
Sapien 3 or Evolut R: Different Indications?

Alan C. Yeung, MD
Li Ka Shing Professor of Medicine
Chief, Division of Cardiovascular Medicine
Medical Director, Cardiovascular Services
Stanford University School of Medicine



Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Grant/Research Support
- Scientific Advisory Board
- Executive Physician Council

Company

- Edwards Lifesciences, Abbott
- Medtronic, Abbott
- Boston Scientific Corp



Balloon-expandable THV Sapien 3

(Cobalt frame, bovine pericardium, outer skirt,
precise positioning)



Self-expandable THV, REPOSITIONABLE Medtronic EvolutR

(Nitinol frame, porcine pericardium, longer skirt)

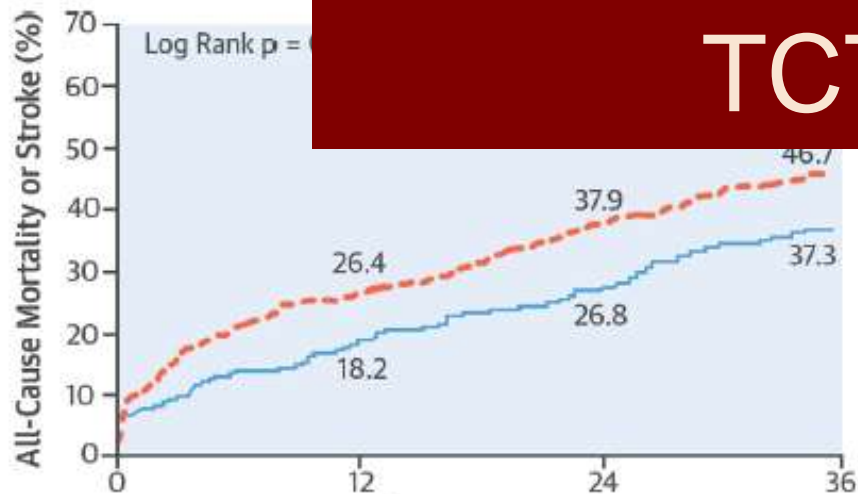


3-Year Outcomes in High-Risk Patients Who Underwent Surgical or Transcatheter Aortic Valve Replacement

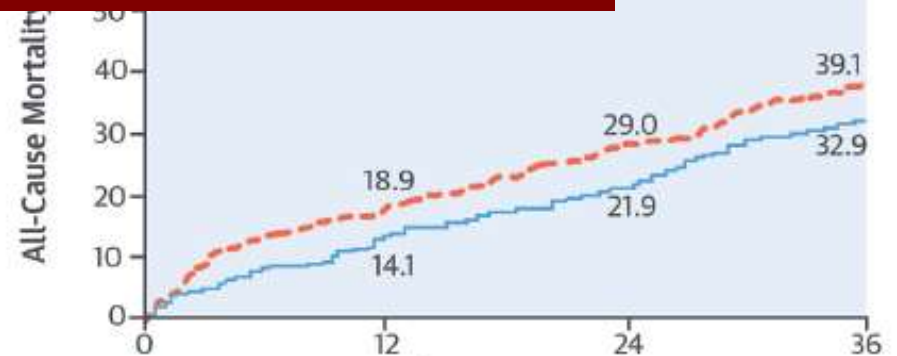


G. Michael Deeb, MD,^a Michael J. Reardon, MD,^b Stan Chetcuti, MD,^a Himanshu J. Patel, MD,^a
 P. Michael Grossman, MD,^a Steven J. Yakubov, MD,^c Neal S. Kleiman, MD,^b Joseph S. Coselli, MD,^d

5 Year High Risk Results
Tom Gleason et al
TCT2019



At Risk	0	12	24	36
TAVR	391	319	273	165
SAVR	359	257	208	128



At Risk	0	12	24	36
TAVR	391	335	292	180
SAVR	359	283	235	148

Our Most Recent Landmark Clinical Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients

M.J. Reardon, N.M. Van Mieghem, J.J. Popma, N.S. Kleiman, L. Søndergaard, M. Mumtaz, D.H. Adams, G.M. Deeb, B. Maini, H. Gada, S. Chetcuti, T. Gleason, J. Heiser, R. Lange, W. Merhi, J.K. Oh, P.S. Olsen, N. Piazza, M. Williams, S. Windecker, S.J. Yakubov, E. Grube, R. Makkar, J.S. Lee, J. Conte, E. Vang, H. Nguyen, Y. Chang, A.S. Mugglin, P.W.J.C. Serruys, and A.P. Kappetein, for the SURTAVI Investigators*

SURTAVI Study Features

SURTAVI RCT

17 sites



65 sites

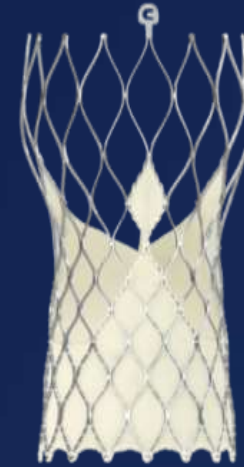


5 sites



CoreValve (n=724)

94% TF
4% DA
2% SCA



Evolut R (n=139)

16%
second
generation
valves

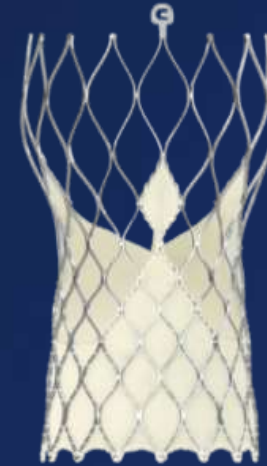
SURTAVI CAS

59 sites



CoreValve (n=20)

95.6% TF
0.4% DA
4% SCA



Evolut R (n=254)

