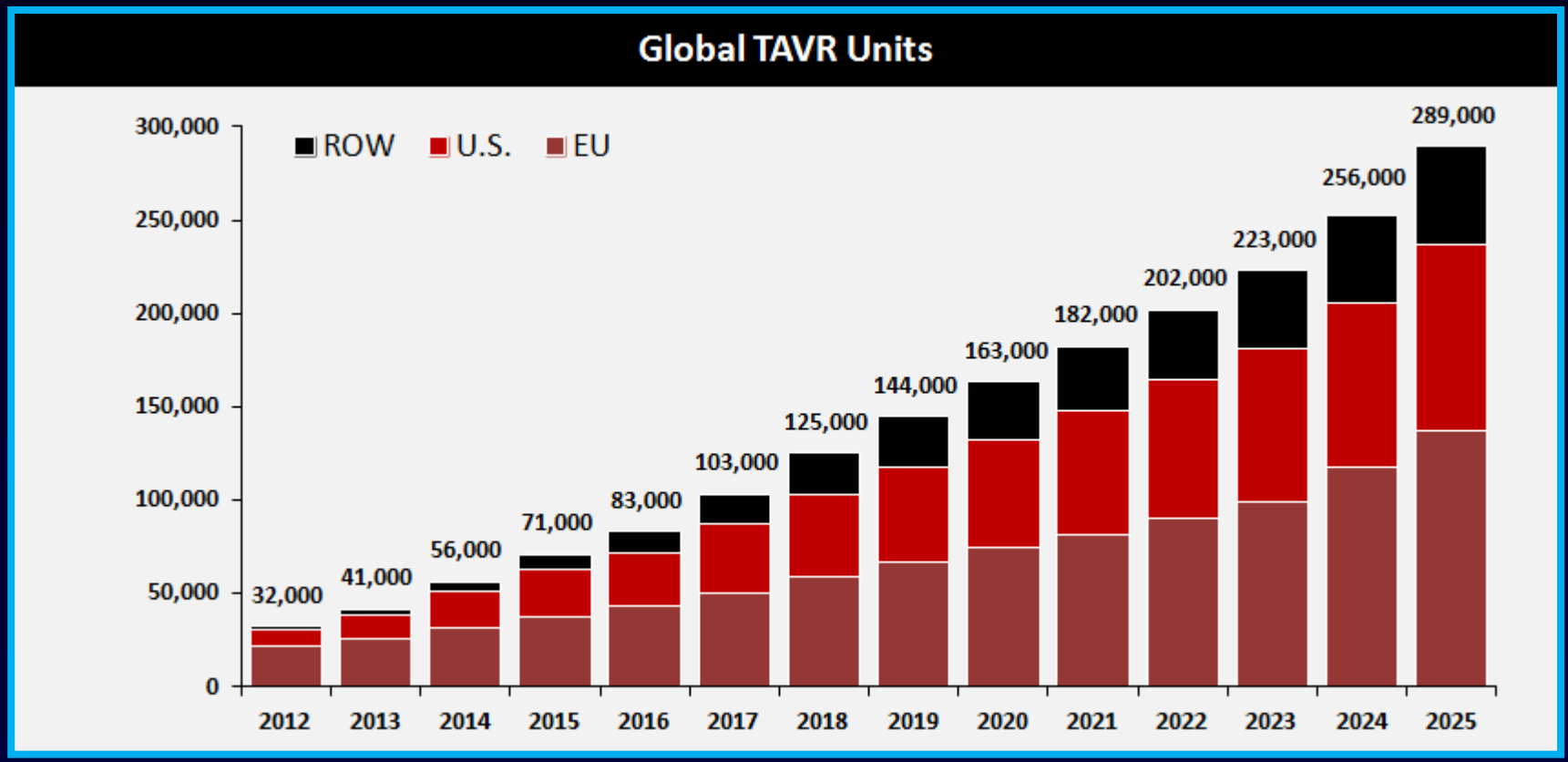
Considerations for
Optimal valve choice in TAVR

Park, Chang-Soon

**Cardiology Division, Yonsei Cardiovascular Hospital,
Yonsei University College of Medicine**

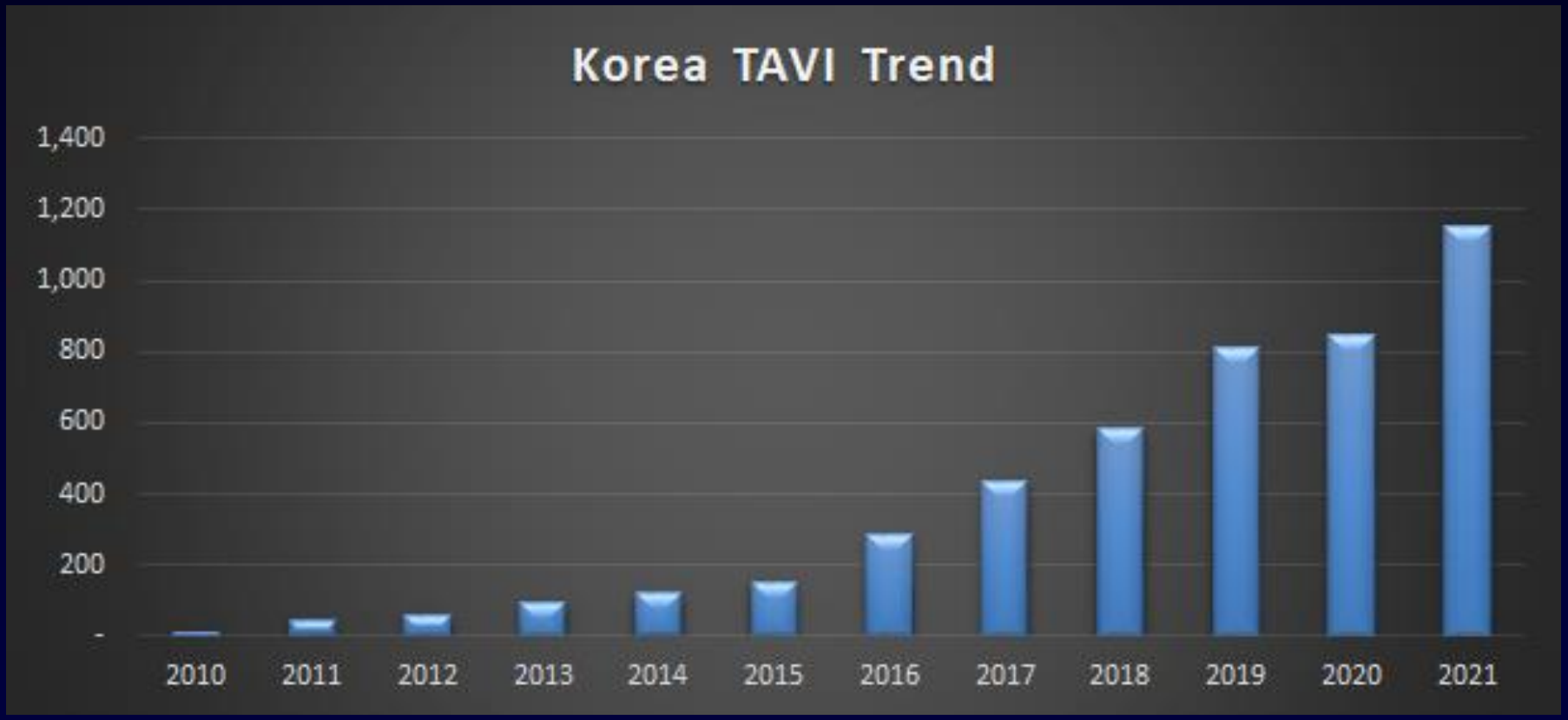
Estimated Global TAVR Growth



SOURCE: Credit Suisse TAVI Comment –January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

