Independent Predictor Analysis

Paravalvular Leak and Conduction Disturbance

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Predictor Analysis

AMC SAPIEN Registry

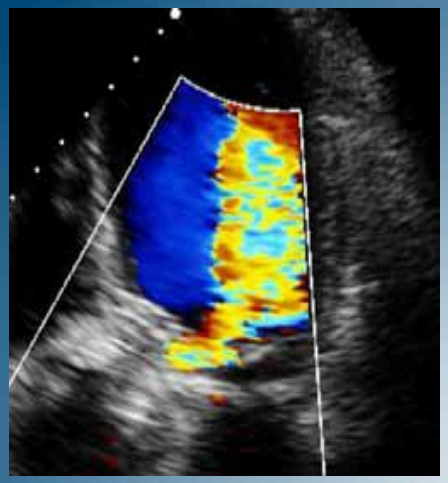
AMC CoreValve Registry

Feb 2010 to Apr 2014

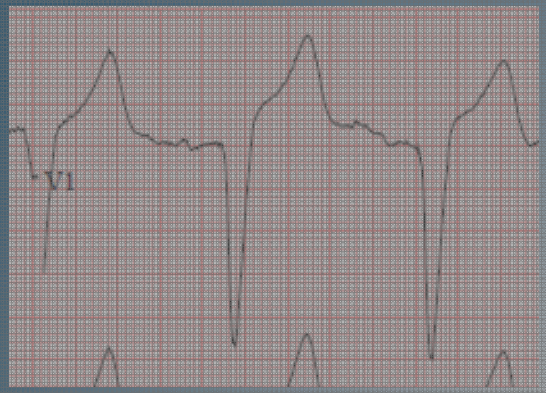
Total	SAPIEN	CoreValve
131	61	70

Current Limitations of TAVI

Paravalvular Leak



Conduction Disturbance

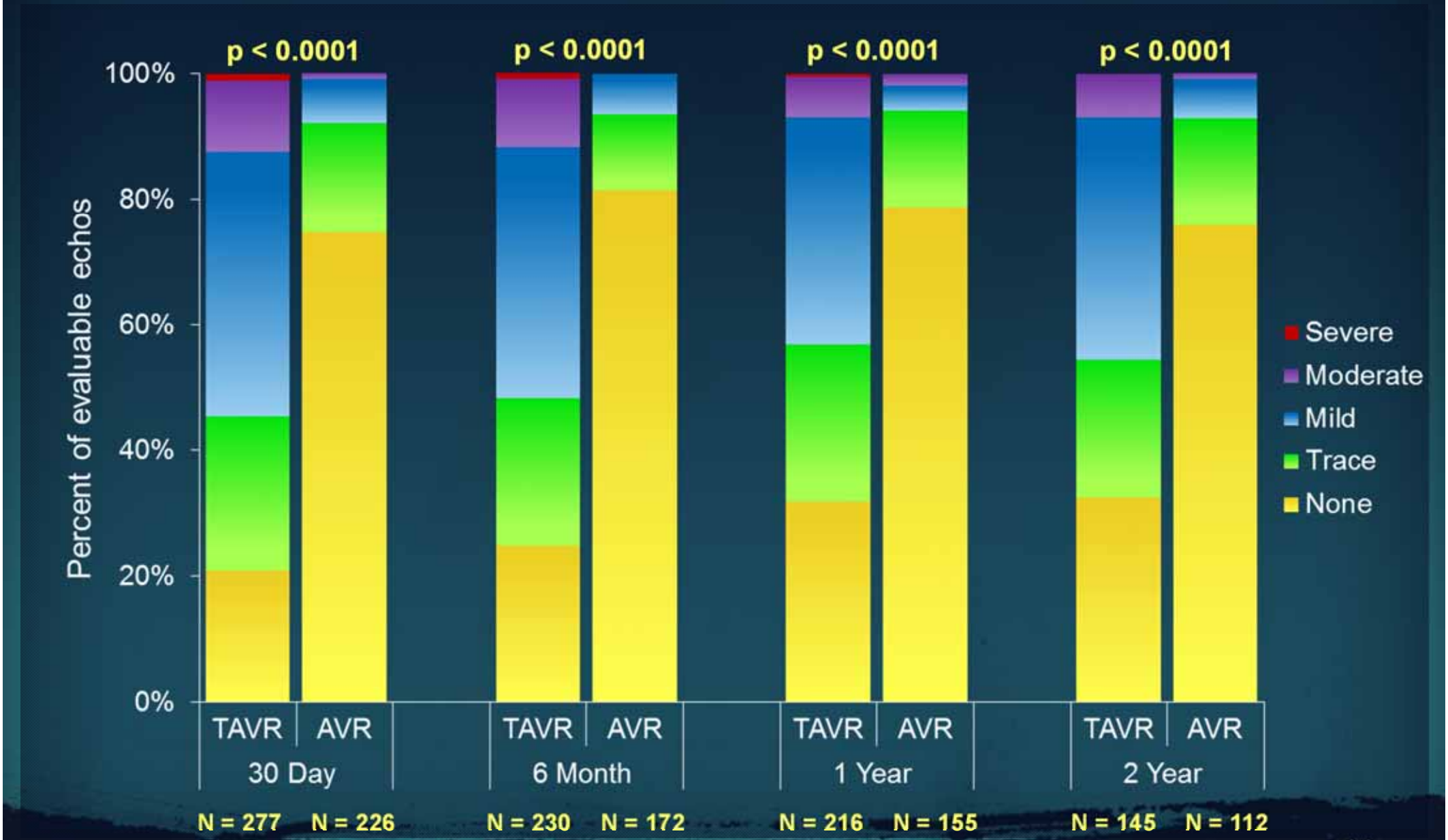


Vascular Complication

Stroke

Incidence of PVL

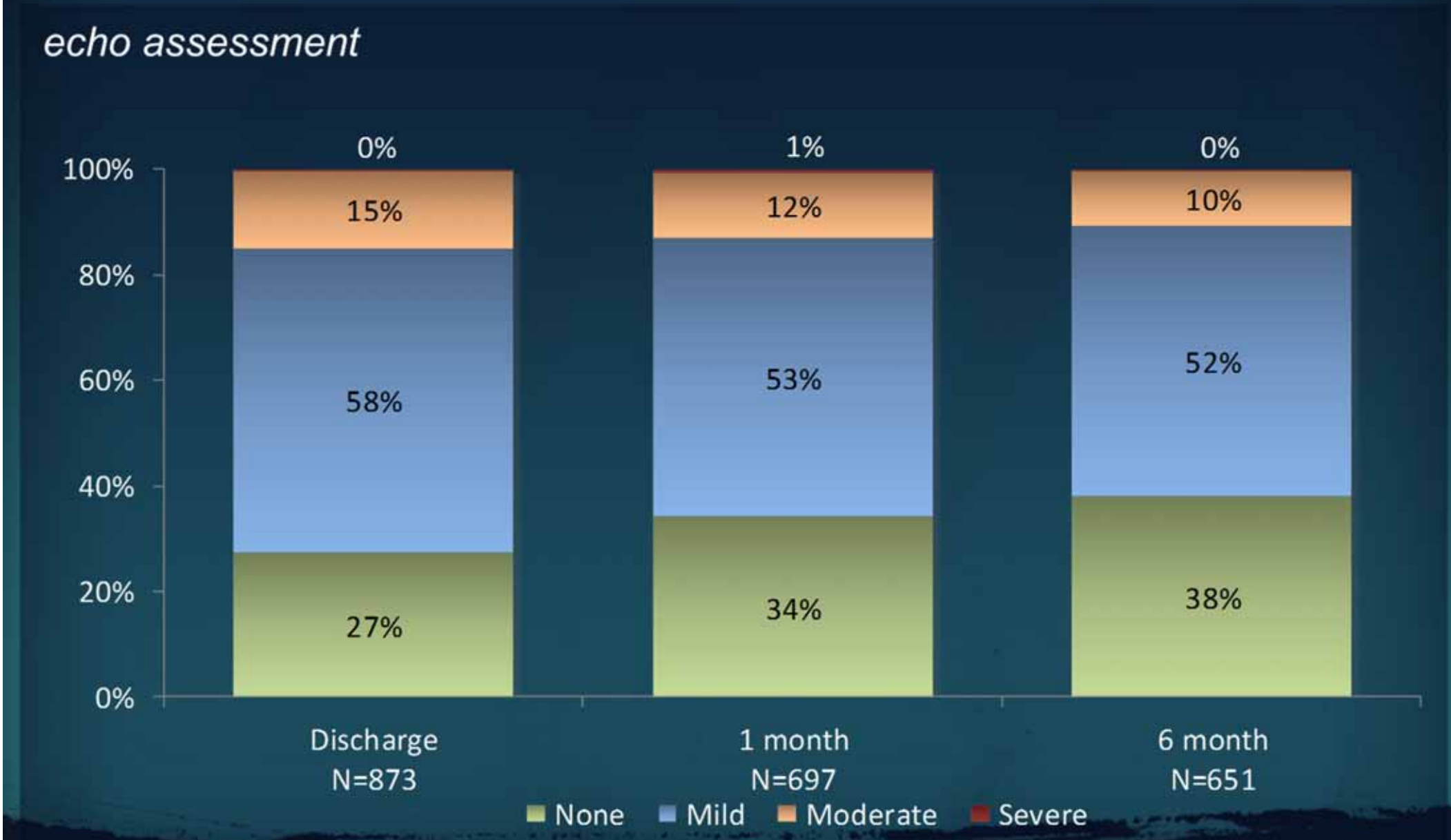