93%
second
generation
valves

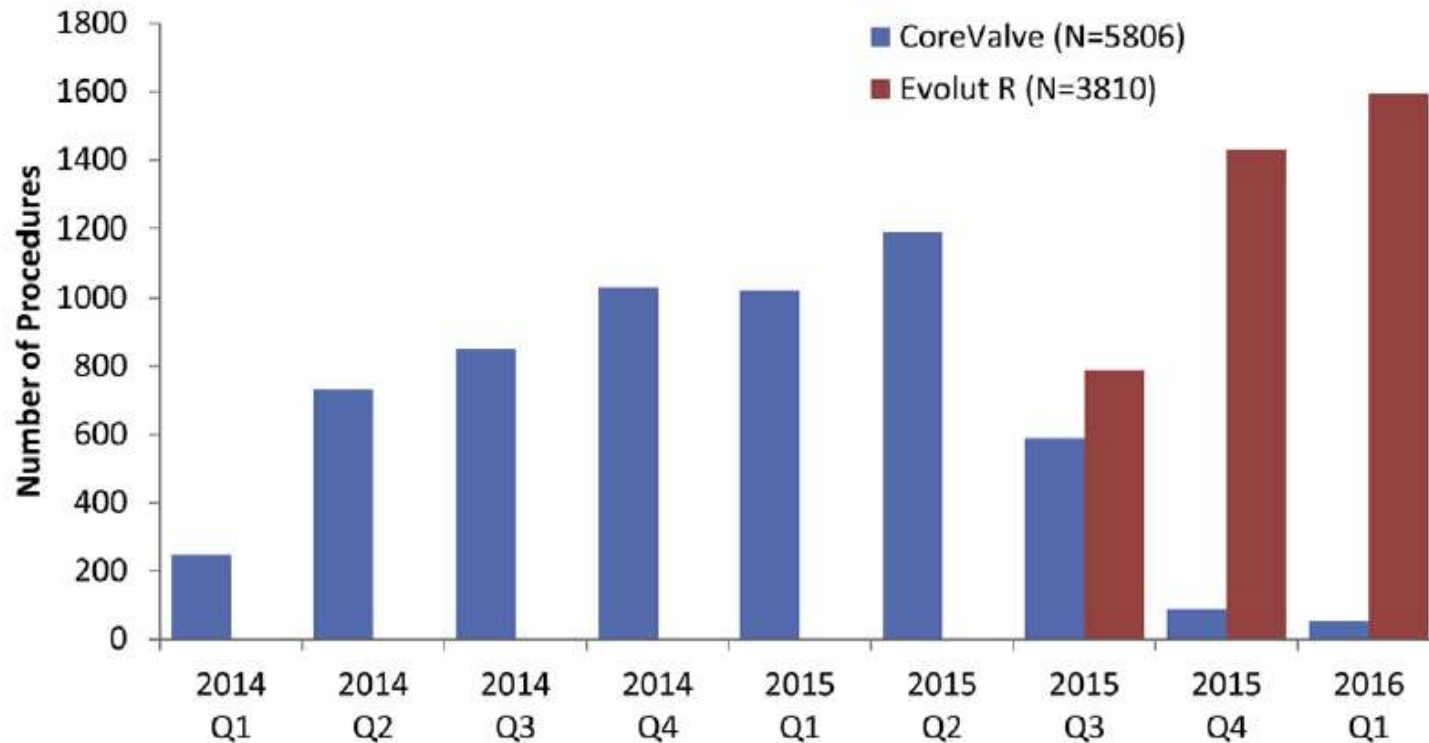
SURTA VI – Continued Access Study (CAS)

30 Days	RCT			CAS
	SAVR (N=796)	TAVR (N=864)	P	TAVR (N=275)
All-cause mortality or disabling stroke	3.8	2.8	0.26	0.4
All-cause mortality	1.6	2.1	0.50	0.0
Disabling stroke	2.4	1.2	0.06	0.4
All stroke	5.4	3.3	0.03	1.5

¹Van Meighem et al., presented at TCT 2017

Evolut R Commercial Adoption in the US

FIGURE 1 Commercial Adoption of TAVR



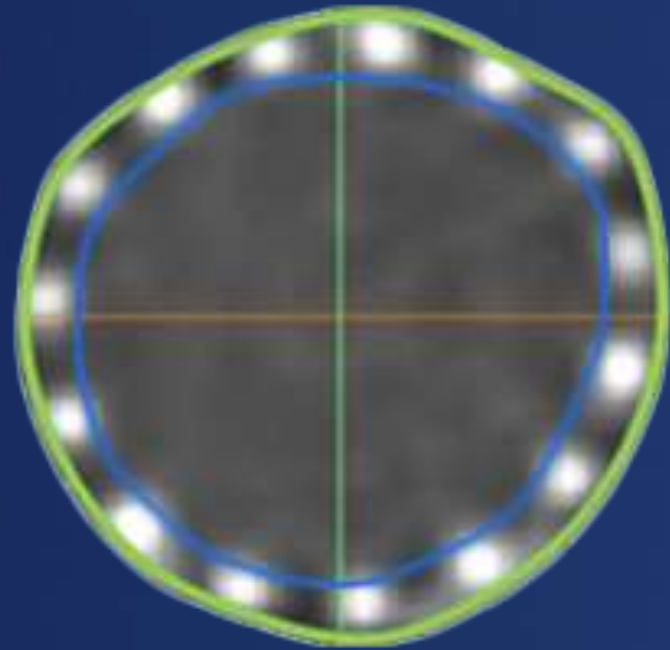
Commercial adoption of transcatheter aortic valve replacement (TAVR) with the CoreValve and Evolut R prostheses in the United States. Q = quarter.

TVT Registry: CoreValve v. Evolut R

	CoreValve N=5,806	Evolut R N=3,810	p Value
Need for a 2nd valve	4.5	2.2	<0.001
Device migration	0.6	0.2	0.01
Device success	94.9	96.3	0.001
Vascular complication	4.8	4.9	0.69
Unplanned vascular surgery	4.2	3.4	0.04
New PPM or ICD	19.2	16.6	0.002
Atrial fibrillation	4.3	3.0	0.001
Stroke	2.7	2.6	0.74
All-cause mortality	3.7	2.7	0.01

