

CoreValve Evolut R – Technology review and Clinical Results

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Updates on CoreValve

- Product Innovations: next generation platform Evolut R System received CE Mark September 2014
- Clinical Evidence: continued results reported from US and European trials

CoreValve Evolut R System

Product Overview

Building on the CoreValve Foundation

Proven in More Than 65,000 Implants Worldwide

Self-Expanding Frame

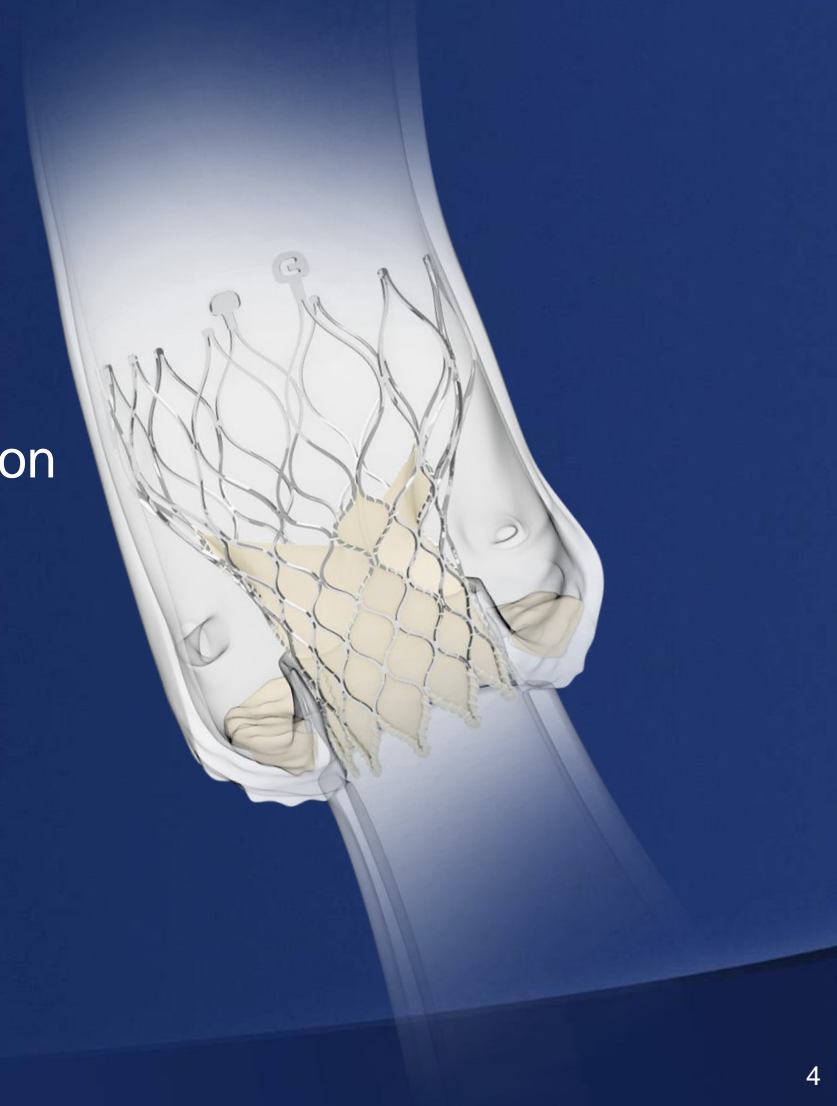
- Conforms and seals to the annulus
- The foundation for recapturability

