

## Severe Calcification: Avoid or Overcome

Eberhard Grube, MD, FACC, FSCAI

University Hospital, Dept of Medicine II, Bonn, Germany

Stanford University, Palo Alto, California, USA

## Severe Calcification: Considerations

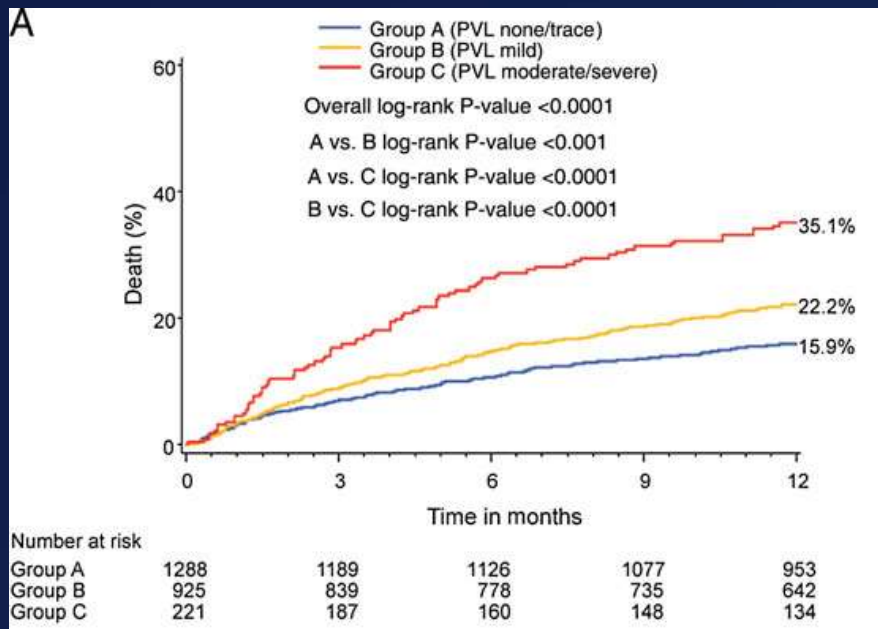
- Patients that have severe annular and/or LVOT calcification are at a higher risk for post-implant paravalvular leak and annular rupture.
- The risk for each complication will vary on a case by case basis, and all available information should be weighed to come up with an individualized plan for each patient.

# Paravalvular Leak

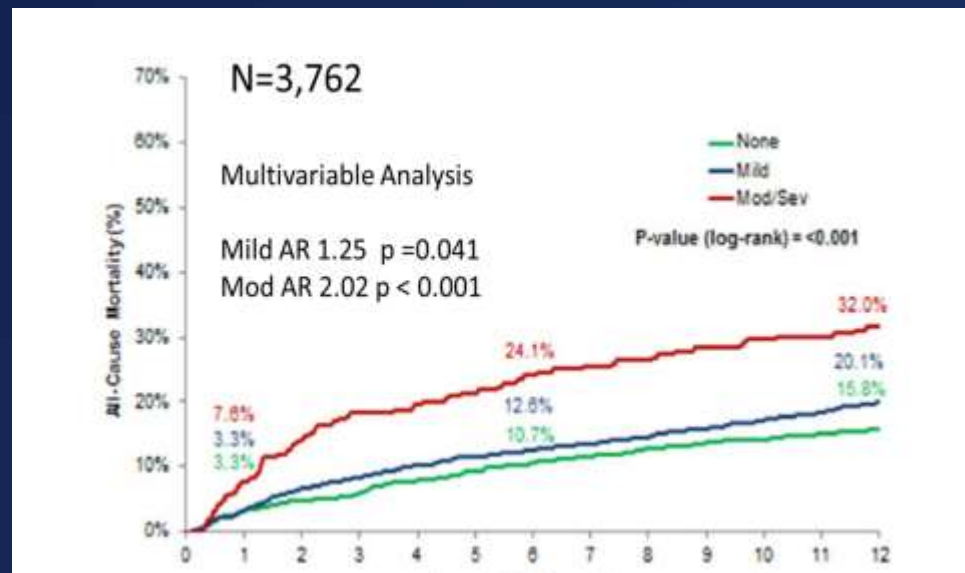
## Clinical Impact

- Moderate / severe PVL is a multivariable predictor of all-cause mortality in multiple studies with various valve types, increasing the risk of death by 2x at 1 year.