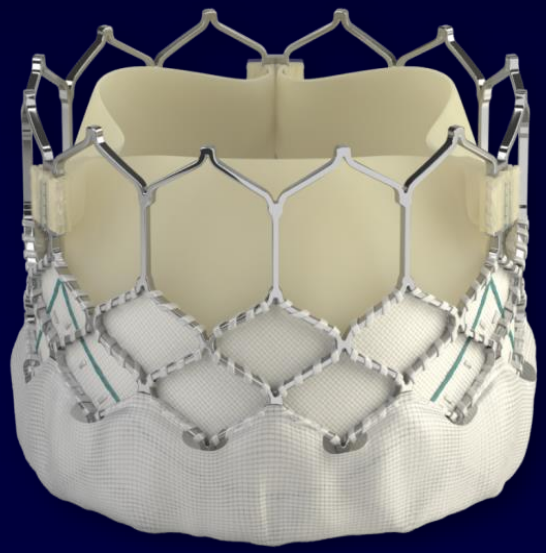
In the next 10 years, TAVR growth will increase X4!

KOREA TAVR

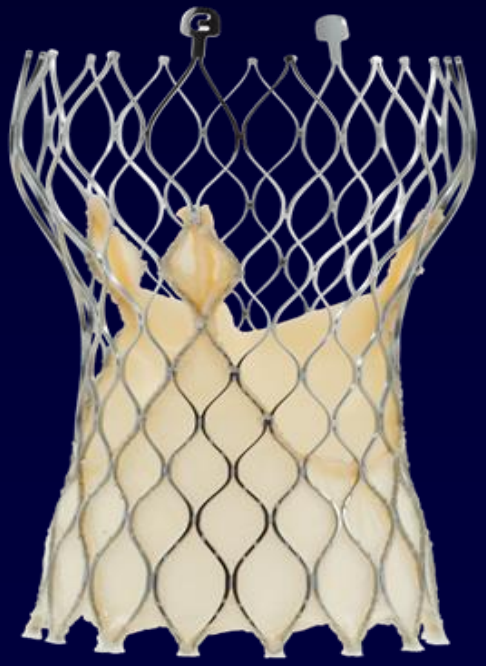

Korea TAVI Trend
1,400
1,200
1,000
800
600
400
200
-
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021

Two TAVR Options

- Edwards Sapien3 Valve
- Bovine Pericardial Tissue
- Balloon expandable
- Intraannular
- Stainless Steel Frame
- Need rapid pacing
- PolyEthylene Terephthalate (PET)



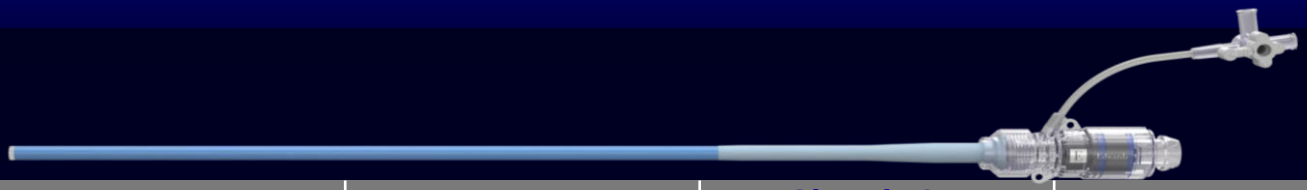
- Medtronic EvoluteR/Pro
- Porcine Pericardial Tissue
- Supraanular
- Nitinol Frame-self expanding
- Recapture available
- External Wrap



Consider for Valve Choice

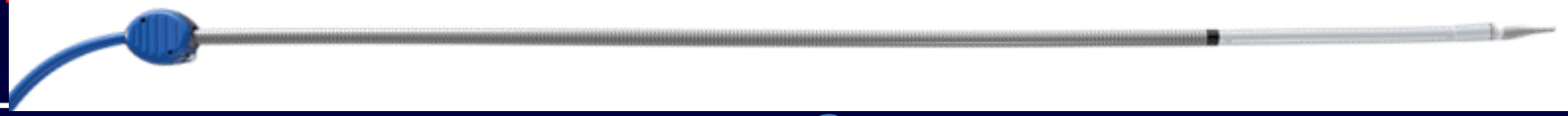
- Access Site/Size
- Anatomic Restrictions
  - Bicuspid aortic Valve
  - *Valve in valve*
  - Small aortic annulus
  - Distorted/Horizontal Ao
- Annular Rupture Risk
- High Risk Coronary
  - Implantation risks
  - Re-access to coronaries risk
  - Delayed Coronary Obstruction (DCO)
- Deployment technique
  - Post-dilatation rates
  - Repositioning
- Pacemaker Rate
- Risk for Structural Valve Deterioration
- Paravalvular regurgitation Rate
- Prosthesis-patient Mismatch
- Outcomes

