CoreValve: Pros and Cons.

A. Pichard,
L. Satler, R Waksman, I Ben-Dor, N Bernardo,
P Corso, C Shults, S Goldstein, Z Wang,
F Asch, J Weidel, T. Weddington, G Weissman,
G Weigold, P Okubagzi, A. Taylor

Medstar Washington Hospital Center.
Washington, DC

Snowmass 2015

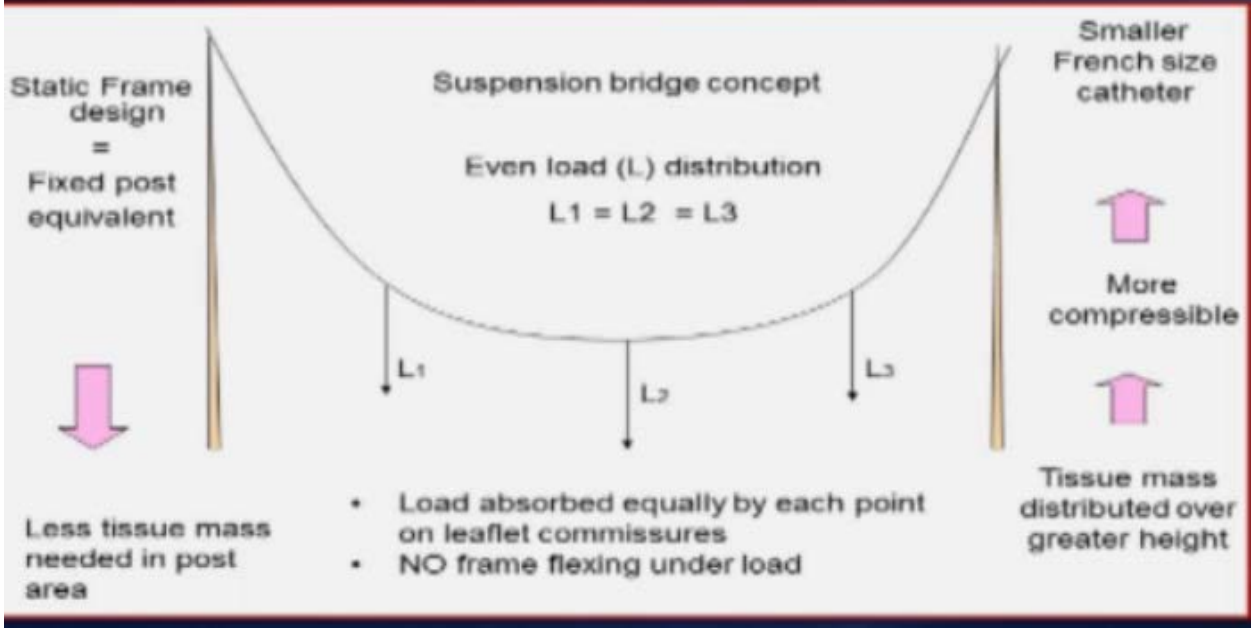
Medstar Heart Institute

Cleveland Clinic
Heart and Vascular Institute

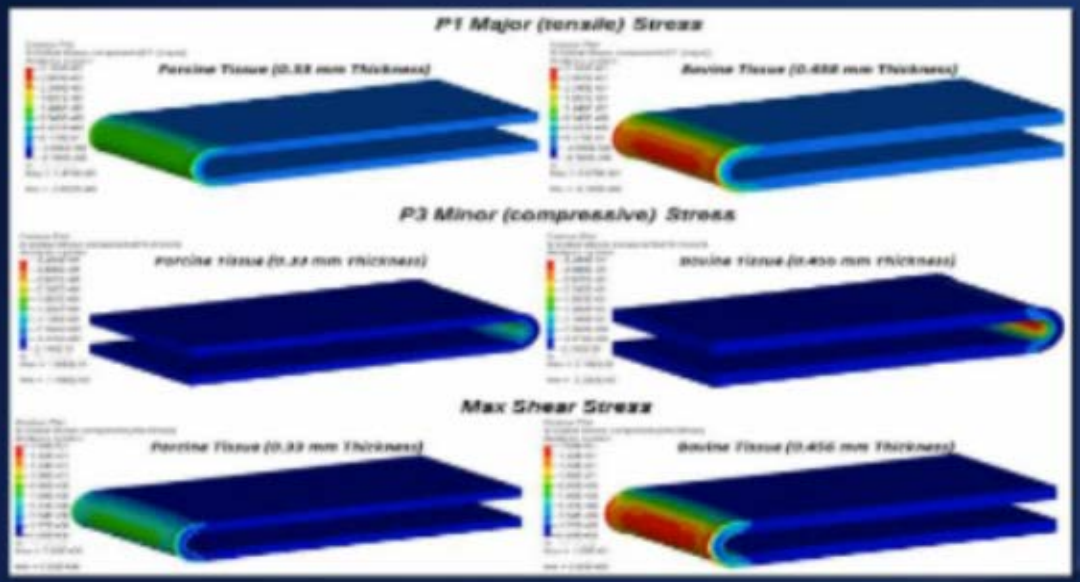
TAVR in US

>100,000 cases done in 750 Centers worldwide.

CoreValve Bioprosthesis Design



FEA Demonstrates Porcine Pericardium Experiences Less Bending Stresses Than Bovine Pericardium[1]