Supra Annular Valve

- Maximize flow and optimize coaptation

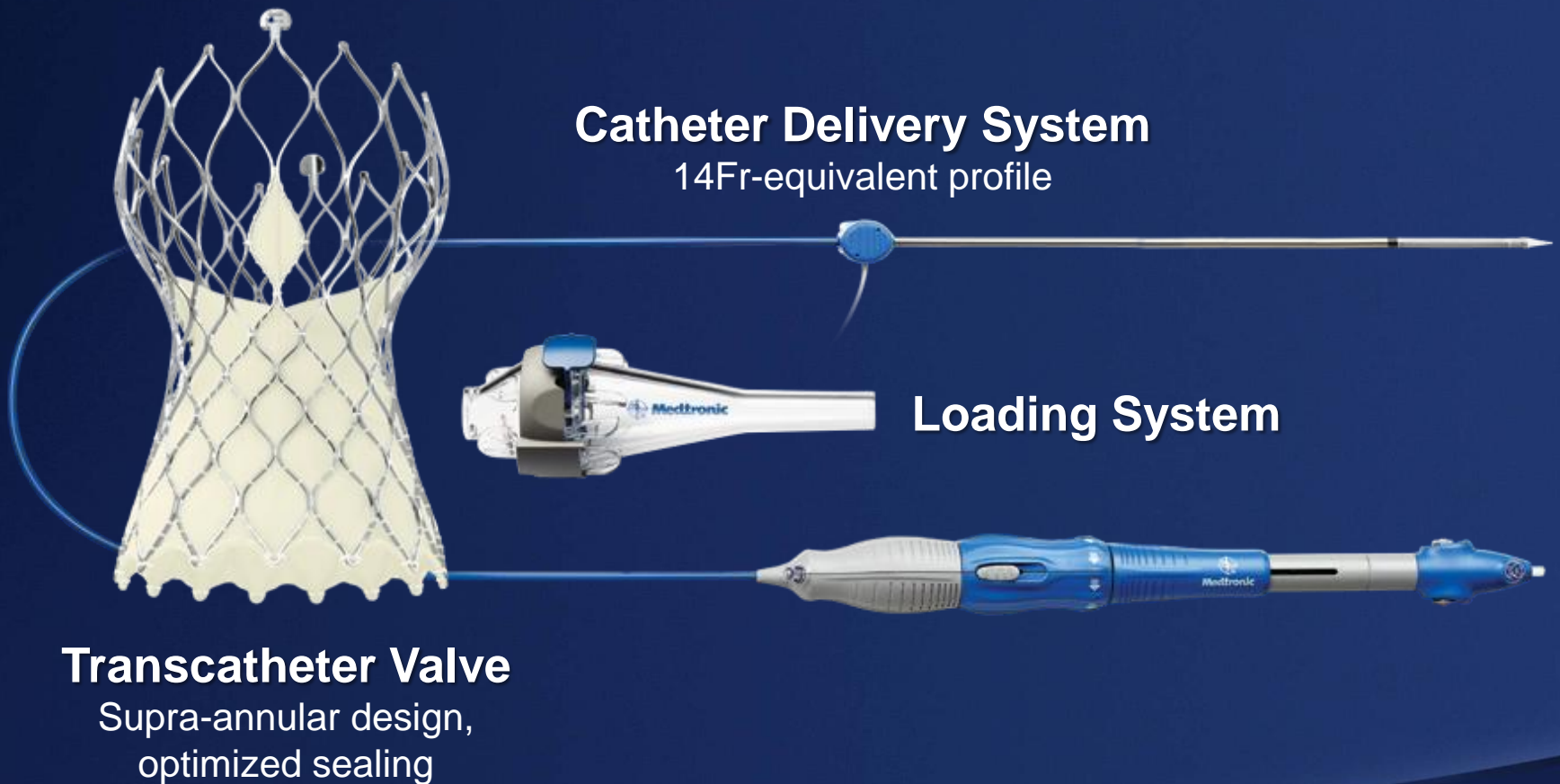
Porcine Pericardial Tissue

- Thinness for low profile delivery
- Strength and pliability for long-term durability



CoreValve Evolut R System

Recaptureable valve and delivery catheter with loading system



EnVeo R Delivery Catheter

14Fr-Equivalent Delivery Profile with InLine Sheath for Reduced Risk of Major Vascular Complications and Expanded Access



