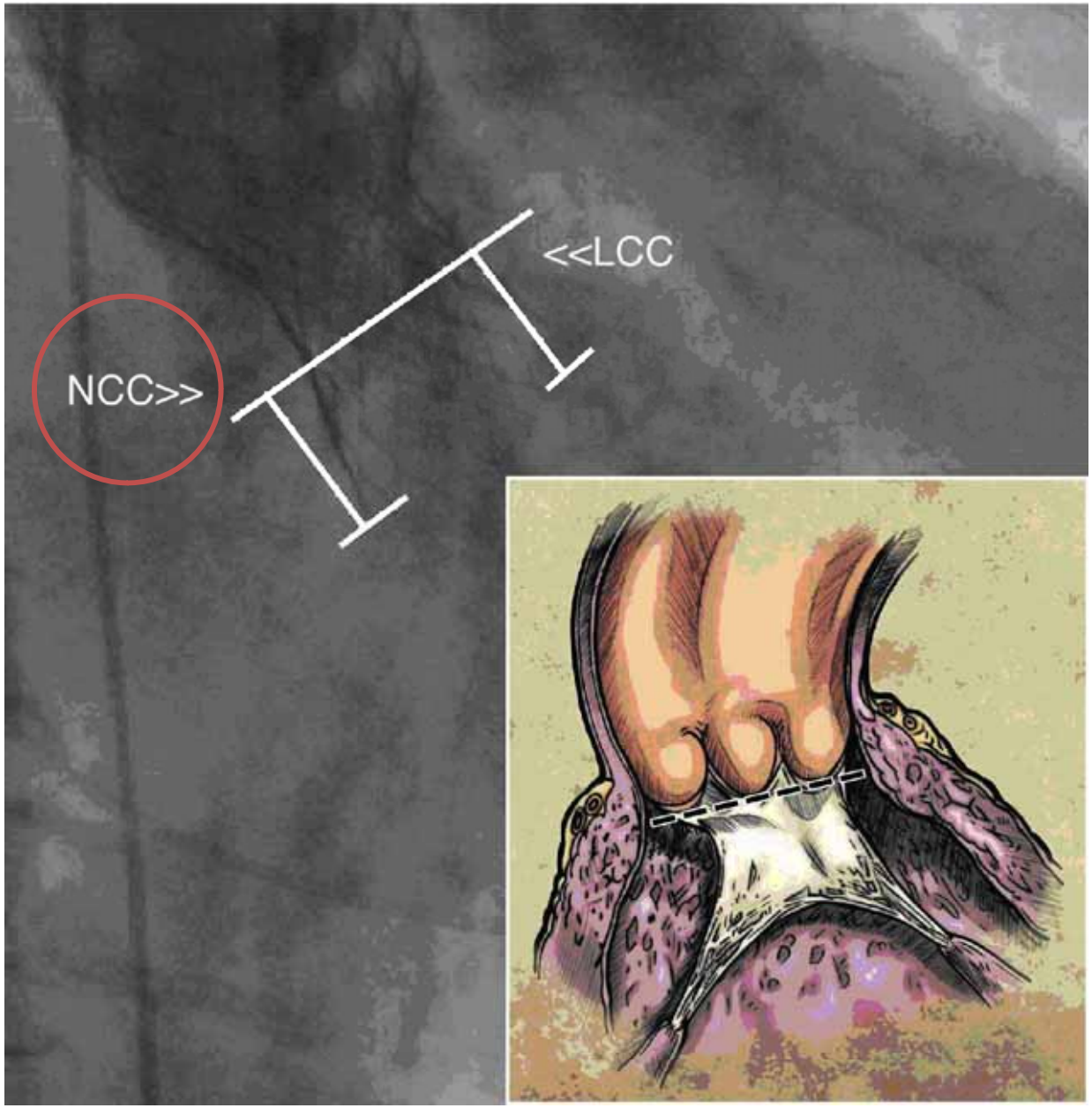
# Landmark for optimal positioning




self-expandable valve
(Medtronic-Corevalve)

The chance of significant PVL is a minimum when depth of the device into LV is ~10 mm

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Sherif AB. J Am Coll Cardiol 2012;59:1287–94

# Strategy to avoid PVL

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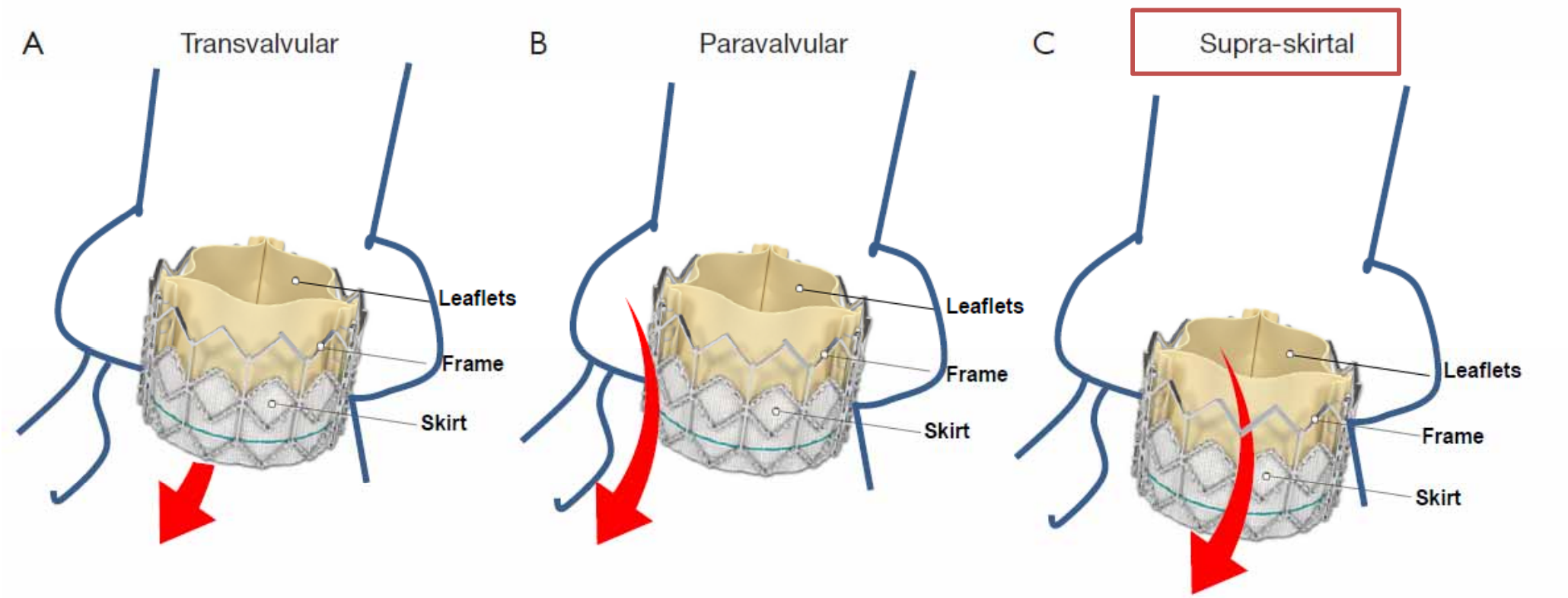
# three kinds of regurgitation after TAVI



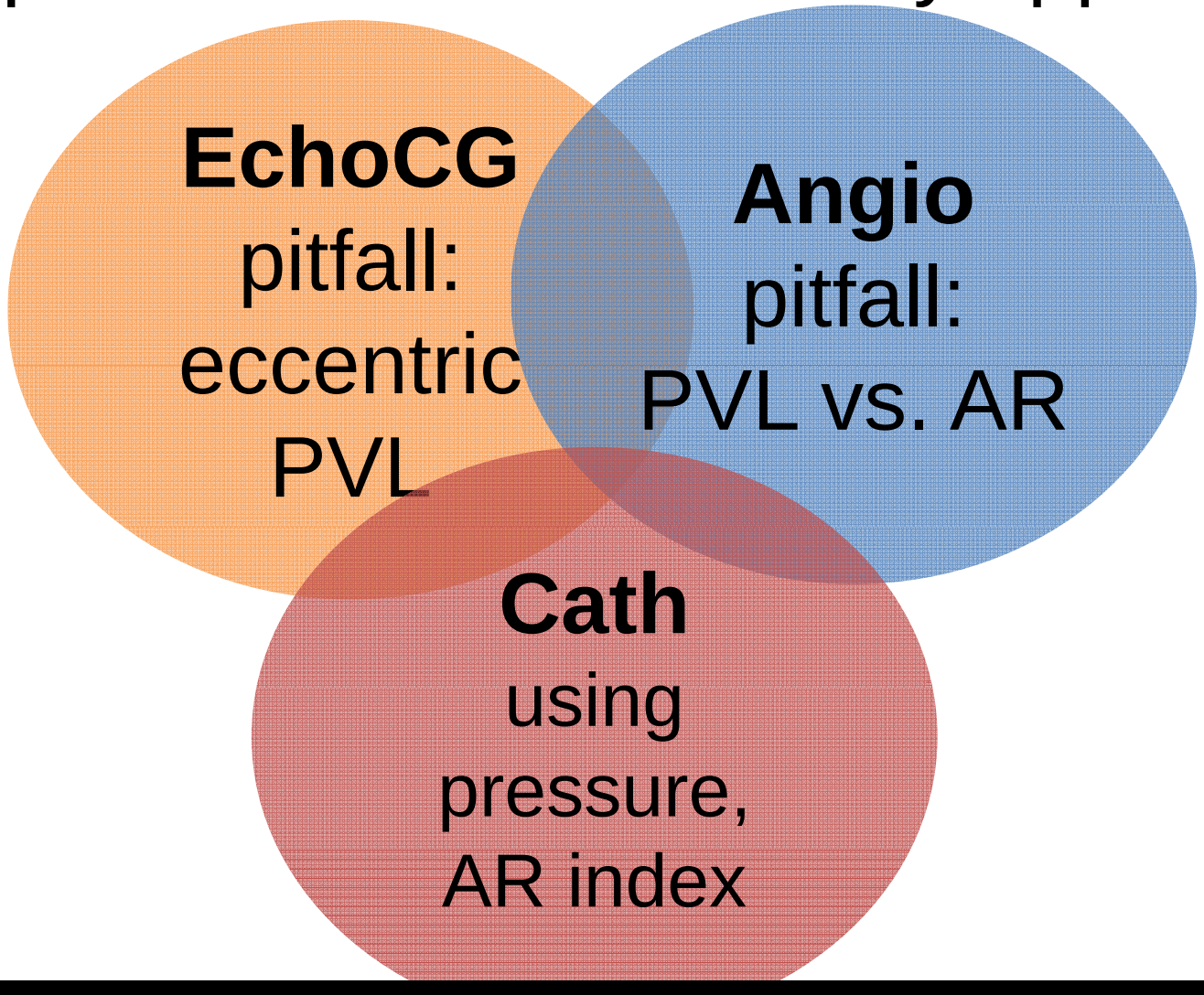

leakage through the uncovered part of the prosthesis above the skirt may occur if implanted too low in the aortic position

a substantial number of AR classified as ‘paravalvular’ might indeed be ‘supra-skirtal’.