### PARTNER



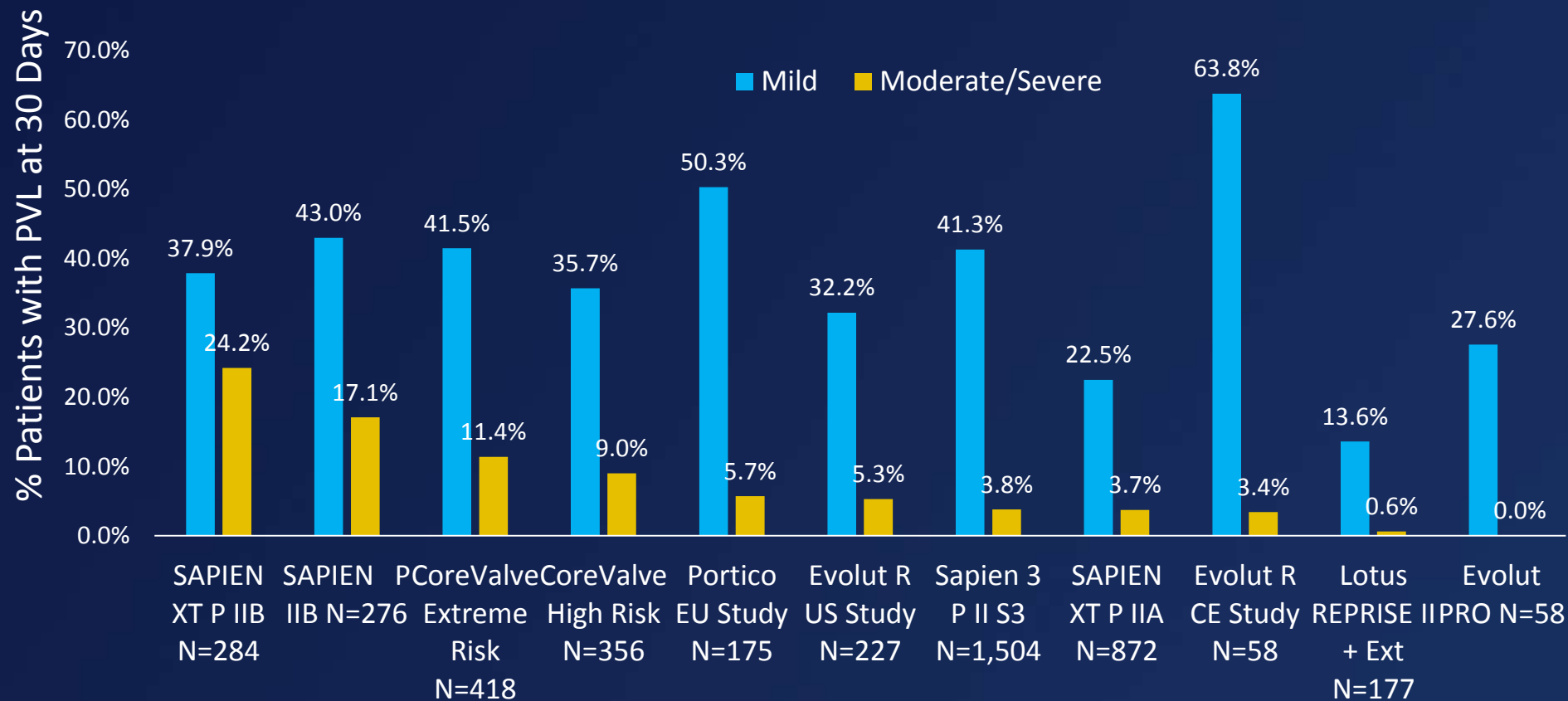
### US CoreValve Pivotal Trial



# Paravalvular Leak

## Rates at 30 Days

- The rates of moderate and severe PVL in contemporary practice are low due to sealing skirts and careful sizing practices using MSCT



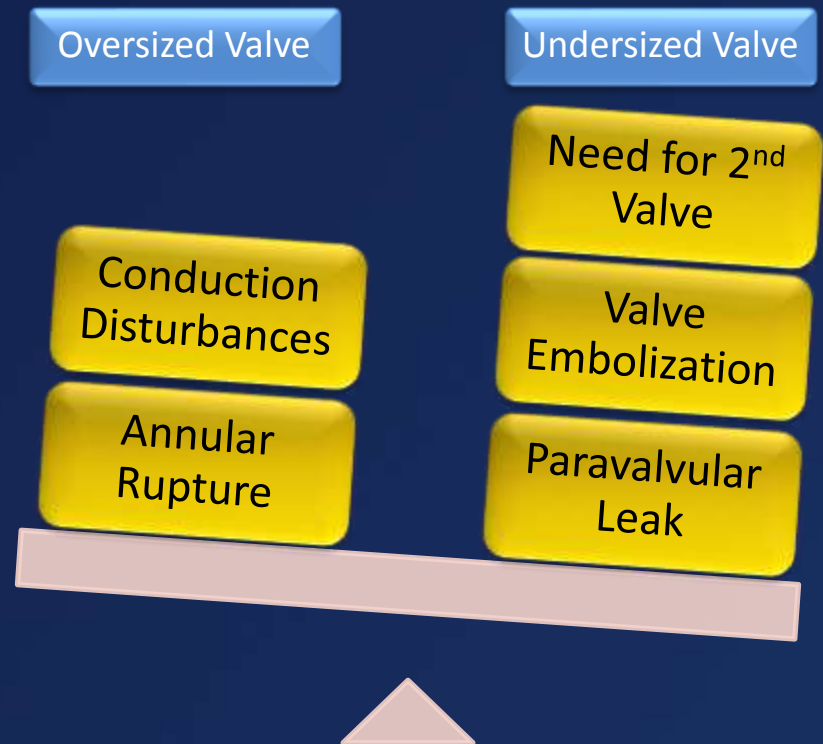
<sup>1</sup>Webb, et al. *J Am Coll Cardiol Interv* 2015; 8: 1797-806; <sup>2</sup>Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; <sup>3</sup>Adams, et al., *N Engl J Med* 2014; 370: 1790-8; <sup>4</sup>Linke, et al. presented at PCR London Valves 2015; <sup>5</sup>Williams, et al., presented at ACC 2016; <sup>6</sup>Kodali, et al., *Eur Heart J* 2016; doi:10.1093/eurheartj/ehw112; <sup>7</sup>Manoharan, et al., *J Am Coll Cardiol Interv* 2015; 8: 1359-67; <sup>8</sup>Lefevre, et al., *J Am Coll Cardiol Interv* 2016; 9: 68-75; <sup>9</sup>Meredith, et al., presented at PCR London Valves 2014; <sup>10</sup>Forrest et al., presented at ACC 2017; <sup>11</sup>Mollmann et al. *J Am Coll Cardiol Interv* 2017; Aug 14;10(15):1538-1547

# Valve Selection

## A Patient-Centered Approach

MSCT is the gold-standard tool for pre-TAVI assessment of aortic root anatomy. It should be used in all indicated cases.