Medtronic Enveo R delivery catheter InLine Sheath

CoreValve w/
18 Fr Cook Sheath

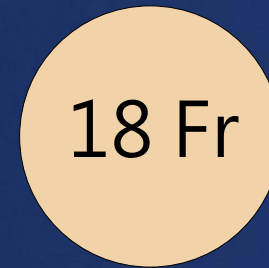


7.3 mm

4 Fr reduction

68% cross-sectional
area reduction

EnVeo R w/
InLine Sheath

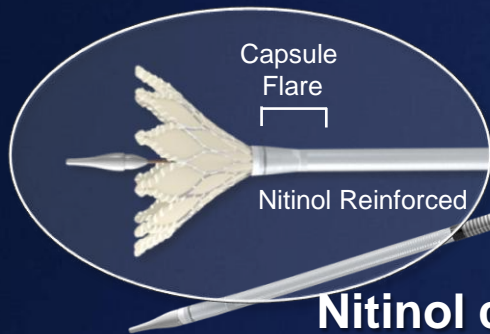


6.0 mm

Minimal lumen artery diameter = 5 mm

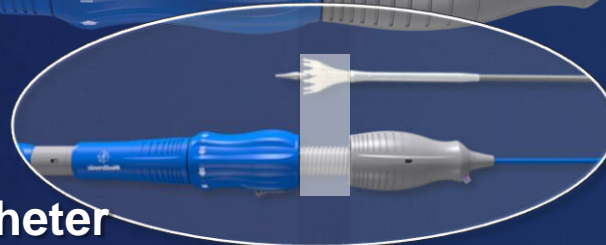
EnVeo R Delivery Catheter

Designed for First Time Positioning Accuracy



Nitinol capsule with flare for uniform, controlled expansion

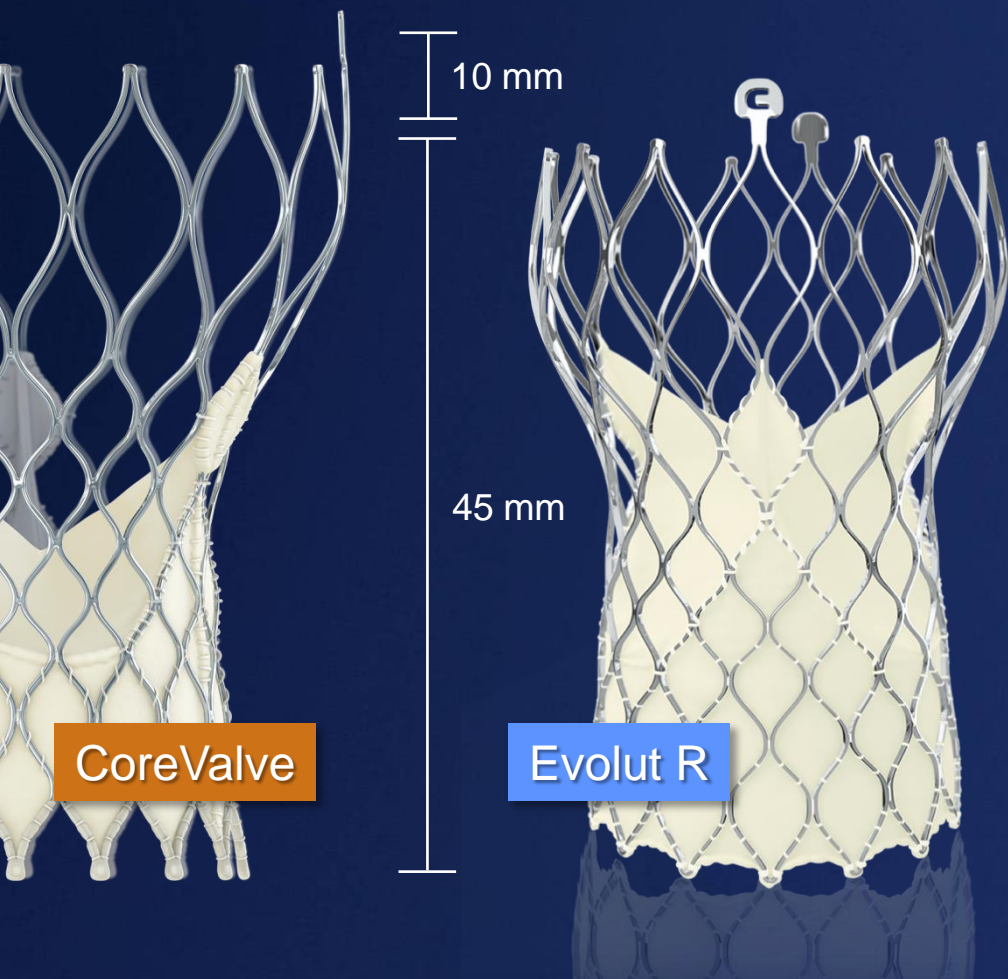
Flexible catheter for self-centering



1:1 catheter response

Evolut R Valve Design

Hemodynamic Performance with Reduced PVL



Redesigned Outflow

- Reduced height, reshaped for improved fit, especially in angulated anatomy

Enhanced sealing

- Optimized cover index (sizing),
- Consistent radial force
- Extended skirt (1mm)

Note: Measurements provided are approximate and do not include paddles/frame loops
Images may not be to scale and are for illustration purposes only.

EnVeo R Catheter Shaft Design



Video is for illustration purposes only.

Redesigned catheter shaft enables:

- Deployment accuracy
- 1:1 response
- Flexible catheter construction
- Ability to recapture, if needed

Evolut R Optimized Annular Sealing

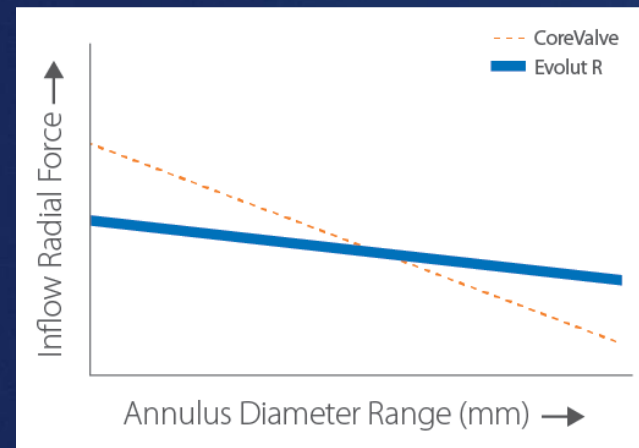
Cover Index (% oversizing)

Optimized cover index associated with reduced PVL

Authors	# Patients	Cover Index (%)	
		PVL \geq 2	PVL < 2
Vasa-Nicotera et al. 2012 ¹	122	13.5 \pm 3.6	16.0 \pm 4.4
Gotzmann et al. 2012 ²	198	13.7 \pm 6.1	15.9 \pm 6.2
Sinning et al. 2012 ³	146	10.1 \pm 6.3	16.0 \pm 4.6