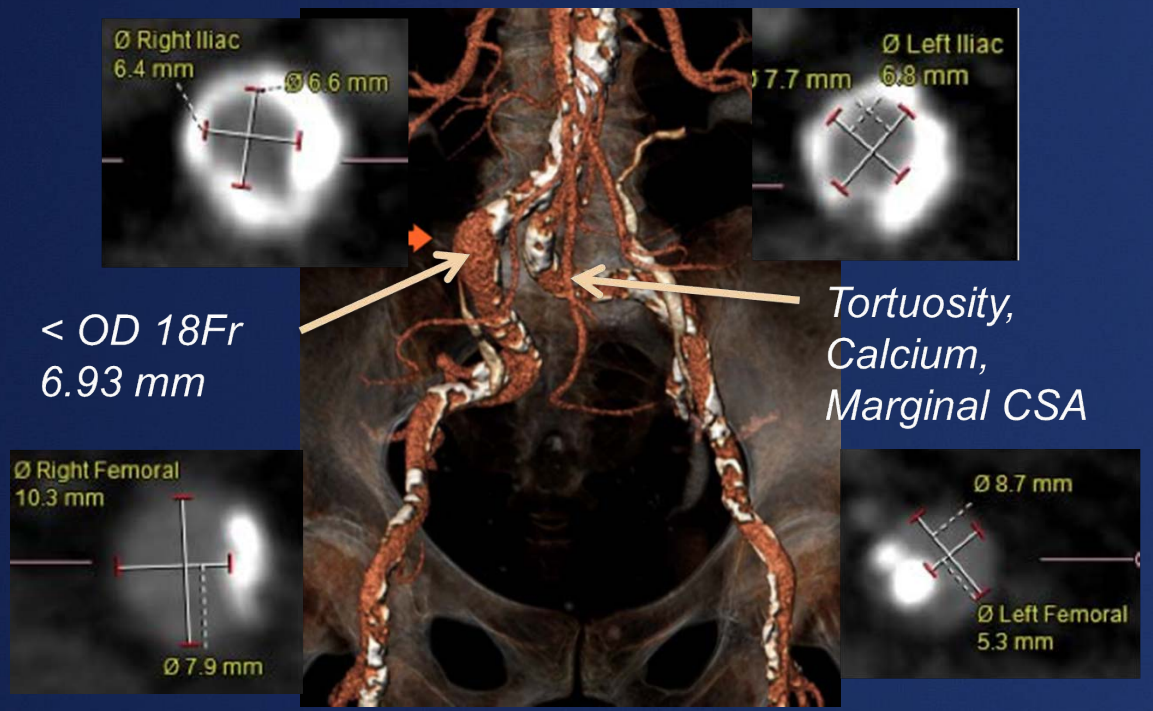
Ease of Use

- **Simple training.**
- **Delivery is easy, if following instructions.**
- **Easily crosses the valve.**
- **May not require predilatation.**
- **No rapid pacing required during deployment.**

Vessel Size Considerations

18F Sheath for all valve sizes. Requires vessels >/= 6mm

CoreValve® and CoreValve Evolut	23mm (18-20mm)	26mm (20-23mm)	29mm (23-27mm)	31mm (26-29mm)
AccuTrak® with Cook Sheath	18FR 21.8FR	18FR 21.8FR	18FR 21.8FR	18FR 21.8FR



universitäts klinikum bonn

Medtronic Evolut R
Enveo R delivery catheter InLine Sheath

CoreValve w/
18 Fr Cook Sheath

22 Fr

7.3 mm

4 Fr reduction

68% cross-sectional area reduction

EnVeo R w/ 14F
InLine Sheath

18 Fr

6.0 mm

Minimal lumen artery diameter = 5 mm

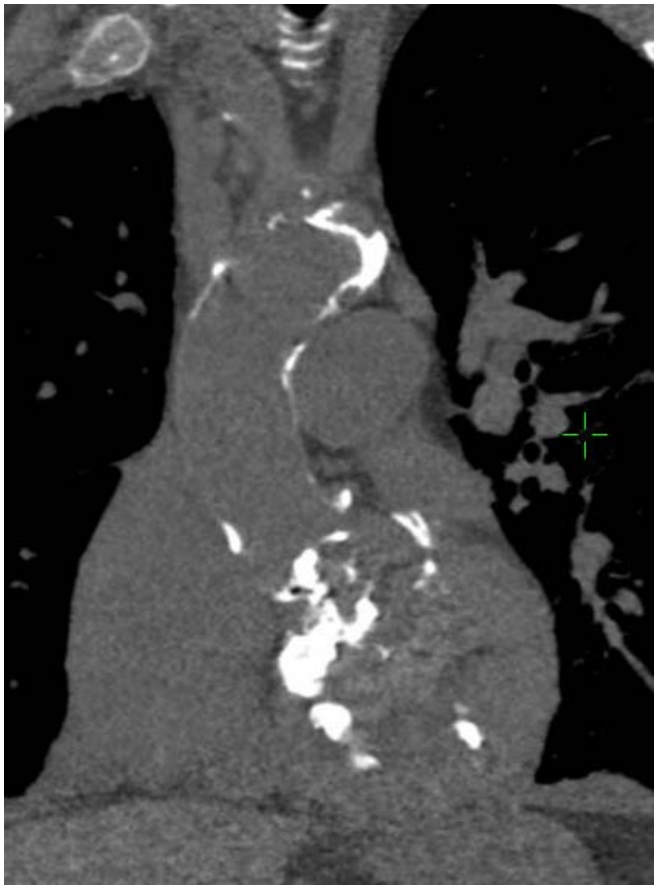
Medtronic Evolut R

Retrievable, Repositionable

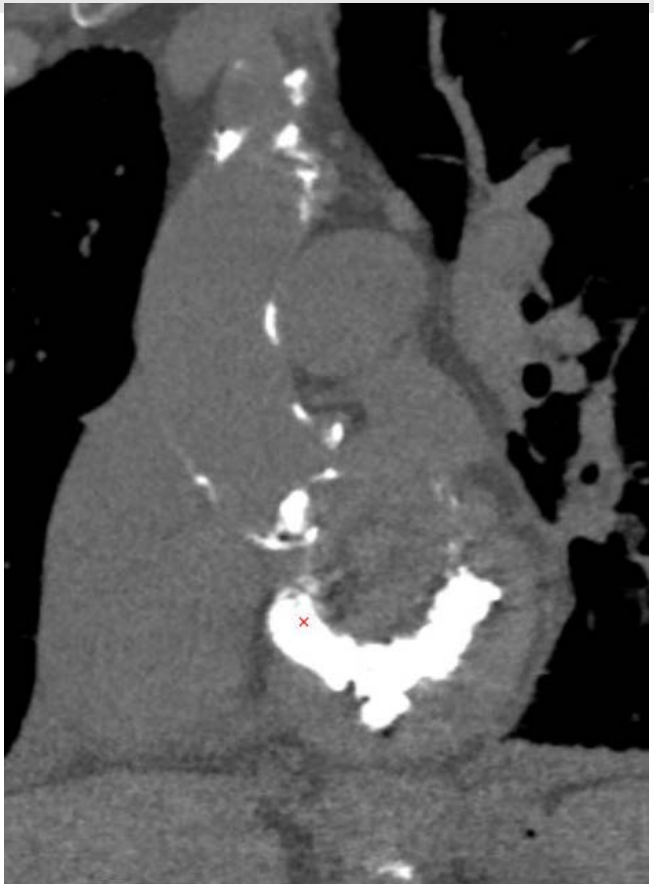
Self Expanding Valves and Annular Rupture