Clinical Need: Low Profile Access

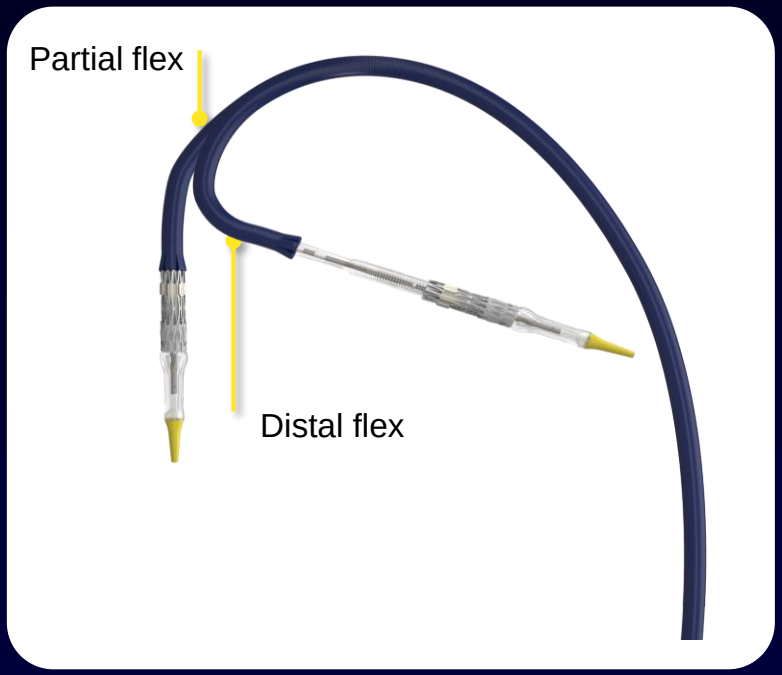


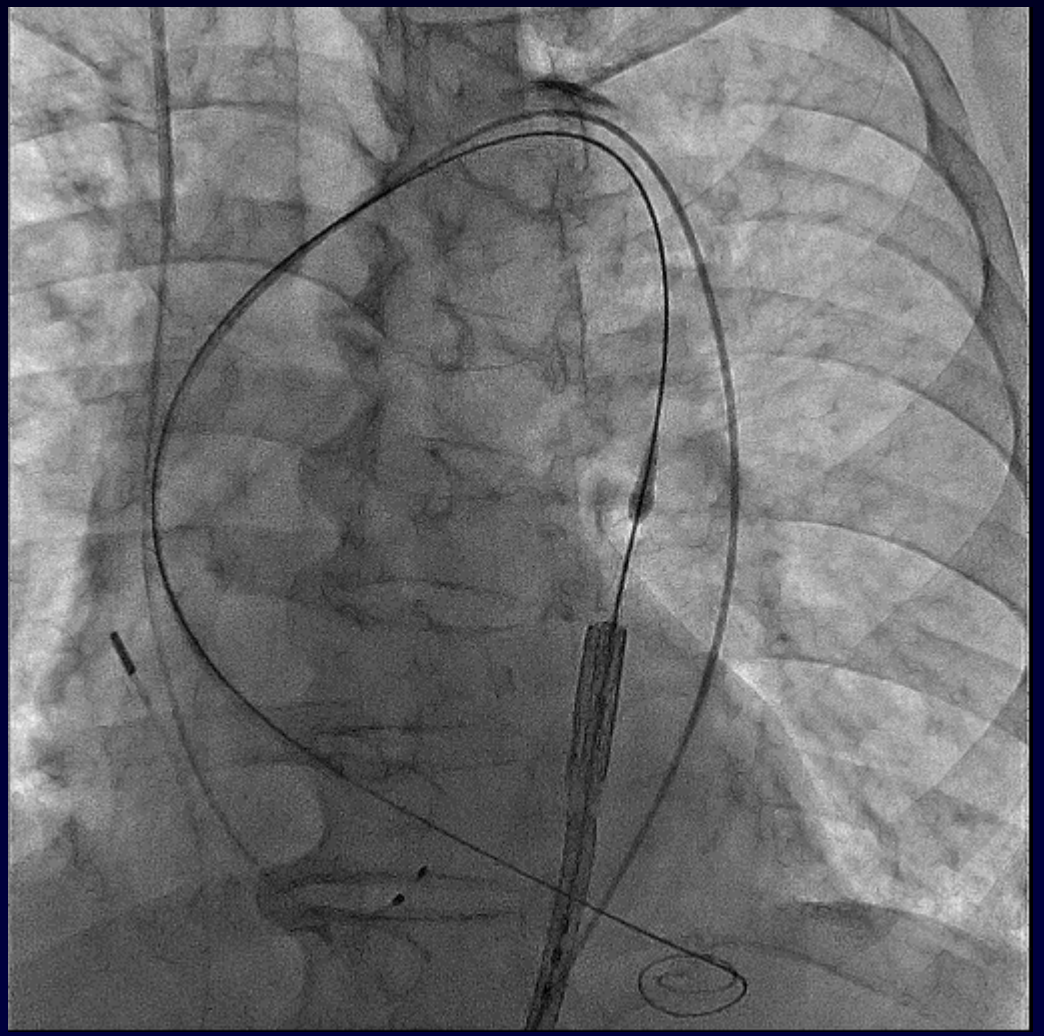
THV	Sheath ID (unexpanded)	Sheath OD (unexpanded) -> will be expanded	Minimum Vessel Diameter*
20 mm SAPIEN 3 valve	14F (4.6 mm)	18F (6.0 mm)	5.5 mm
23 mm SAPIEN 3 valve	14F (4.6 mm)	18F (6.0 mm)	5.5 mm
26 mm SAPIEN 3 valve	14F (4.6 mm)	18F (6.0 mm)	5.5 mm
29 mm SAPIEN 3 valve	16F (5.3 mm)	20F (6.7 mm)	6.0 mm

THV	In-line Sheath ID	In-line Sheath OD	External Sheath ID	Minimum Vessel Diameter*
23mm , 26mm, 29mm EVOLUT R valve	14F (4.6 mm)	18F (6.0 mm)	18F (6.0 mm)	5.0 mm
34mm EVOLUT R valve	16F (5.3 mm)	20F (6.6 mm)	20F (6.6 mm)	5.5 mm
23mm, 26mm, 29mm EVOLUT PRO valve	16F (5.3 mm)	20F (6.6 mm)	20F (6.6 mm)	5.5 mm