Consistent Radial Force

Improved sealing across full annulus range



Extended Skirt
Expanded landing zone

Updates in Clinical Evidence

US Pivotal Extreme Risk Study – 2 year results

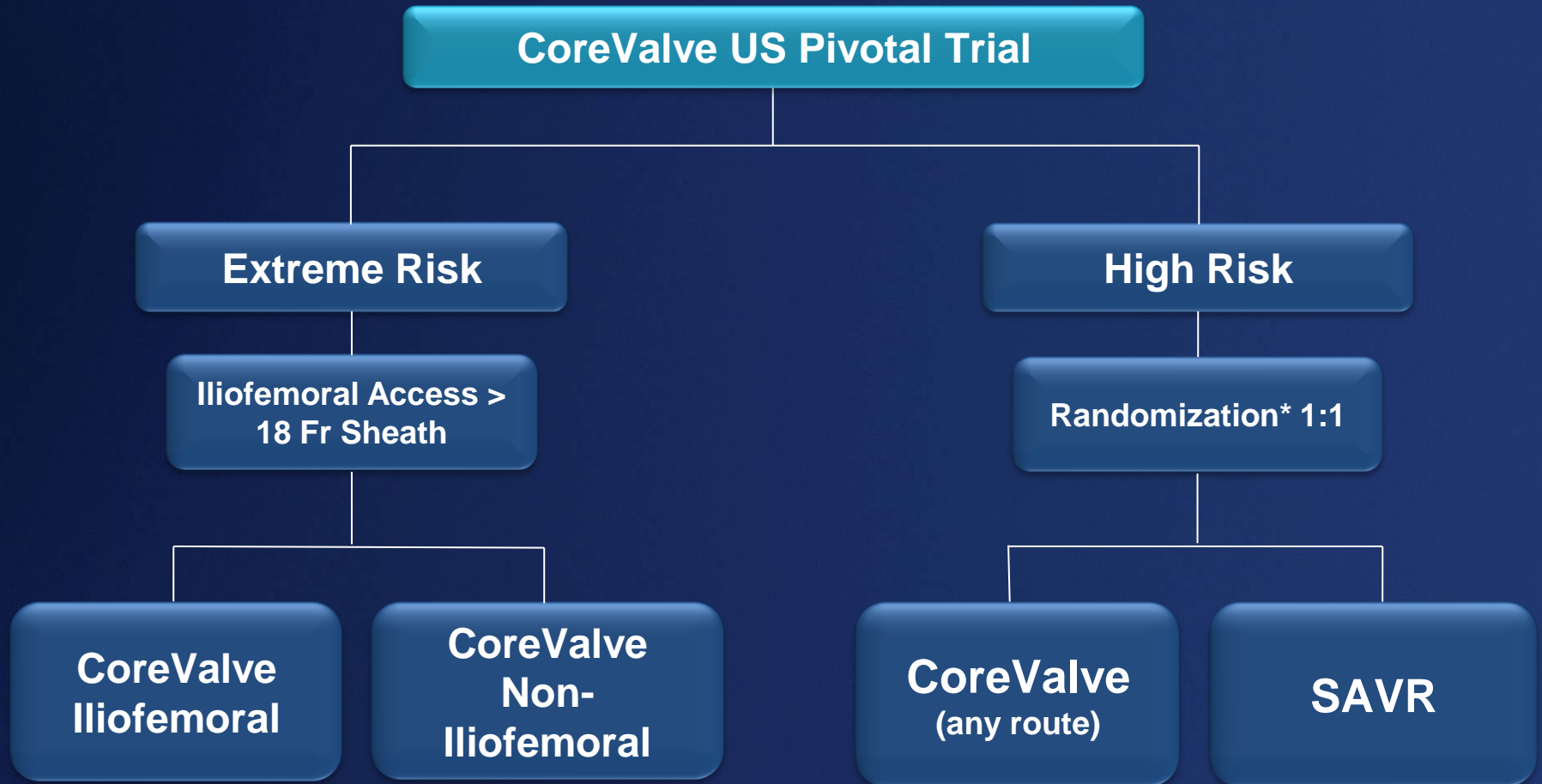
US Pivotal Extreme Risk Non-Iliofemoral 1 year results