Stähli BE. Cardiovasc Diagn Ther 2013;3:15-22

# Three methods to evaluate PVL (importance of multimodality approach)




Each one can potentially underestimate PVL in a particular situation

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# 2-D echo is a standard for Severity of PVL (VARC 2):

| | Prosthetic aortic valve regurgitation | | |
|---|---|---|---|
| | Mild | Moderate | Severe |
| **Semi-quantitative parameters** | | | |
| Circumferential extent of paravalvular regurgitation* | <10% | 10-29% | ≥30% |
| Diastolic flow reversal in the descending aorta (PW) | Absent or only early diastolic | Intermediate | Prominent, holo-diastolic |
| **Quantitative parameters** | | | |
| Regurgitant volume, ml/beat | <30ml | 30-50ml | ≥60ml |
| Regurgitant fraction | <30% | 30-49% | ≥50% |
| ERO area | 0.10cm$^2$ | 0.10-0.29cm$^2$ | ≥0.30cm$^2$ |

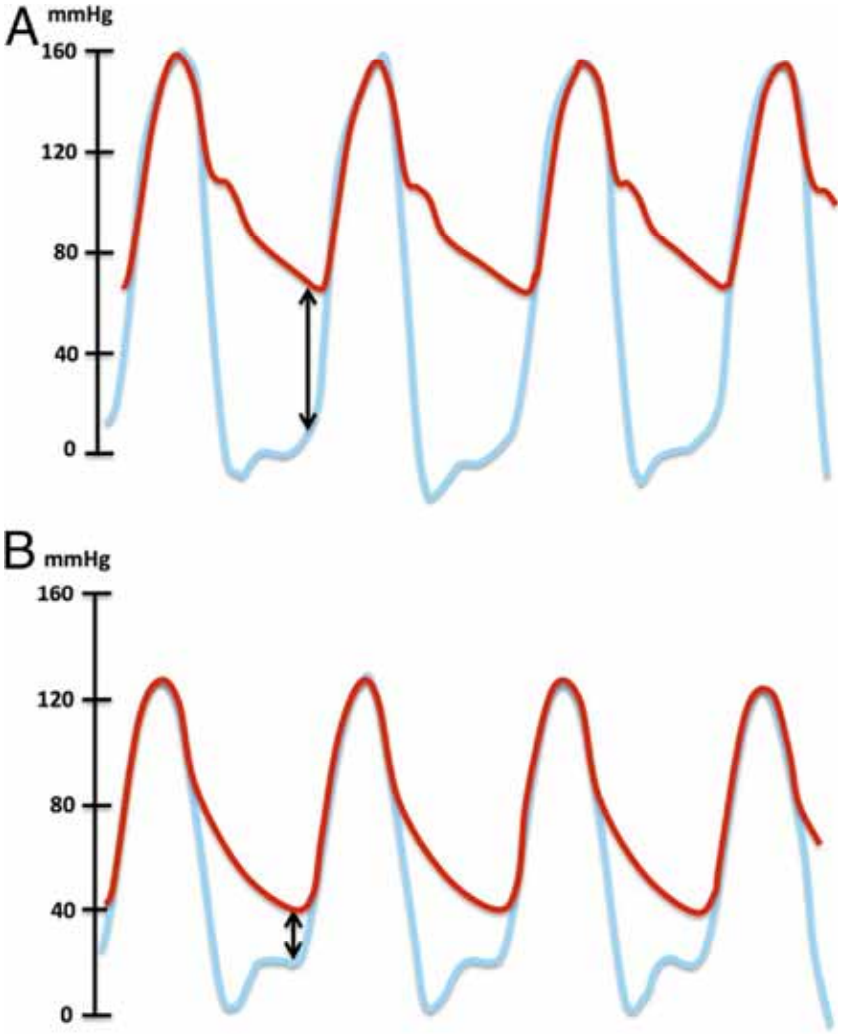
*Not well validated and may overestimate the severity c/w the quantitative Doppler

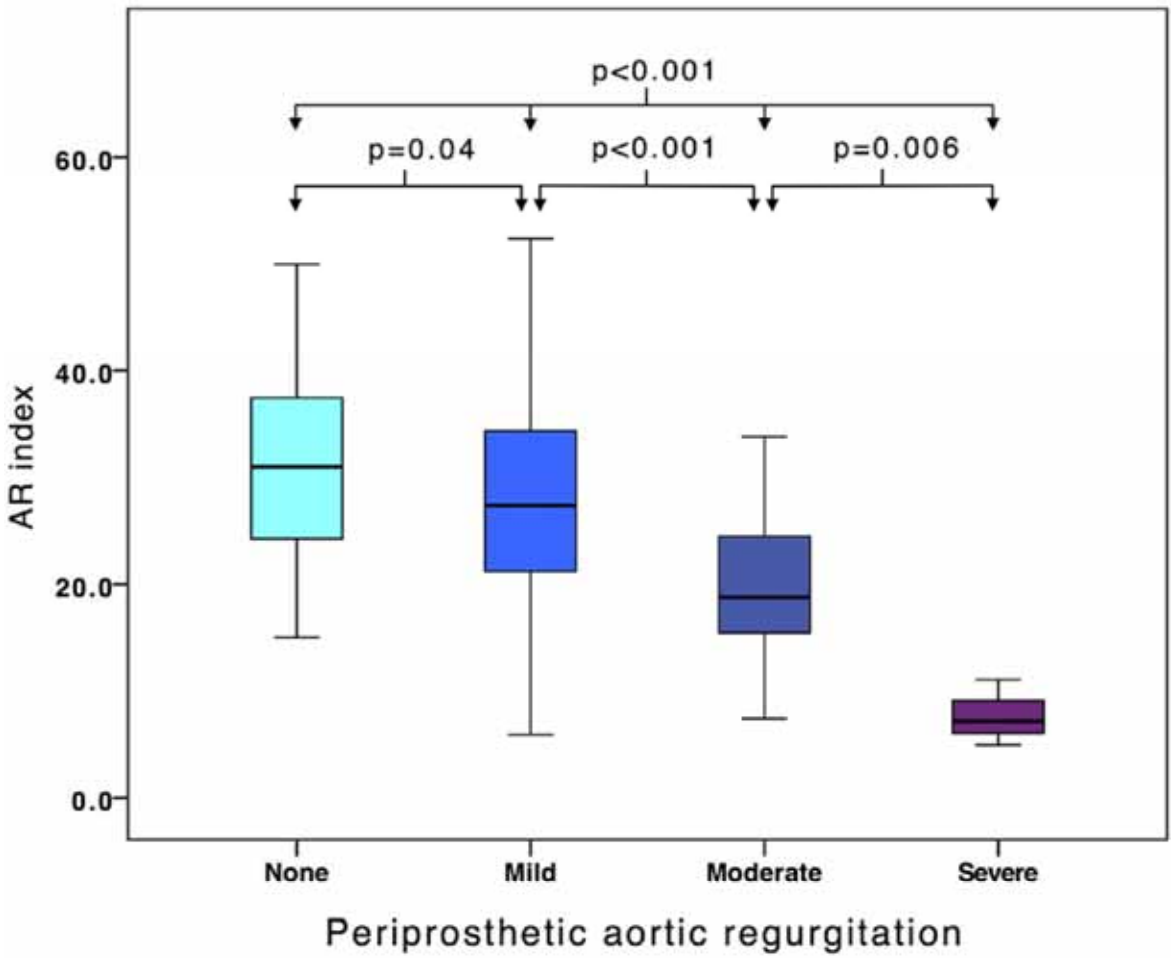


Kappetein AP. J Am Coll Cardiol. 2012;60:1438-54

# AR index based on AoDBP

AR index = [(AoDBP – LVEDP)] / SBP] x100




AR index can be complementary to
the echocardiographic severity of PVL

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Sinning JM. et al. J Am Coll Cardiol. 2012;59:1134–41