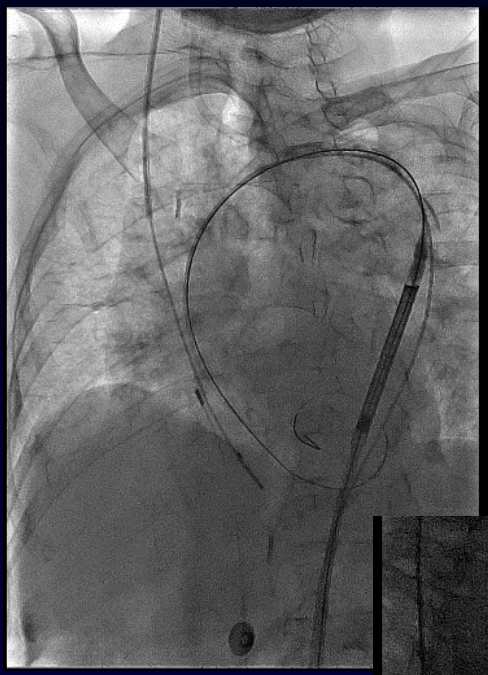


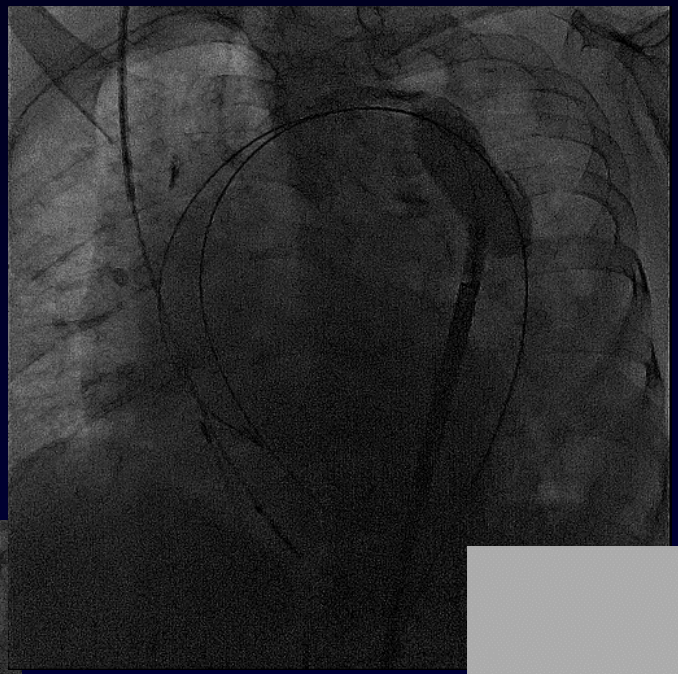
Sapien arch pass

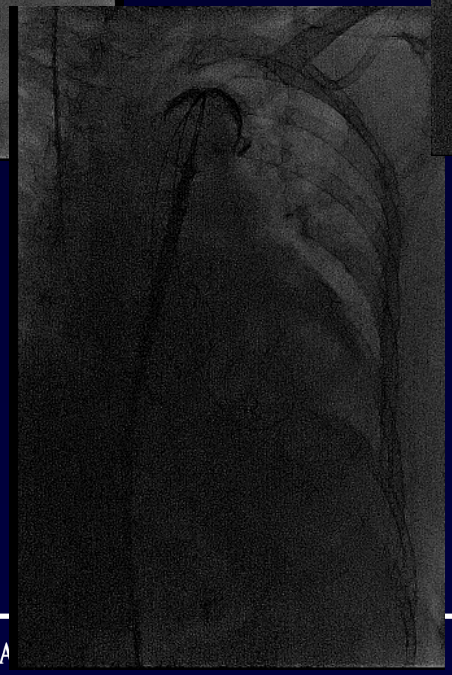




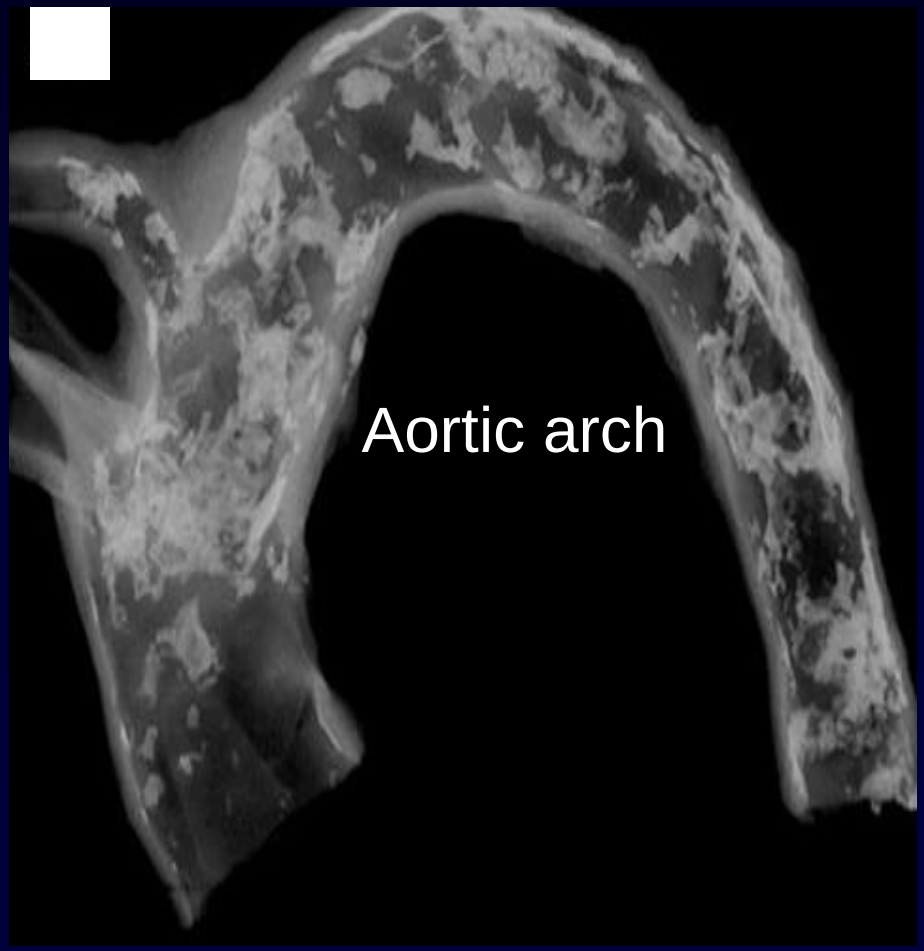
Evolute arch pass







Why Gentle Valve Passage Is Important?
Mechanism of Stroke after TAVR



- Primarily ischemic in nature due to either embolic events or cerebral hypoperfusion
- Embolic events
  - Aortic atheroma
  - Gaseous emboli
- Cerebral hypoperfusion
  - Watershed infarcts on CPB
- Multiple other etiologies postulated including atrial fibrillation, hyperglycemia, cerebral hyperthermia, etc.

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Balloon Versus Self-Expandable Valve for the Treatment of Bicuspid Aortic Valve Stenosis

Insights From the BEAT International Collaborative Registry

Antonio Mangieri, MD; Didier Tchetchè, MD; Won-Keun Kim, MD; Matteo Pagnesi, MD; Jean-Malte Sinning, MD; Uri Landes, MD; Ran Kornowski, MD; Ole De Backer, MD; Georg Nickenig, MD; Alfonso Ielasi, MD; Chiara De Biase, MD; Lars Søndergaard, MD; Federico De Marco, MD; Matteo Montorfano, MD; Mauro Chiarito, MD; Damiano Regazzoli, MD; Giulio Stefanini, MD; Patrizia Presbitero, MD; Stefan Toggweiler, MD; Corrado Tamburino, MD; Sebastiano Immè, MD; Giuseppe Tarantini, MD; Horst Sievert, MD; Ulrich Schäfer, MD; Jörg Kempfert, MD; Jochen Wöehrle, MD; Francesco Gallo, MD; Alessandra Laricchia, MD; Azeem Latib, MD; Francesco Giannini, MD; Antonio Colombo, MD

BACKGROUND: Large data comparing the performance of new-generation self-expandable versus balloon-expandable transcatheter heart valves in bicuspid aortic stenosis are lacking. We aim to compare the safety and performance of balloon-expandable and self-expandable transcatheter heart valves in the treatment of bicuspid aortic stenosis.

METHODS: The BEAT (balloon versus self-expandable valve for the treatment of bicuspid aortic valve stenosis) registry included 353 consecutive patients who underwent transcatheter aortic valve implantation using new-generation Evolut R/PRO or Sapien 3 valves in bicuspid aortic valve.