PARTNER A trial Edward SAPIEN



Kodali S et al. N Engl J Med:2012;266,1686-95

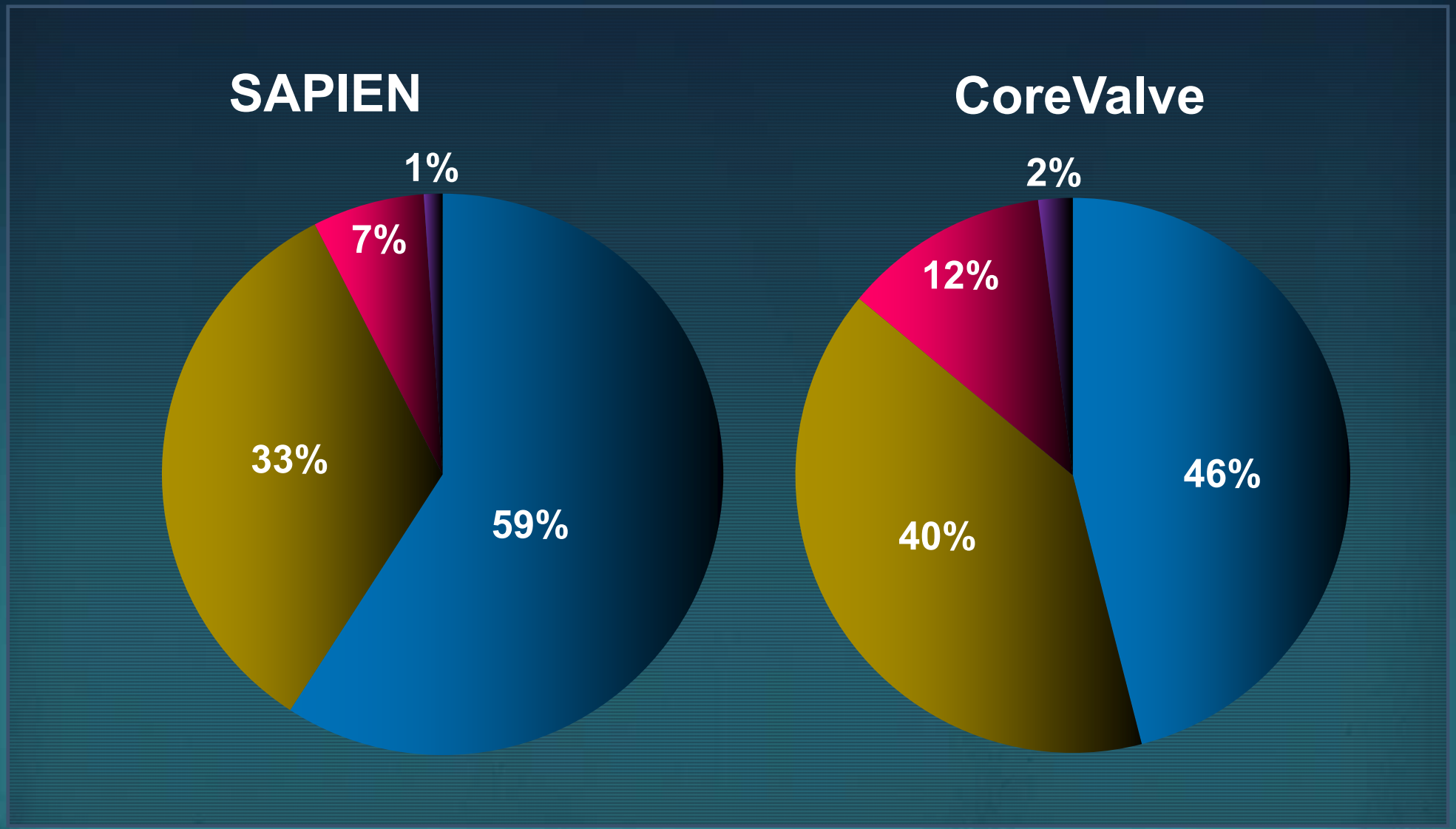
Incidence of PVL

ADVANCE Registry CoreValve



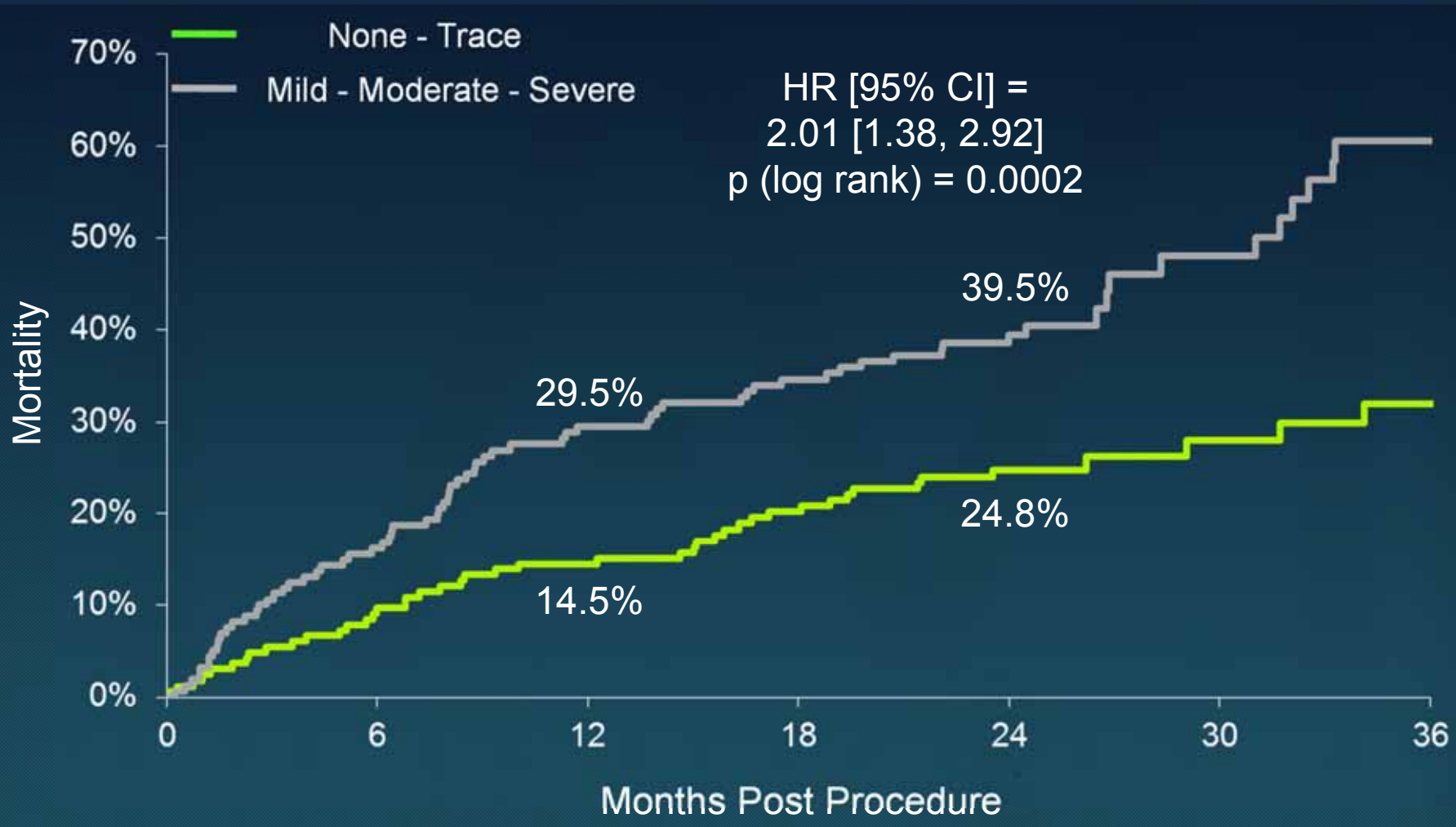
Incidence of AR

Asian TAVI Registry



PVL and Mortality

PARTNER A trial Edward SAPIEN



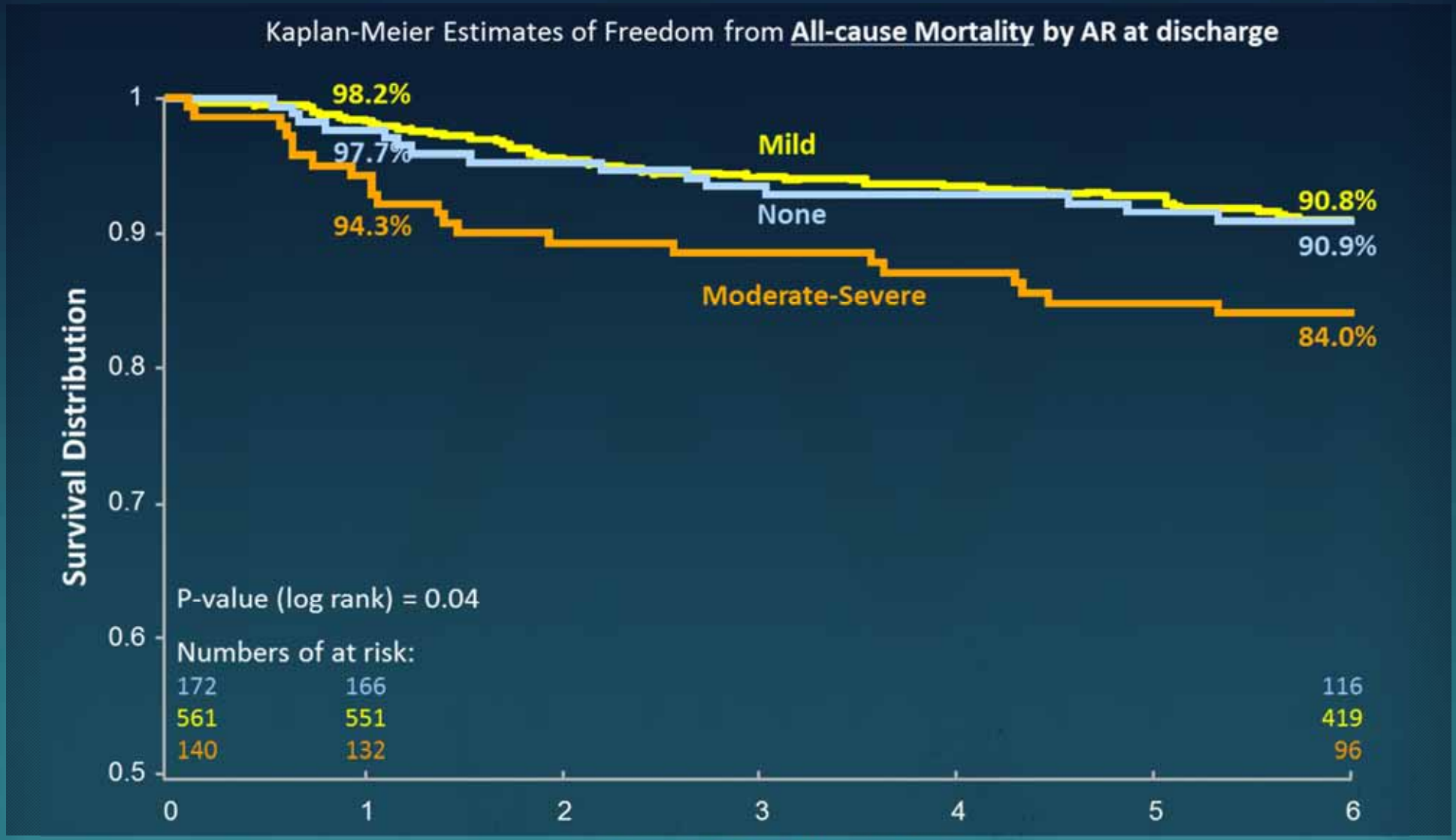
Numbers at Risk

None-Tr	167	149	140	126	87	41	16
Mild-Mod-Sev	160	134	112	101	64	26	12

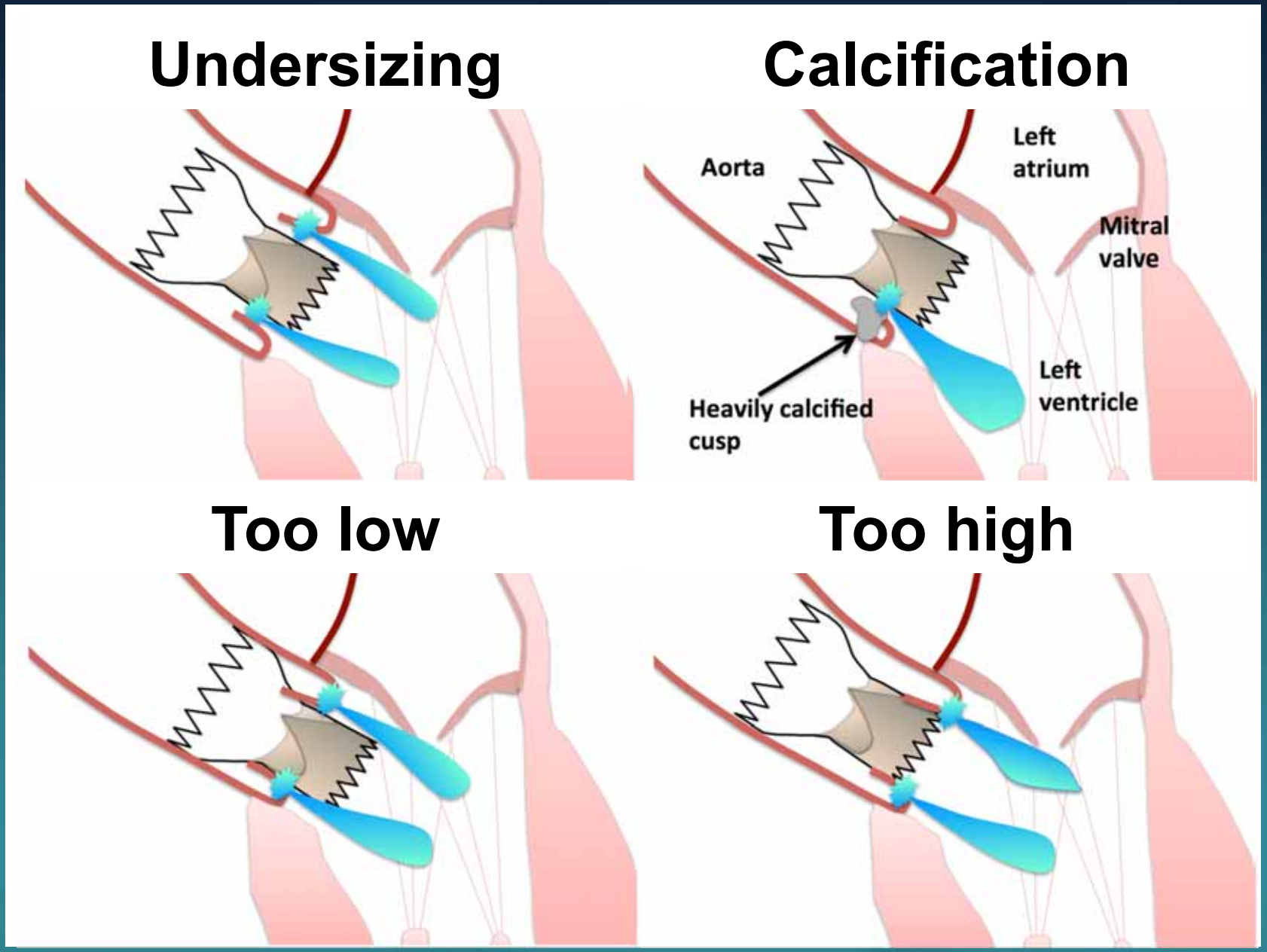
Kodali S et al. N Engl J Med:2012;266,1686-95