US Pivotal High Risk Study – 1 year results

ADVANCE – 2 year results

ADVANCE II

Pivotal Trial Design

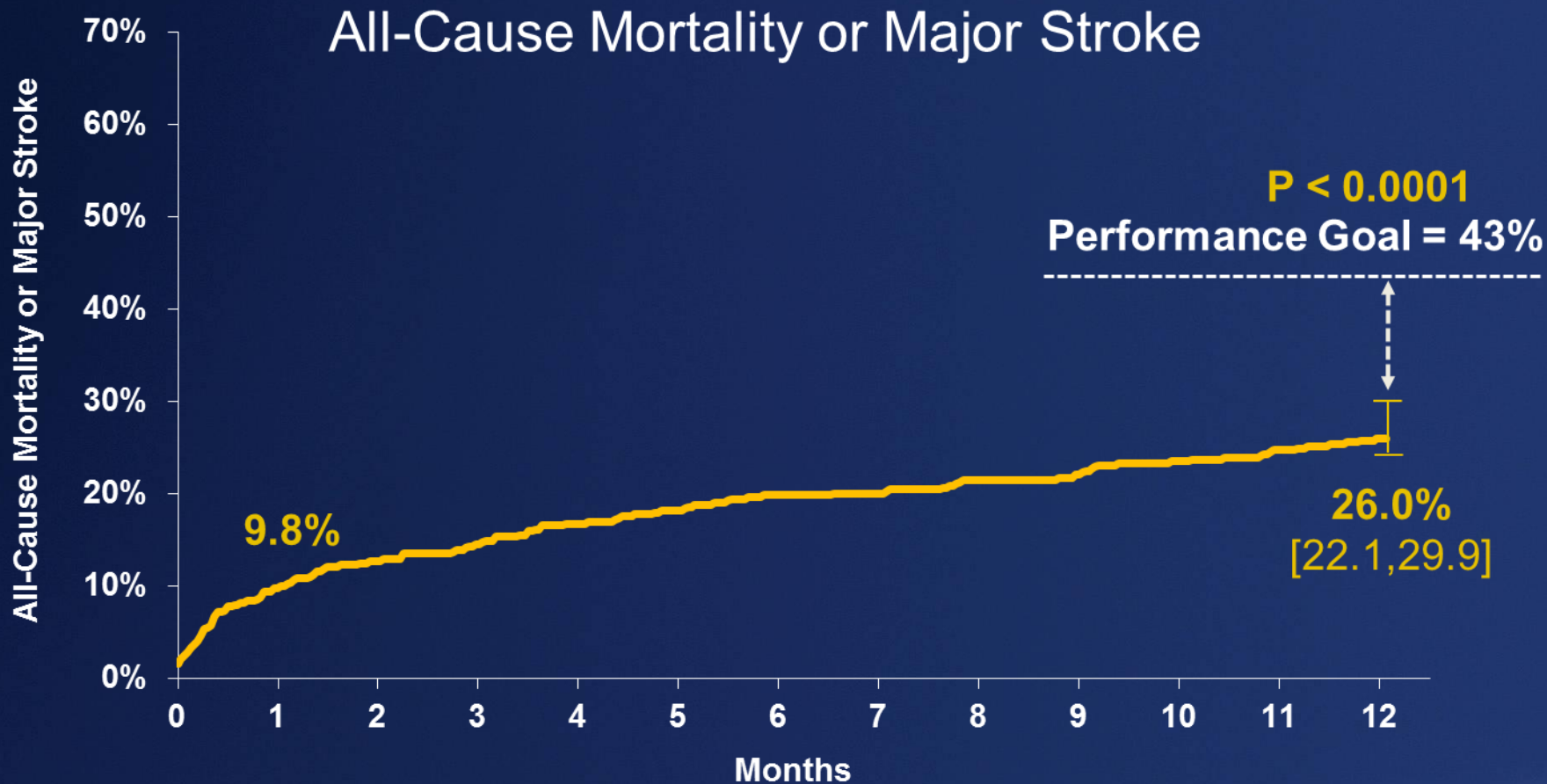


* Randomization stratified by intended access site

CoreValve US Pivotal Trial Extreme Risk

Two Year results presented at TCT 2014 (September 2014)

Extreme Risk | 1 Year Primary Endpoint



Extreme Risk | All-Cause Mortality or Major Stroke

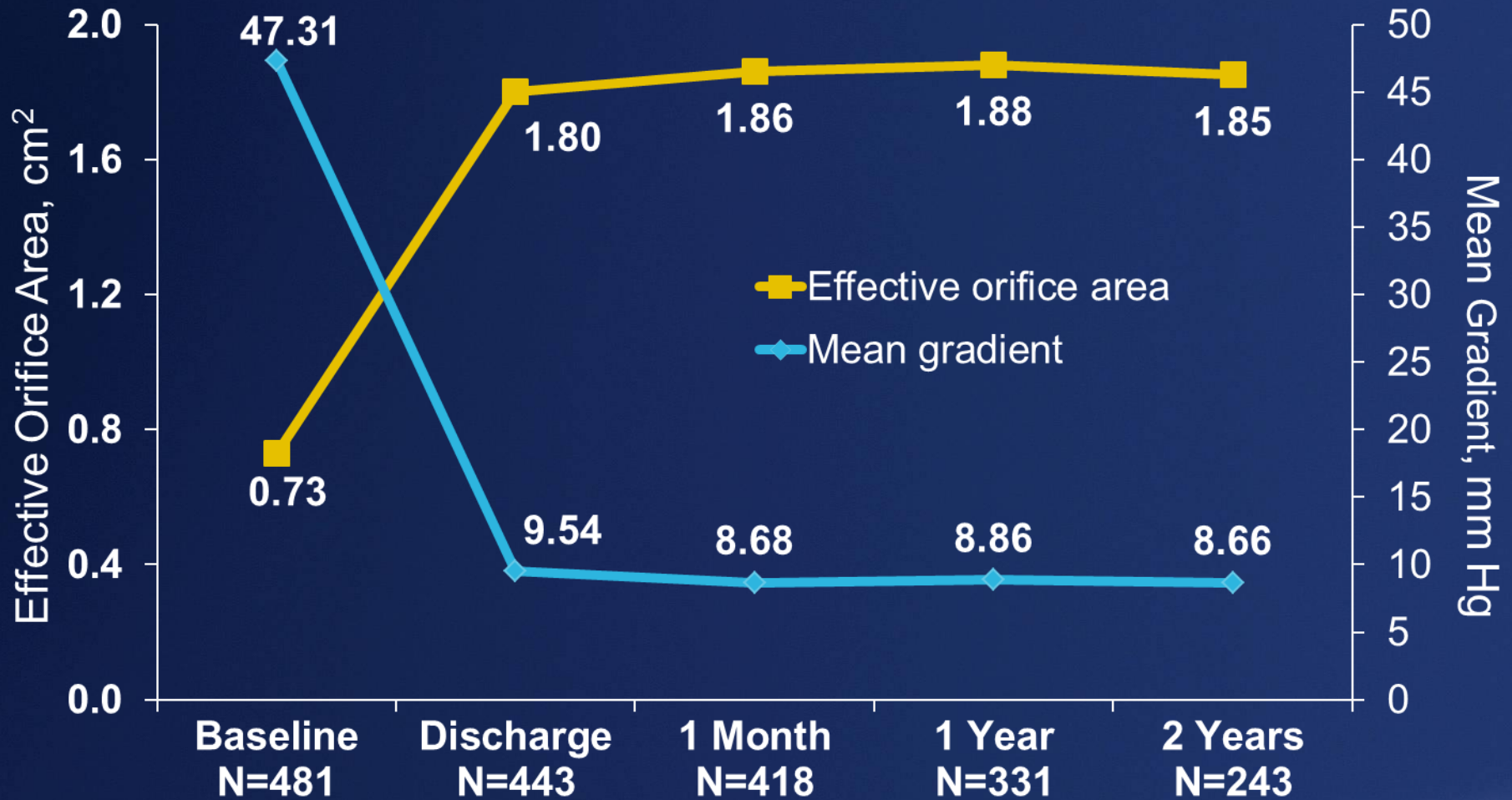


* Calculated rate for 117 events in 179 patients (65.4%, lower confidence bound of 57.9% by Exact method) (Makkar RR, et al, New Engl J Med, 2012)