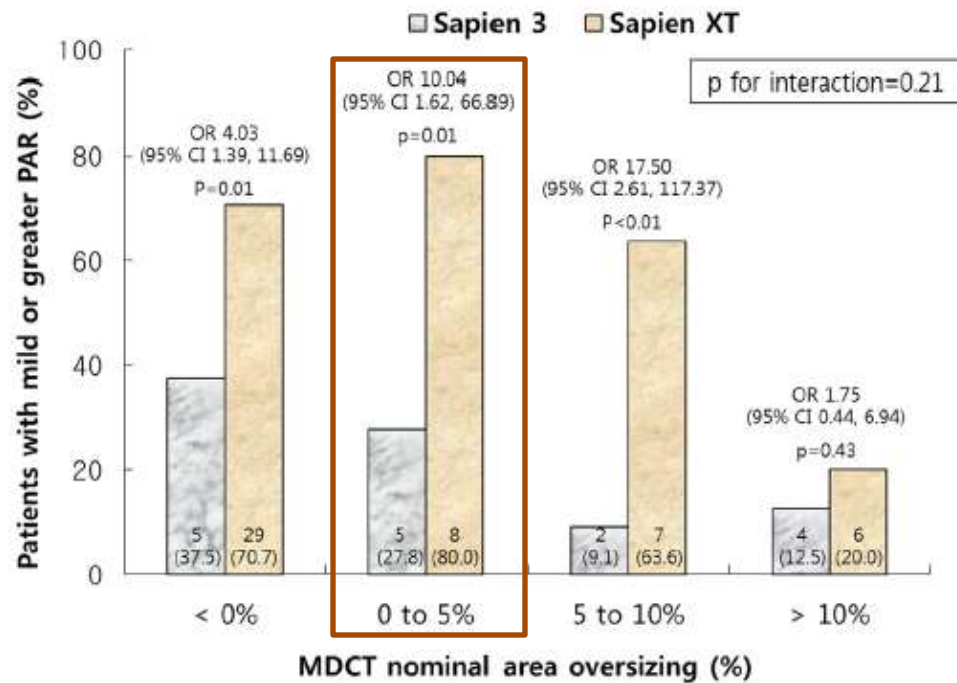
- Assess annulus geometry
- Identify adverse features which may precipitate PVL, annular rupture, or coronary occlusion (Calcium!!)
- Select an appropriate bioprosthesis type and size.
  - In cases where the valve is on the borderline between two sizes, the relative complication risks should be considered for the individual patient



# Oversizing the Balloon-Expandable Valve

## Different Strategies for SAPIEN XT and SAPIEN 3

**FIGURE 5** Rates of Mild or Greater PAR According to MDCT Nominal Area Oversizing Group in Patients With Systolic MDCT Measurements



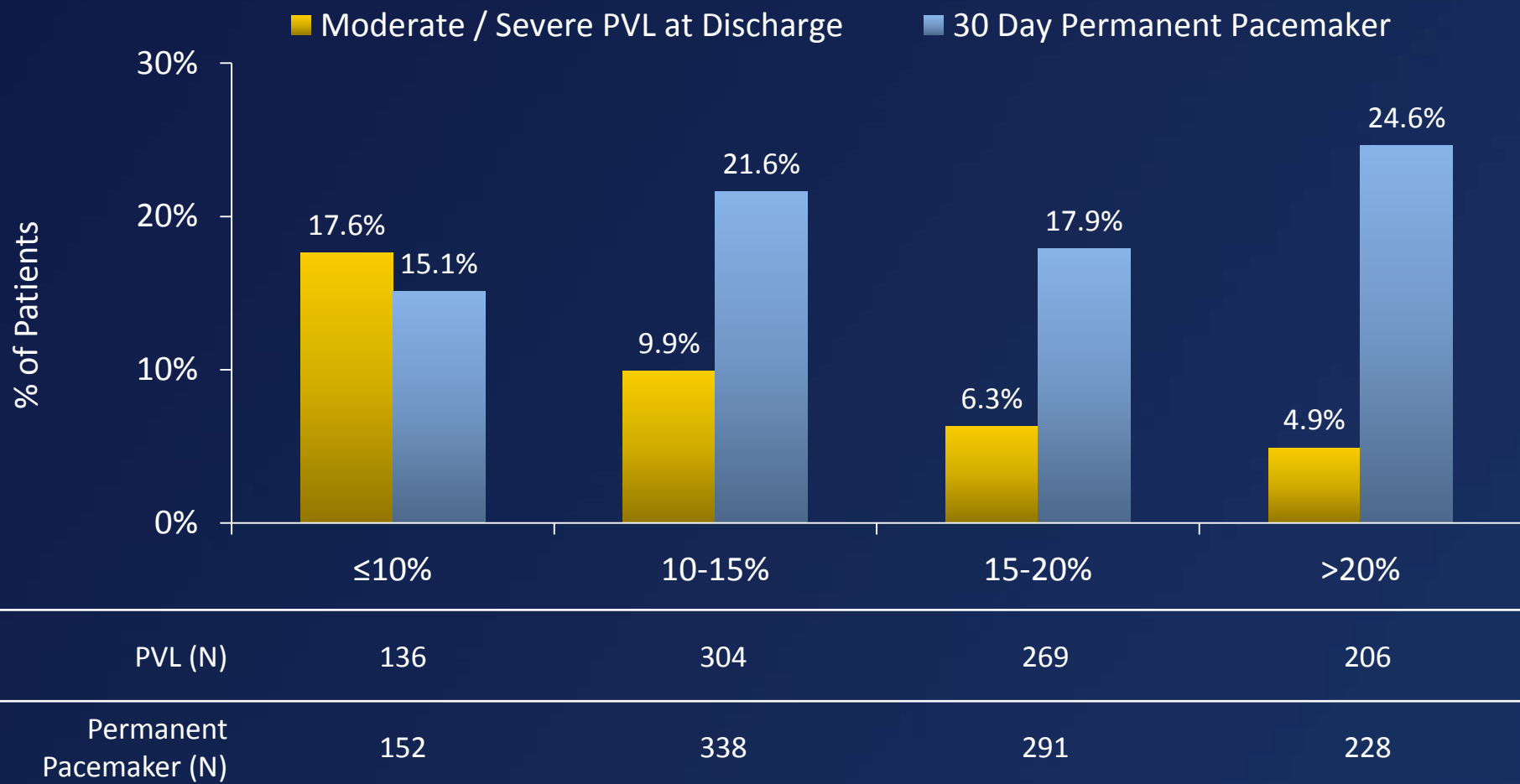
The numbers in the columns denote the absolute numbers and rates of mild or greater PAR. Abbreviations as in [Figures 1 and 3](#).

- Because SAPIEN 3 has a sealing skirt, less oversizing is needed to hold the rate of any PVL (mild or more) to <5%.
- Current recommendations are to oversize the S3 valve by 1-5% by area to further reduce the risk of annular rupture.