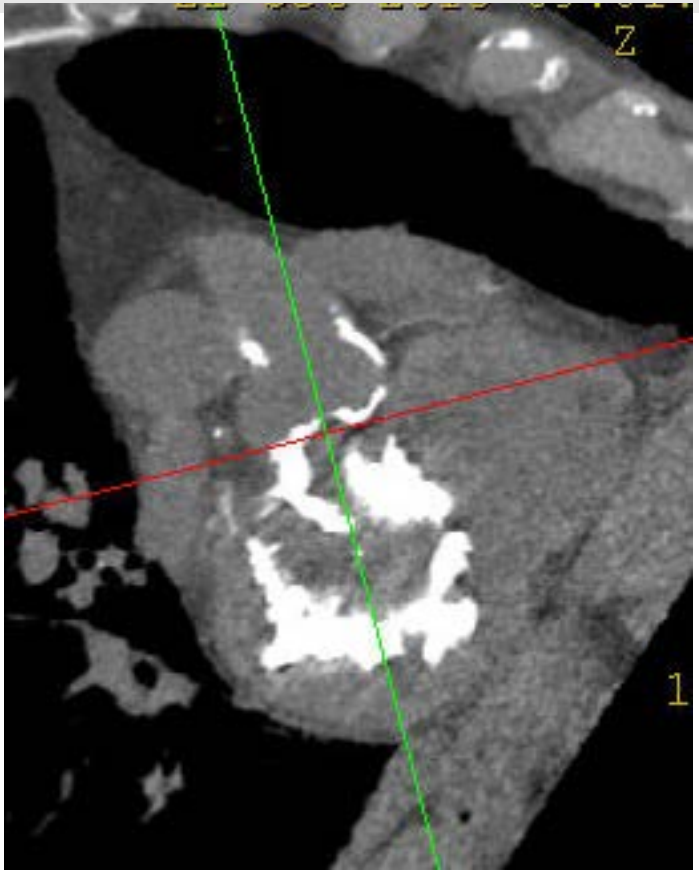
- **The CoreValve has no reported cases of annular rupture (except for post dilatation).**
- **A safe option for heavily calcified aorto-valvar and LVOT regions.**

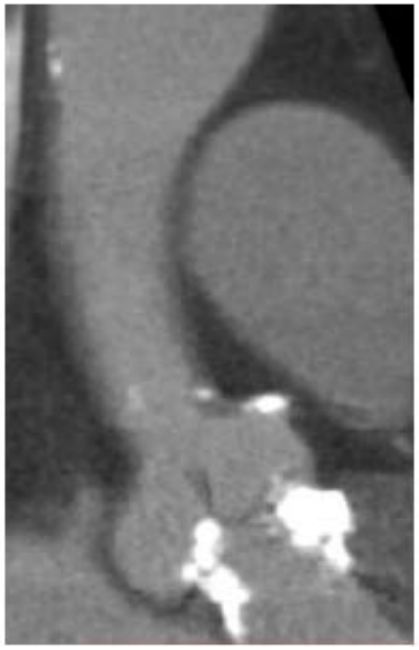
LVOT Calcification
Predictor for Annular Rupture