PVL and Mortality

ADVANCE Registry CoreValve



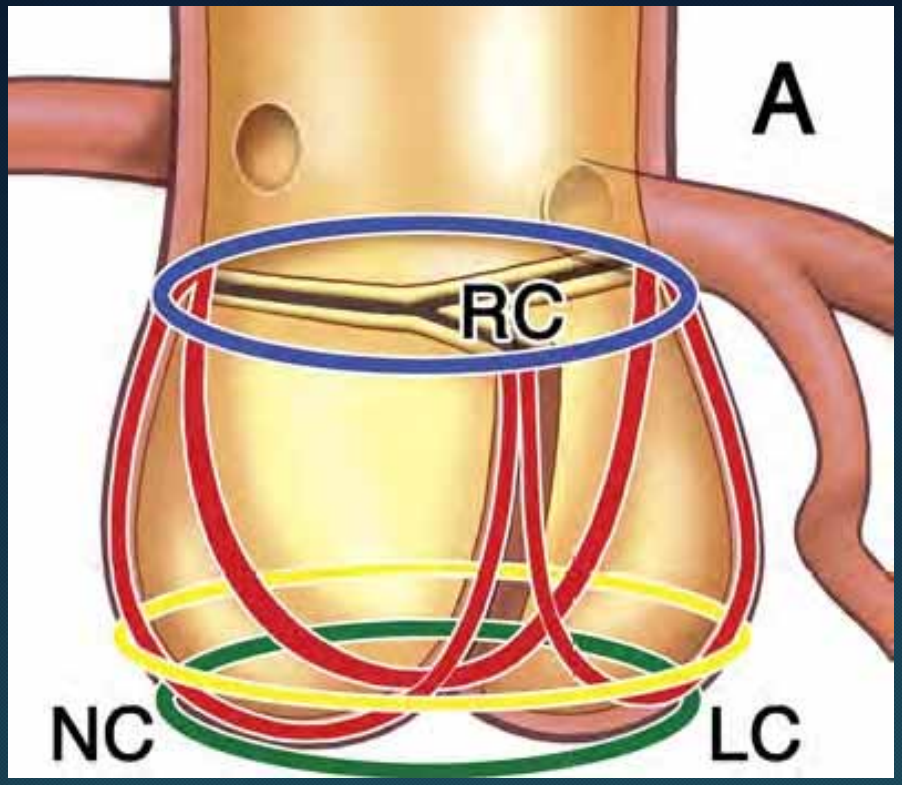
Mechanism of Paravalvular Leak

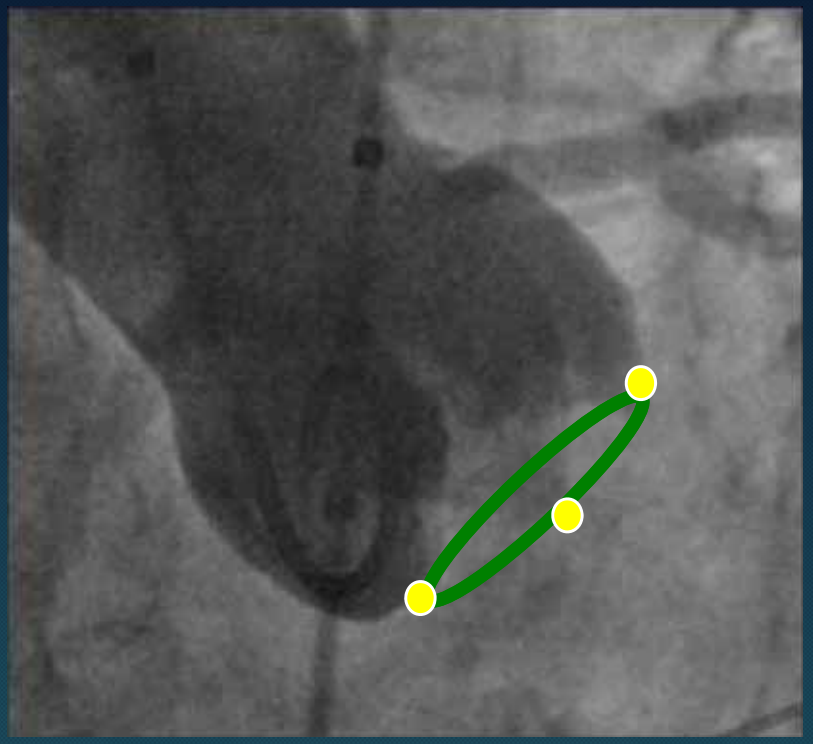


Sinning JM et al., JACC 2012

Virtual Basal Ring

Correct Assessment of Annulus Size





Sinotubular junction

Aortic leaflets

Aortic Annulus

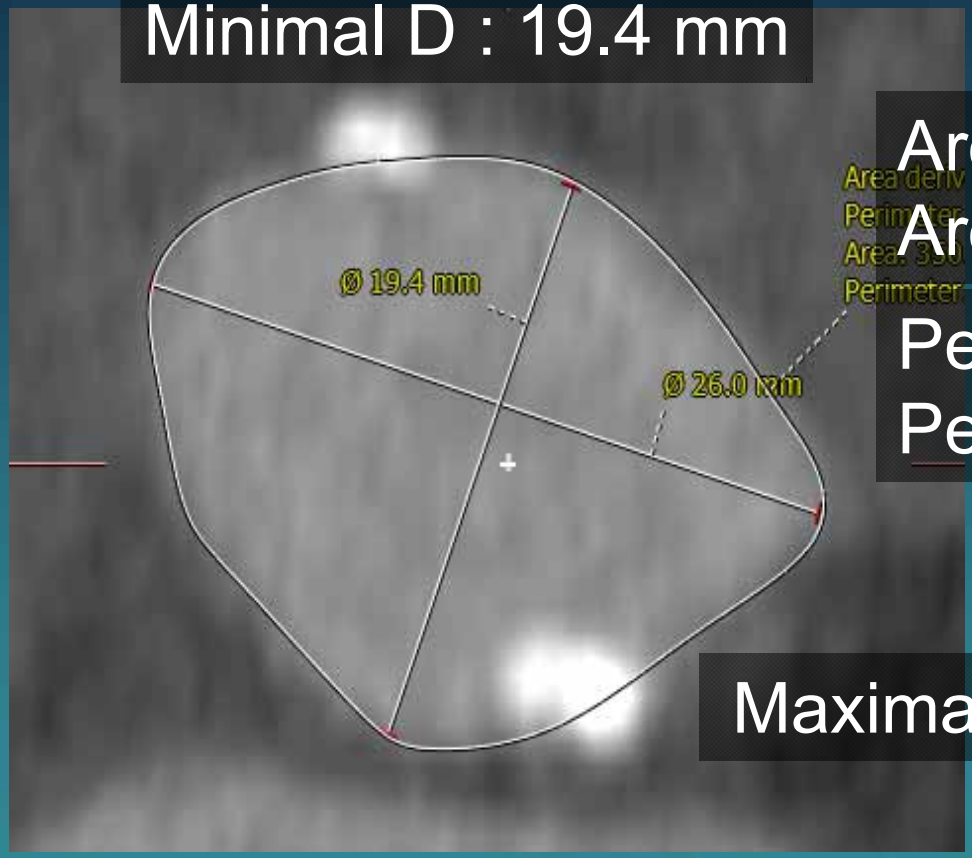
Aortic Annular Diameter

RC = Right coronary cusp; NC = Non-coronary cusp;
LC = Left coronary cusp

Leipsic et al JACC Img April 2011

Virtual Basal Ring

MDCT Assessment of Annulus Size

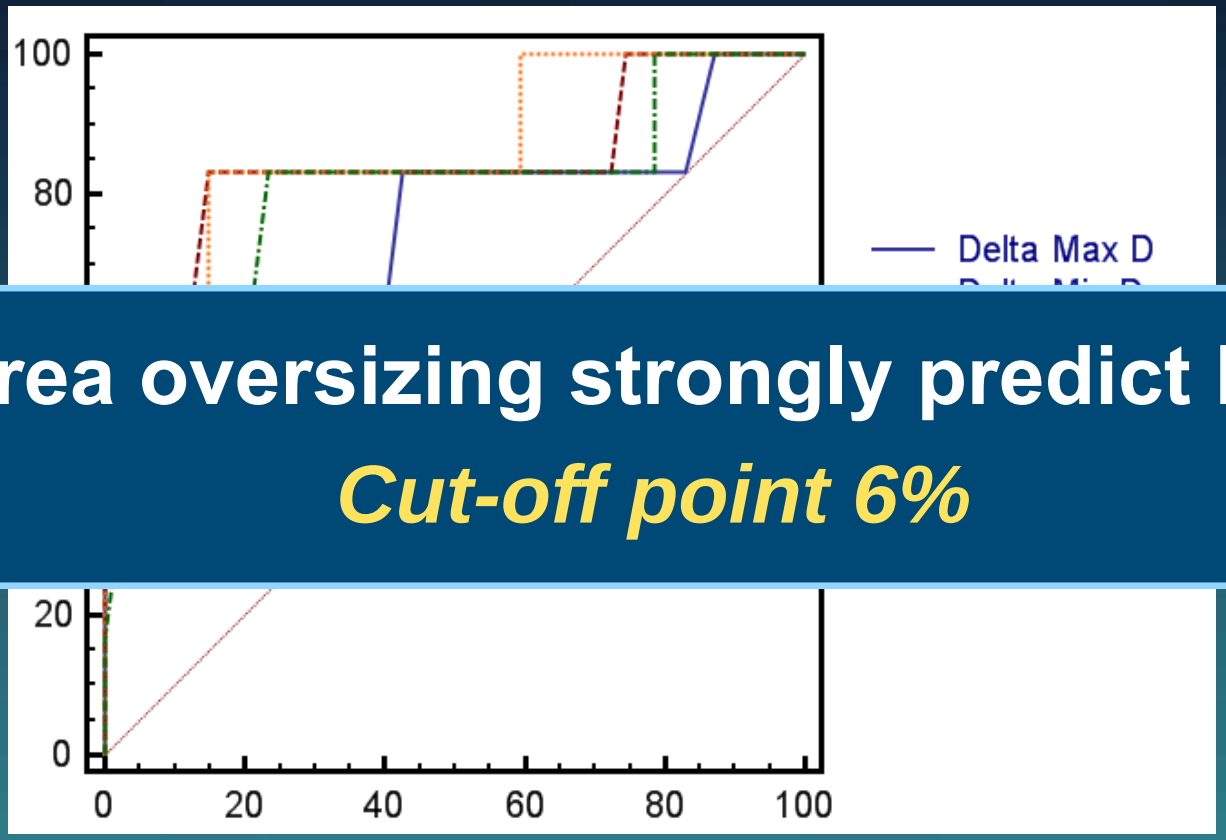


Area : 350.7 mm^2
Area derived D : 21.1 mm

Perimeter: 69.0 mm
Perimeter derived D: 22.0 mm