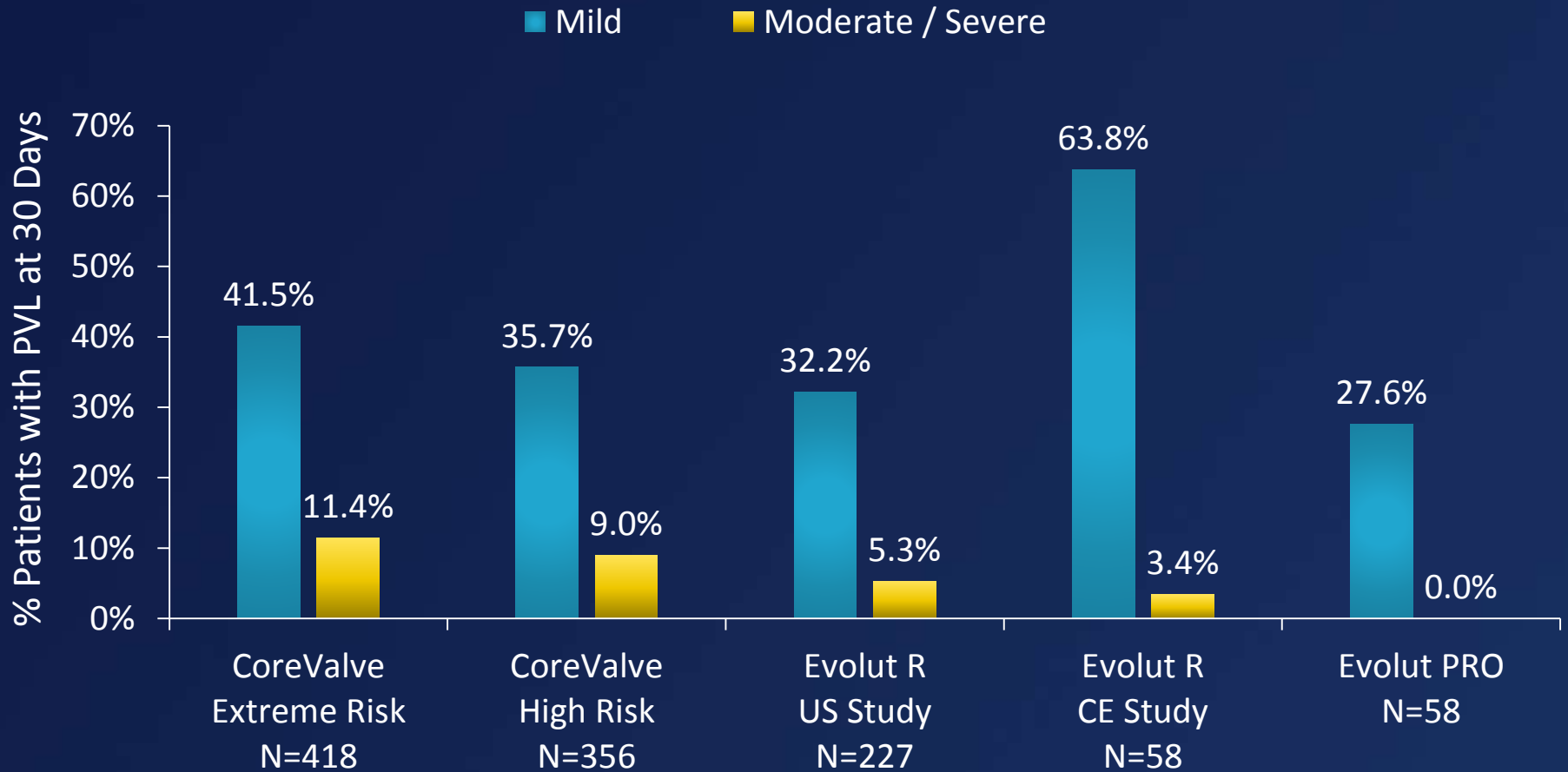
Evolut Pro

The thin pericardial wrap provides 8 x increase in surface area contact and reduces “open spaces” between frame struts



Paravalvular Leak

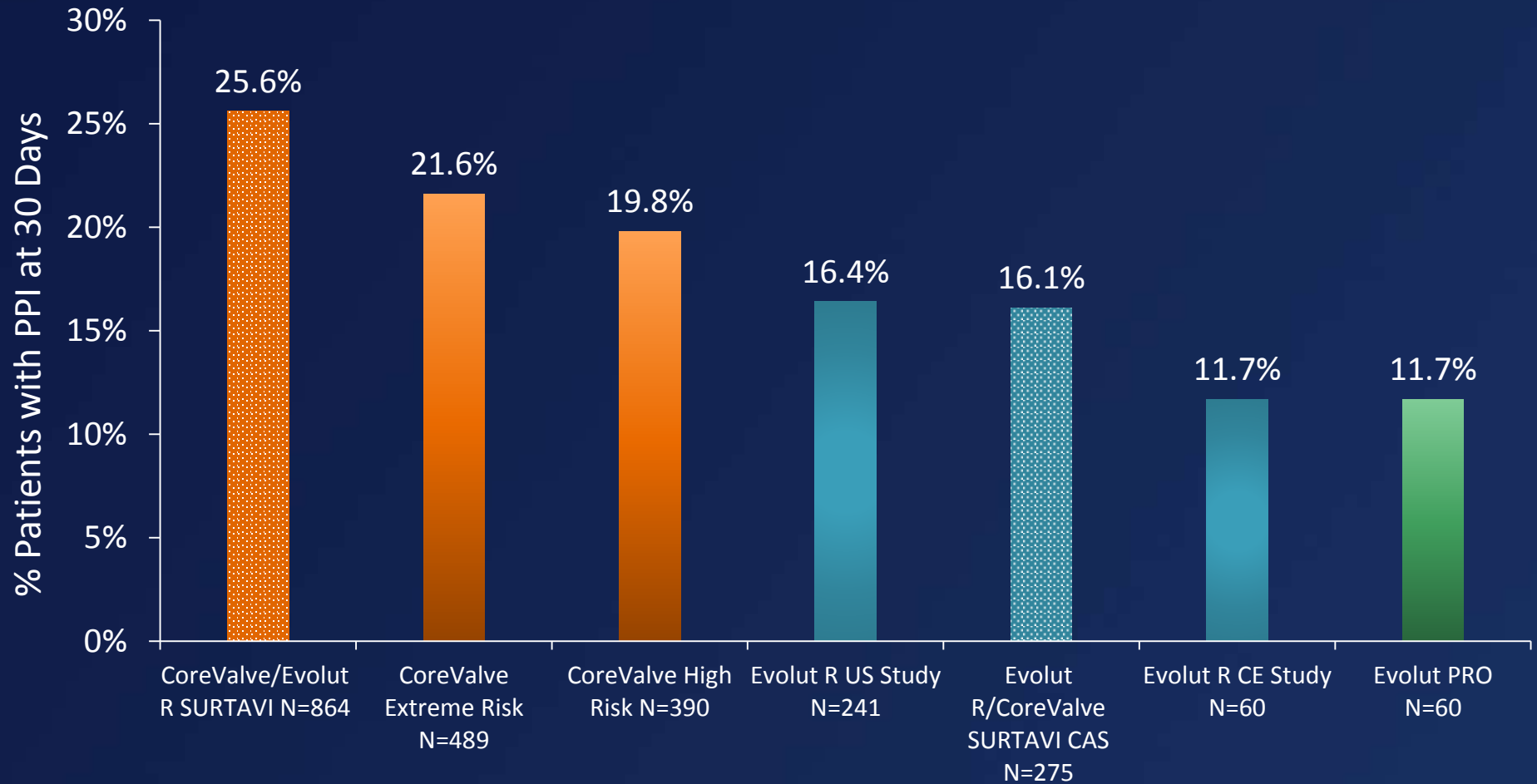
Rates at 30 Days



¹Adams, et al., *N Engl J Med* 2014; 370: 1790-8; ²Manoharan, et al., *J Am Coll Cardiol Interv* 2015; 8: 1359-67; ³Popma et al., *JACC Cardiovasc Interv.* 2017 Feb 13;10(3):268-275; ⁴Popma et al., *J Am Coll Cardiol.* 2014 May 20;63(19):1972-81; ⁵Forrest et al., Presented at TCT 2017