# Strategy to avoid PVL

1. Proper preparation for procedure: sizing
2. Optimal procedure: positioning
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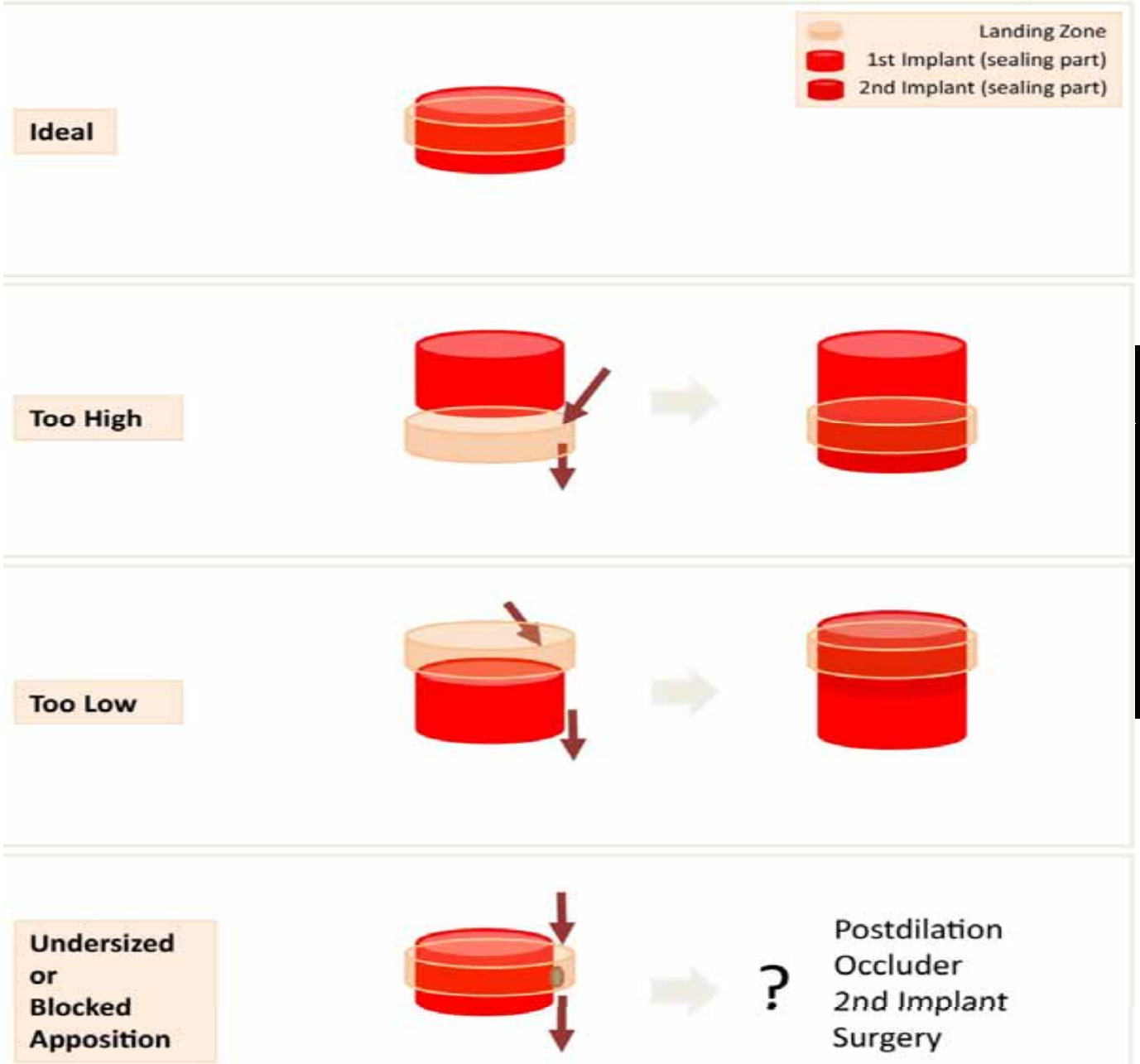
4. Correction

# ‘valve-in-valve’ or ‘post-dilation’ for PVL




Valve-in-valve is a suitable technique to deal with PVL after TAVI in selected cases

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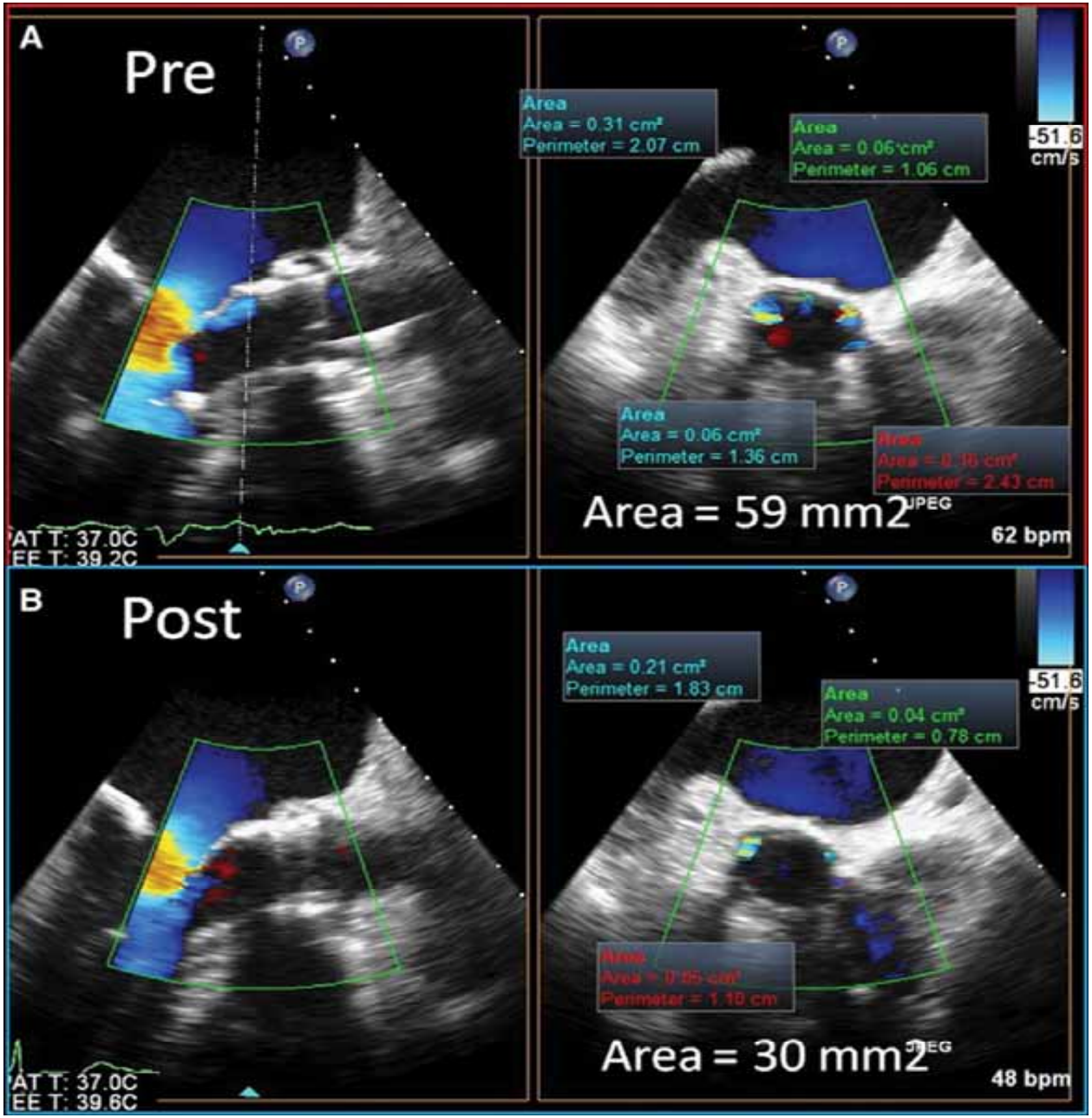
Buellesfeld M. et al. J Am Coll Cardiol Intv. 2012;5:578-81

# Post-dilatation as an feasible option




Post-dilatation can reduce the magnitude of PVL

Post-dilatation may lead to cerebrovascular events

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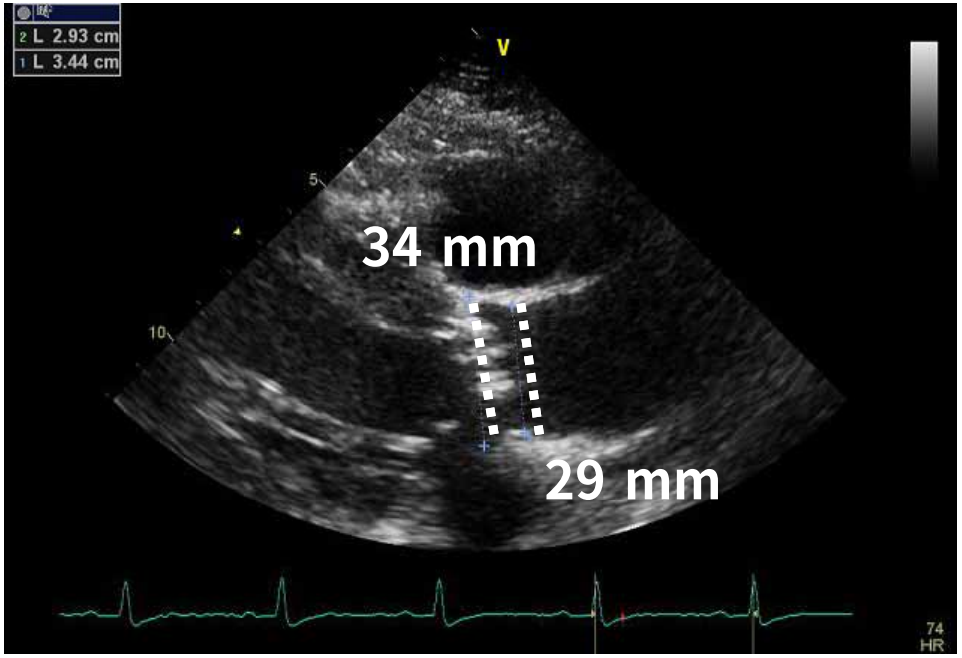
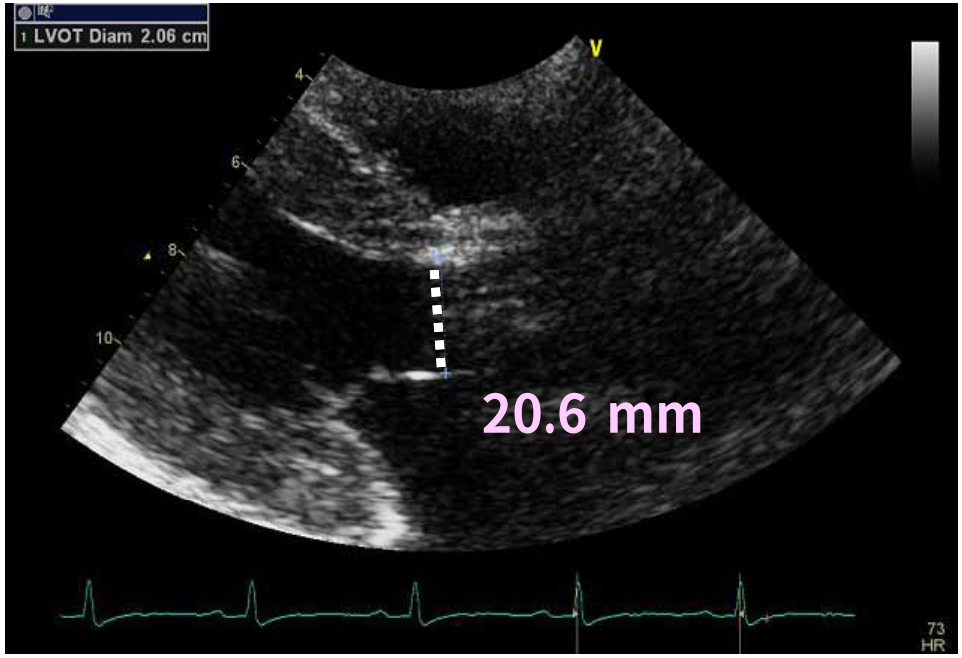
Daneault B. et al. Circ Cardiovasc Interv. 2013;6:85-91