RESULTS: A total of 353 patients (n=242 [68.6%] treated with Sapien 3 and n=111 [68.6%] treated with Evolut R (n=70)/PRO [n=41]) were included. Mean age was 77.8±8.3 years and mean Society of Thoracic Surgeons Predicted Risk of Mortality was 4.4±3.3%. Valve Academic Research Consortium-2 device success was similar between Sapien 3 and Evolut R/PRO (85.6% versus 87.2%; *P*=0.68). In the Sapien 3 group, 4 patients experienced annular rupture whereas this complication did not occur in the Evolut R/PRO group. After propensity score matching, Valve Academic Research Consortium-2 device success was similar between both groups (Sapien 3=85.7% versus Evolut R/Pro=84.4%; *P*=0.821). Both in the overall and in the matched population, no differences in the rate of permanent pacemaker implant were observed. At 1-year follow-up, the rate of overall death and cardiovascular death were similar between the 2 groups. In the unmatched population, the 1-year echocardiographic follow-up demonstrated similar rate of moderate-to-severe paravalvular aortic regurgitation (Evolut R/PRO 10.5% versus Sapien 3 4.2%, *P*=0.077); however, after propensity matching, the rate of moderate-to-severe paravalvular leak became significantly higher among patients treated with self-expandable valves (9.3% versus 0%; *P*=0.043).

CONCLUSIONS: Our study confirms the feasibility of both Sapien 3 and Evolut R/PRO implantation in bicuspid aortic valve anatomy; a higher rate of moderate-severe paravalvular aortic regurgitation was observed in the Evolut R/PRO group at 1-year follow-up in the matched cohort, although patients treated with balloon-expandable valve had a higher rate of annular rupture.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: aortic valve ■ bicuspid valve ■ pacemaker ■ propensity score ■ surgeons ■ transcatheter aortic valve replacement

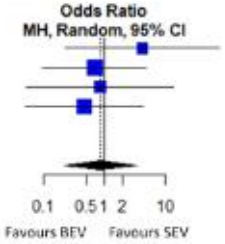
Bicuspid valve

Balloon versus self-expandable transcatheter aortic valve implantation for bicuspid aortic valve stenosis: A meta-analysis of observational studies (BEV: n = 620; SEV: n = 460)

(a) – Procedural death

Study	BEV Events	BEV Total	SEV Events	SEV Total	Weight	Odds Ratio MH, Random, 95% CI
Mangieri 2020	4	242	0	111	16.5%	4.21 [0.22; 78.83]
Yoon 2016	2	178	2	123	36.5%	0.69 [0.10; 4.95]
Jilaihawi 2016	1	70	1	60	18.2%	0.86 [0.05; 13.97]
Mylotte 2014	1	48	4	91	28.8%	0.46 [0.05; 4.26]
Hayashida 2013	0	11	0	10	0.0%	
Total (95% CI)		**549**		**395**	**100.0%**	**0.86 [0.22; 3.35]**

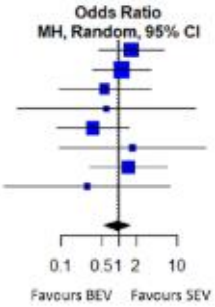
Heterogeneity: $Tau^2 = 0$; $Chi^2 = 1.52$, df = 3 (P = 0.678); $I^2 = 0\%$
Test for overall effect: $t_3 = -0.35$ (P = 0.749)



(b) – 30-day all-cause death

Study	BEV Events	BEV Total	SEV Events	SEV Total	Weight	Odds Ratio MH, Random, 95% CI
Mangieri 2020	11	228	3	100	20.8%	1.64 [0.45; 6.01]
Yoon 2016	8	178	5	123	26.9%	1.11 [0.35; 3.48]
Jilaihawi 2016	2	70	3	60	10.6%	0.56 [0.09; 3.46]
Kosek 2015	0	2	1	5	2.8%	0.60 [0.02; 20.96]
Yousef 2015	3	61	6	47	16.9%	0.35 [0.08; 1.50]
Costopoulos 2014	1	8	1	13	4.1%	1.71 [0.09; 31.92]
Mylotte 2014	3	48	4	91	14.8%	1.45 [0.31; 6.76]
Hayashida 2013	0	11	1	10	3.2%	0.28 [0.01; 7.57]
Total (95% CI)		**606**		**449**	**100.0%**	**0.92 [0.54; 1.57]**

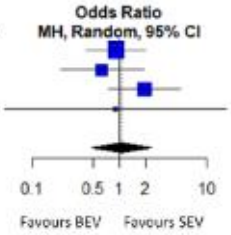
Heterogeneity: $Tau^2 = 0$; $Chi^2 = 3.92$, df = 7 (P = 0.789); $I^2 = 0\%$
Test for overall effect: $t_7 = -0.37$ (P = 0.721)



(c) – 1-year all-cause death

Study	BEV Events	BEV Total	SEV Events	SEV Total	Weight	Odds Ratio MH, Random, 95% CI
Mangieri 2020	20	242	10	111	43.2%	0.91 [0.41; 2.01]
Yousef 2015	7	61	8	47	22.7%	0.63 [0.21; 1.89]
Mylotte 2014	10	48	11	91	30.9%	1.91 [0.75; 4.90]
Hayashida 2013	1	11	1	10	3.2%	0.90 [0.05; 16.59]
Total (95% CI)		**362**		**259**	**100.0%**	**1.05 [0.48; 2.29]**

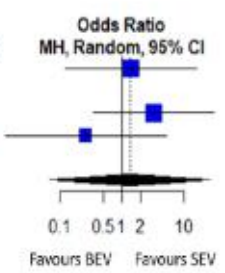
Heterogeneity: $Tau^2 = 0$; $Chi^2 = 2.53$, df = 3 (P = 0.470); $I^2 = 0\%$
Test for overall effect: $t_3 = 0.21$ (P = 0.845)



(a) – Coronary obstruction

Study	BEV Events	BEV Total	SEV Events	SEV Total	Weight	Odds Ratio MH, Random, 95% CI
Yoon 2016	2	178	1	123	35.4%	1.39 [0.12; 15.46]
Jilaihawi 2016	0	70	0	60	0.0%	
Yousef 2015	4	61	1	47	41.5%	3.23 [0.35; 29.89]
Mylotte 2014	0	48	3	91	23.1%	0.26 [0.01; 5.15]
Total (95% CI)		**357**		**321**	**100.0%**	**1.34 [0.07; 25.59]**

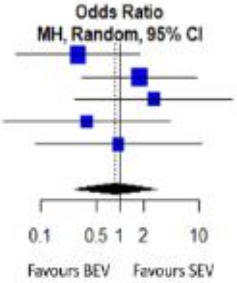
Heterogeneity: $Tau^2 = 0$; $Chi^2 = 1.77$, df = 2 (P = 0.412); $I^2 = 0\%$
Test for overall effect: $t_2 = 0.43$ (P = 0.712)