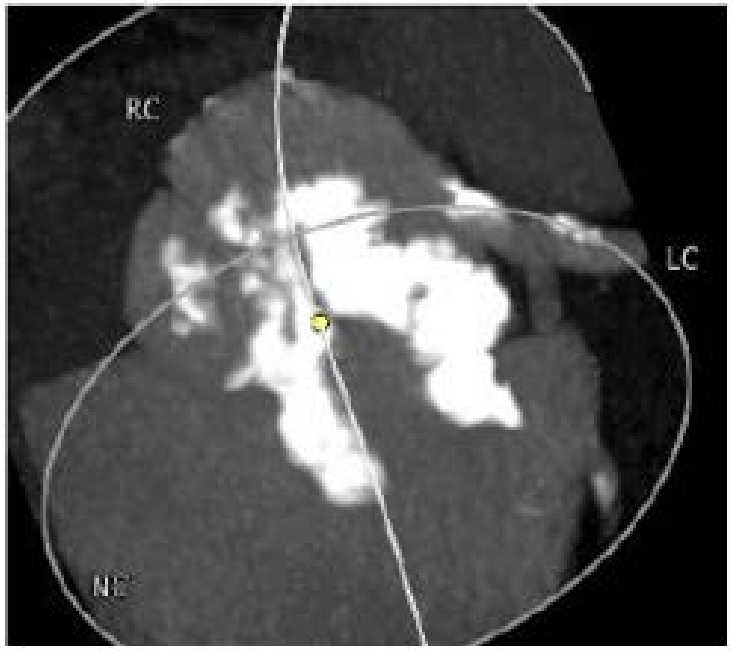


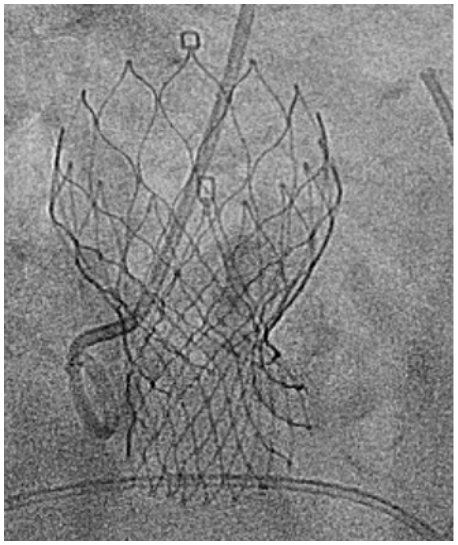
Severe LVOT Calcification

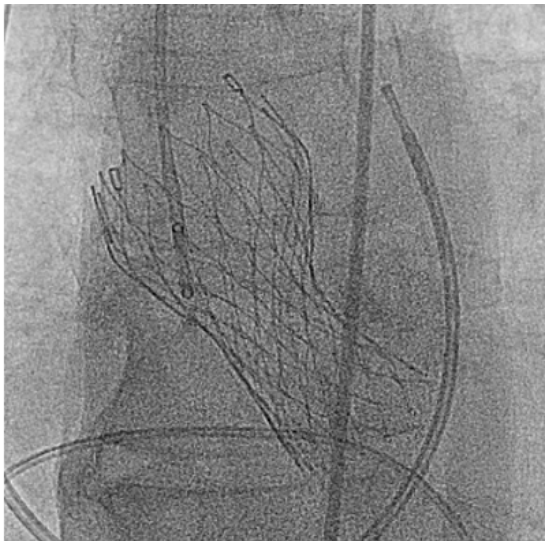






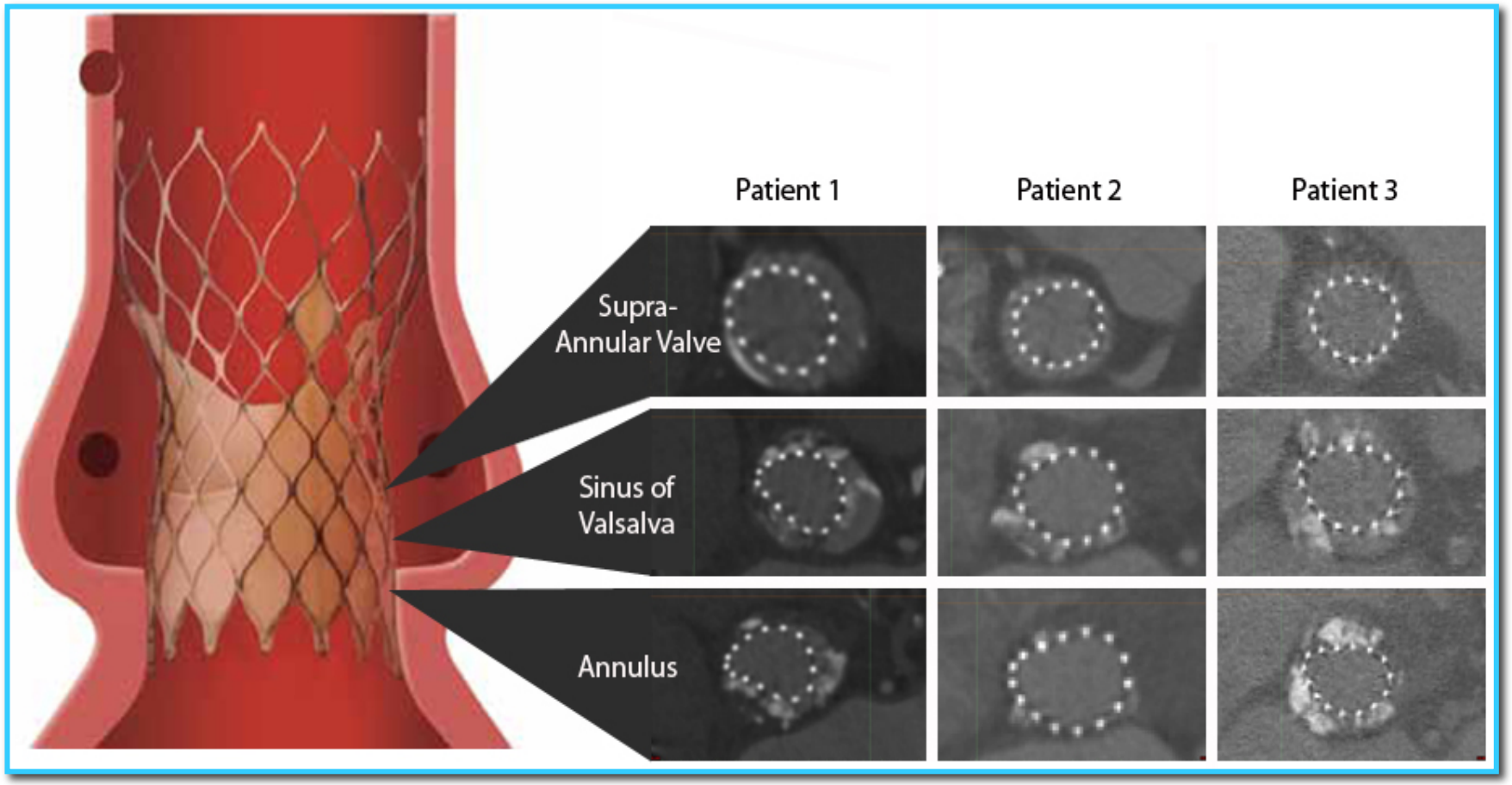






Asymmetric expansion at the annulus.
Supra annular function, without gradient.

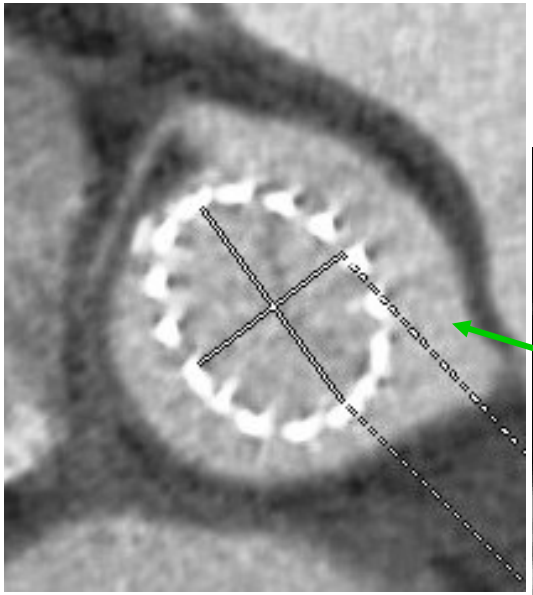
Supra-annular valve location



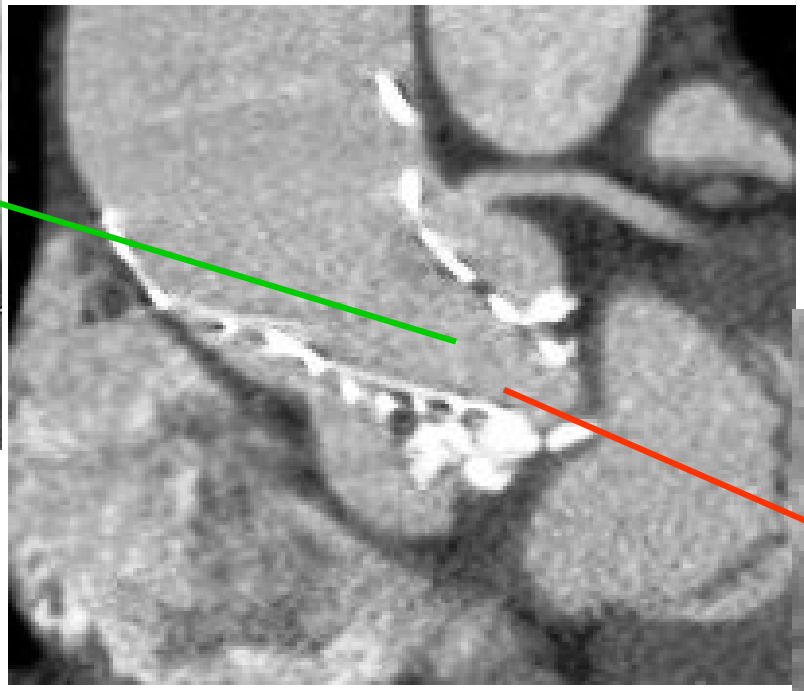
TAVI in Bicuspid Aortic Valve.