# SNUH experience: sizing (1)

## TTE

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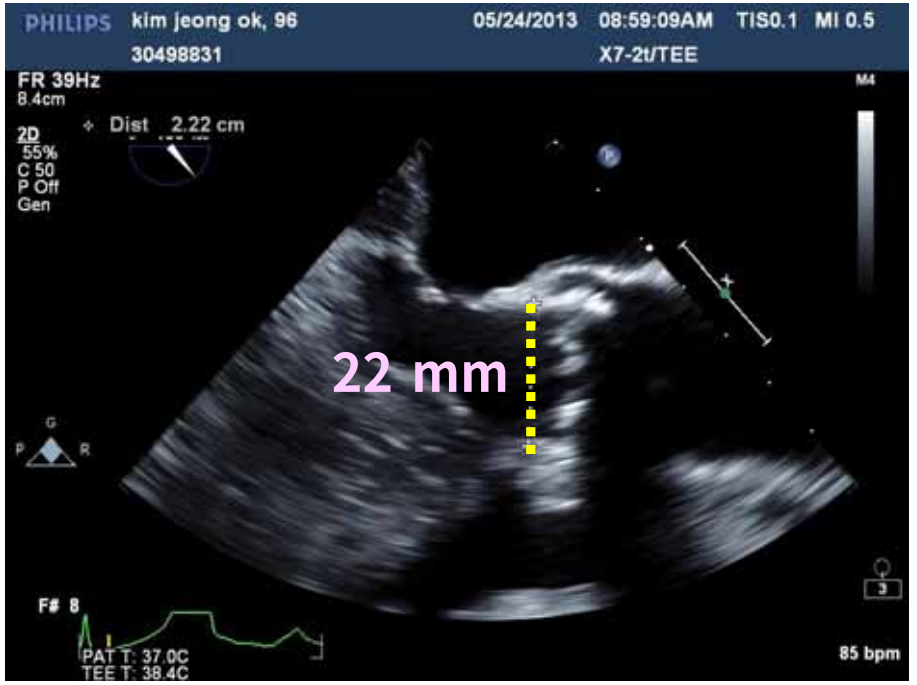
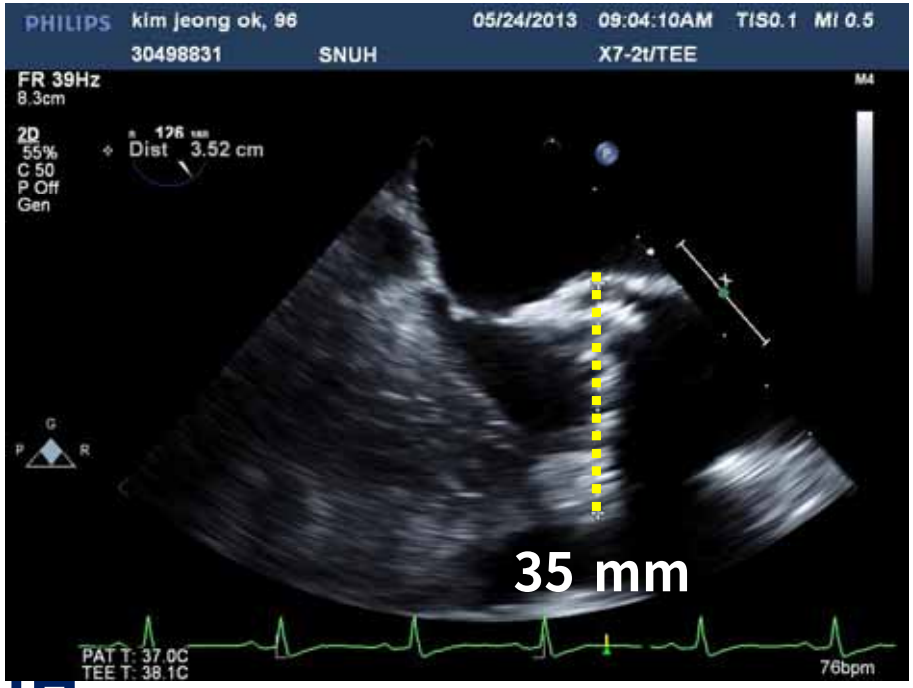
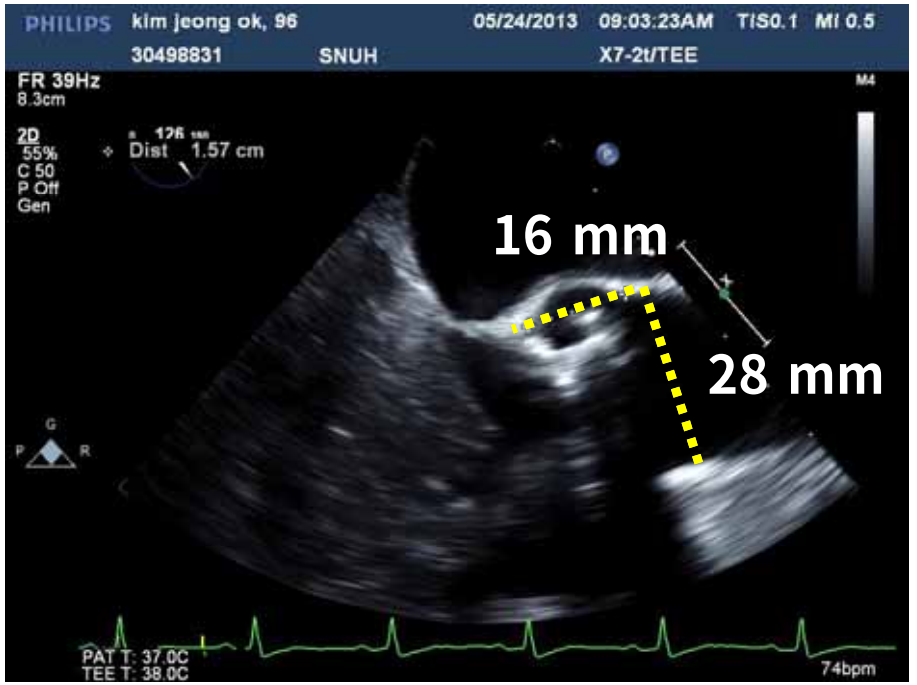
# SNUH experience: sizing (2)

TEE

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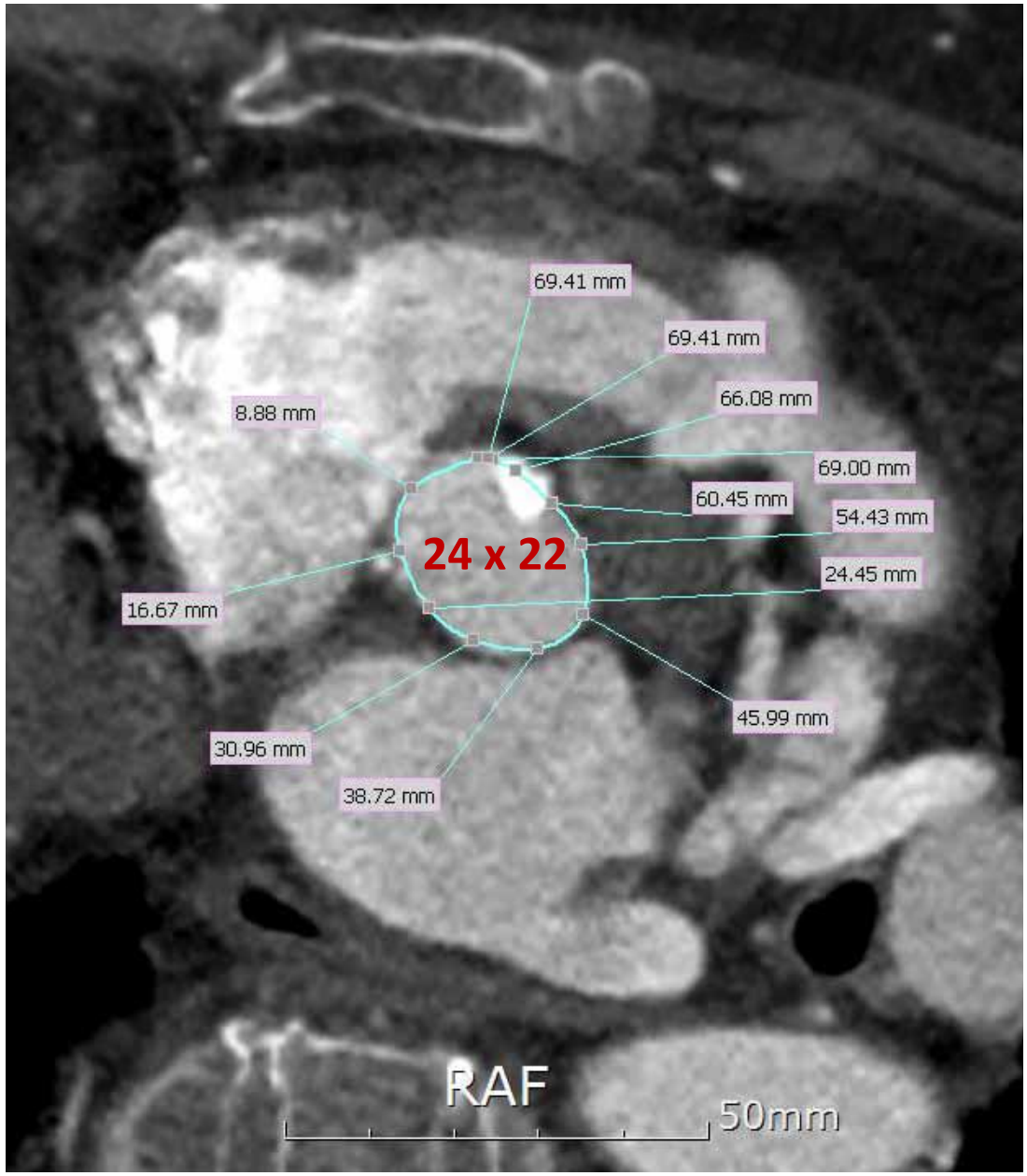
# SNUH experience: sizing (3)