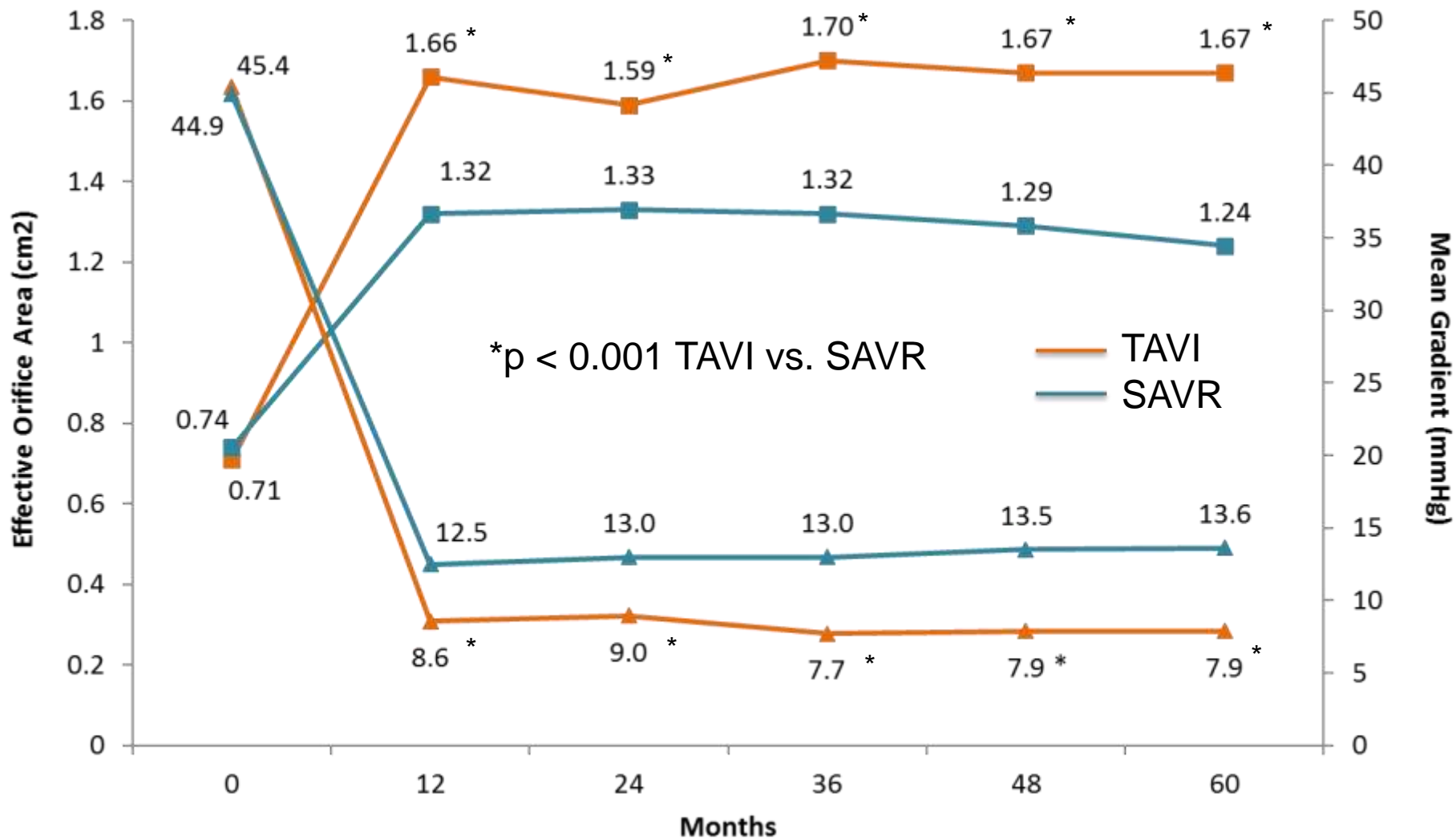
Permanent Pacemakers

Rates at 30 Days

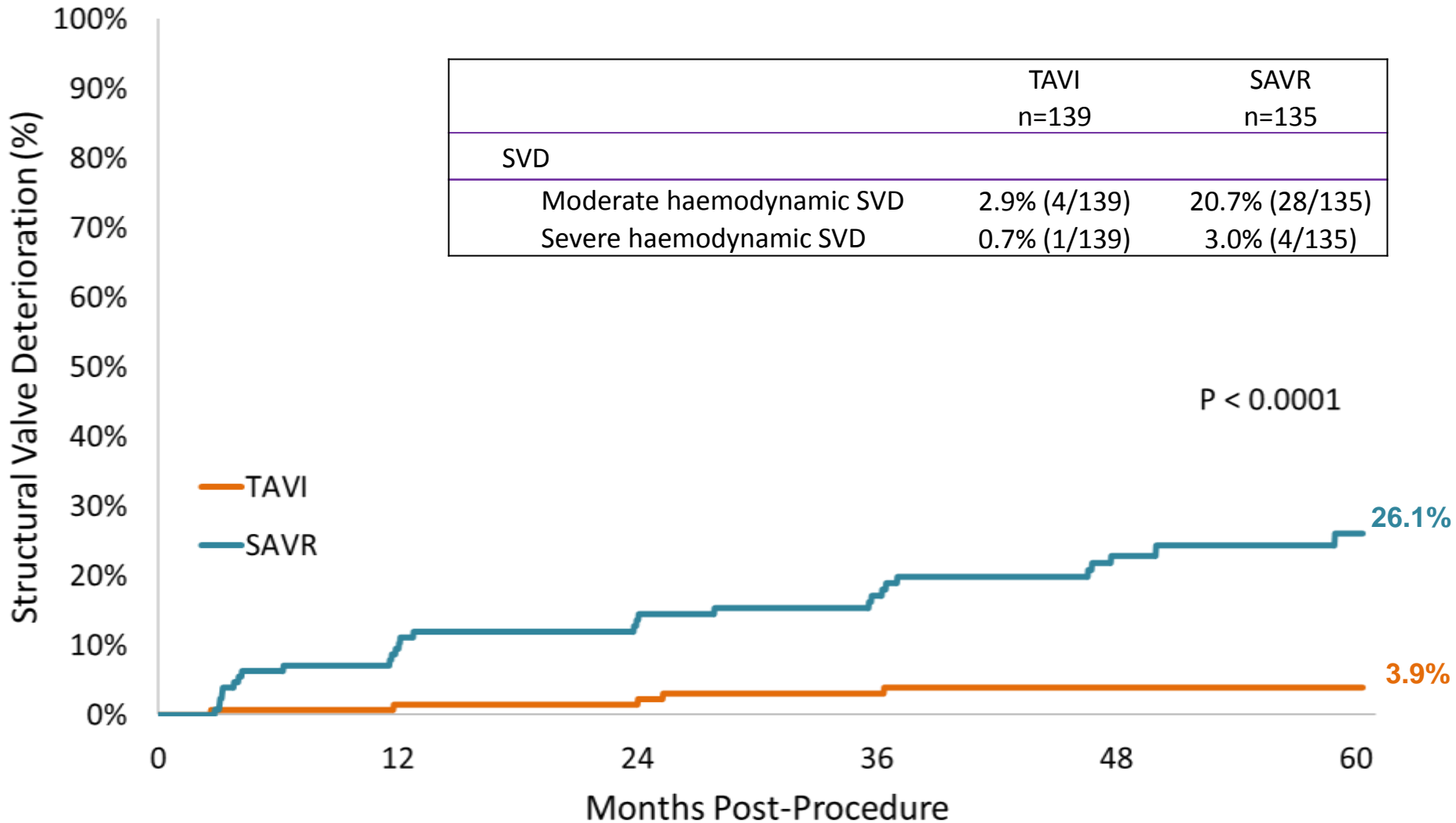


¹Adams, et al., *N Engl J Med* 2014; 370: 1790-8; ²Manoharan, et al., *J Am Coll Cardiol Interv* 2015; 8: 1359-67; ³Popma et al., *JACC Cardiovasc Interv.* 2017 Feb 13;10(3):268-275; ⁴Popma et al., *J Am Coll Cardiol.* 2014 May 20;63(19):1972-81; ⁵Forrest et al., Presented at TCT 2017; ⁶Van Mieghem et al., presented at TCT 2017