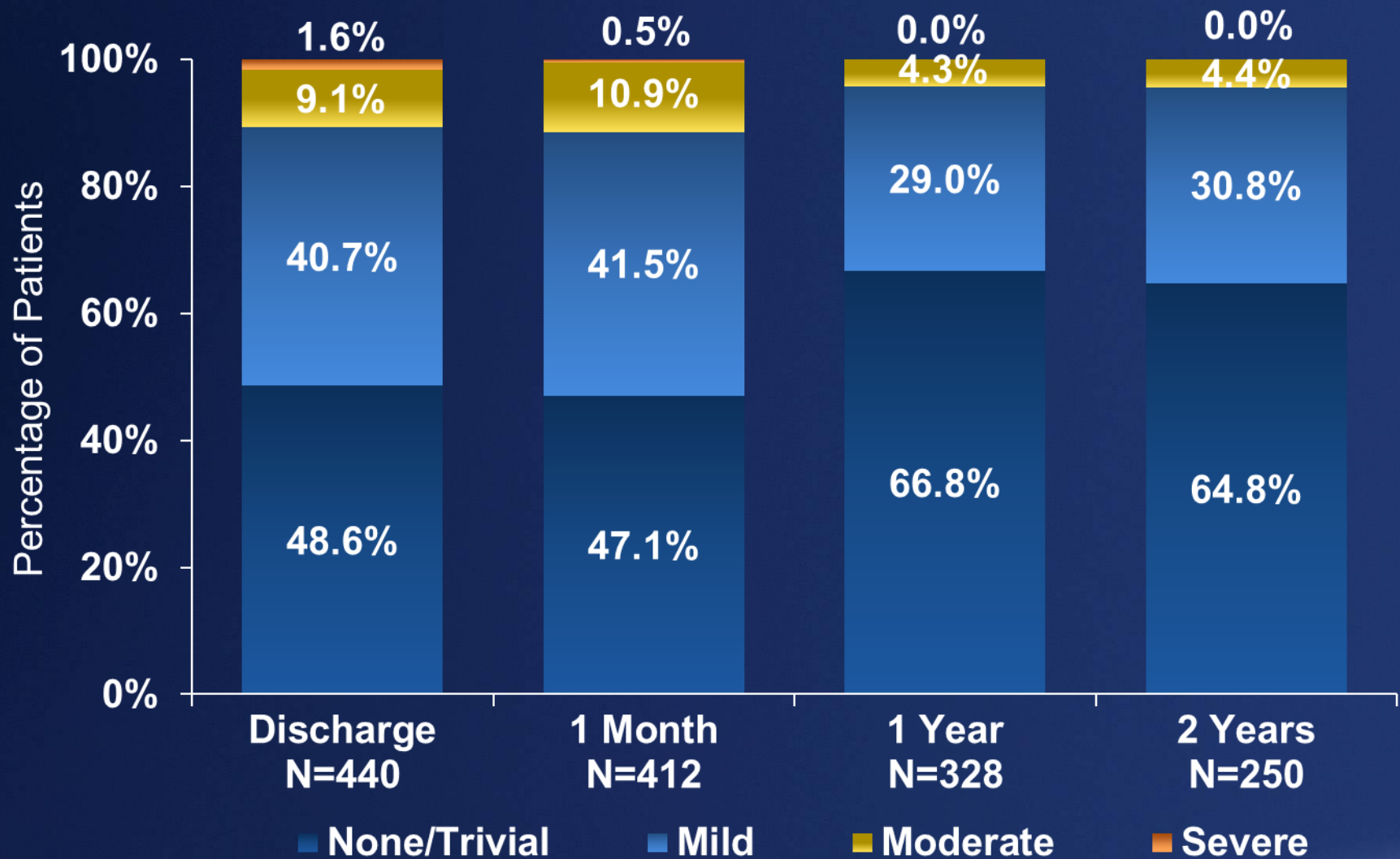
Extreme Risk | 2 Year Mortality – Landmark Analysis