(b) – Stroke

Study	BEV Events	BEV Total	SEV Events	SEV Total	Weight	Odds Ratio MH, Random, 95% CI
Mangieri 2020	2	217	3	98	25.5%	0.29 [0.05; 1.79]
Yoon 2016	5	178	2	123	30.4%	1.75 [0.33; 9.16]
Jilaihawi 2016	3	70	1	60	15.9%	2.64 [0.27; 26.09]
Yousef 2015	1	61	2	47	14.1%	0.38 [0.03; 4.27]
Mylotte 2014	1	48	2	91	14.1%	0.95 [0.08; 10.72]
Total (95% CI)		**574**		**419**	**100.0%**	**0.87 [0.26; 2.90]**

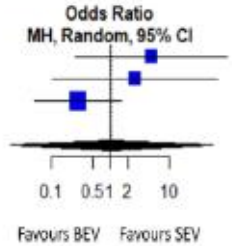
Heterogeneity: $Tau^2 = 0$; $Chi^2 = 3.44$, df = 4 (P = 0.487); $I^2 = 0\%$
Test for overall effect: $t_4 = -0.31$ (P = 0.771)



(c) – Acute kidney injury

Study	BEV Events	BEV Total	SEV Events	SEV Total	Weight	Odds Ratio MH, Random, 95% CI
Yoon 2016	3	178	0	123	27.2%	4.93 [0.25; 96.22]
Jilaihawi 2016	1	70	0	60	24.4%	2.61 [0.10; 65.30]
Yousef 2015	2	61	5	47	48.4%	0.28 [0.05; 1.54]
Total (95% CI)		**309**		**230**	**100.0%**	**1.06 [0.02; 54.49]**

Heterogeneity: $Tau^2 = 1.2496$; $Chi^2 = 3.45$, df = 2 (P = 0.178); $I^2 = 42\%$
Test for overall effect: $t_2 = 0.06$ (P = 0.954)



Michel Pompeu B.O. Sá MD, MSc, PhD1

Catheter Cardiovasc Interv. 2021;98:E746–E757.

Small Aortic Annulus in YUHS

kcj
Korean Circulation Journal

Comparison of Transcatheter Aortic Valve Replacement between Self-Expanding versus Balloon-Expandable Valves in Patients with Small Aortic Annulus

Yong-Joon Lee, MD, Seung-Jun Lee, MD, Sung-Jin Hong, MD, Chi-Young Shim, MD, Chul-Min Ahn, MD, Jung-Sun Kim, MD, Byeong-Keuk Kim, MD, Geu-Ru Hong, MD, Young-Guk Ko, MD, Donghoon Choi, MD, Yangsoo Jang, MD, and Myeong-Ki Hong, MD, PhD

Division of Cardiology, Department of Internal Medicine, Severance Cardiovascular Hospital, Yonsei University Health System, Seoul, Korea

ABSTRACT

Background and Objectives: Transcatheter aortic valve replacement (TAVR) has been reported as a good alternative for surgical aortic valve replacement in patients with small aortic annulus. Head-to-head comparisons of different transcatheter aortic valves in these patients are insufficient. We compared the outcomes after TAVR between two different types of recent transcatheter aortic valves (self-expanding vs. balloon-expandable) in patients with small aortic annulus.

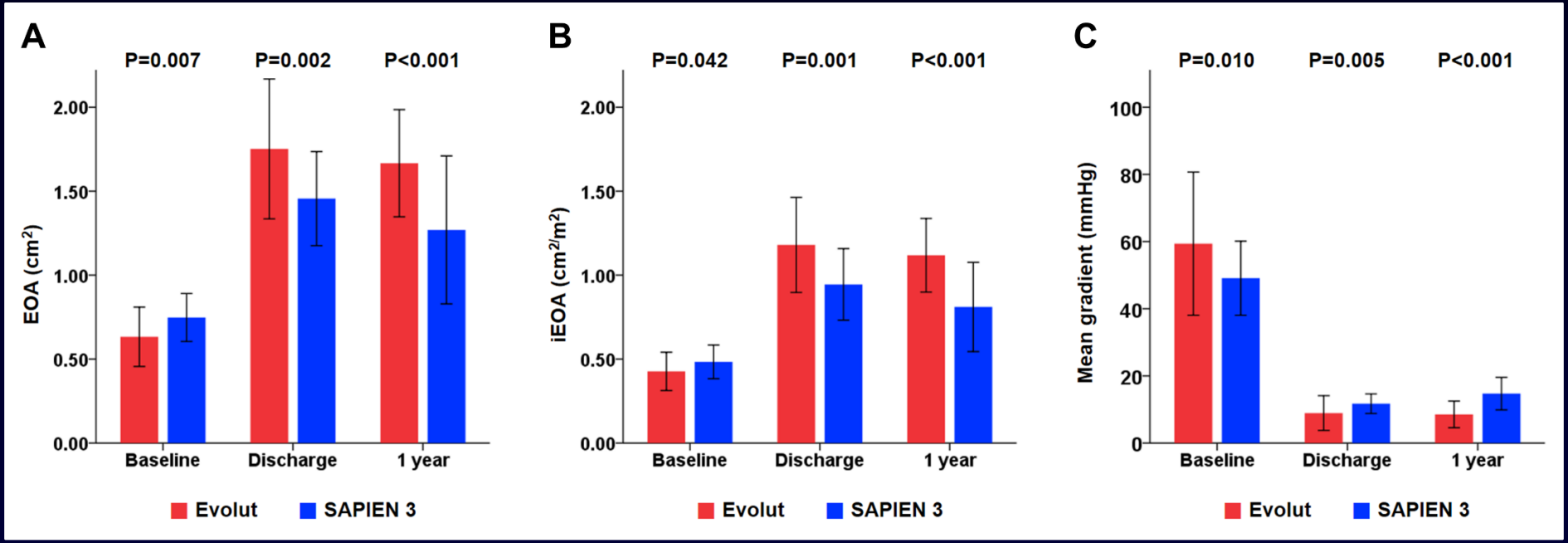
Methods: A total of 70 patients with severe aortic stenosis and small annulus (mean diameter ≤23 mm or minimal diameter ≤21 mm on computed tomography) underwent TAVR with either a self-expanding valve with supra-annular location (n=45) or a balloon-expandable valve with intra-annular location (n=25). The echocardiographic hemodynamic parameters after TAVR and 1-year follow-up were compared.