# Oversizing CoreValve

Optimal Degree of Oversizing is ~20% by Perimeter

- The US CoreValve Pivotal Trial also showed that appropriate oversizing minimized PVL while having no negative impact on permanent pacemaker rate
- Physicians should feel comfortable oversizing this valve according to best practices

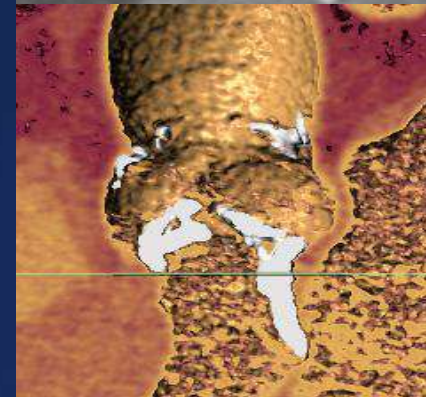
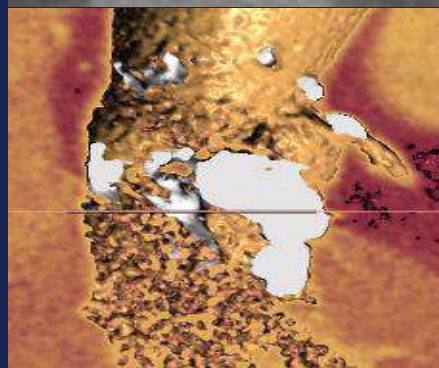
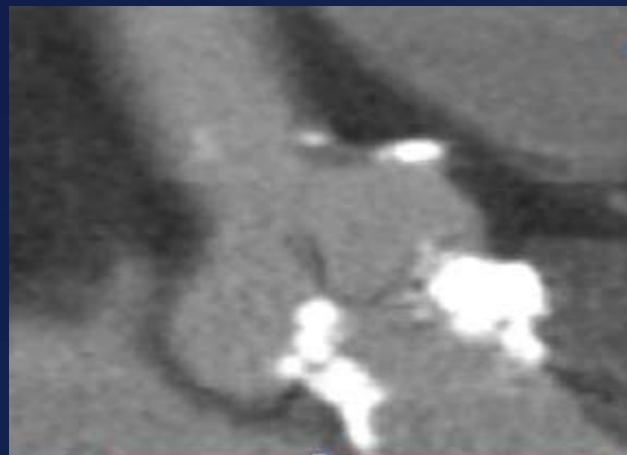
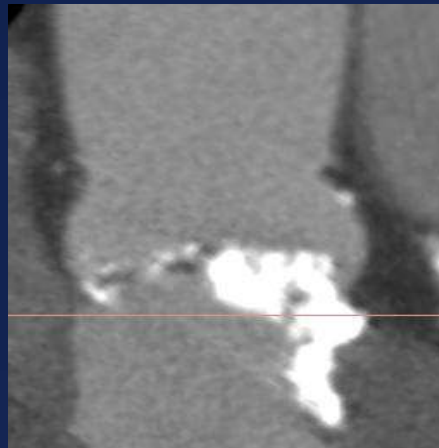




# Valve Selection

## Calcification

- MSCT images should be analyzed for each patient to assess the extent and location of calcium.
- Nodular calcium near the leaflets may be best treated by a valve with a sealing skirt, while patients with moderate or severe LVOT calcification may have better results with a self-expanding valve.

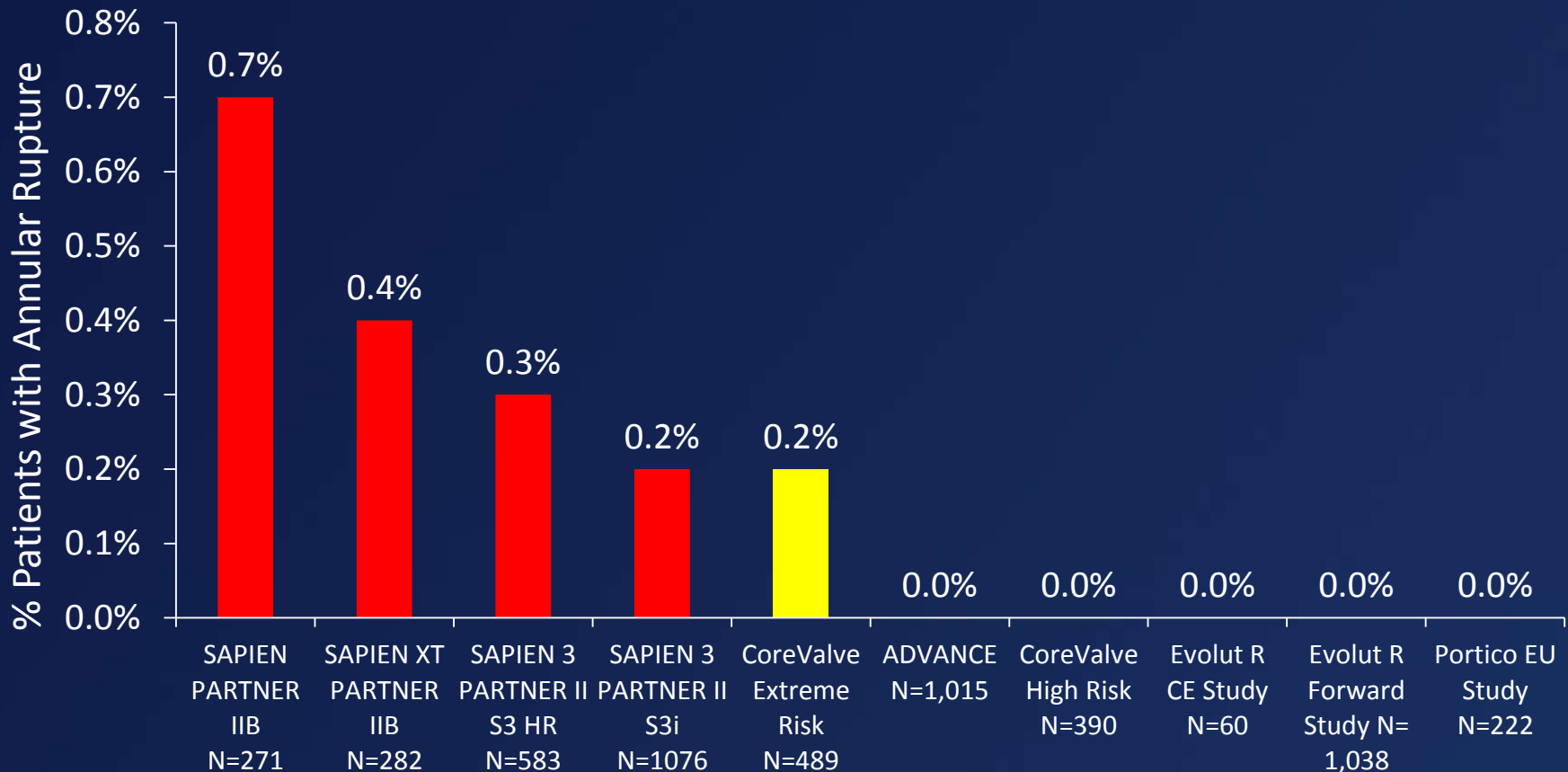




# Annular Rupture

## Rare but Catastrophic

- Annular rupture is a rare event, but is associated with a mortality rate of ~50%.
- It is typically associated with balloon expansion, and is therefore very uncommon with self-expanding valves