CoreValve NOTION Trial aortic valve performance



CoreValve NOTION Trial structural valve deterioration



Valve-in-Valve | Clinical Outcomes from CoreValve Expanded Use Study ViV

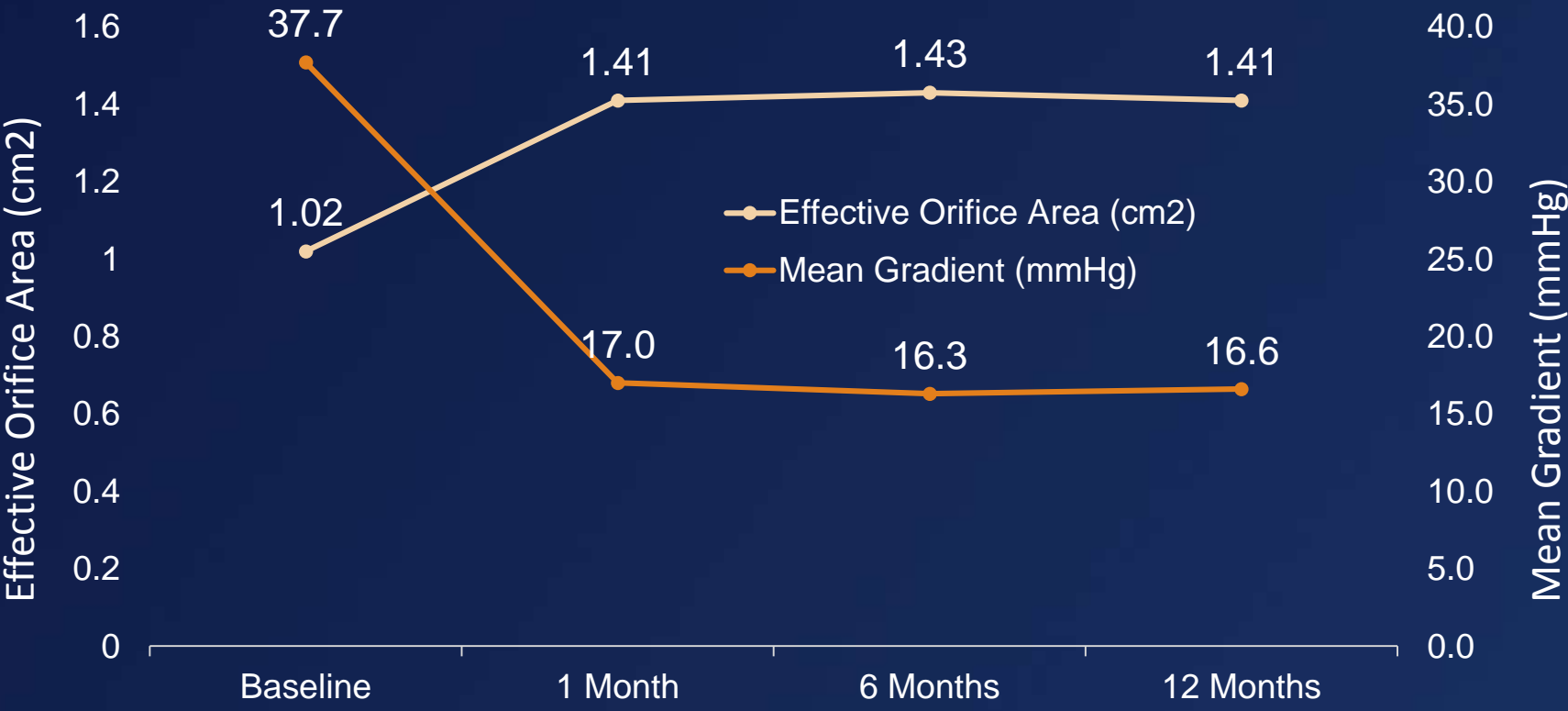
- The CoreValve Expanded Use Study was a prospective, nonrandomized study that enrolled 233 patients with symptomatic surgical valve failure who were deemed unsuitable for reoperation

1-Year Results in Patients Undergoing Transcatheter Aortic Valve Replacement With Failed Surgical Bioprostheses



G. Michael Deeb, MD,^a Stanley J. Chetcuti, MD,^b Michael J. Reardon, MD,^c Himanshu J. Patel, MD,^a P. Michael Grossman, MD,^b Theodore Schreiber, MD,^d John K. Forrest, MD,^e Tanvir K. Bajwa, MD,^f Daniel P. O'Hair, MD,^g George Petrossian, MD,^h Newell Robinson, MD,ⁱ Stanley Katz, MD,^j Alan Hartman, MD,^k Harold L. Dauerman, MD,^l Joseph Schmoker, MD,^m Kamal Khabbaz, MD,ⁿ Daniel R. Watson, MD,^o Steven J. Yakubov, MD,^p Jae K. Oh, MD,^q Shuzhen Li, PhD,^r Neal S. Kleiman, MD,^s David H. Adams, MD,^t Jeffrey J. Popma, MD^u

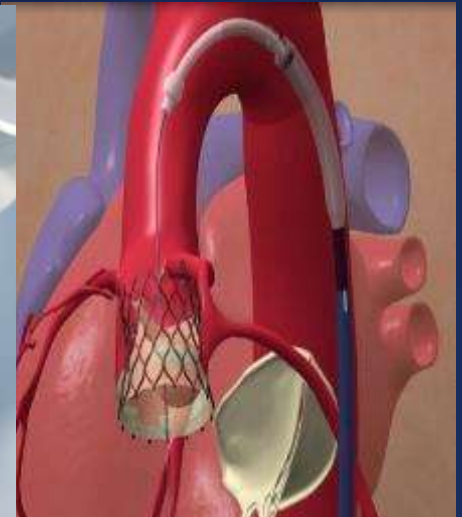
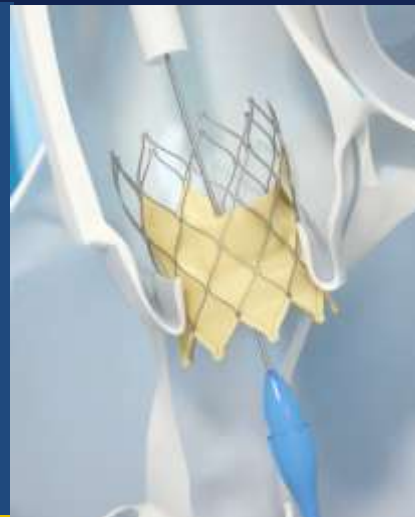
- Hemodynamic data from the CoreValve Expanded Use valve-in-valve cohort demonstrated acceptable results out to 1 year, with avg gradients below 20 mmHg