Results: Between the self-expanding and balloon-expandable valve-treated patients, the clinical outcomes including permanent pacemaker implantation (11.1% vs. 8.0%), acute kidney injury stage 2 or 3 (4.4% vs. 4.0%), and major vascular complication (4.4% vs. 0.0%) were similar without all-cause mortality, stroke, and life-threatening bleeding during 30-day follow-up. Compared with the balloon-expandable valve-treated patients, the self-expanding valve-treated patients presented larger effective orifice area (EOA) (1.46±0.28 vs. 1.75±0.42 cm^2, p=0.002) and indexed EOA (0.95±0.21 vs. 1.18±0.28 cm^2/m^2, p=0.001), whereas mean aortic valve gradient (11.7±2.9 vs. 8.9±5.2 mmHg, P=0.005) and incidence of ≥moderate prosthesis-patient mismatch (36.0% vs. 8.9%, p=0.009) were lower. These hemodynamic differences were maintained at 1-year follow-up.

Conclusions: TAVR with self-expanding valves was associated with superior hemodynamic outcomes compared with balloon-expandable valves in patients with small aortic annulus.

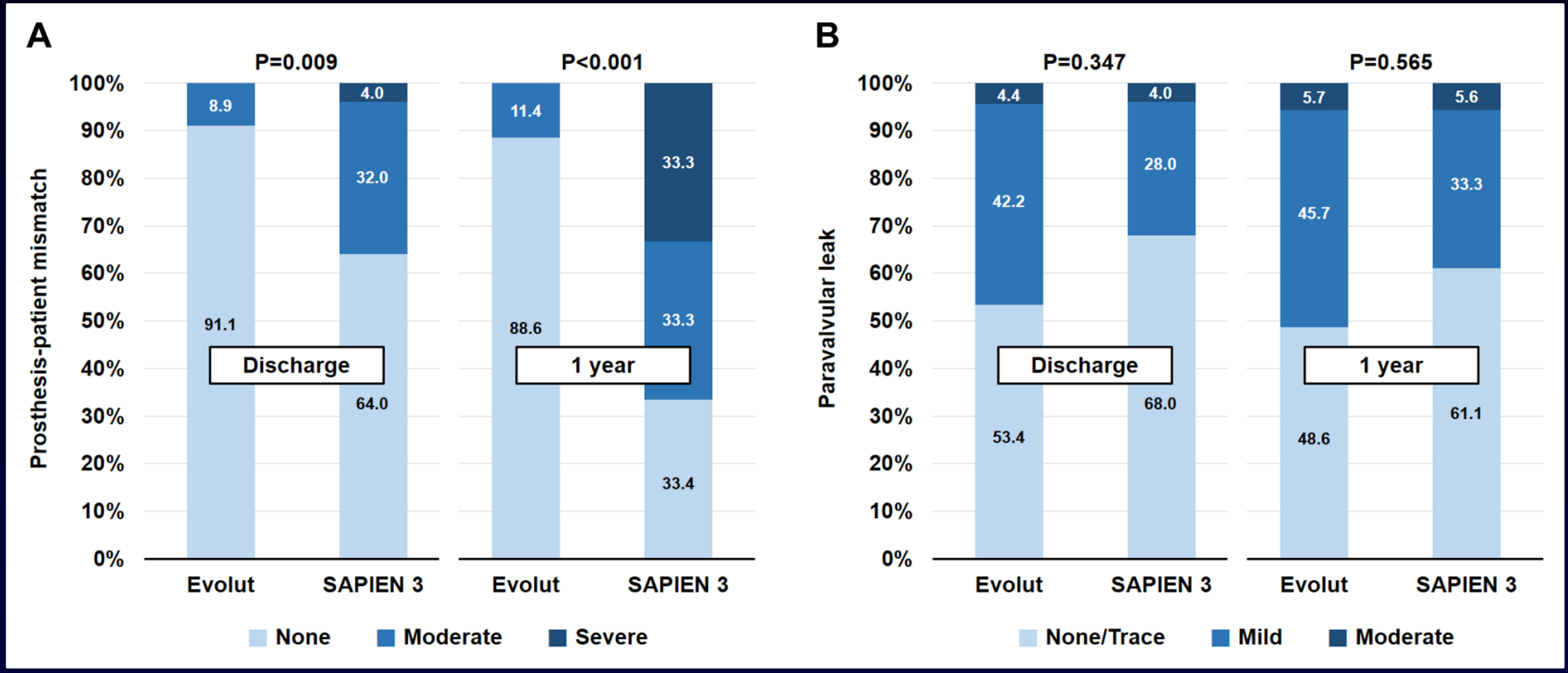
Keywords: Transcatheter aortic valve replacement; Aortic valve stenosis

Echocardiographic outcomes (1)



- The Evolut group presented larger EOA and iEOA, whereas mean aortic valve gradient was lower than the SAPIEN 3 group.
- The differences in hemodynamic outcomes were maintained at 1-year follow up.

Echocardiographic outcomes (2)



- The Evolut group presented lower incidence of ≥moderate PPM than the SAPIEN 3 group. The incidence of ≥moderate paravavular leak was rare in both groups.