MDCT

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# SNUH experience: sizing (4)

## Summary

| | TTE | TEE | CTCA |
|---|---|---|---|
| LVOT | 21 | - | - |
| Annulus | 21 | 22 | 24 x 22 |
| Sinus of Valsalva | 34 | 35 | 36 |
| ST junction | 31 | 28 | 28 |
| Height of sinus | - | 16 | 16 |
| Ascending aorta | 37 | - | - |

**Perimeter = 69.41 mm → 26mm CORE-VALVE**

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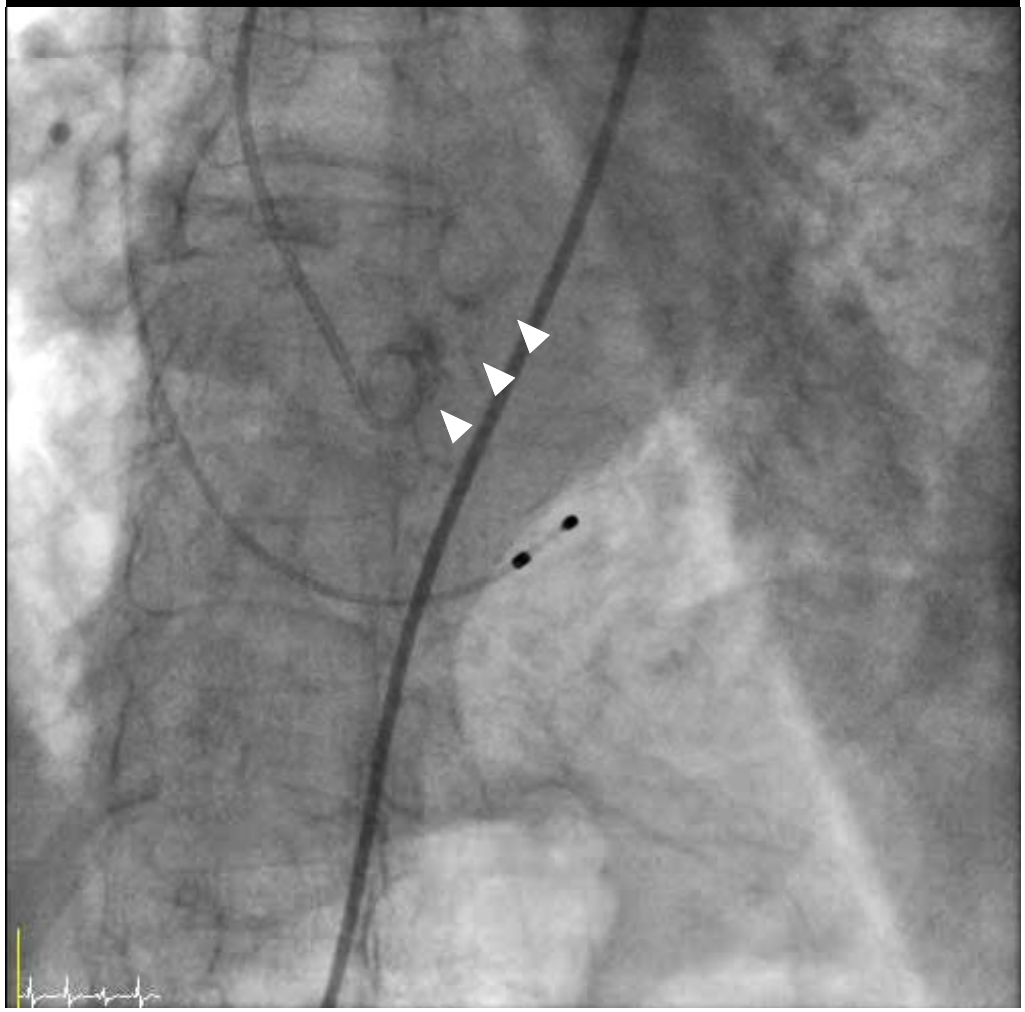
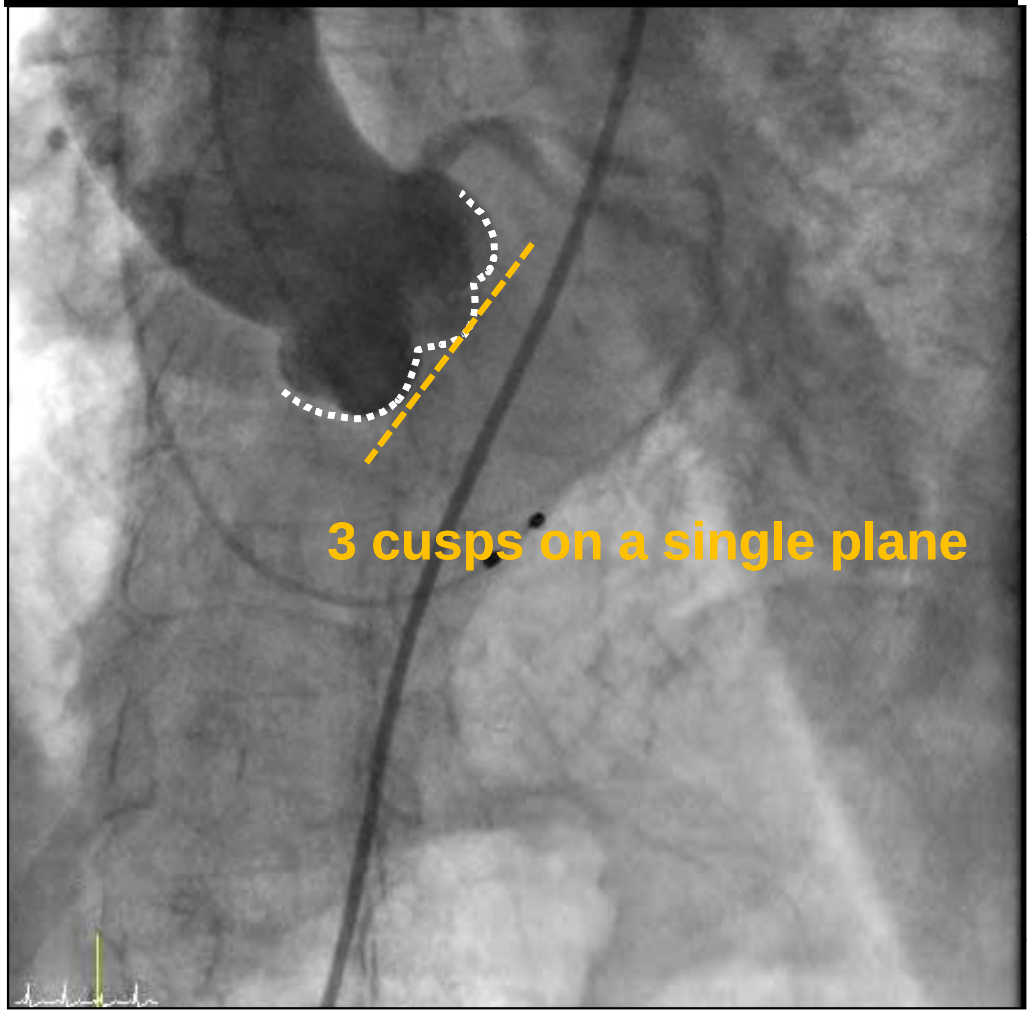
# SNUH experience: positioning landmark & best angle