JC Laborde

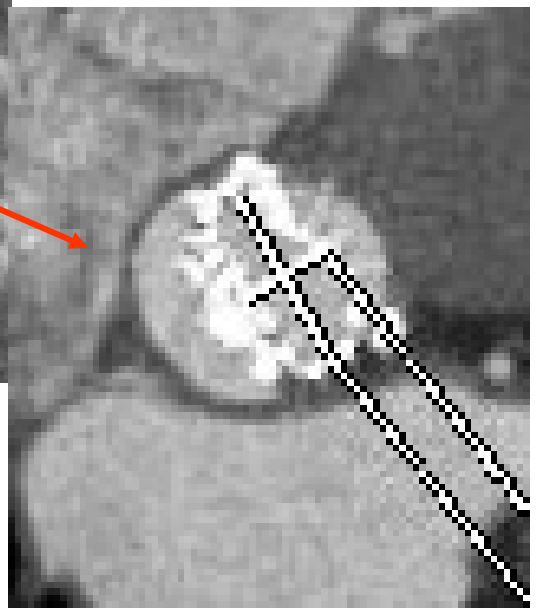
CT Scan, post implantation



Supra annular level

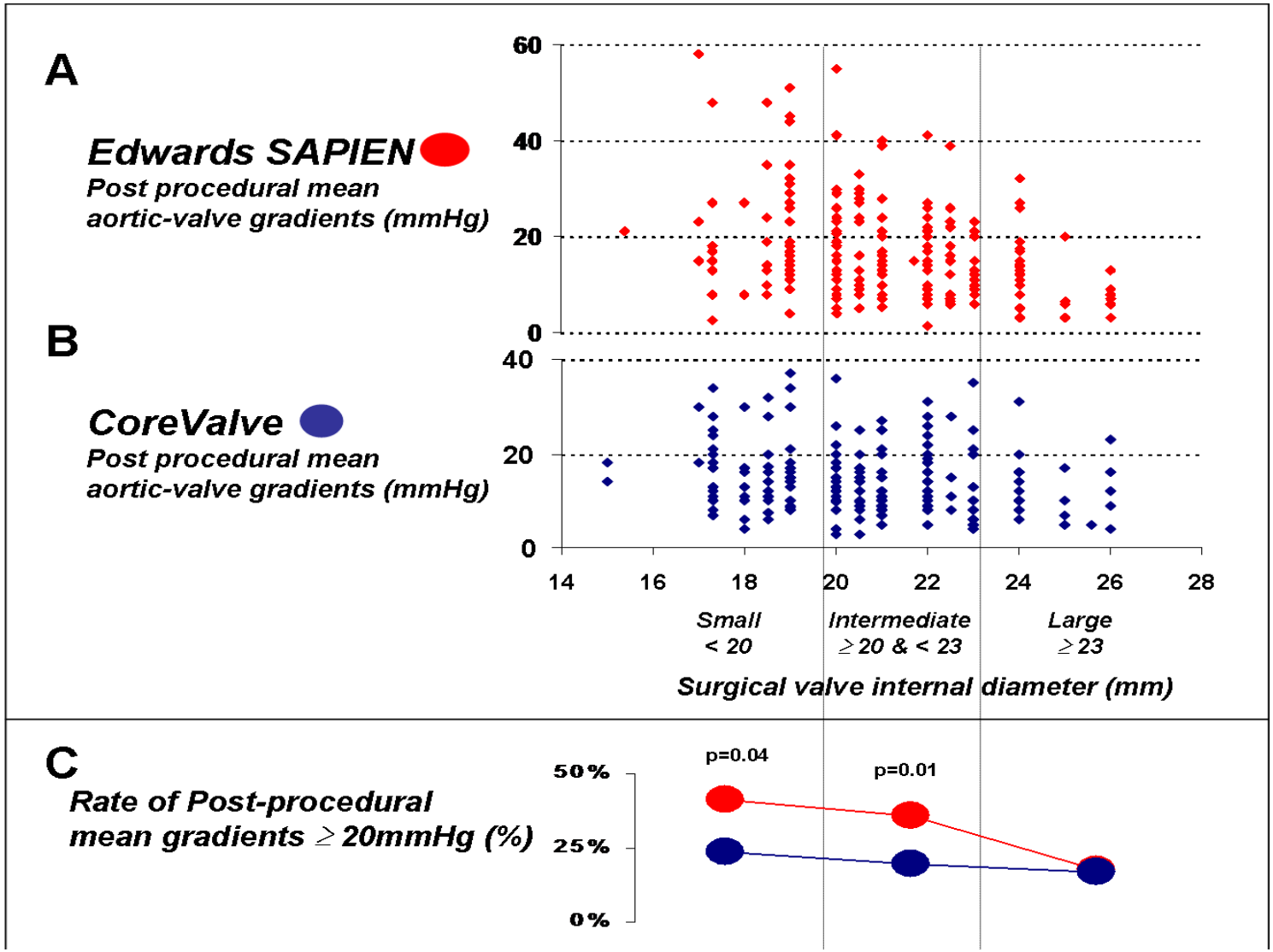


Annular level



Valve in Valve Registry

Dvir et al. JAMA. 2014;312(2):162-170



CoreValve for Pure AR

Roy et al. JACC 2013; 61:1577–84

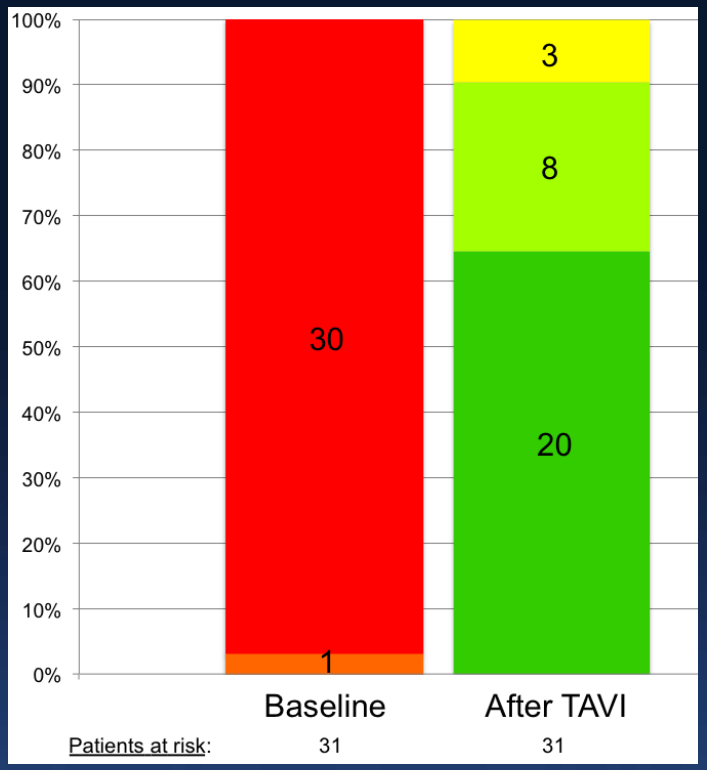
43 patients with pure or predominant AR.