MDCT measurements and SAPIEN

AMC SAPIEN/ XT Registry



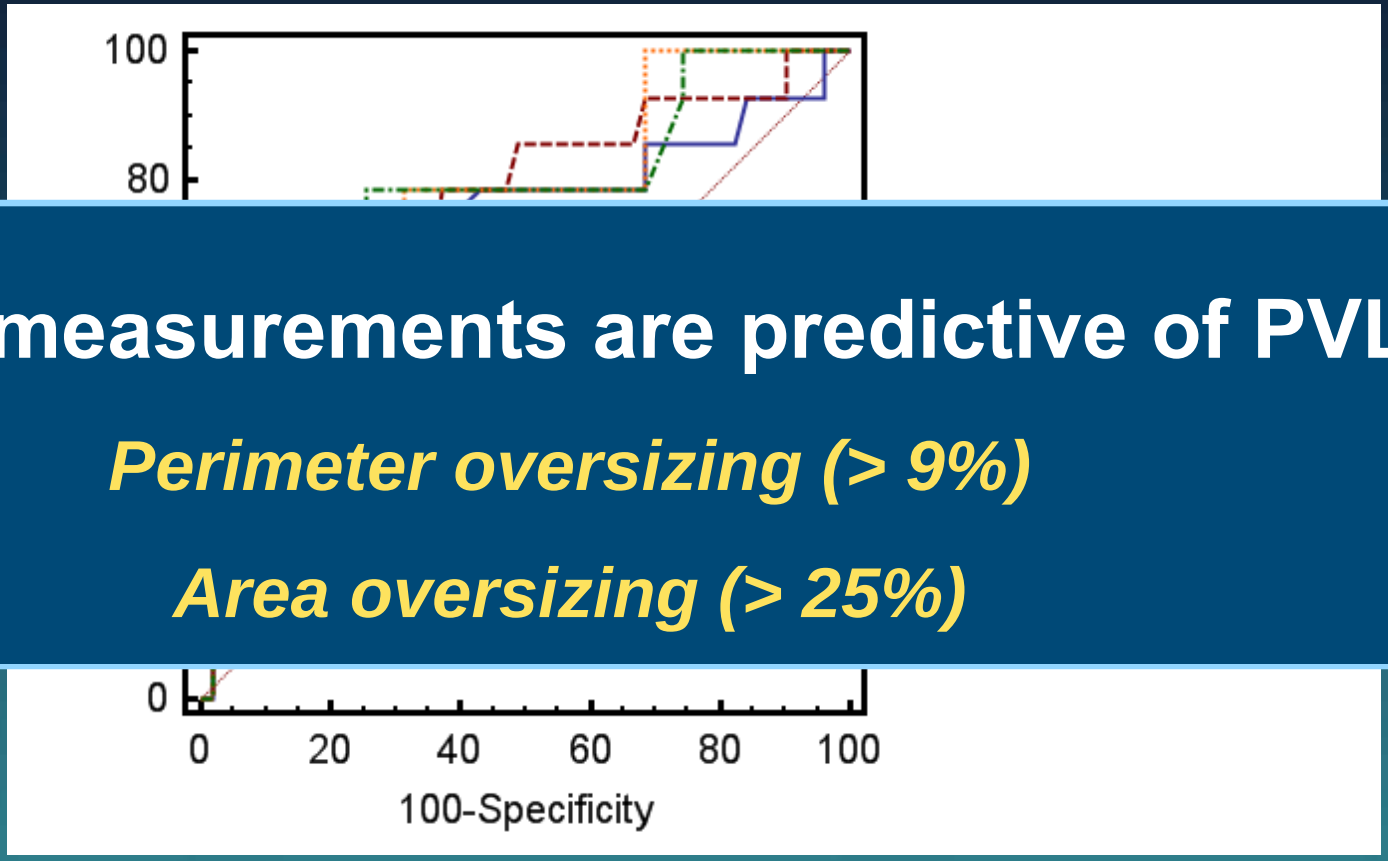
Area oversizing strongly predict PVL

Cut-off point 6%

	AUC	95% CI
Δ Valve D – Maximum D, mm	0.75	0.61 – 0.86
Δ Valve D – Min D, mm	0.83	0.71 – 0.92
Perimeter oversizing, %	0.80	0.67 – 0.90
Area oversizing, %	0.86	0.74 – 0.94

MDCT measurements and CoreValve

AMC CoreValve Registry



MDCT measurements are predictive of PVL

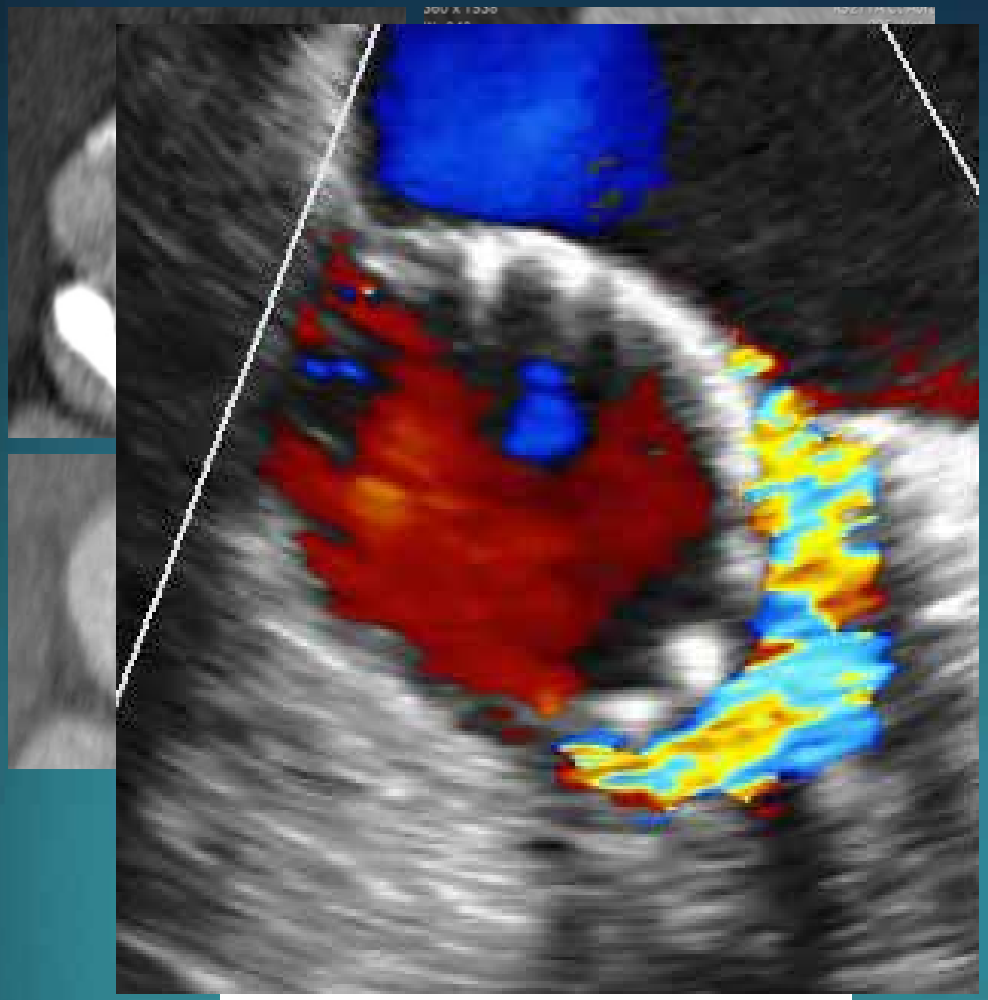
Perimeter oversizing (> 9%)

Area oversizing (> 25%)

	AUC	95% CI
Δ Valve D – Maximum D, mm	0.68	0.56 – 0.79
Δ Valve D – Min D, mm	0.71	0.59 – 0.82
Perimeter oversizing, %	0.77	0.65 – 0.86
Area oversizing, %	0.77	0.64 – 0.86