Next Generation

Evolut NG

Horizon



Low
Profile

Controlled
Release

Concentric
Deployment

Superior
Alignment

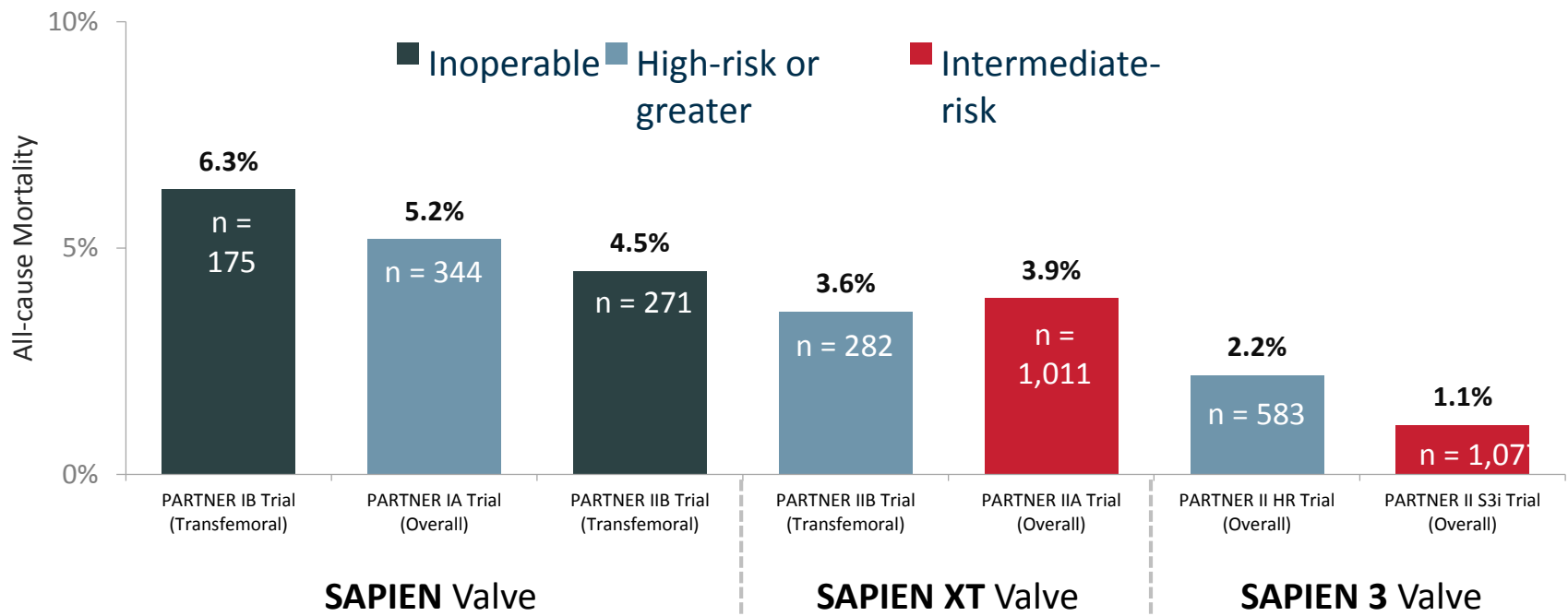
Improved
Visualization

Consistent
Implant Depth

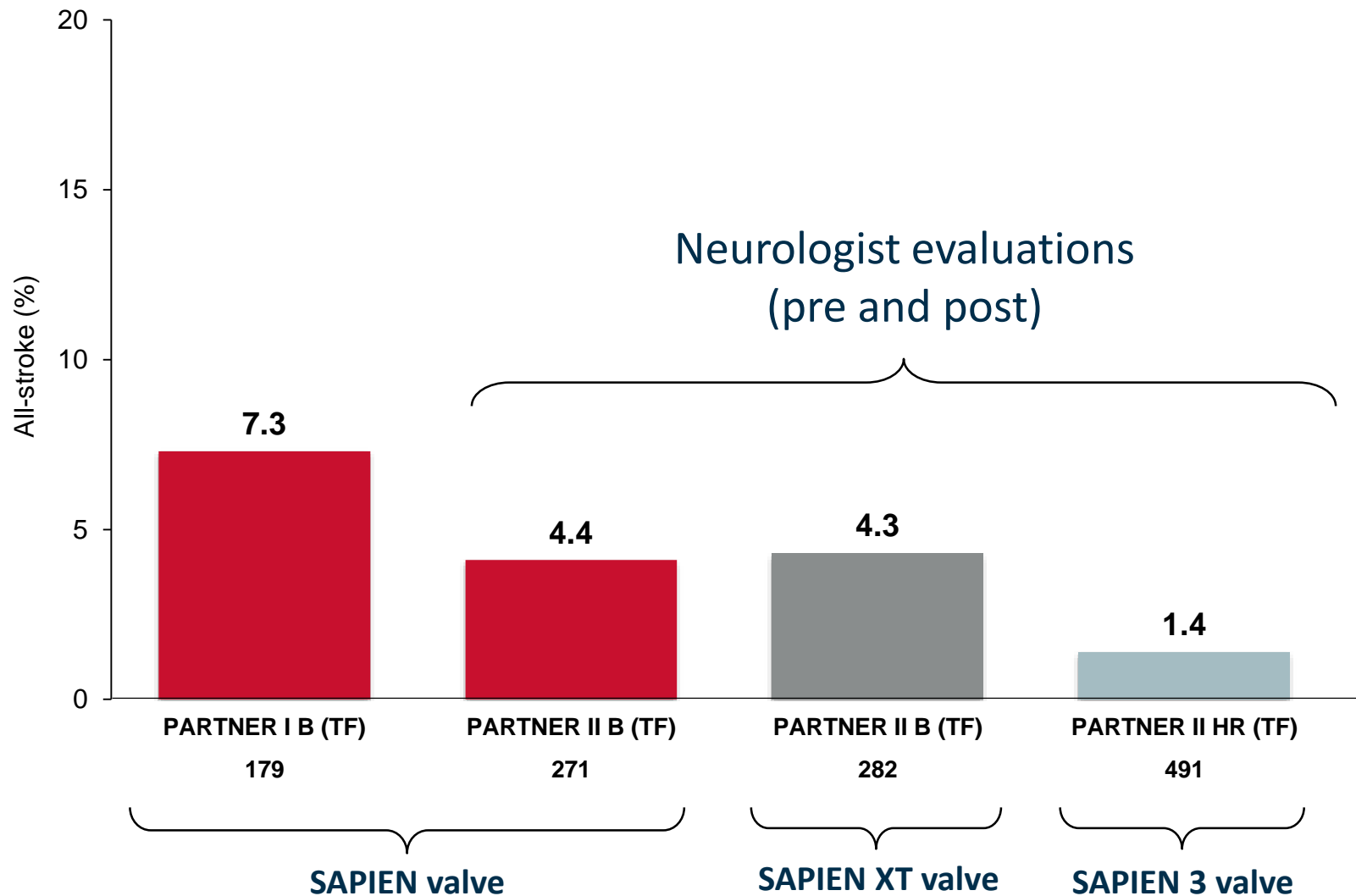
Enhanced
Sealing

Full
Control

30-day Mortality by Valve Platform in the PARTNER Trials



Stroke Rates Continue to Decline

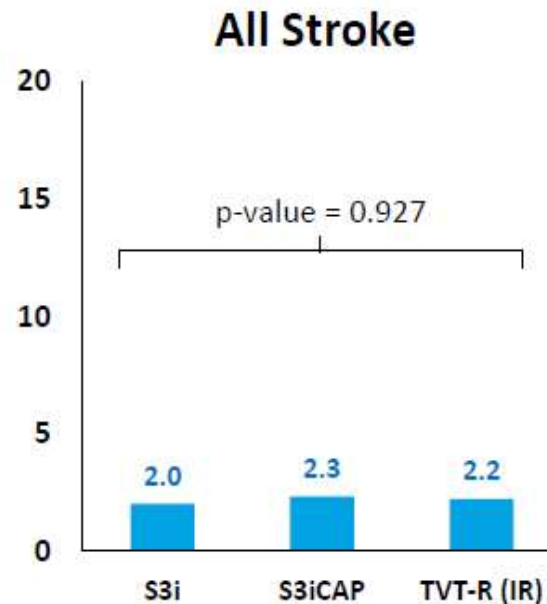
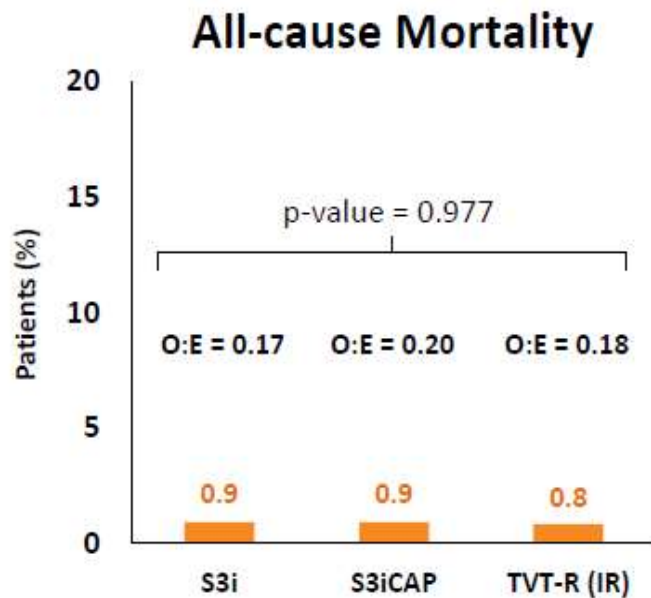