91% with none or mild calcification.

Second valve required	8 (18.6)
Post-procedure AR grade	
I or lower	34 (79.1)
II	7 (16.3)
III	2 (4.7)
New permanent pacemaker	7 (16.3)

Jena Valve for Aortic Regurgitation. 31 pts.

German Registry. Seiffert et al, TVT 2014



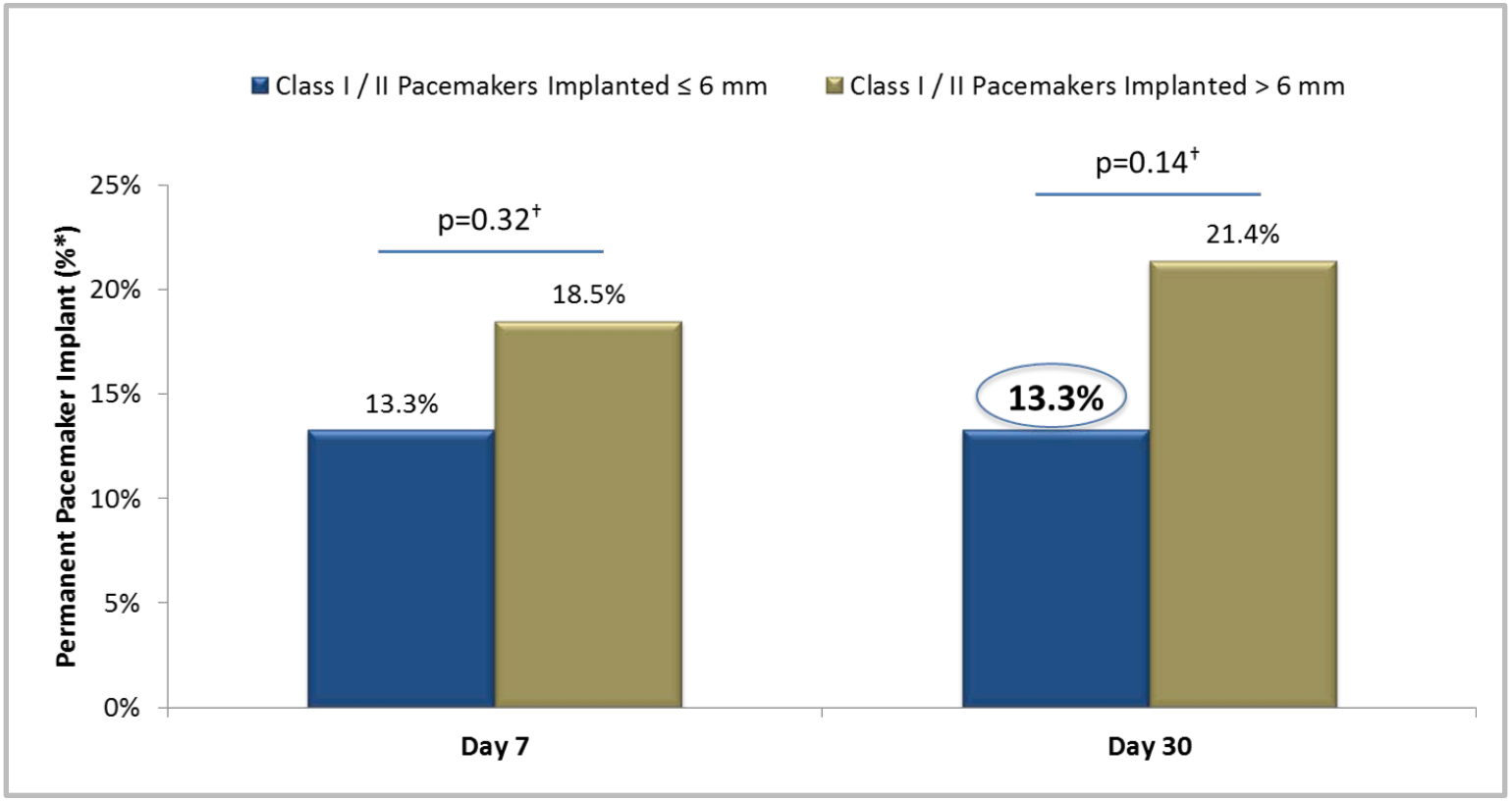
- Aortic regurgitation before and after implantation of the JenaValve (n=31)

CoreValve

Disadvantages:

- **Not retrievable until now.**
- **More contrast used by some operators.**
- **AV block: 19% PPM in IDE US trial**
- **PVL**
- **Precise deployment difficult.**
- **Possible embolization during deployment**