## Heavily calcified AV



## Best angle for TAVI: LAO 15º, Caudal 15º

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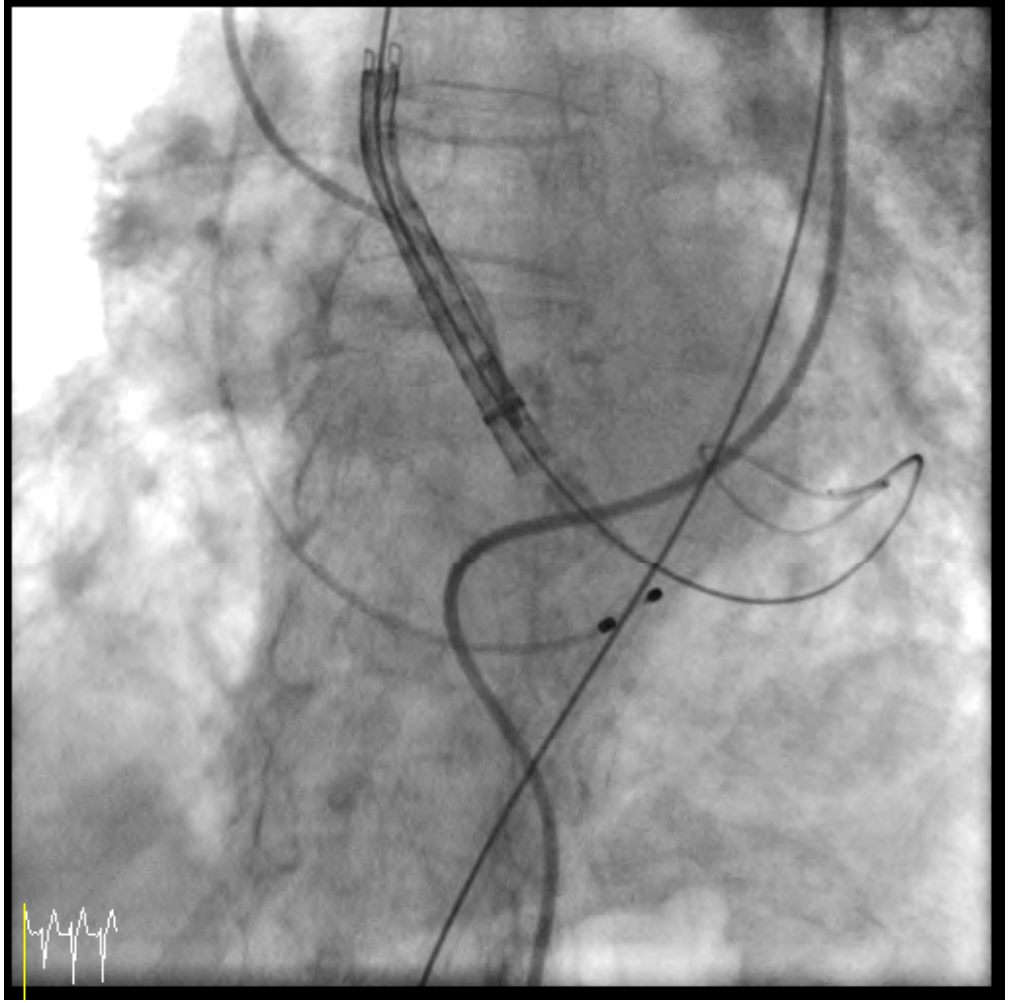
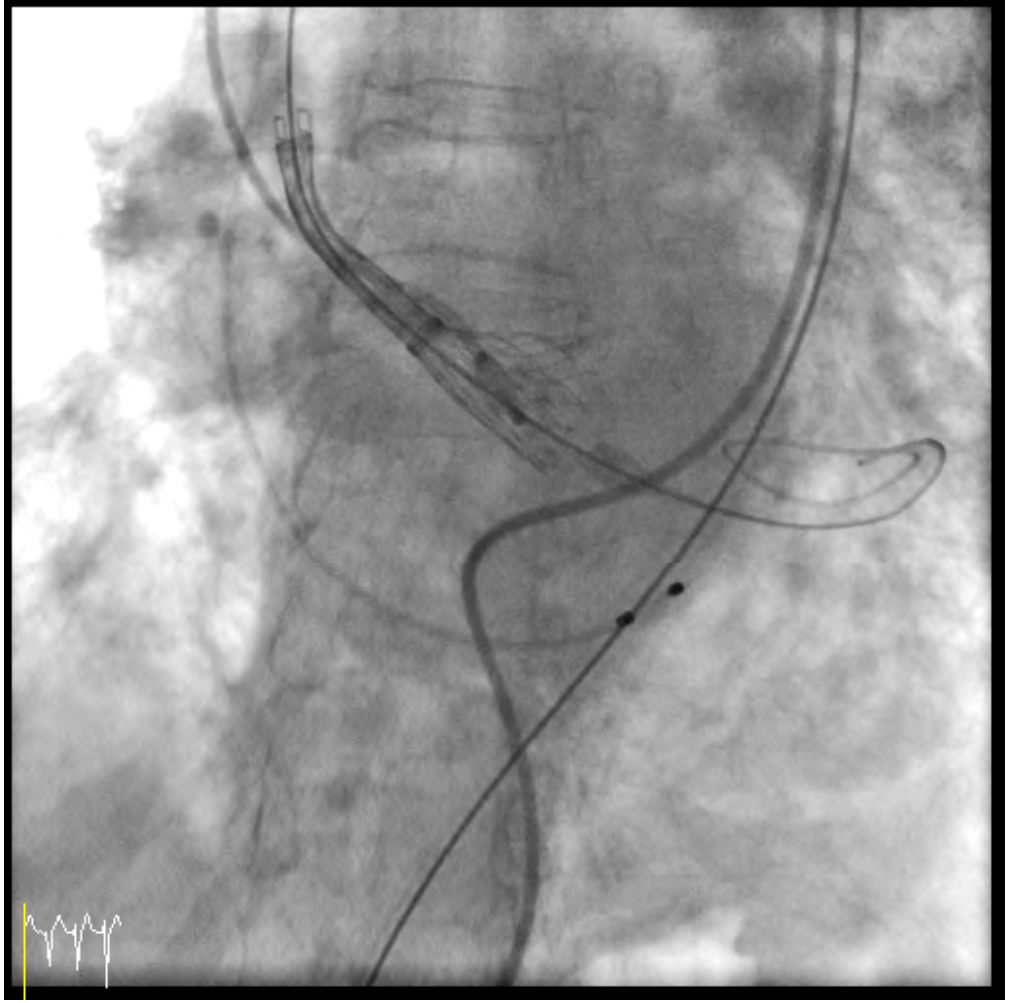
# SNUH experience: positioning without pre-dilatation

26mm CoreValve was passed across AV without pre-dilation



High positioning considering jump-in without predilation



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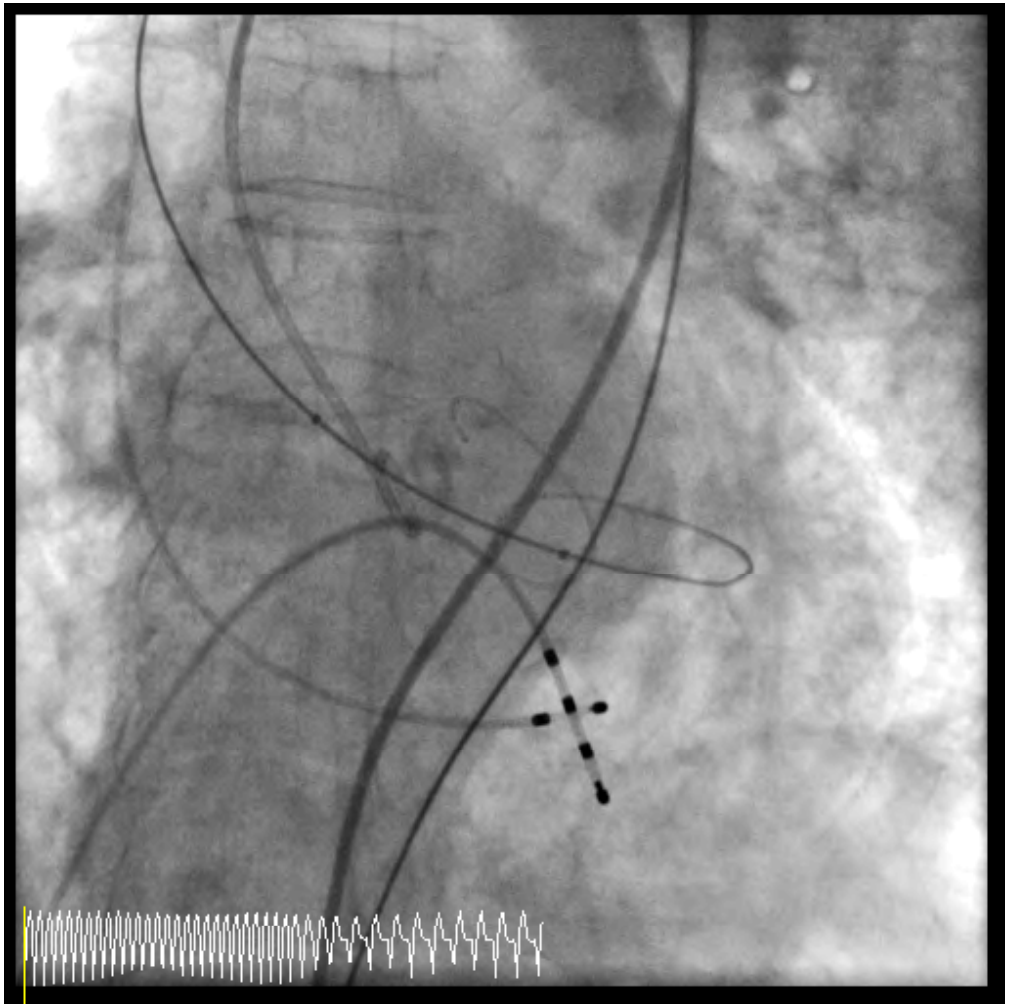
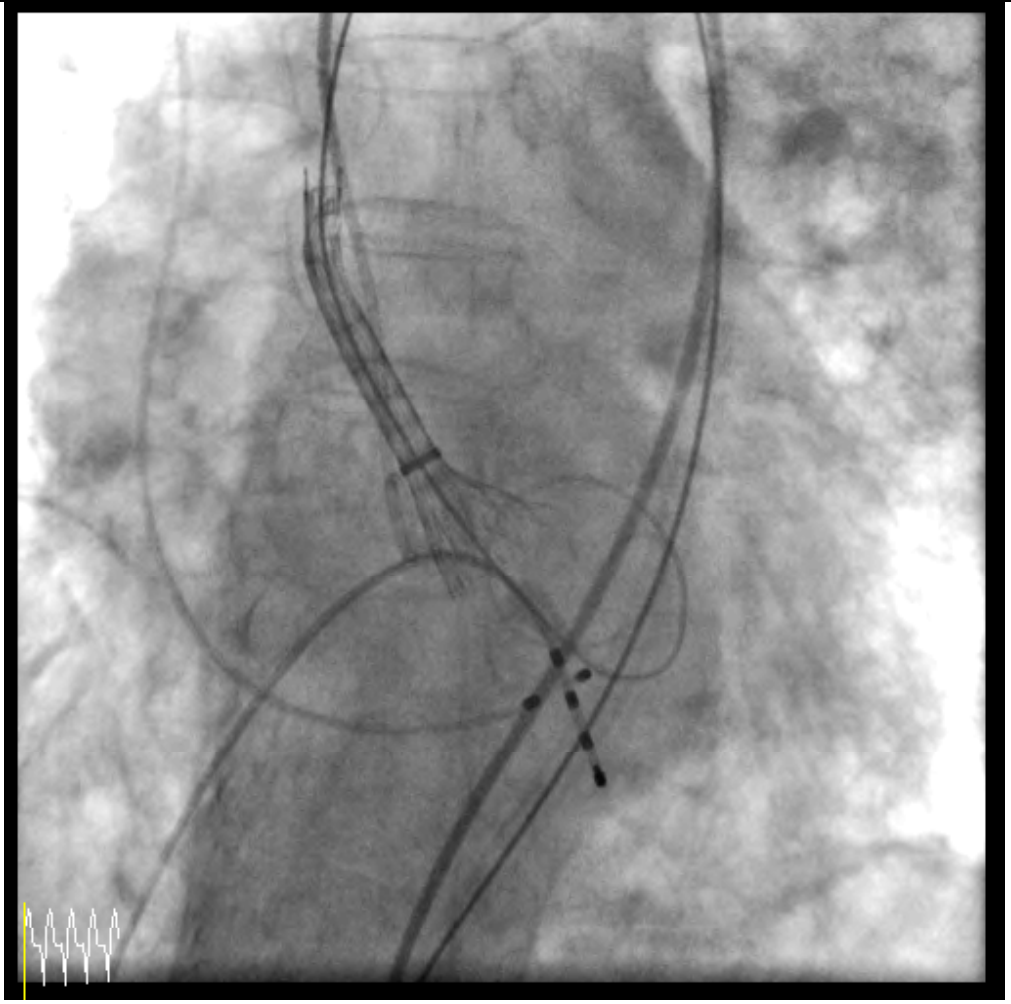
# SNUH experience: positioning after pre-dilatation