Real World Outcomes of TAVR with the SAPIEN-3 Valve in Intermediate Risk Patients: Comparison of Data from the TVT Registry with PARTNER S3 Studies

E. Murat Tuzcu MD, Samir R. Kapadia MD, Susheel Kodali MD, Lars G. Svensson MD, Vinod H. Thourani MD, Michael J. Mack MD, John G. Webb MD, D. Craig Miller MD, Jeffrey Moses MD, Craig R. Smith MD, Martin B. Leon, MD

From: Cleveland Clinic (EMT, SRK, LGS), Columbia University Medical Center (SK, JM, CRS, MBL), Medstar Washington Hospital Center (VHT), Baylor Scott & White Health (MJM), St. Paul's Hospital (JGW), Stanford University (DCM)





STS	5.19	4.47	4.44
# Patients	652	652	1956
# Sites	51	60	453

	652	652	1956
	51	60	453

30-Day Clinical Outcomes

Propensity Matched - TF Patients - AT

	S3i N = 652	S3iCAP N = 652	TVT-R (IR) N = 1956	Overall P-value
All-Cause Mortality %	0.9	0.9	0.8	0.977
All Stroke %	2.0	2.3	2.2	0.927
New Pacemaker %	11.1	12.0*	10.2*	0.356
Major Vasc Complications %	6.9	5.8*	4.0*	0.007
Length of Stay Median [IQR]	3.0 [2.0, 4.0]	2.0* [2.0, 3.0]	2.0* [2.0, 3.0]	<0.001
PVL (Mod/Sev) %	4.6	4.3*	1.3*	<0.001

*Site Reported and Unadjudicated

Edwards SAPIEN 3 Ultra System

Edwards SAPIEN 3 Ultra Valve



Frame and Leaflet Design

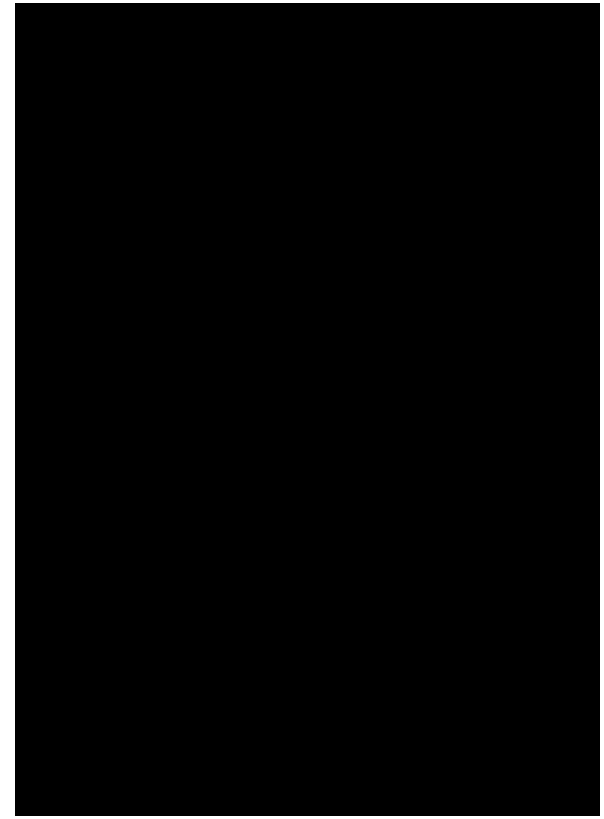
- Proven SAPIEN 3 leaflet and frame design

Outer Skirt

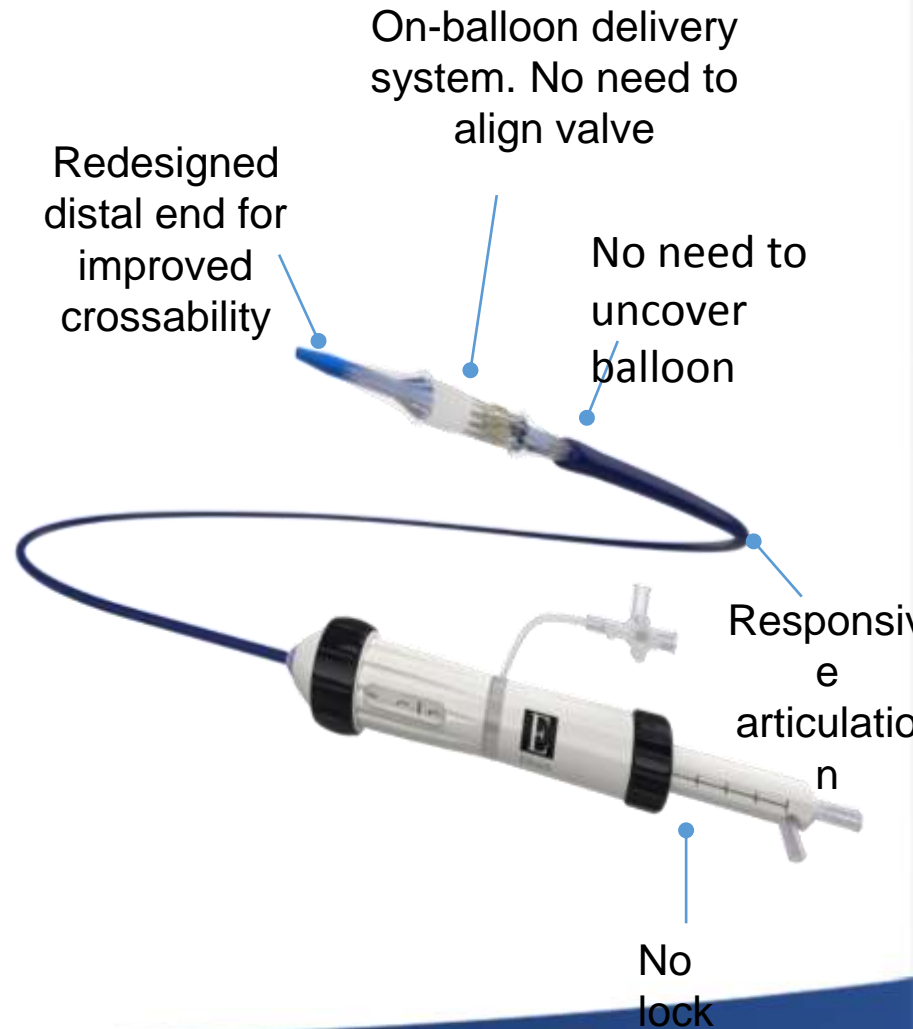
- Textured 3-dimensional PET skirt design
- 40% taller skirt
- 14F sheath compatible