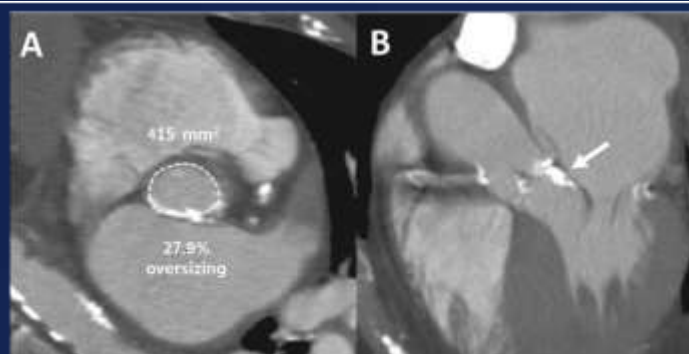
<sup>1</sup>Leon, et. al. presented at ACC 2013; <sup>2</sup>Kodali, et al., presented at ACC 2015; <sup>3</sup>Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; <sup>4</sup>Linke, et al., *Eur Heart J* 2014; 35: 2672-84; <sup>5</sup>Adams, et al., *N Engl J Med* 2014; 370: 1790-8; <sup>6</sup>Meredith, et. al. presented at EuroPCR 2015; Grube et al, Presented at Euro PCR 2017. Mollmann et al., *J Am Coll Cardiol Intv* 2017; Aug 14;10(15):1538-1547

# Risk of Annular Rupture with SAPIEN XT

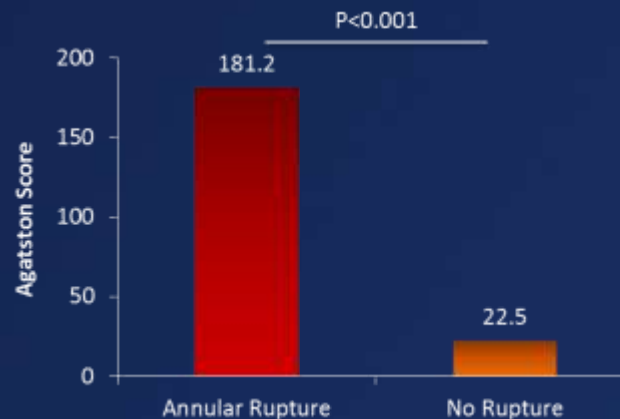
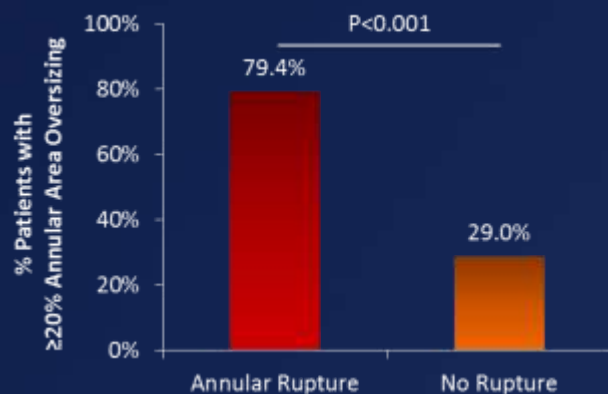
- A recent multicenter study showed that extensive oversizing with SAPIEN XT ( $\geq 20\%$  by area) increased the risk of annular rupture by 8.4-fold, while moderate / severe LVOT calcification increased the risk by 11-fold.
- The general recommendation is to oversize SAPIEN XT by 5-15% to balance the risk of PVL and annular rupture.
- In borderline annuli consider a larger valve size or a self-expanding valve

Moderate / severe LVOT calcification  
OR: 10.92, 95% CI: 3.23-36.91,  $P < 0.001$

Prosthesis oversizing  $\geq 20\%$   
OR: 8.38, 95% CI: 2.67-26.33,  $P < 0.001$



Oversized 26 mm SAPIEN XT and severely calcified LVOT leading to annular rupture

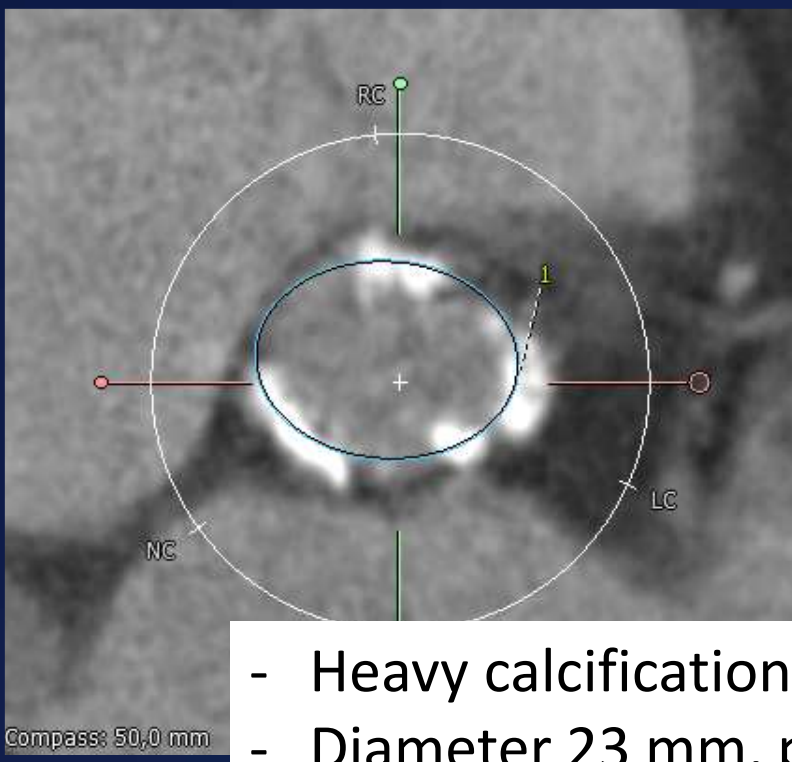


Case Example:

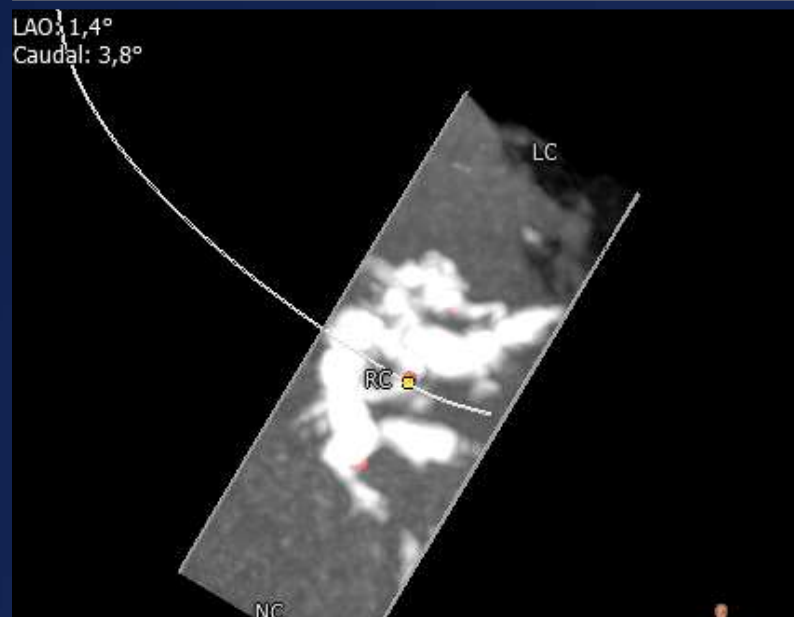
# Extremely calcified Annulus

Classic CV 29, No predilation,  
Postdilation with Z-MED 28

Perpendicular Plane (MPR)

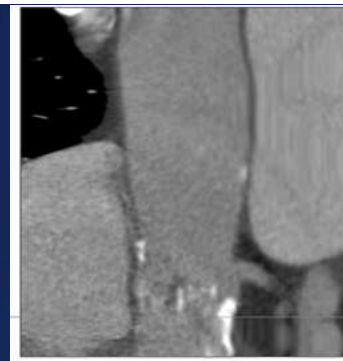


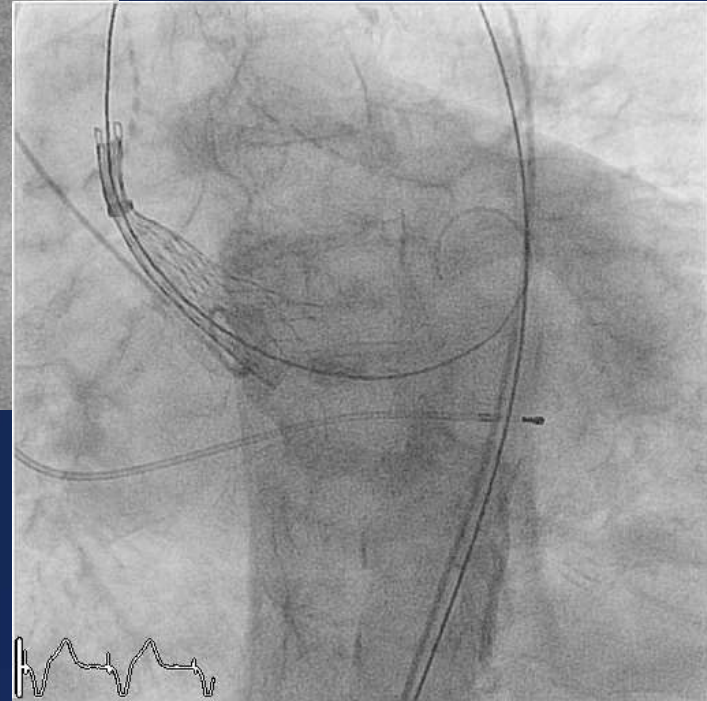
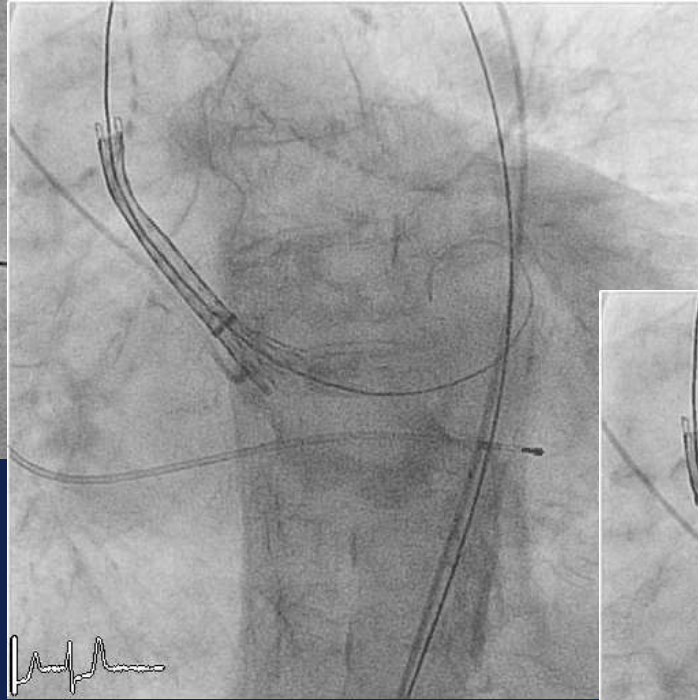
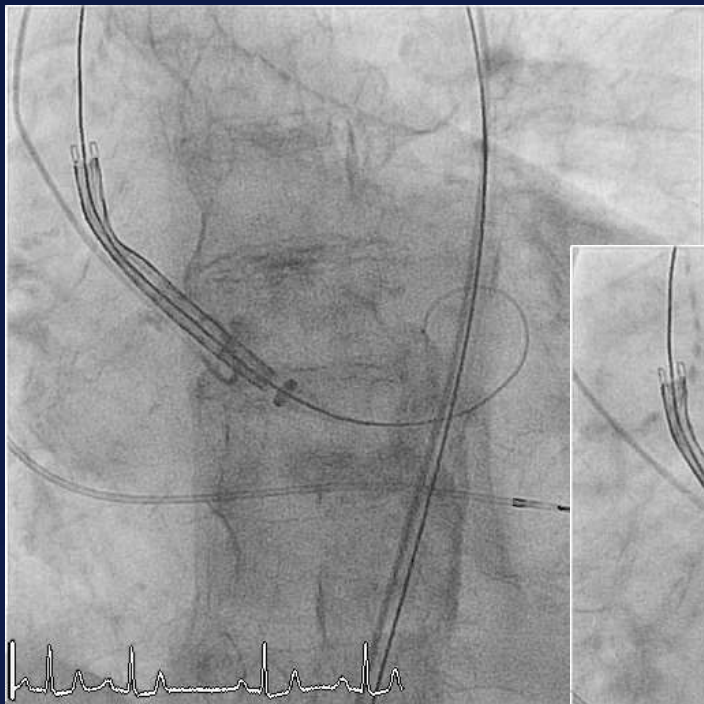
Hockey Puck (MIP, Phase 75%)