## Balloon pre-dilatation



## Proper positioning



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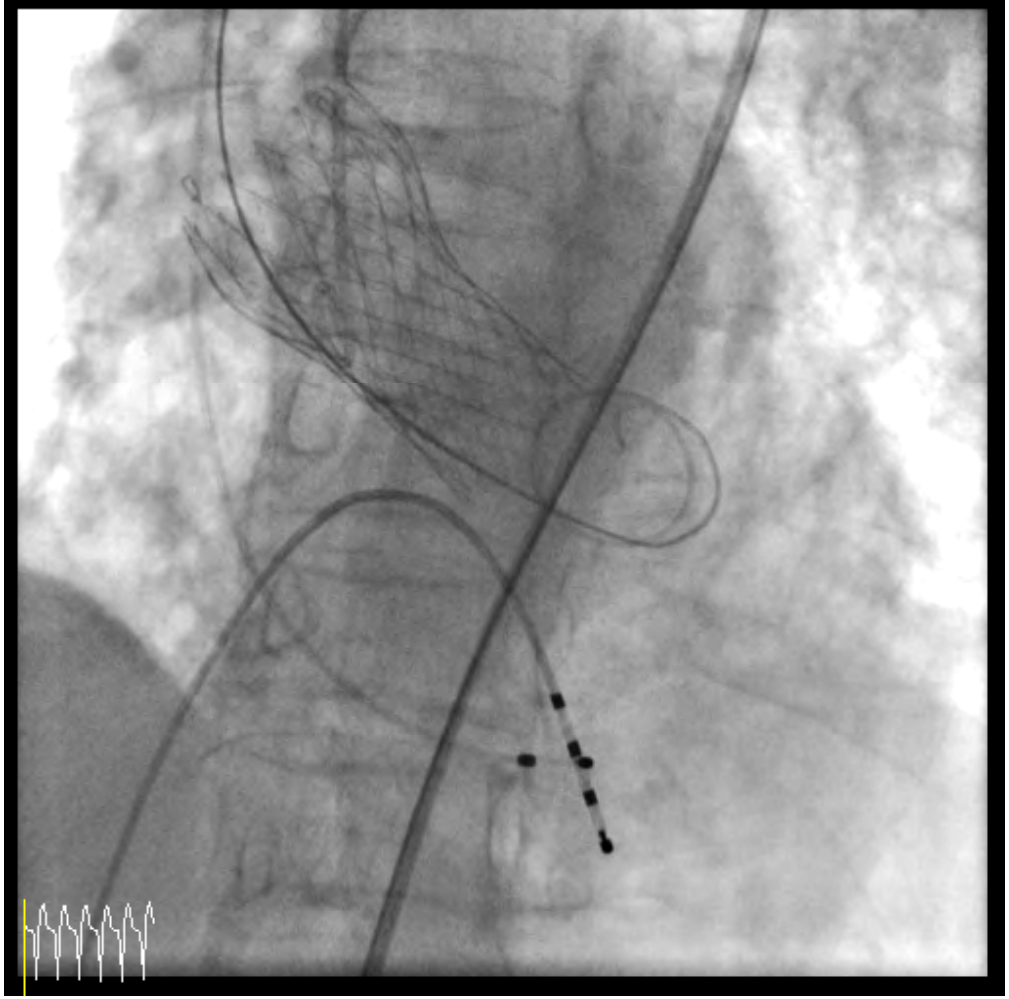
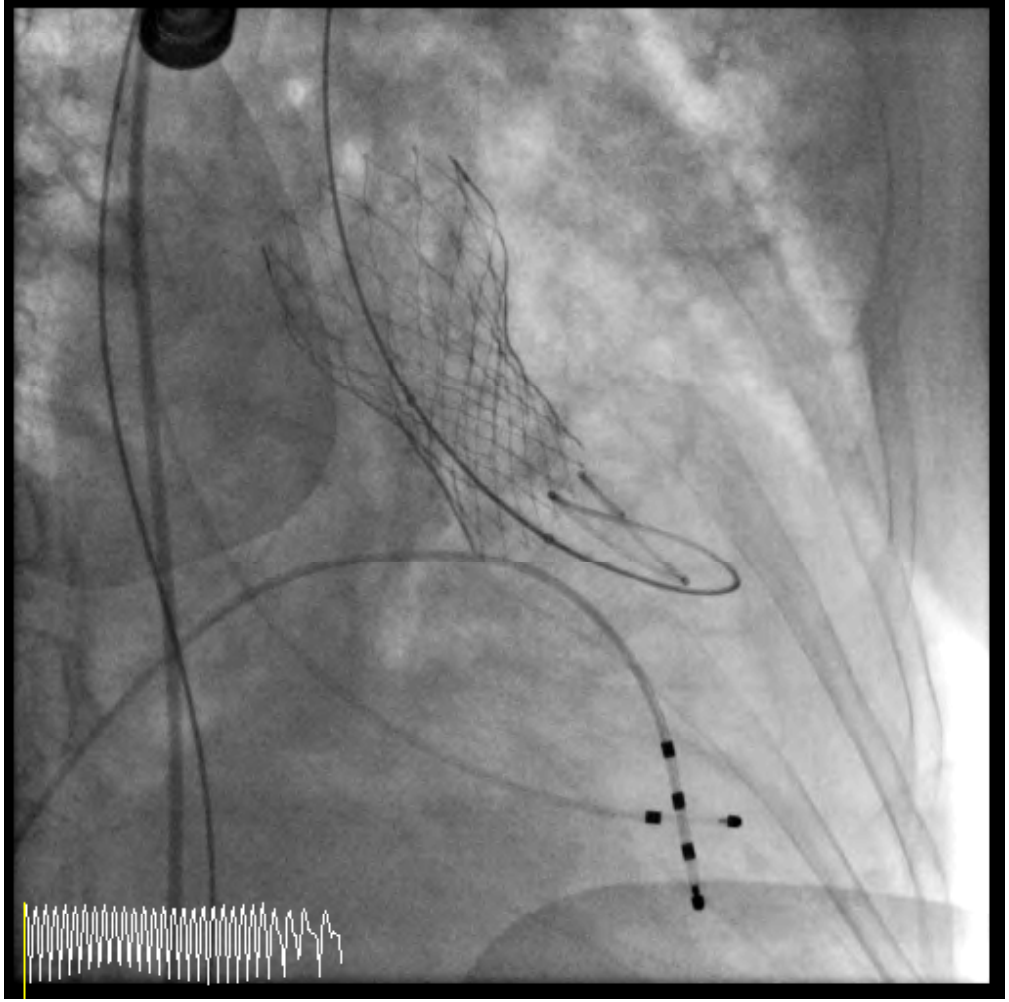
# SNUH experience: identification and correction (1)