Case 1: Edwards SAPIEN 3 Ultra System

- 74 year old male
- **Bicuspid** aortic valve
 - Area: 640 mm²
 - MG: 43 mmHg
- **Thoracic aortic replacement** and LITA graft
- Severe tortuosity



SAPIEN 3 Ultra Delivery System



SAPIEN 3 Ultra System: Final Result

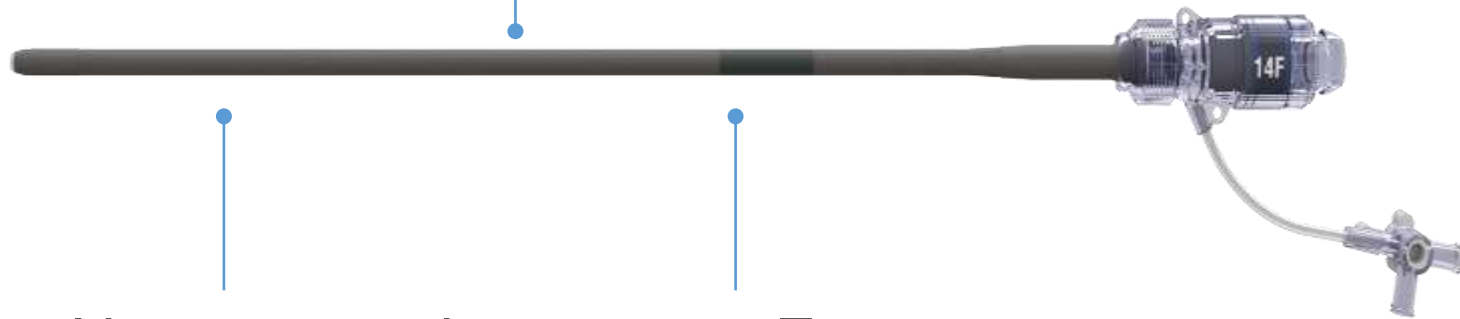


Final Result

- No paravalvular leak
- Temporary pacemaker removed
- Mobilized that evening
- Next-day discharge

Edwards Axela Sheath

Elastic outer layer transiently expands, then actively contracts



Next-generation seamless expandable sheath design

14F sheath for all valve sizes

Comprehensive Echocardiographic Assessment of Normal Transcatheter Valve Function

Rebecca T. Hahn, MD,^a Jonathon Leipsic, MD,^b Pamela S. Douglas, MD,^c Wael A. Jaber, MD,^d Neil J. Weissman, MD,^e Philippe Pibarot, DVM, PhD,^f Philipp Blanke, MD,^b Jae K. Oh, MD^g

TABLE 3 Normal Reference Values for the SAPIEN 3 Valve by Pre-Procedural Native Annular Area by Quintiles of 3D Annular Areas for the Enrolled Patients

	248 to 384 mm ² (n = 189)	385 to 439 mm ² (n = 191)	440 to 488 mm ² (n = 192)	489 to 537 mm ² (n = 191)	538 to 678 mm ² (n = 188)	p Values for Trend
EOA, cm ²	1.41 ± 0.27	1.58 ± 0.33	1.73 ± 0.36	1.79 ± 0.35	1.91 ± 0.42	<0.0001
EOAi, cm ² /m ²	0.80 ± 0.16	0.86 ± 0.19	0.92 ± 0.21	0.90 ± 0.20	0.93 ± 0.21	<0.0001
Mean gradient, mm Hg	13.96 ± 5.28	11.94 ± 4.82	10.93 ± 5.04	10.56 ± 4.16	9.17 ± 3.35	<0.0001
DVI	0.43 ± 0.1	0.44 ± 0.1	0.42 ± 0.09	0.43 ± 0.09	0.42 ± 0.09	0.13

3D = 3-dimensional; EOAI = effective orifice area indexed to body surface area; other abbreviations as in Table 1.

SAPIEN 3: Smallest quintile annulus → 14 mmHg to largest quintile annulus → 9 mmHg

Better Hemodynamics with Evolut-R

TABLE 5 Normal Reference Values for the CoreValve and Evolut R Valves by Native Annular Diameter Quintiles at 30 Days

Quintiles	≤22.8 mm	>22.8 to 24.5 mm	>24.5 to 25.9 mm	>25.9 to 27.6 mm	>27.6 to 41.5 mm	p Value for Trend
CoreValve						
EOA, cm ²	1.71 ± 0.55 (166)	1.80 ± 0.53 (141)	1.92 ± 0.48 (167)	1.94 ± 0.52 (165)	2.06 ± 0.66 (160)	<0.001
EOAi, cm ² /m ²	1.03 ± 0.33 (166)	1.02 ± 0.30 (141)	1.04 ± 0.29 (167)	1.01 ± 0.30 (165)	1.07 ± 0.36 (160)	0.34
Mean gradient, mm Hg	9.01 ± 4.06 (180)	8.96 ± 4.71 (151)	8.75 ± 3.99 (179)	9.16 ± 4.50 (170)	8.75 ± 3.61 (171)	0.75
DVI	0.59 ± 0.15 (172)	0.55 ± 0.13 (145)	0.54 ± 0.11 (173)	0.53 ± 0.12 (167)	0.55 ± 0.14 (170)	0.001
Quintiles	≤22.3 mm	>22.3 to ≤23.2 mm	>23.2 to ≤24.7 mm	>24.7 to ≤26.2 mm	>26.2 to ≤30.2 mm	p Value for Trend
Evolut R						
EOA, cm ²	1.66 ± 0.42 (53)	1.82 ± 0.43 (38)	1.98 ± 0.56 (62)	1.98 ± 0.59 (49)	2.56 ± 0.77 (53)	< 0.001
EOAi, cm ² /m ²	0.99 ± 0.27 (53)	1.09 ± 0.26 (38)	1.10 ± 0.32 (62)	1.06 ± 0.34 (49)	1.29 ± 0.37 (53)	< 0.001
Mean gradient, mm Hg	7.94 ± 3.10 (58)	6.91 ± 2.58 (43)	7.66 ± 2.94 (63)	8.53 ± 3.49 (56)	6.40 ± 3.34 (57)	0.21
DVI	0.61 ± 0.11 (57)	0.61 ± 0.14 (41)	0.61 ± 0.15 (63)	0.56 ± 0.14 (51)	0.58 ± 0.15 (55)	0.07

Values are mean ± SD (n). Trend test p value from generalized linear modeling with quintiles as independent ordinal variable.

Abbreviations as in Tables 1 and 3.

Evolut R: Smallest quintile annulus → 8 mmHg to largest quintile annulus → 6 mmHg

Hahn et al J Am Coll Cardiol Img 2018, epub prior to prin

S3 vs Evolut R

- Simplicity vs Retrievability
- Femoral/Iliac Access requirement
- Arch Angle
- Pacer Implantation rate
- EOA
- Valve-in-Valve