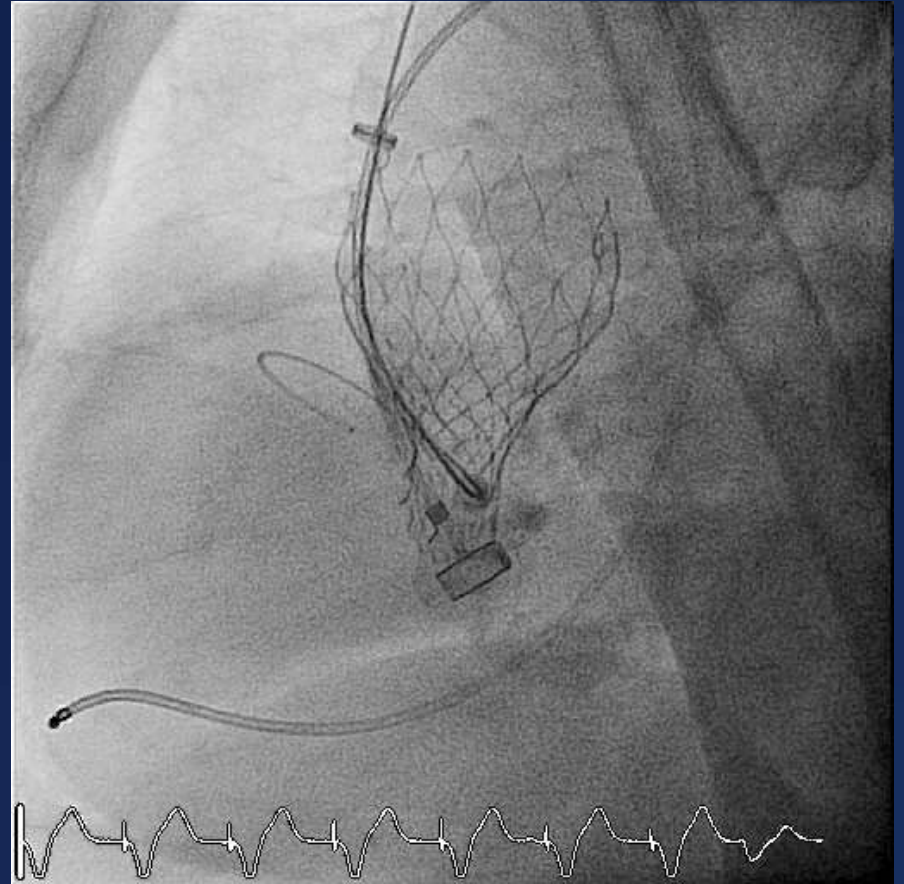
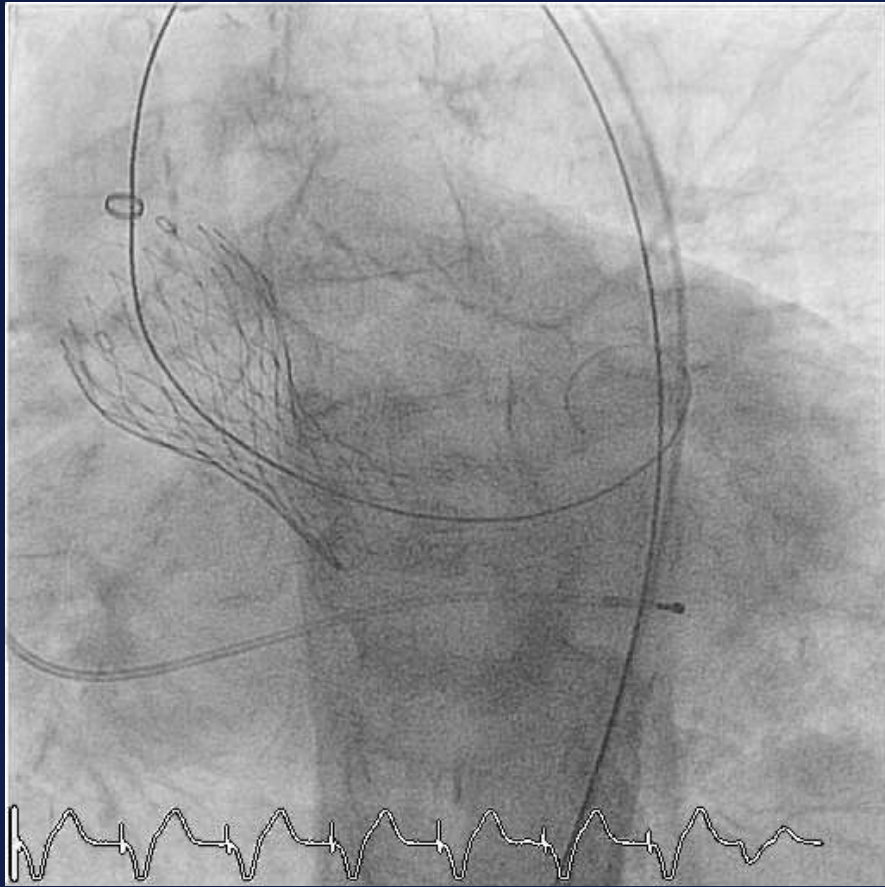
- Heavy calcification valve, annulus and LVOT
- Diameter 23 mm, perimeter 74 mm, area 420mm<sup>3</sup>