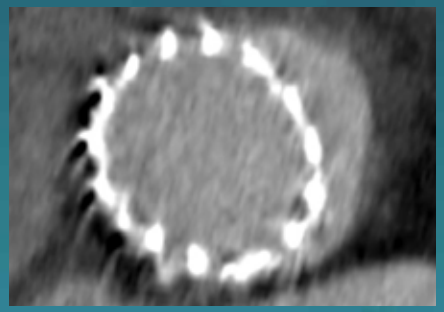
Calcification

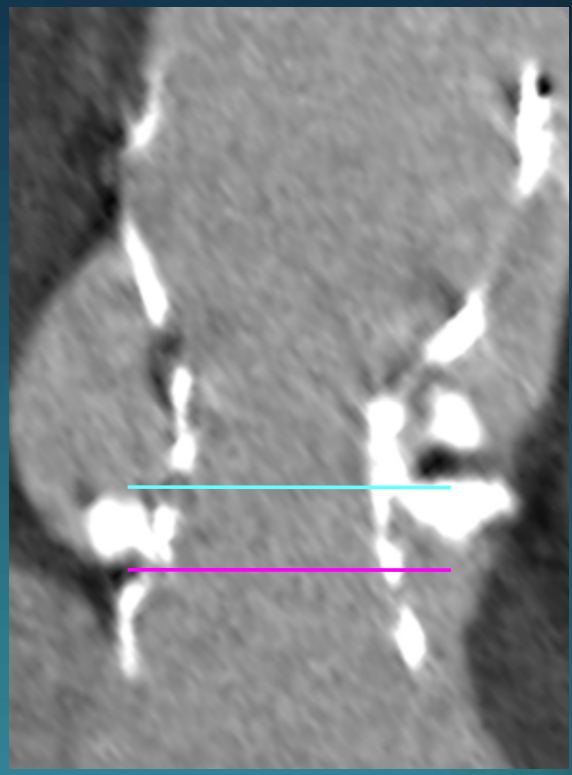
Preprocedure



Severe AR

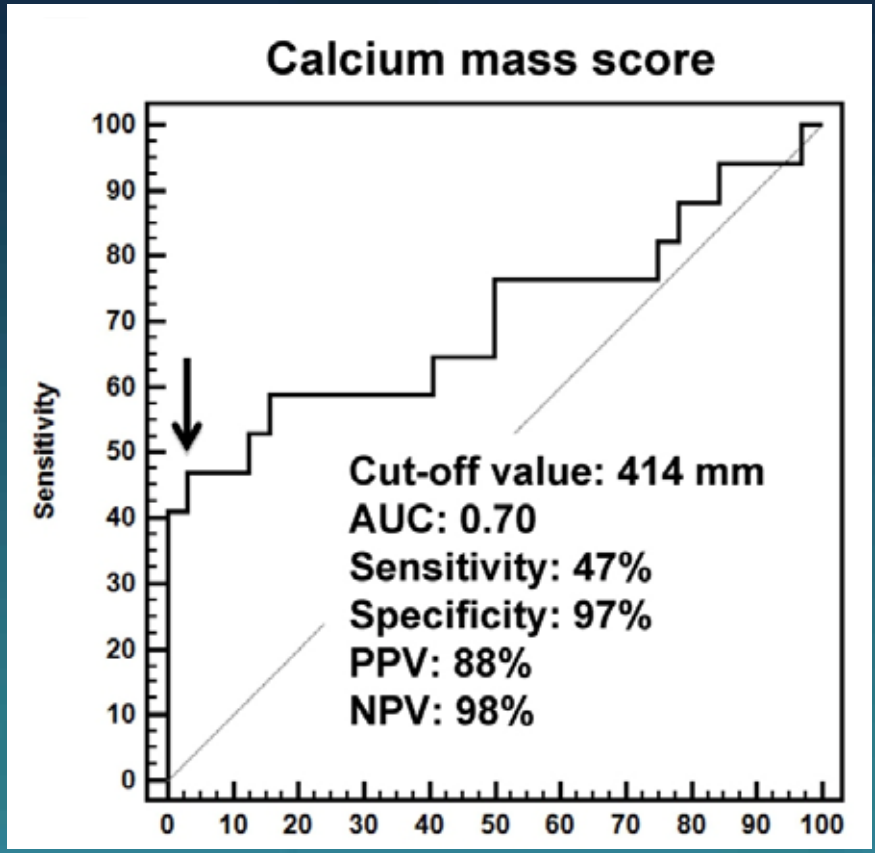
Postprocedure





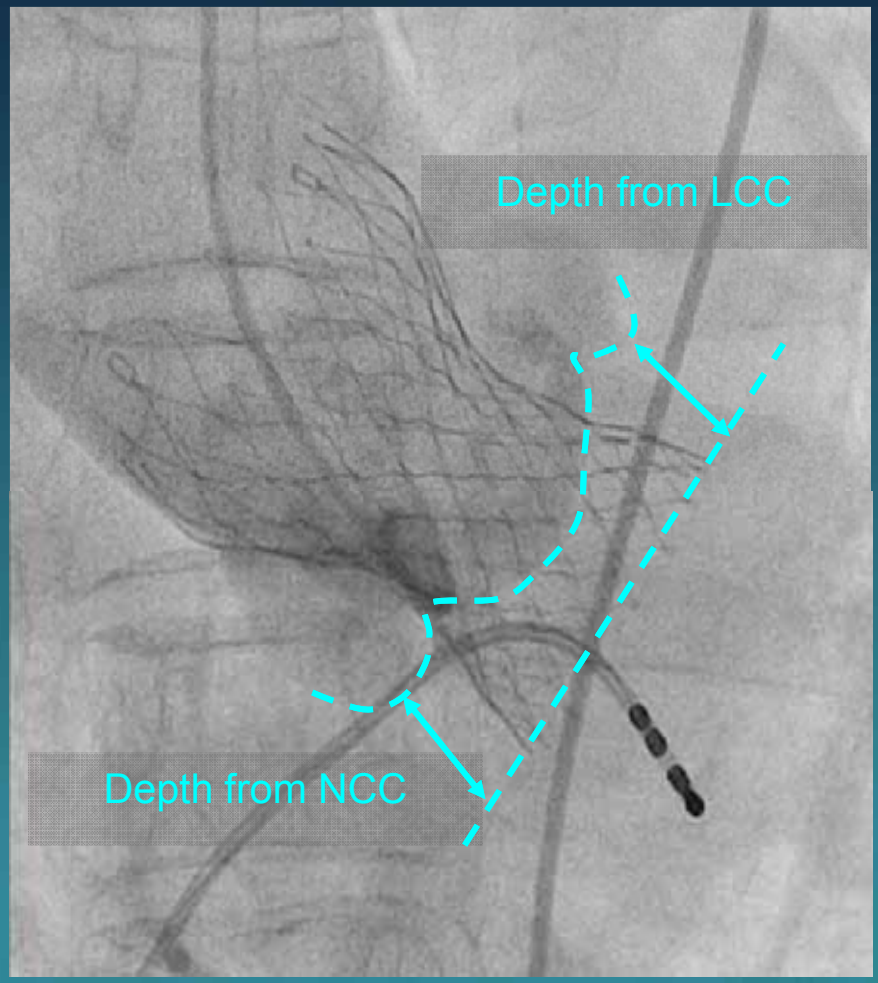
Calcification and PVL

AMC CoreValve Registry



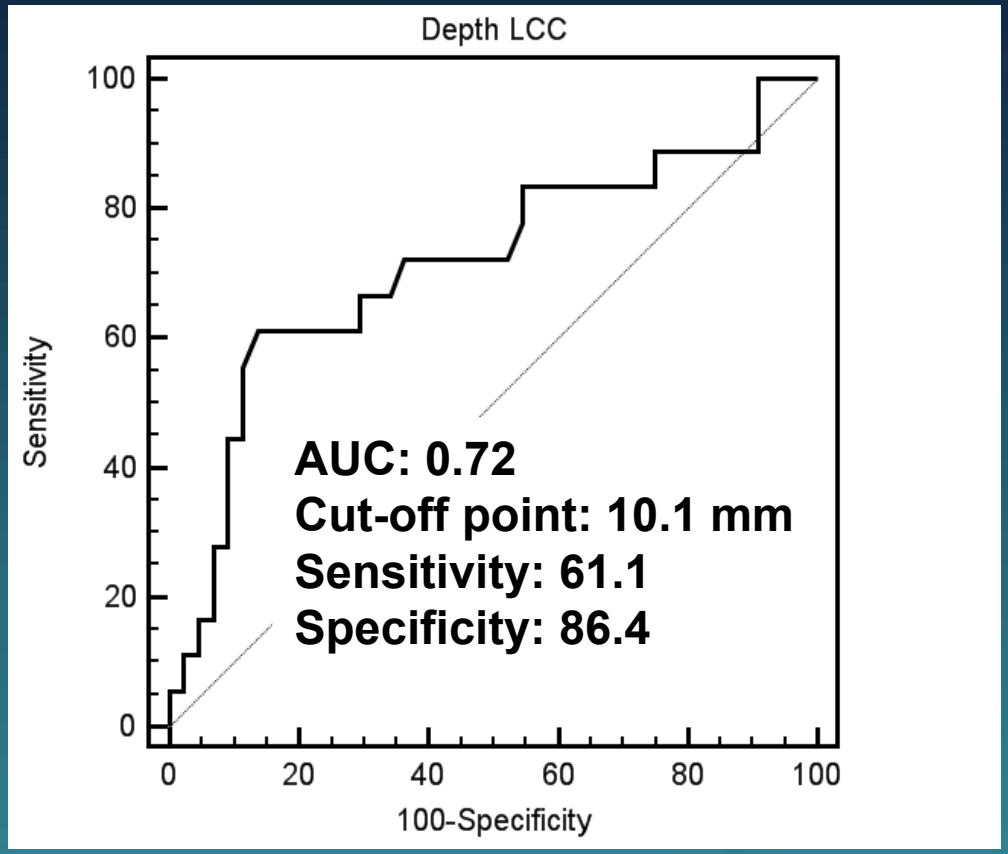
Heavy calcification in basal part of AV was associated with PVL

Depth of Implantation



Implantation Depth predict PVL

AMC CoreValve Registry



Depth from LCC was associated AR > mild

(HR, 1.21; 95% CI, 1.04 – 1.41; p = 0.015)

Predictors of PVL
AMC CoreValve Registry

Multivariate analysis for 69 CoreValve cases

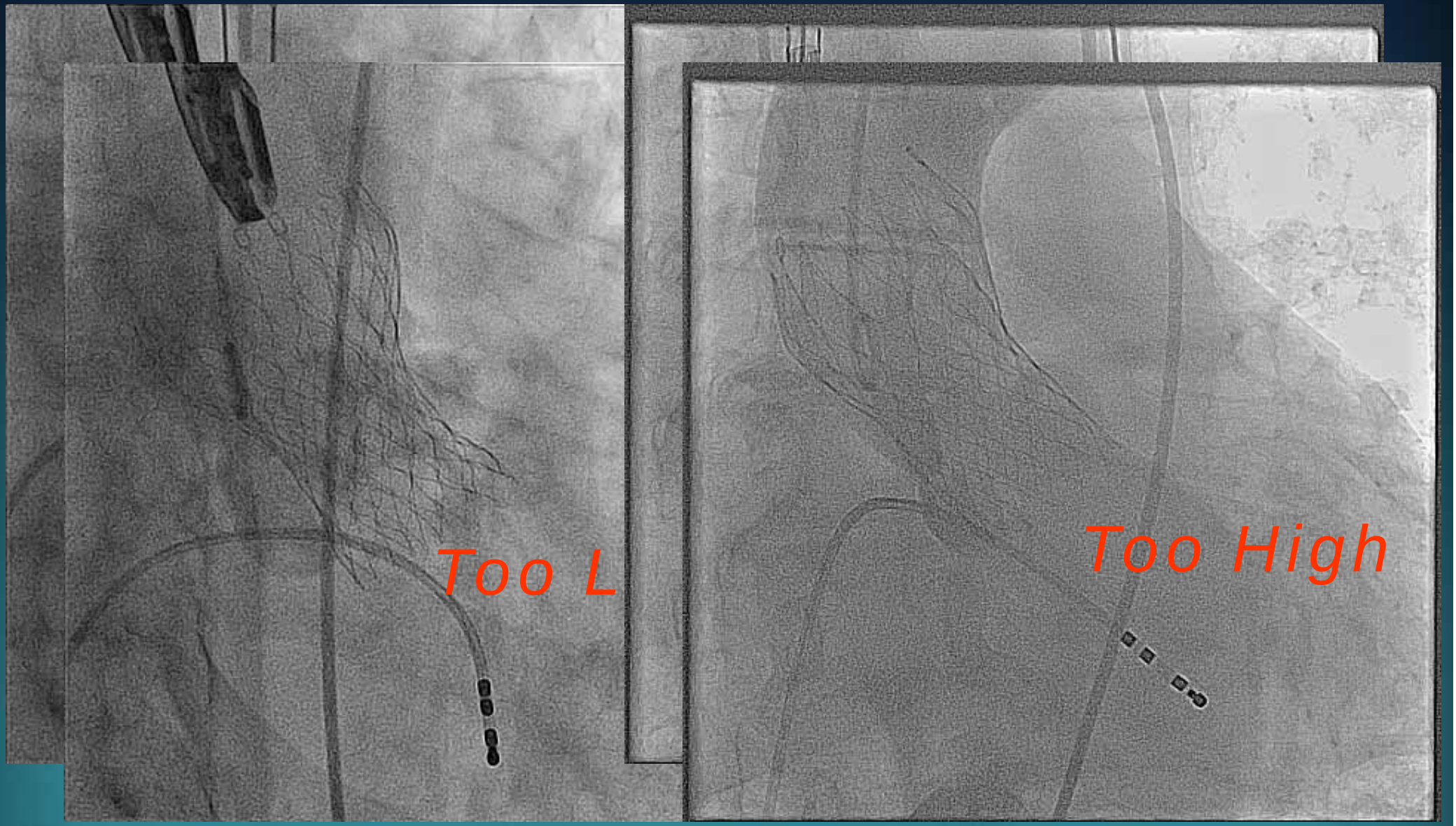
- Valve Undersizing
  - Perimeter, Area oversizing index
- *Implantation Depth of Device*
  - Depth from LCC
- *Calcification of Annulus*
  - Calcium score and calcium volume