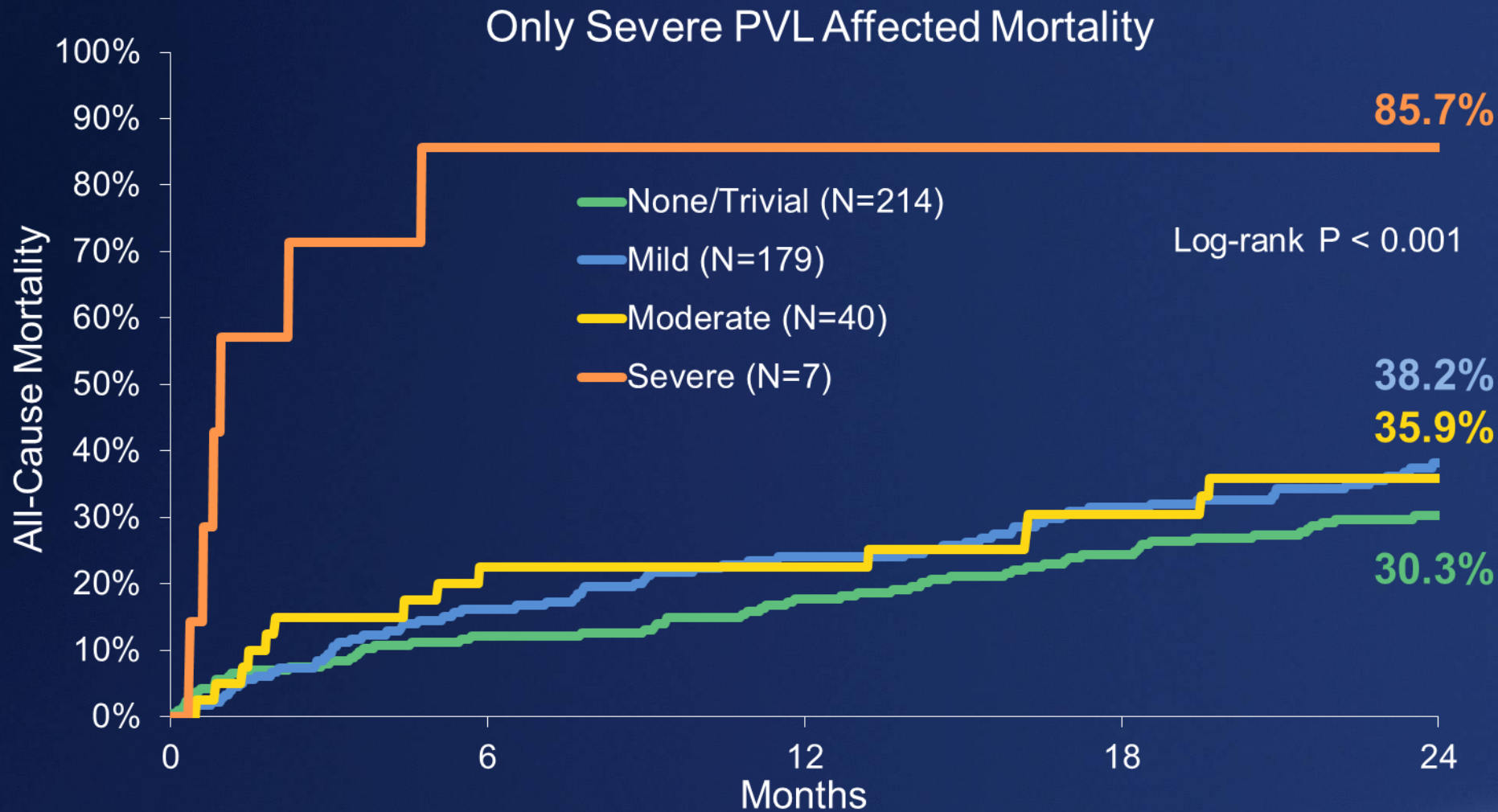
Extreme Risk | Echocardiographic Findings