ID	Type	Value	Label
1	Ellipse	419,6 mm <sup>2</sup>	Area
		20,1 mm	Min. Ø
		26,6 mm	Max. Ø
		23,3 mm	Avg. Ø
		74,0 mm	Perimeter
		23,6 mm	Perimeter derived Ø
		23,1 mm	Area derived Ø

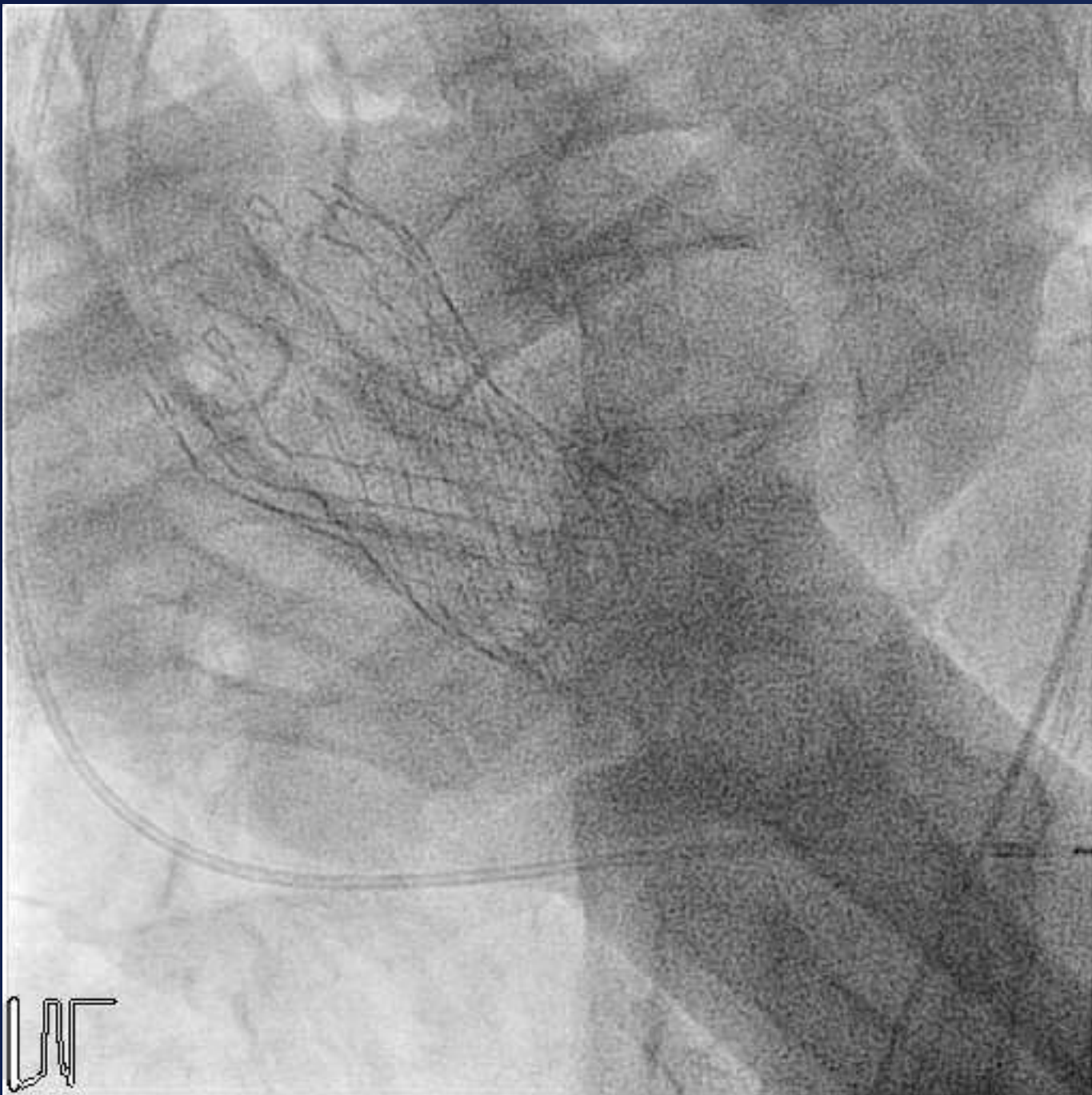


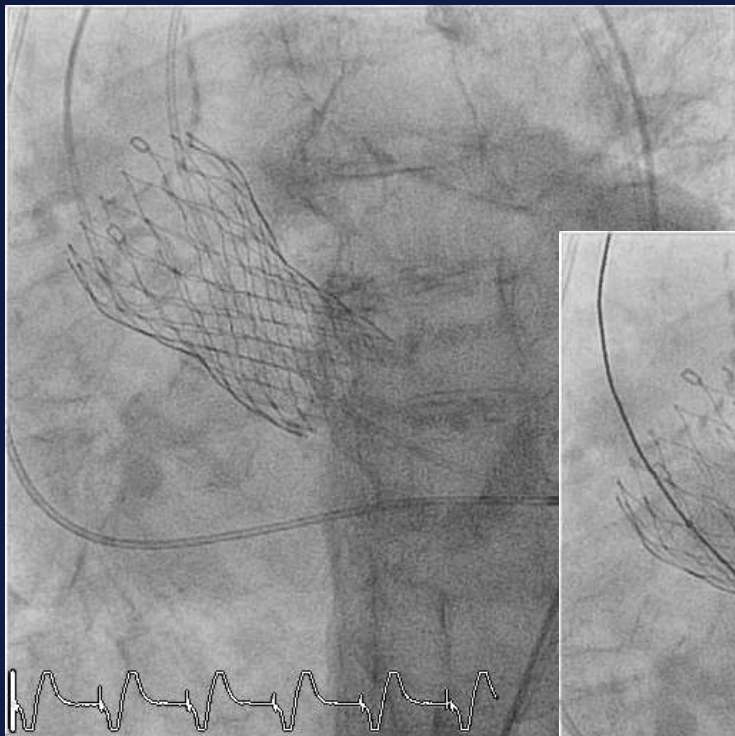












Thank you for your Attention