- In contemporary practice, integration of MDCT measurement of annulus reduced valve undersizing

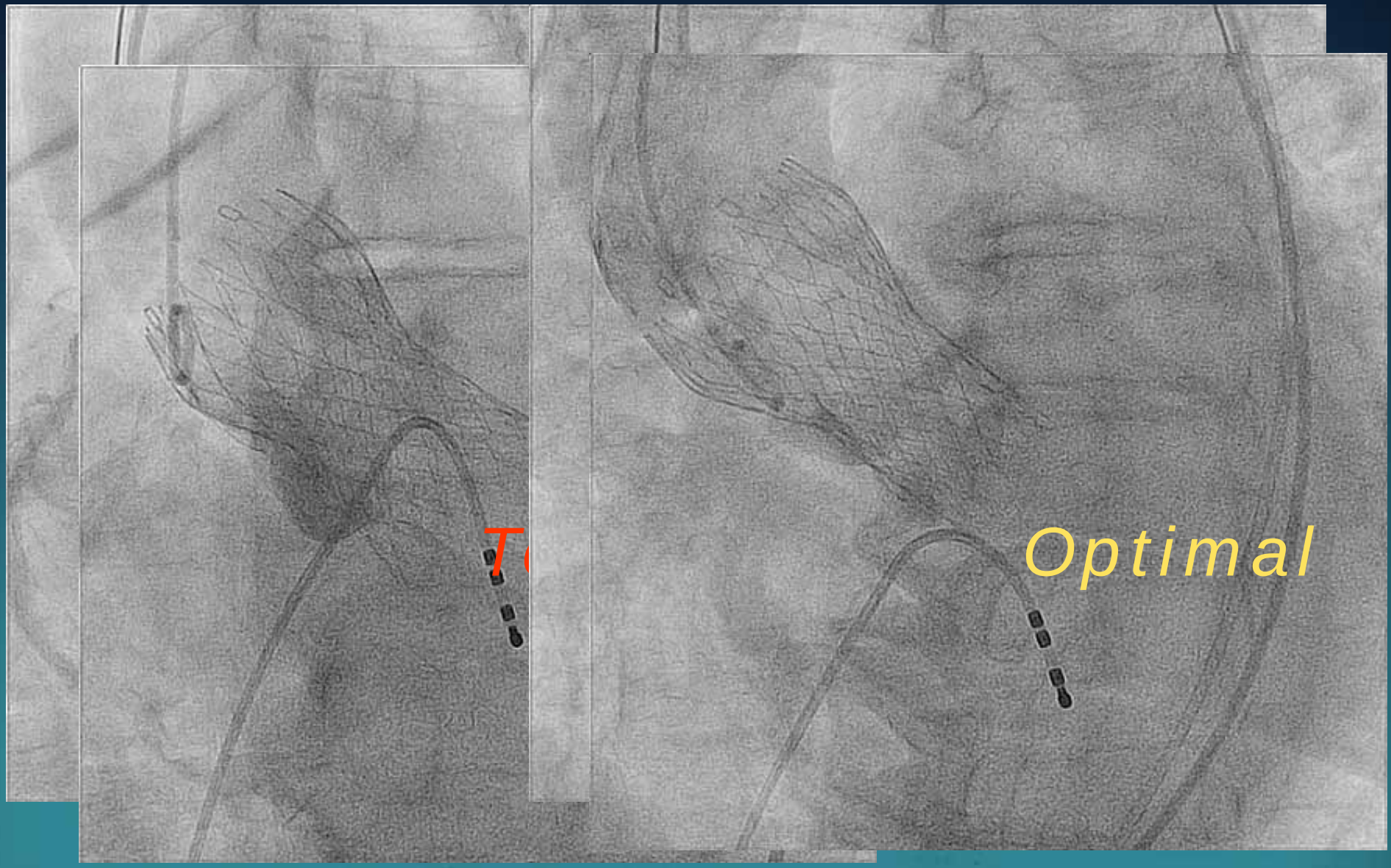
- Reported higher incidence of paravalvular leak after CoreValve implantation is attributable to difficulty of optimal positioning

- Thus, further analysis for optimal implantation depth of CoreValve was performed

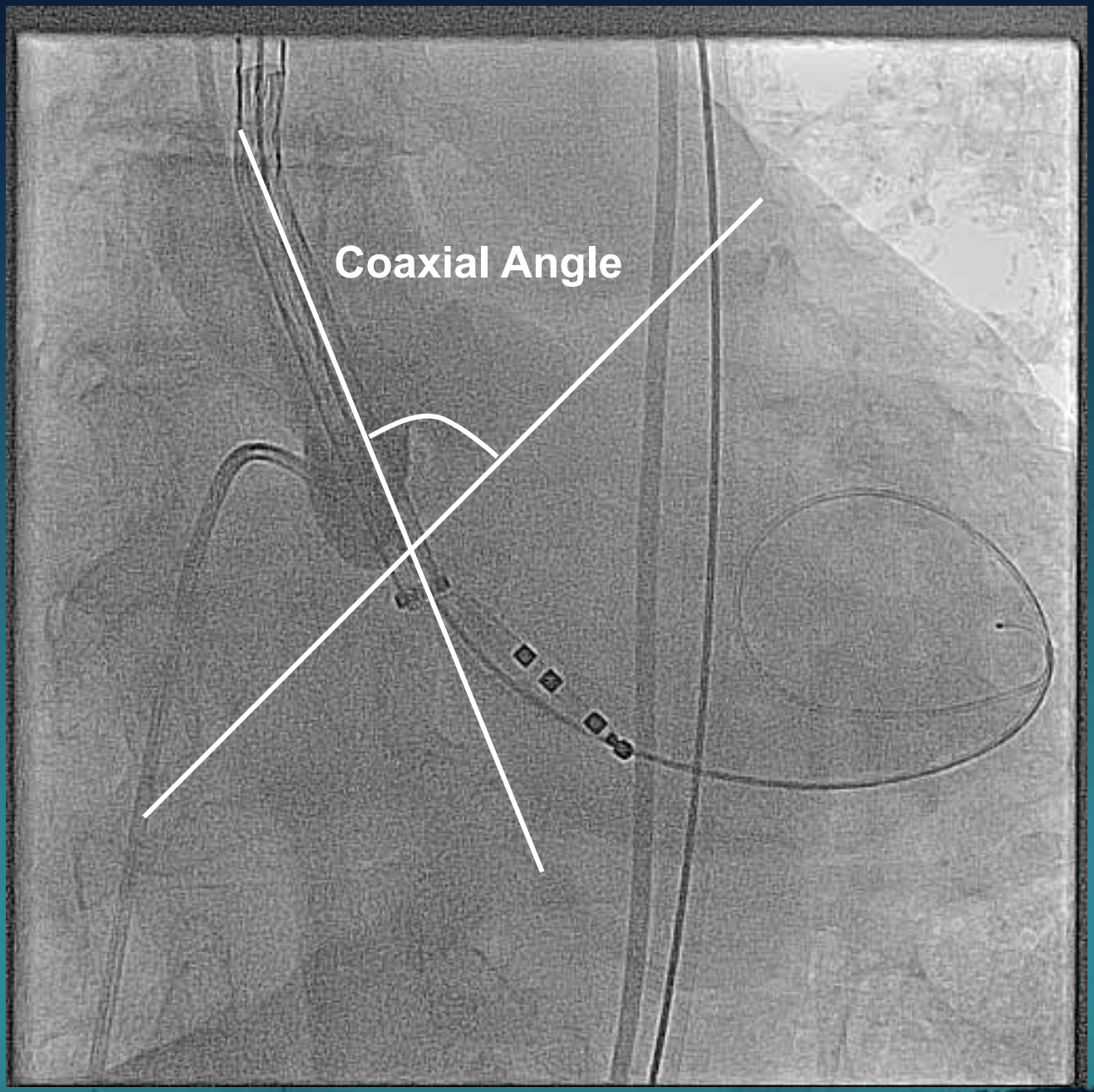
Device Coaxiality



Device Coaxiality



Device Coaxiality

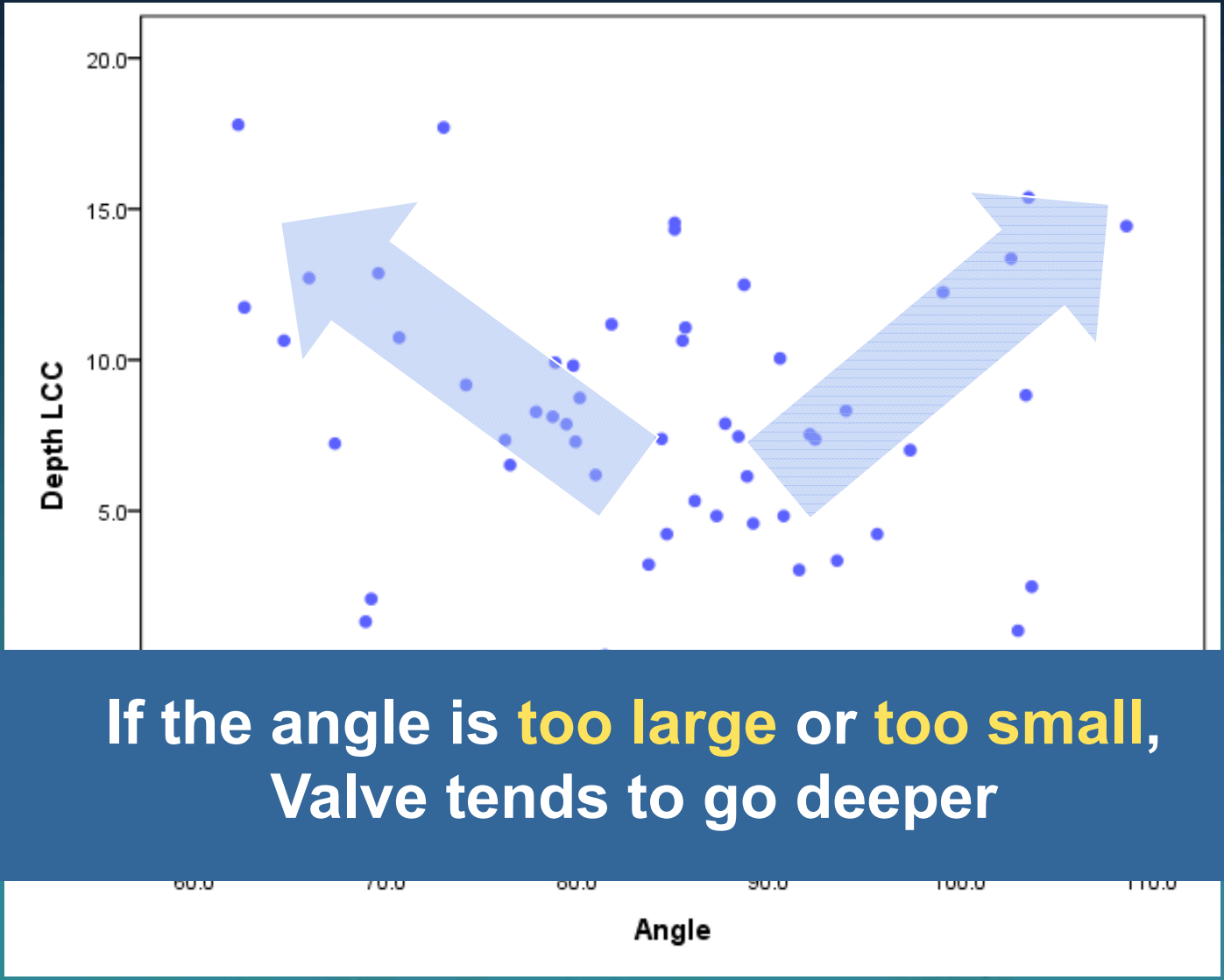


Depth, Coaxiality and PVL

	PVL > mild (n=18)	PVL ≤ mild (n=47)	P value
Area oversizing, %	129.4 ± 14.4	140.5 ± 17.8	0.021
Perimeter oversizing, %	109.7 ± 5.7	114.5 ± 7.3	0.015
Depth from NCC, mm	7.2 ± 5.0	5.2 ± 4.5	0.13
Depth from LCC, mm	10.1 ± 4.4	7.1 ± 3.9	0.009
Coaxial angle, degree	81.7 ± 16.1	85.8 ± 8.2	0.21