## PVL (grade II)



## Balloon post-dilatation



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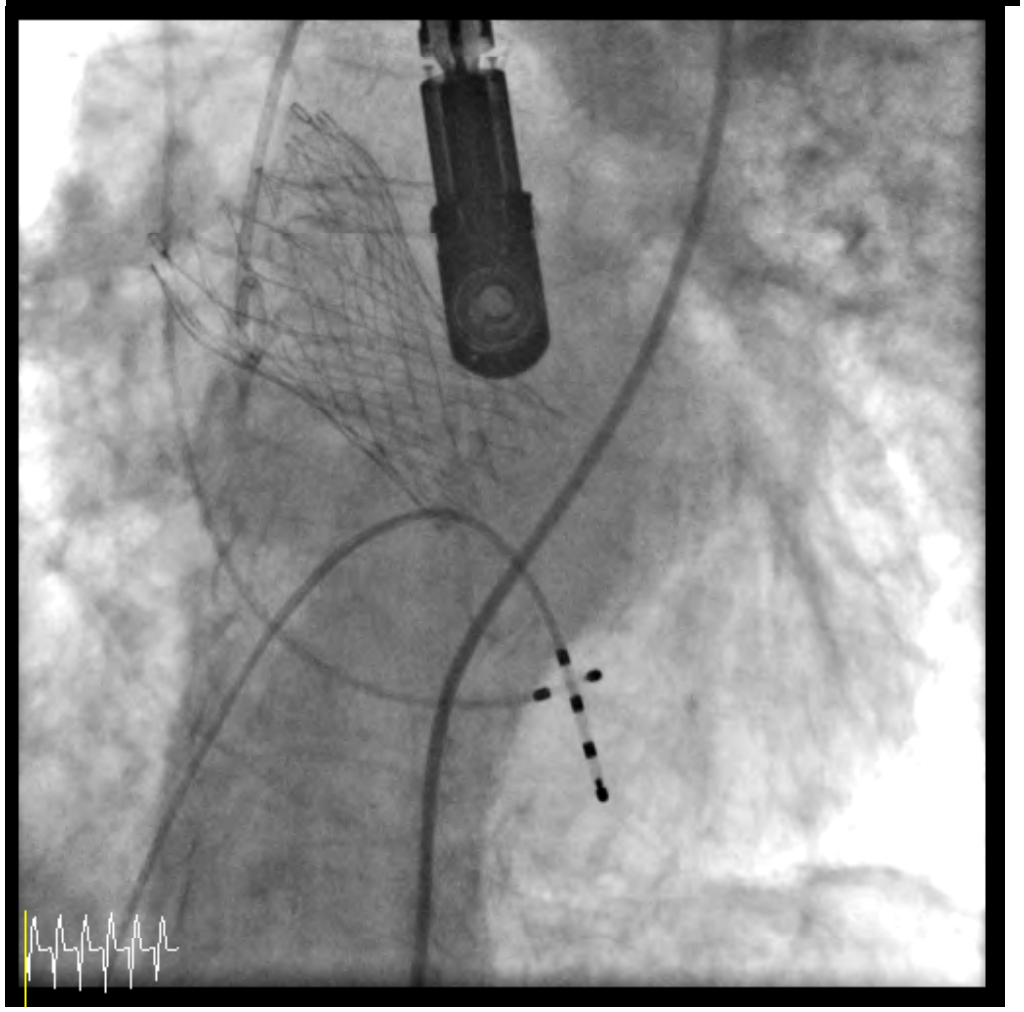
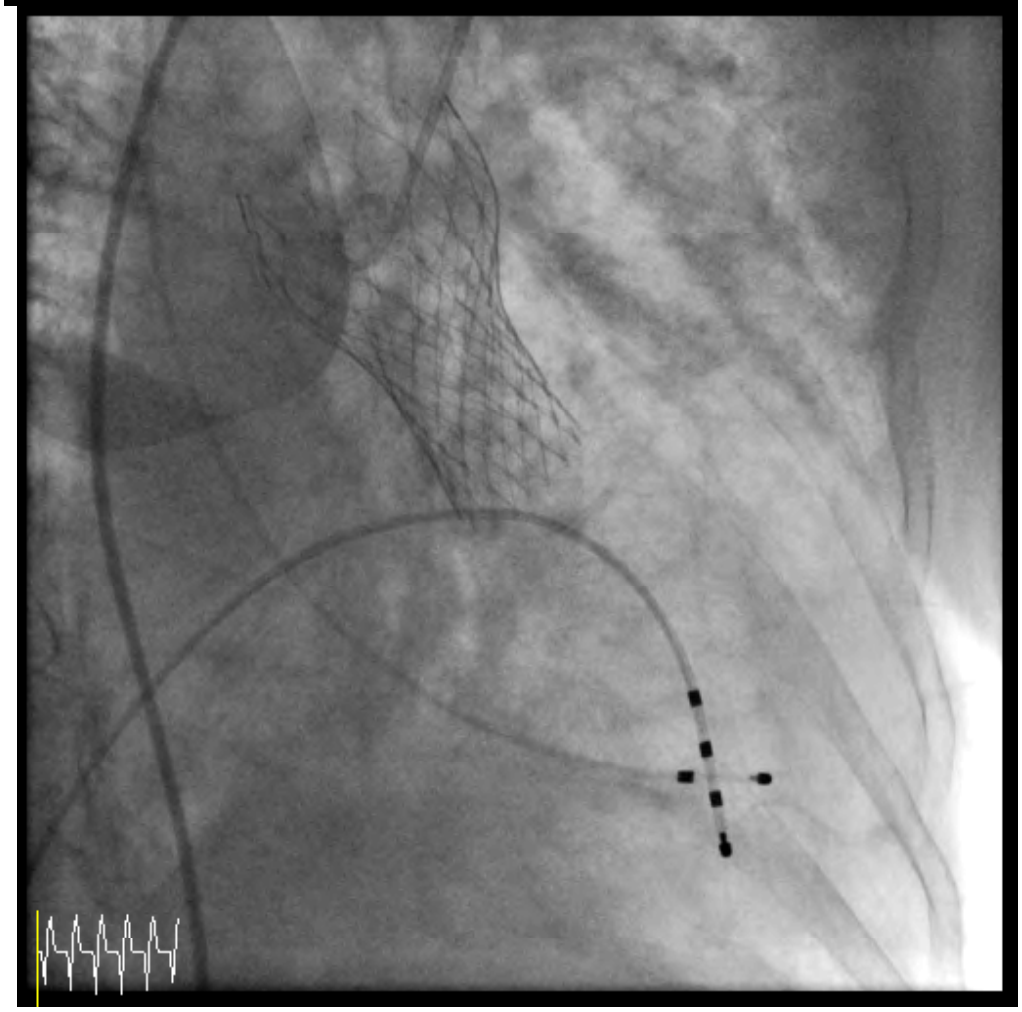
# SNUH experience: identification and correction (2)

LAO 15º, Caudal 15º



RAO 25º, Caudal 10º



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# PVL in the future…

New generation device
: ideal positioning
: dedicated sealing mechanism

3-D or 4-D image tools
: Echocardiography vs. MDCT
: optimal sizing
: precise identification and quantification of PVL

# New devices of TAVI minimizing PVL

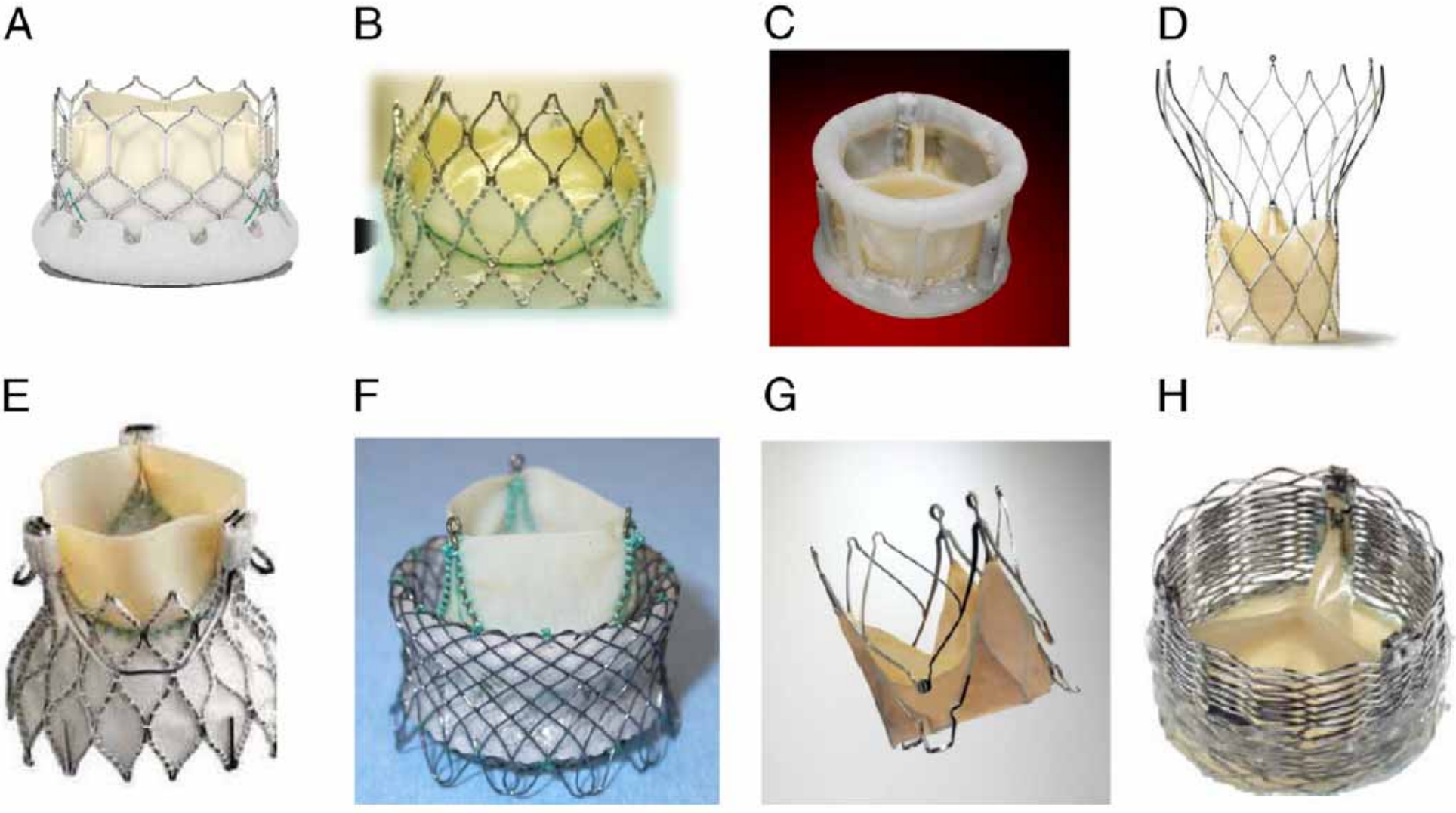


**Figure 5** **Emerging TAVR Devices Involving Improved Technologies, Potentially Minimizing PVL After TAVR**

**(A)** SAPIEN 3 (Edwards Lifesciences, Irvine, California). **(B)** CENTERA (Edwards Lifesciences). **(C)** Direct Flow Medical (Direct Flow Medical, Santa Rosa, California). **(D)** Portico (St. Jude Medical, St. Paul, Minnesota). **(E)** Engager (Medtronic, Minneapolis, Minnesota). **(F)** Heart Leaflet Technologies (Heart Leaflet Technologies, Maple Grove, Minnesota). **(G)** JenaValve (JenaValve Technology, Munich, Germany). **(H)** Sadra Lotus Medical (Boston Scientific SciMed Inc., Maple Grove, Minnesota).

# Take-home messages for PVL

1. Proper sizing before procedure
- 3-D reconstruction (MDCT, 3D-EchoCG)
- Modest over-sizing

2. Optimal positioning during procedure
- Landmark (eq. NCC)

3. Identification / quantification of PLV after procedure
- Supra-skirtal or true para-valvular regurgitation
- TEE, Aortography, and Ao-Pulse Pr(ARi)

4. Correction
- post-dilatation
- valve-in-valve technique