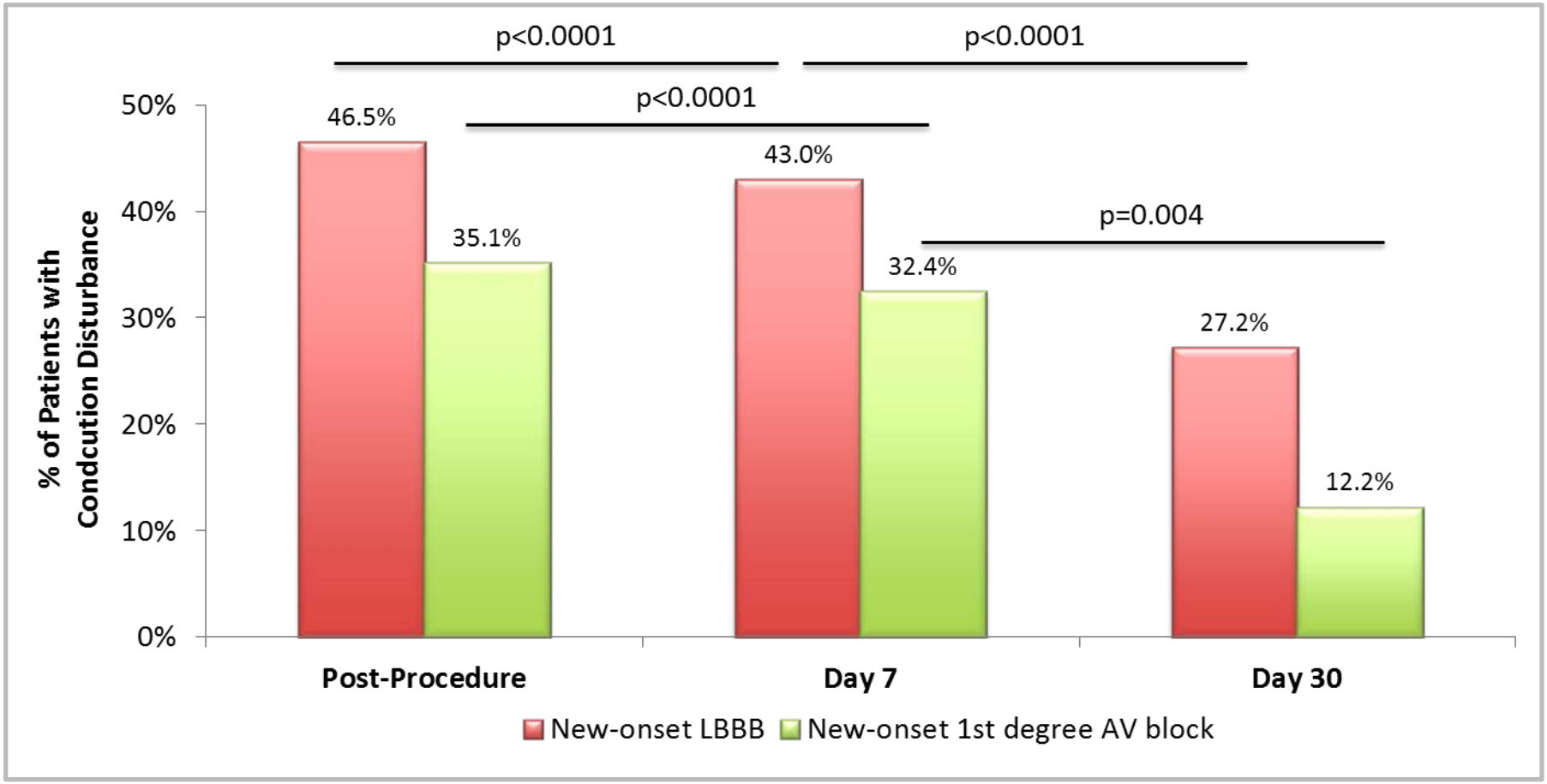
Need for PPM in Advance II Registry. < 6 mm vs > 6mm



Petronio et al.

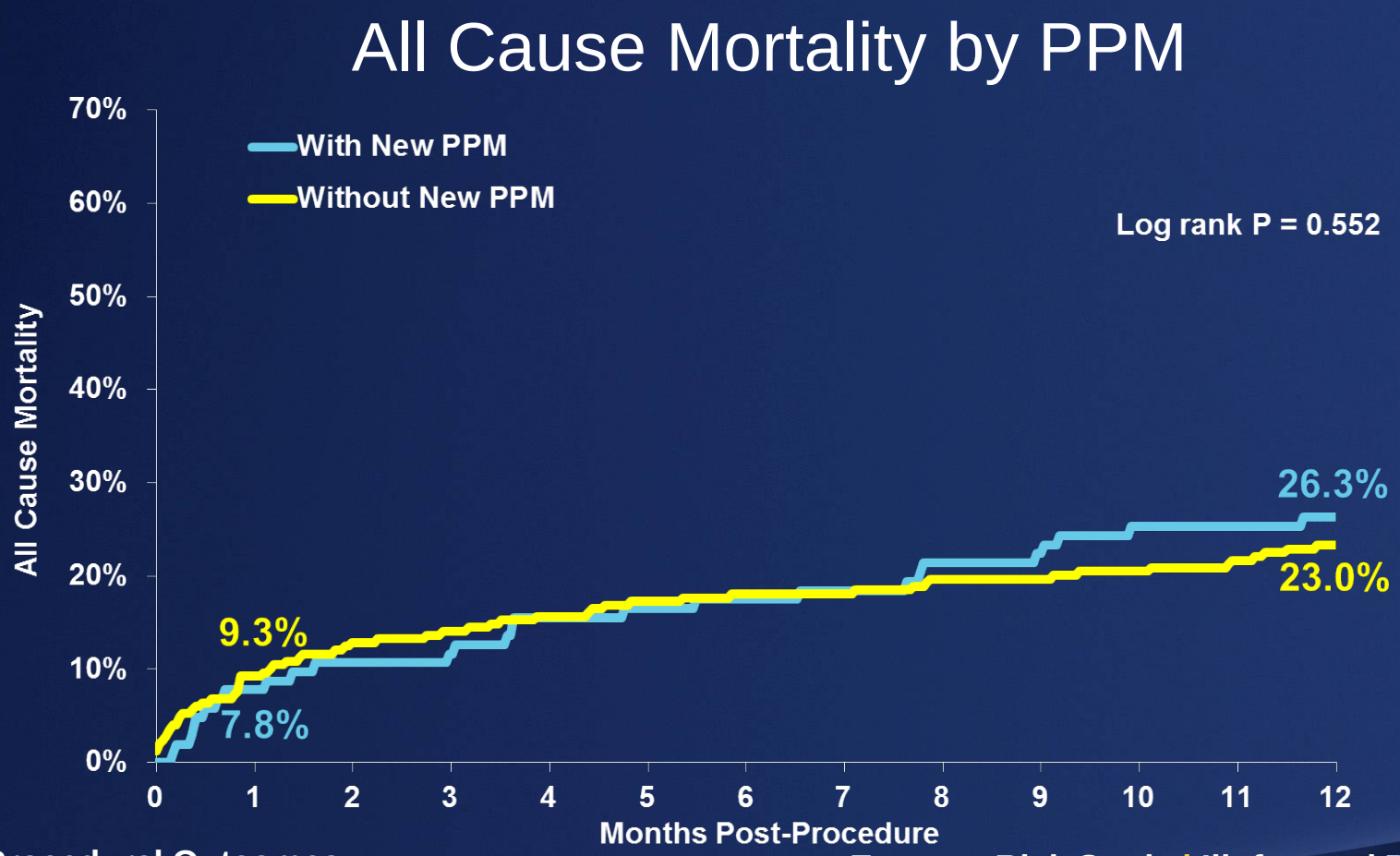
Conduction Disturbance Resolution

- Paired data demonstrated how new-onset conduction disturbances resolved over time
- 42% of new LBBB and 65% of new 1st degree AV block resolved spontaneously by day 30