Device Coaxiality

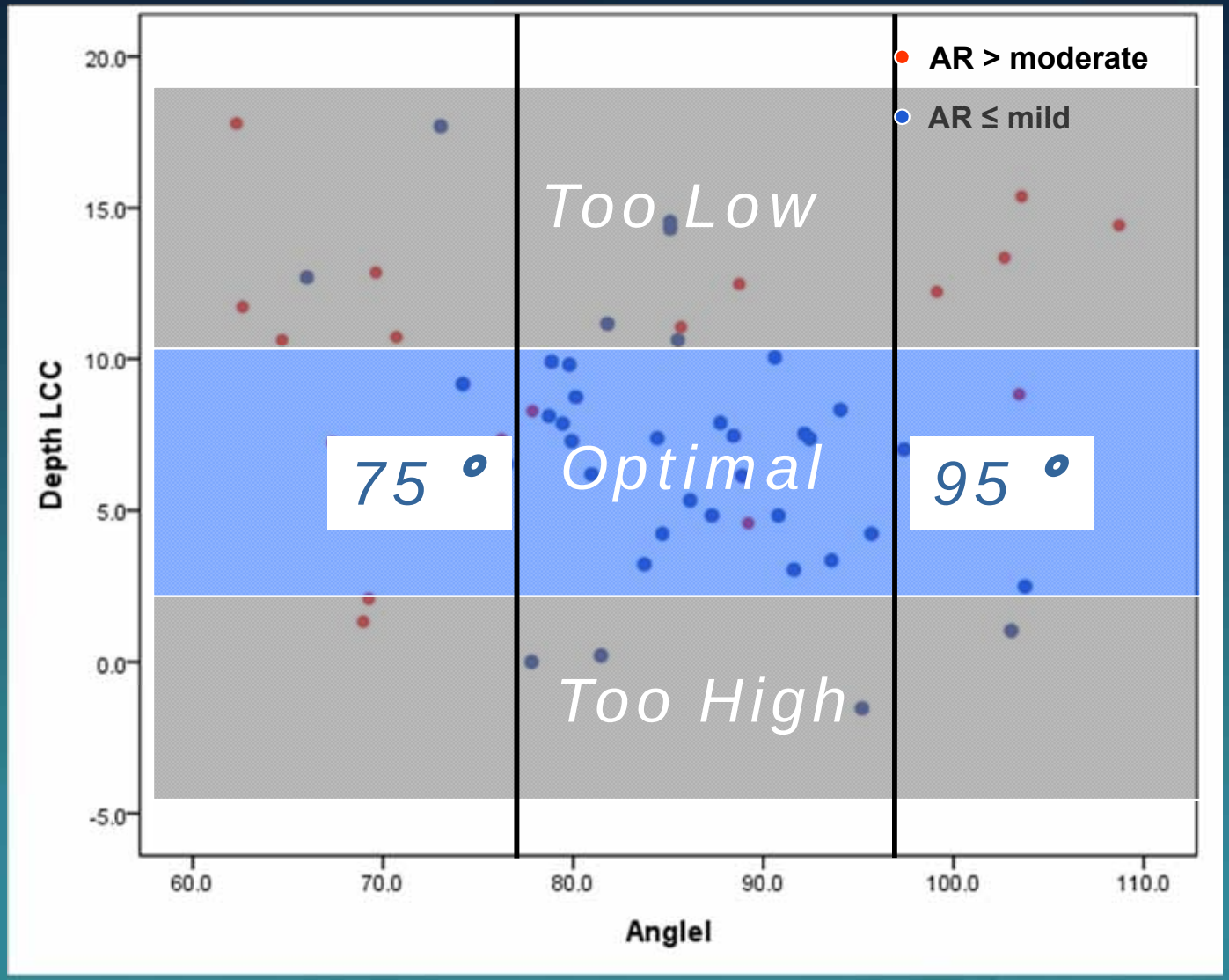
Depth from LCC



If the angle is too large or too small,
Valve tends to go deeper

Device Coaxiality

Depth from LCC



Device Coaxiality

Well controlled device coaxiality (*angle 75 – 95 degree*)

was independent predictor of optimal implantation

(*i.e.* Depth from LCC < 10.0mm)

(HR, 7.75; 95% CI, 1.79 – 33.60; p value = 0.006)

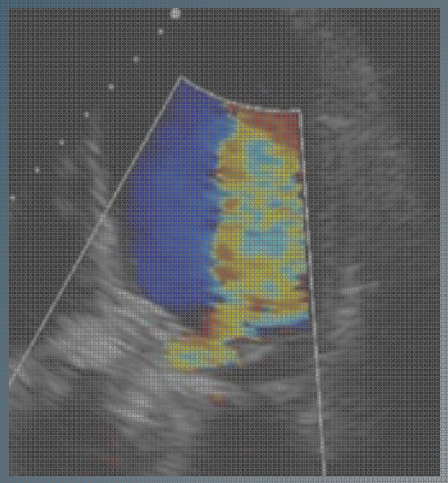
Well controlled device coaxiality (*angle 75 – 95 degree*)

was independent predictor of paravalvular leak > mild

(HR, 0.11; 95% CI, 0.029 – 0.39; p value = 0.001)