Extreme Risk | Paravalvular Regurgitation



Extreme Risk | PVL and All-Cause Mortality



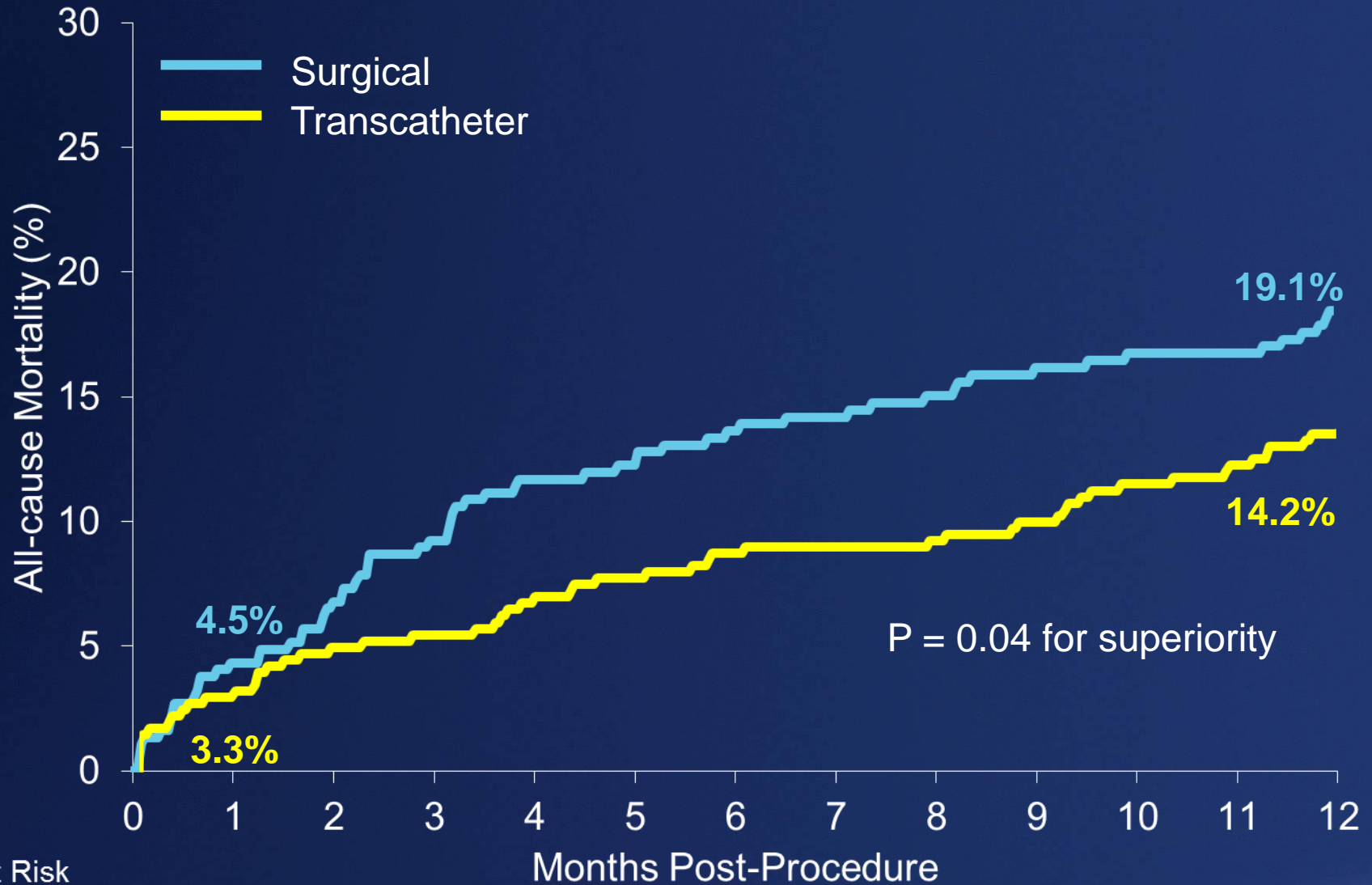
Extreme Risk | Conclusions

- At 2 years the CoreValve US Pivotal Extreme Risk Study showed:
 - Low rates of all-cause mortality
 - Low rates of major stroke
 - Improvement in NYHA classifications
 - Durable improvement in hemodynamic valve performance (EOA and mean gradients)
 - Low rates of moderate or severe aortic insufficiency
 - No association of mild or moderate paravalvular regurgitation on mortality

CoreValve US Pivotal Trial High Risk

Results presented at ACC 2014 (March 2014)

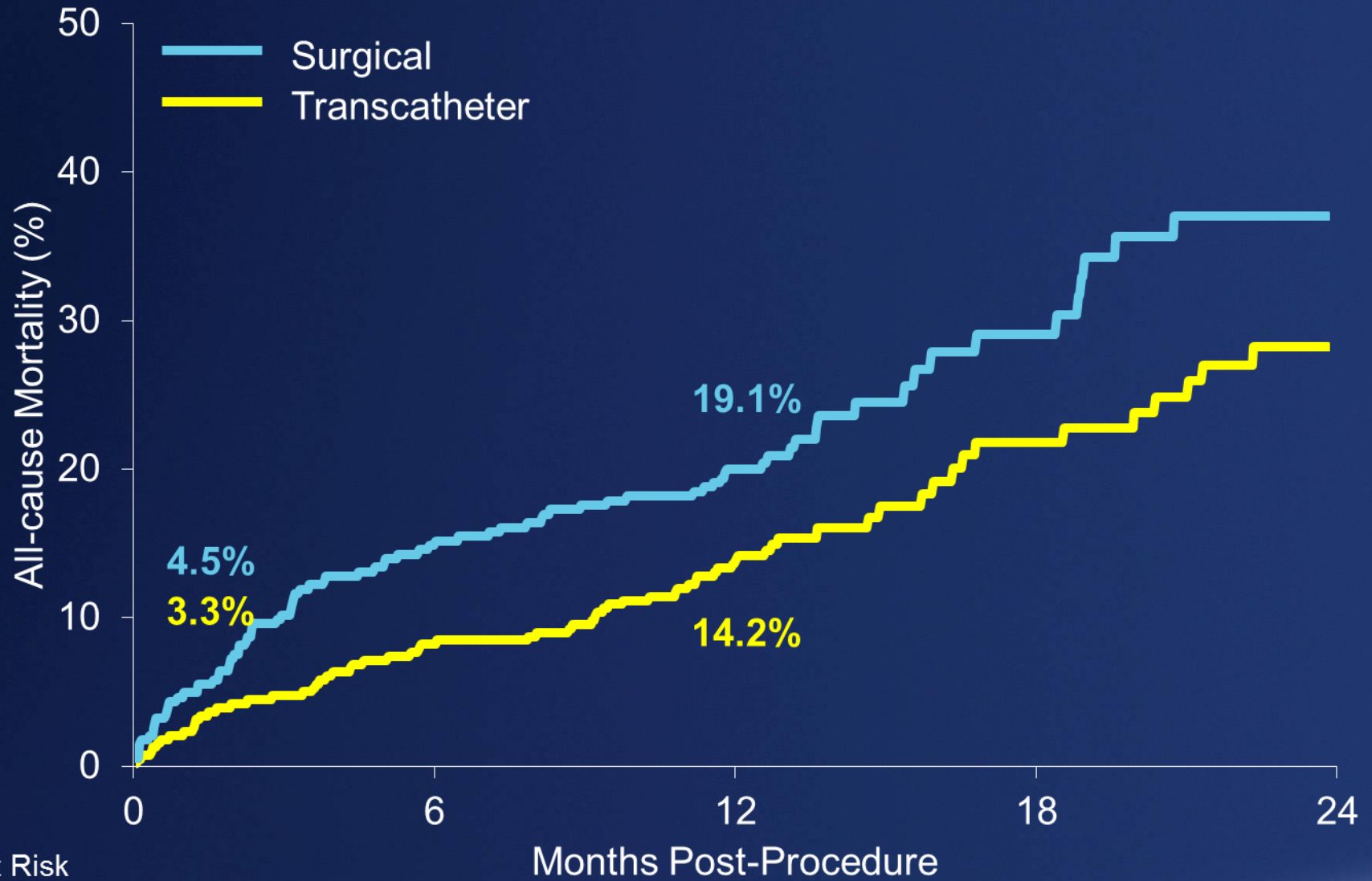
High Risk | Primary Endpoint: 1 Year All-cause Mortality



No. at Risk

Surgical	357	341	297	274
Transcatheter	390	377	353	329

High Risk | 2 Year All-cause Mortality



No. at Risk

Surgical	357	341	274	28
Transcatheter	390	377	329	38

Thank you



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