Pacemaker Implantation Post-TAVR Not Associated With Increased Mortality

The CoreValve US Pivotal Trial



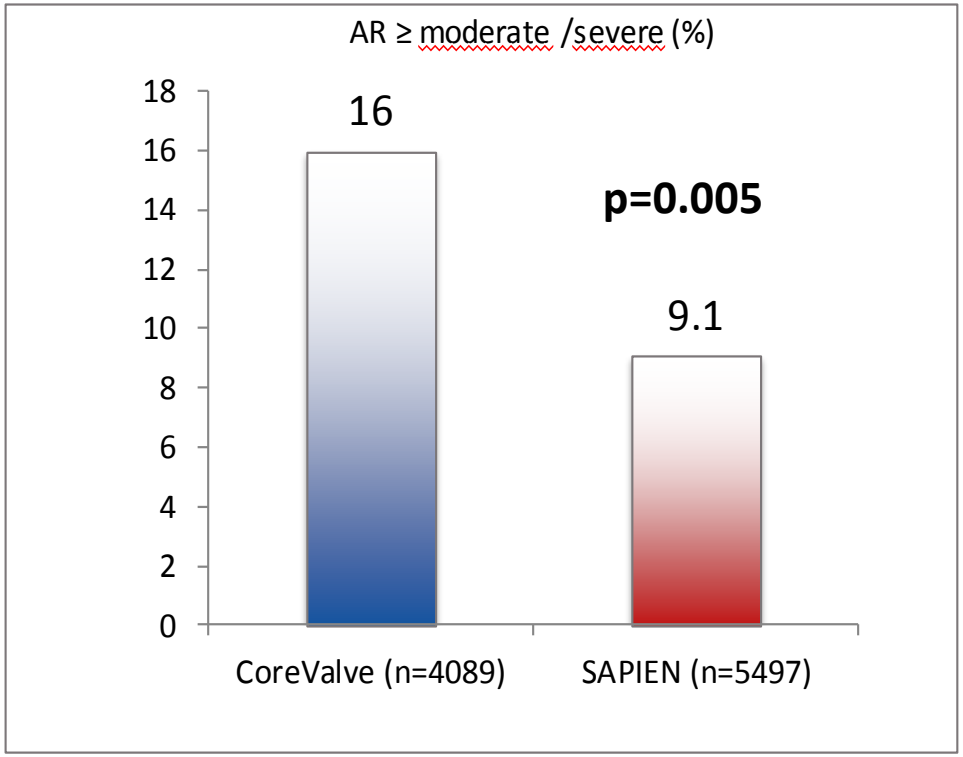
TCT 2013 Procedural Outcomes

Extreme Risk Study | Iliofemoral Pivotal

Perivalvular Leak

AR after TAVR

Meta-Analysis of 12,926 Patients from 45 Studies

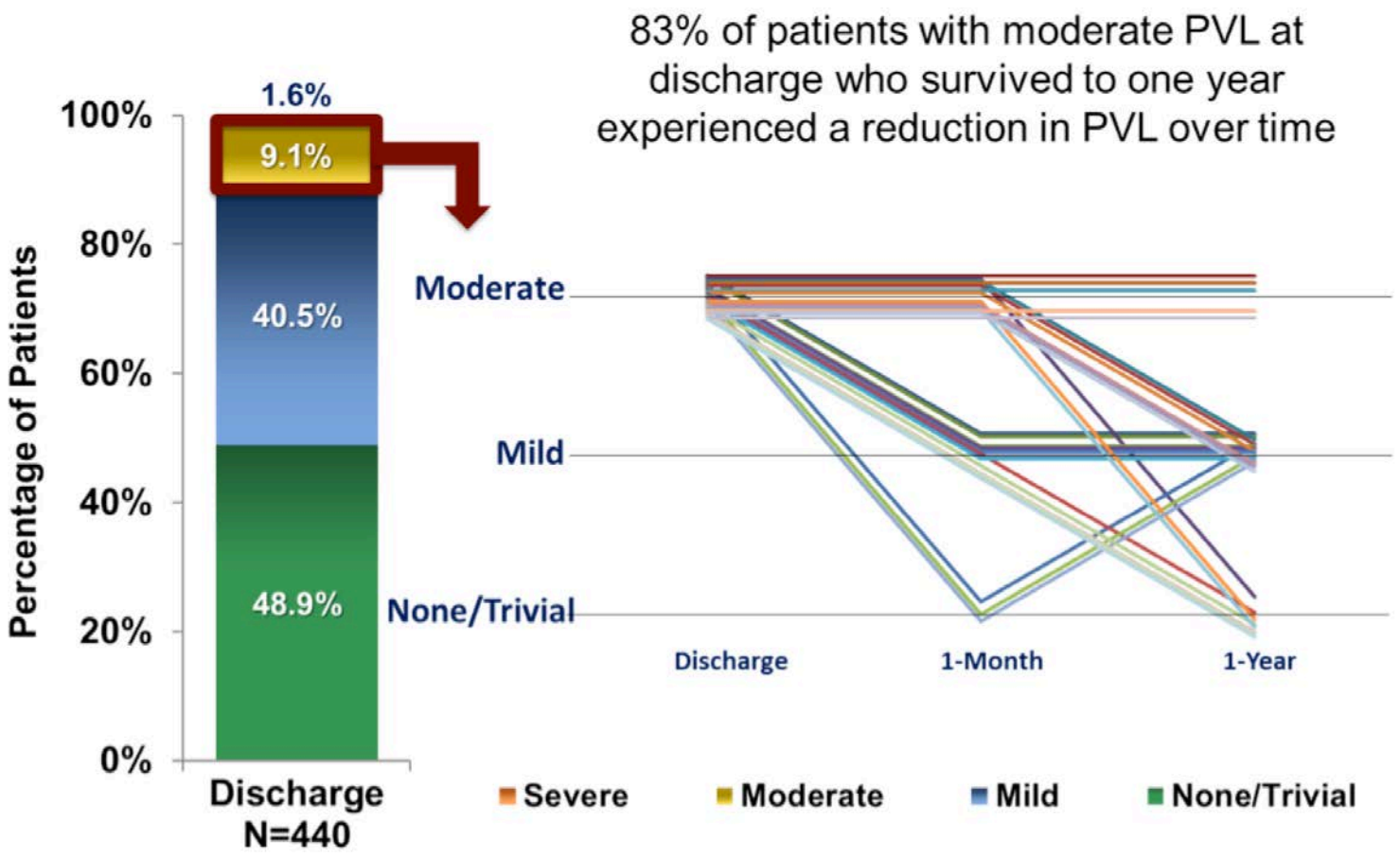


- **7,279 SAPIEN patients and 5,261 CoreValve patients**
- **predictors of AR were implantation depth, valve undersizing and agatston Ca++ score**

Athappan, MD , et al. J Am Coll Cardiol 2013;61: 1585–95

Change in AR post CoreValve.

Popma et al. JACC 2014;63:1872-81



Conclusions

- **CoreValve has proven to be an effective TAVR.**
- **Evolut R is better: repositionable/retrievable, and 14F.**
- **PPM use is high**
- **PVL is common, and can improve by 1 year.**
- **Supra annular function is advantageous in certain situations.**