Current Limitations of TAVI

Paravalvular Leak

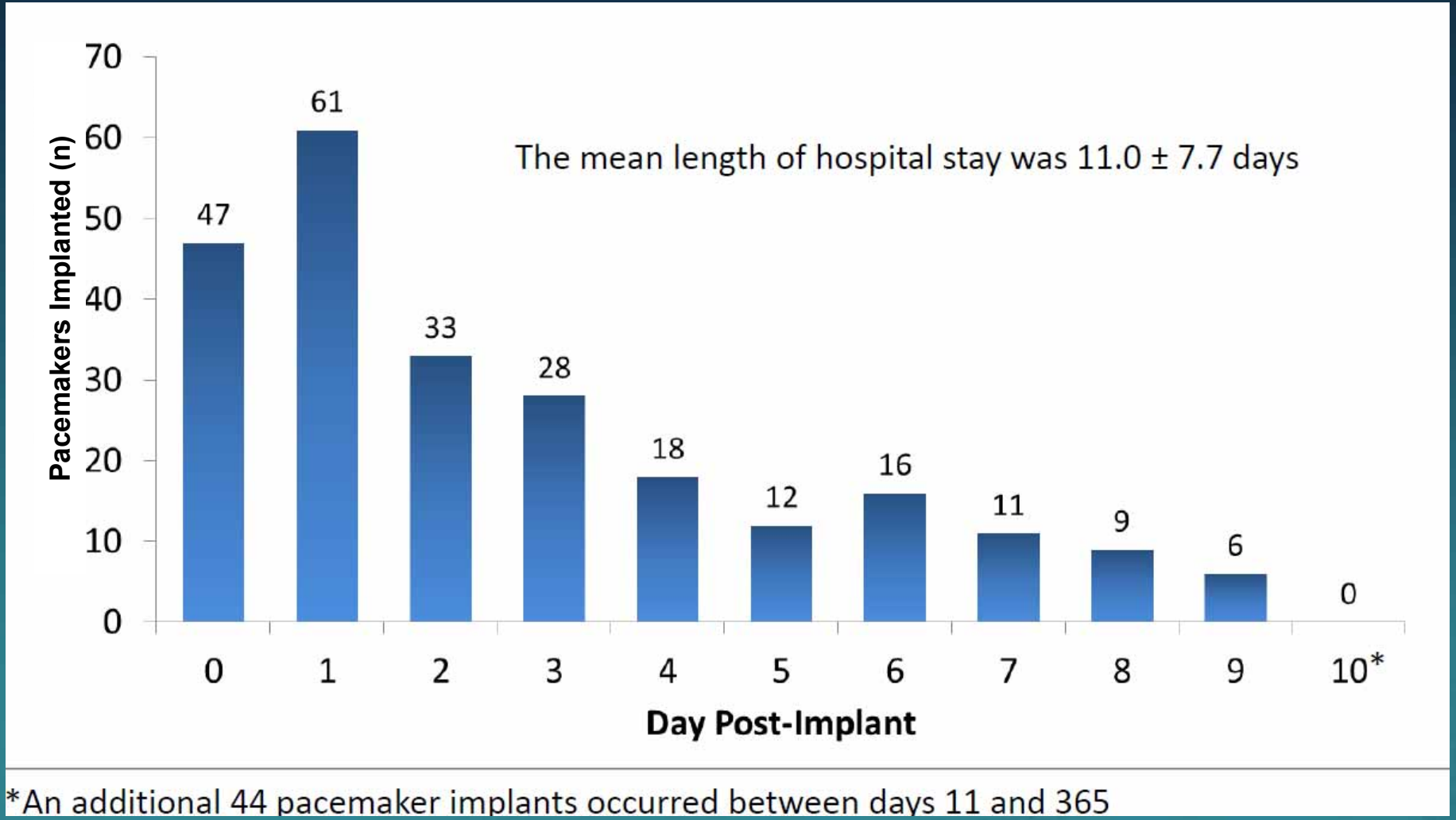


Conduction Disturbance

Vascular Complication

Stroke

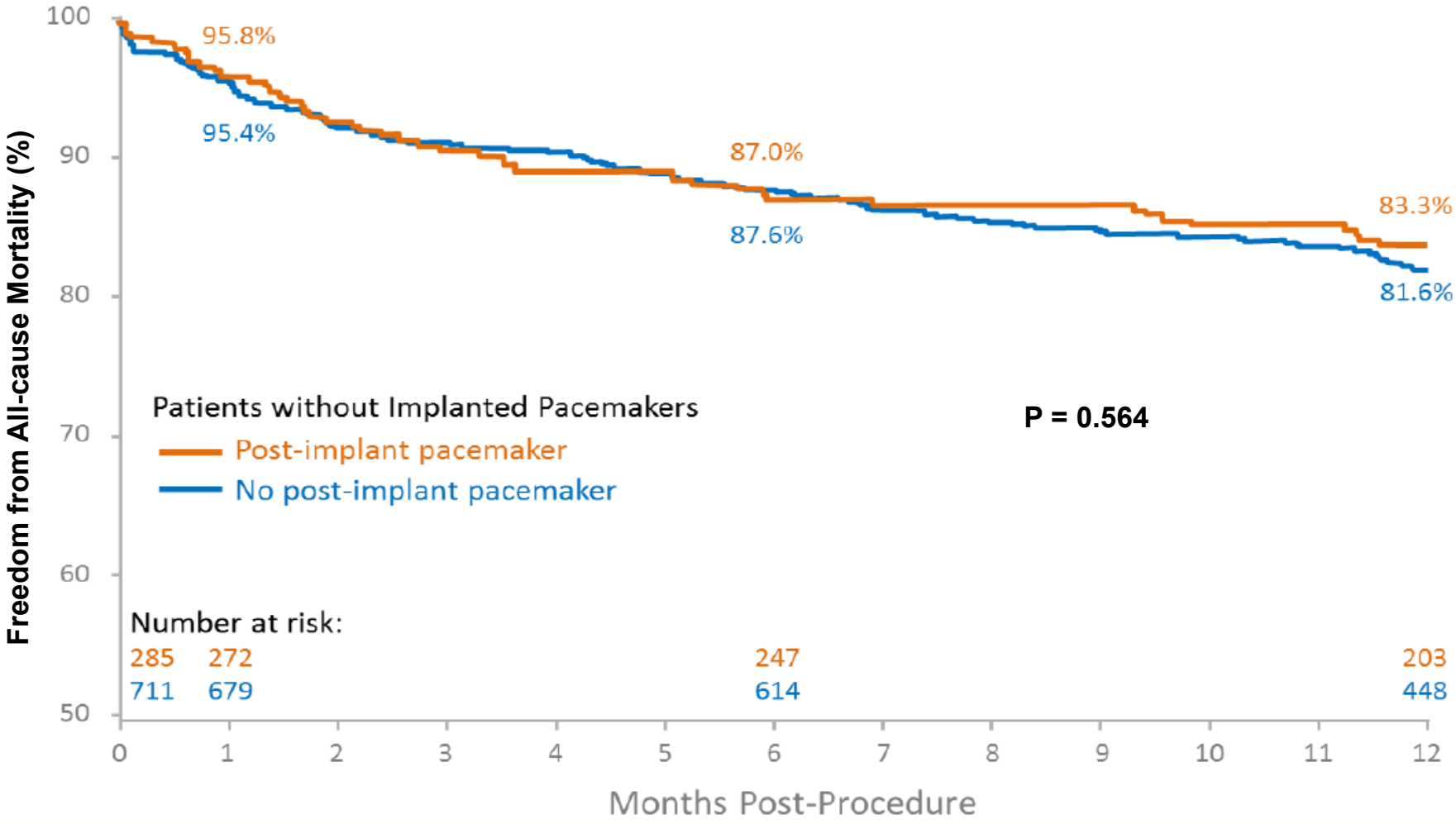
Timing of Pacemaker Implantation
ADVANCE Registry



*An additional 44 pacemaker implants occurred between days 11 and 365

ERKAPIC et al., 2012 Journal of Cardiovascular Electrophysiology 23(4), 391–397

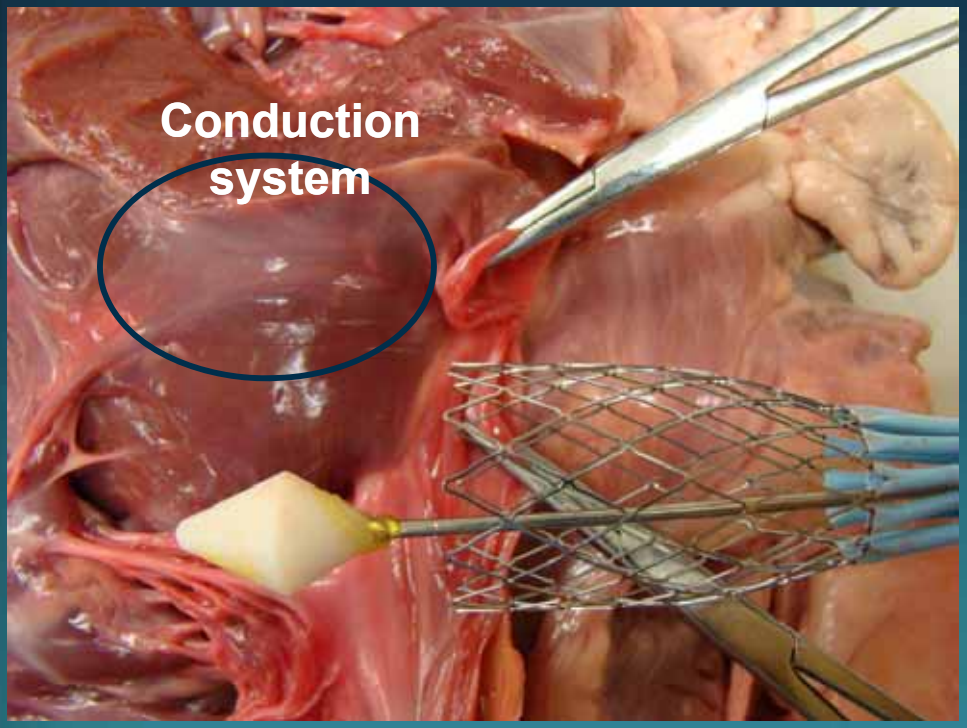
Impact of PPM on Survival
ADVANCE Registry



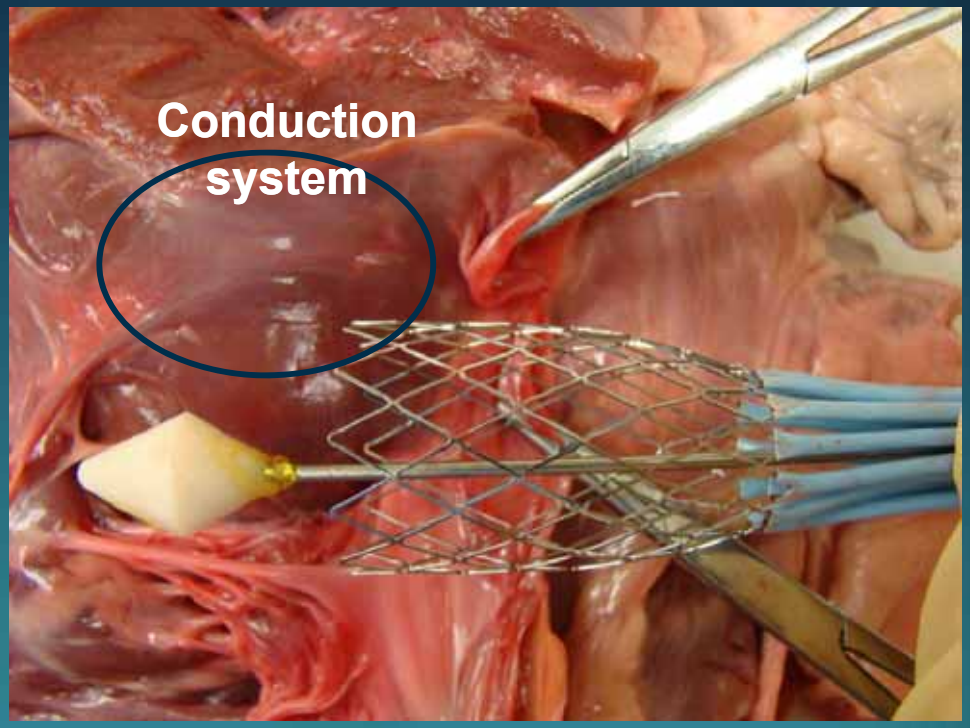
Wenaweser P et al. PCR Paris 2013

Conduction Disturbance

Depth of Device and Conduction System



5mm past annulus

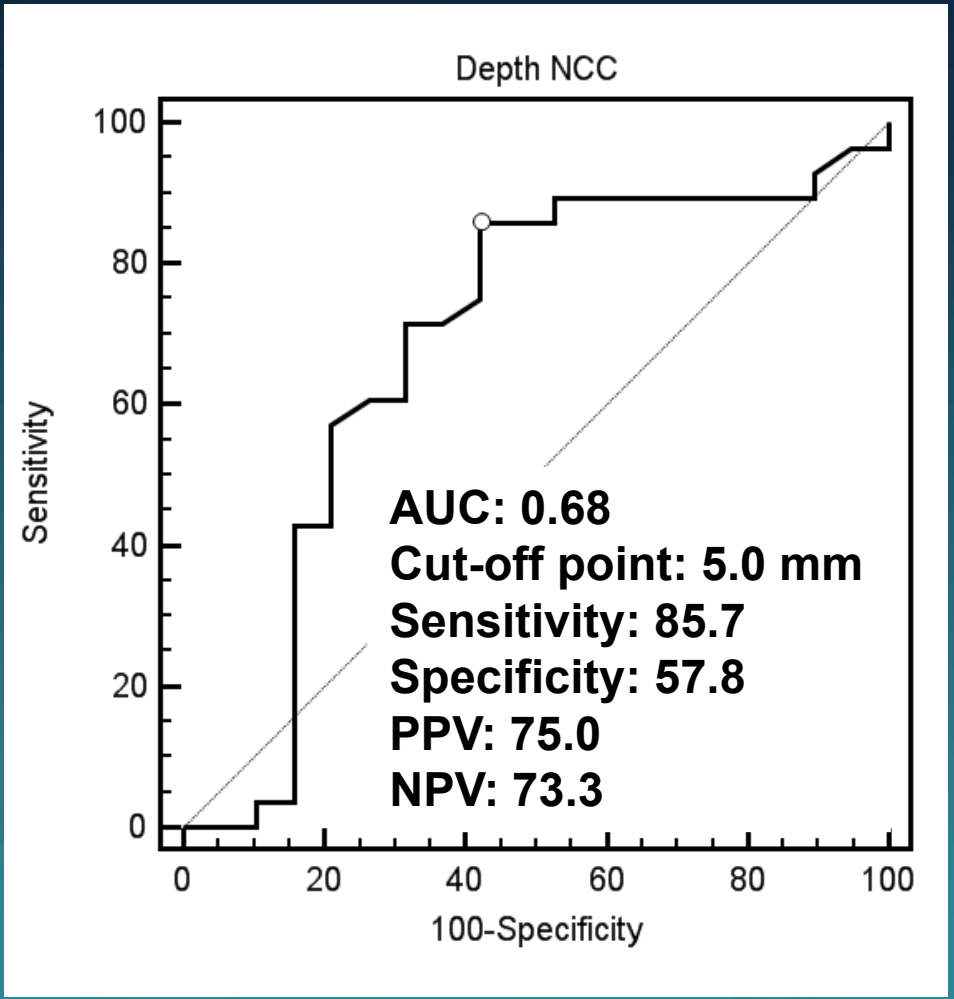


15mm past annulus

Raoul Bonan, TVT 2011

Implantation Depth and Conduction Disturbance

AMC CoreValve Registry



Depth from NCC was associated with conduction disturbance

(HR, 1.29; 95% CI, 1.06 – 1.56; p = 0.01)

Predictors of Need for Permanent Pacemaker

Jilaihawi et al. Am Heart J 2009	• LBBB +left axis deviation • Thickness of non-coronary leaflet • Septal wall thickness
Bleiz	
Baar	
Latsios et al. CCI 2010	• Aortic valve calcification (MSCT) • Female gender • Left ventricular dysfunction
Ferreira et al. Pacing and Clin	• Prosthesis depth in LVOT

Baseline Abnormal Conduction
Small Annulus / LVOT
Amount of Calcification
Implantation Depth

Conclusion

Valve undersizing was associated with PVL for both SAPIEN and CoreValve.

In addition, implantation depth was associated with PVL for CoreValve.

To get optimal implantation position, device coaxiality might be a key factor.

For prevention of conduction disturbance, optimal valve positioning is also important factor.