LVOT Calcification & TAVR: Annular Rupture

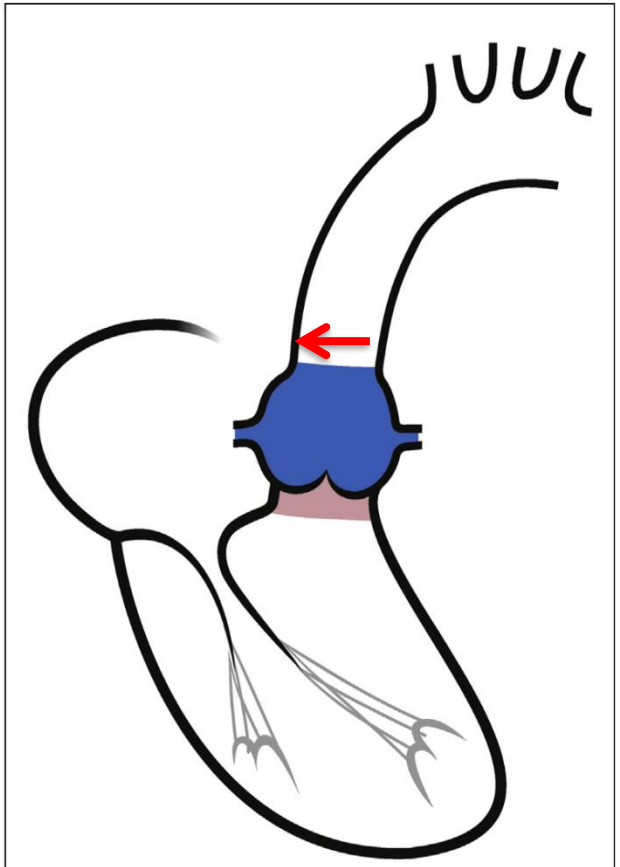


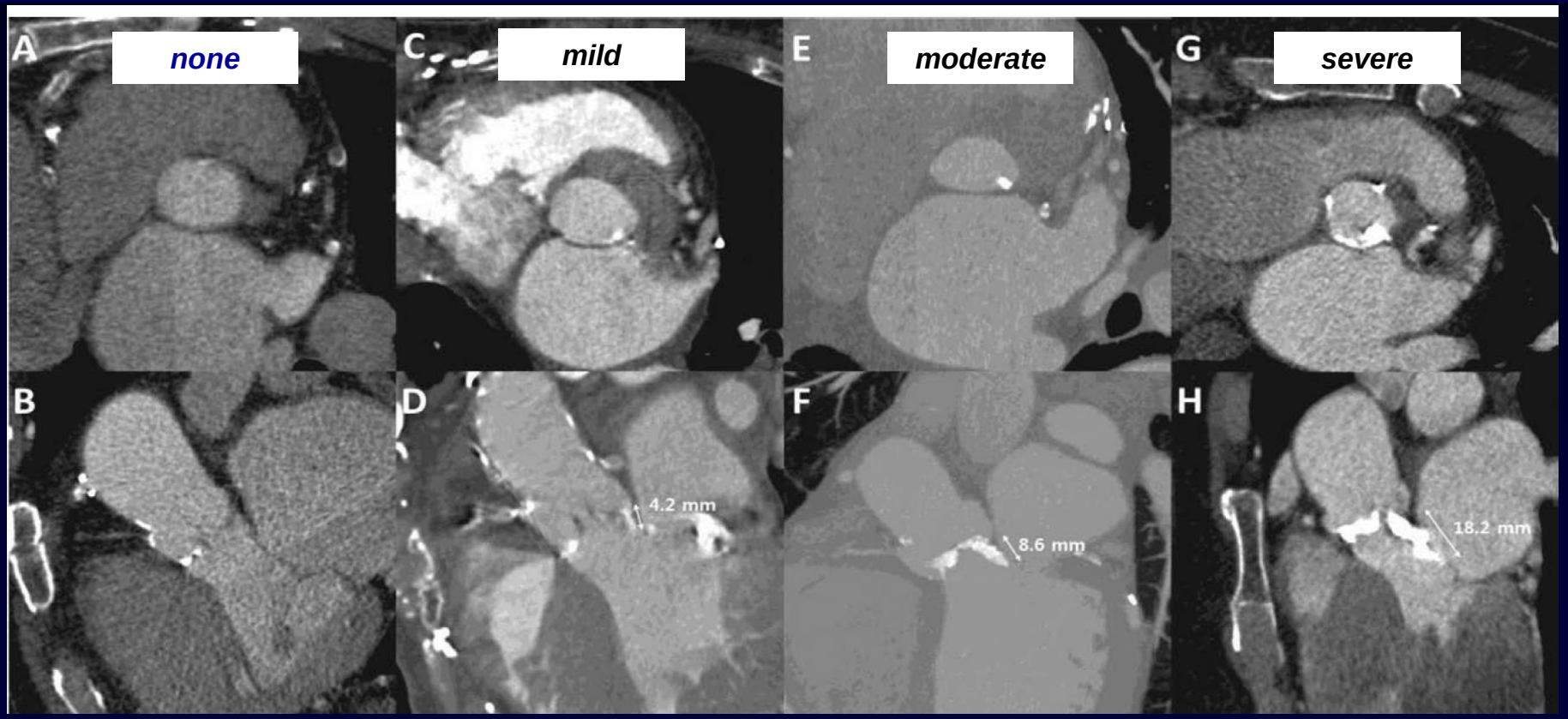
FIGURE 1 Simplified Schema of the "Device Landing Zone"

The aortic root **(blue)** and the left ventricular outflow tract **(pink)** form the "device landing zone."

TABLE 1 Classification of Annular Rupture According to the Anatomical Location

1. Intra-annular
2. Subannular
a. Injury of the free myocardial wall
b. Injury of the anterior mitral leaflet
c. Injury of the interventricular septum
3. Supra-annular
a. Injury of the wall of a sinus of Valsalva
b. Injury of the ostium of a coronary artery
c. Injury of the sinotubular junction
4. Combined
a. Intra-annular and supra-annular
b. Intra-annular and subannular
c. Intra-annular, supra-annular, and subannular

LVOT Calcification & TAVR : Different Degree of LVOT Calcification

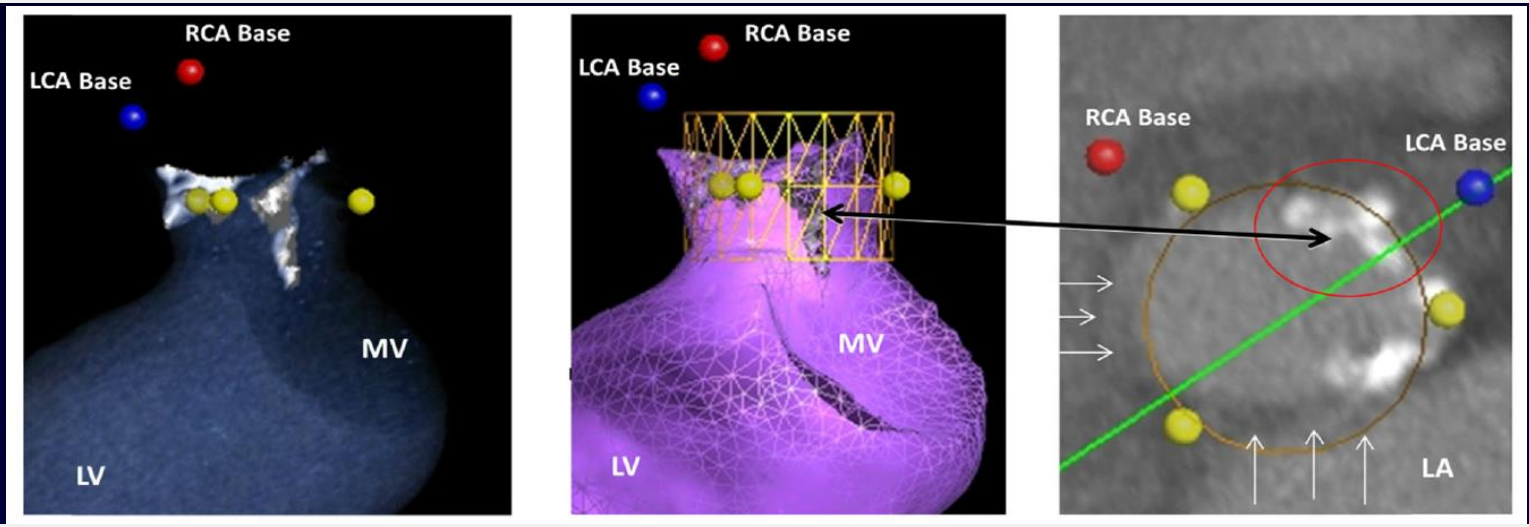


Calcification of the LVOT is not an isolated phenomena. It must be considered as a sign of severe degenerated Valves. Usually it can be detected together with extensive Calcification of the Annulus and Cusps.

Thoughtful Commentary: ***Severe LVOT Calcification and TAVR Markus Kasel, MD, PD*** *Structural Heart Disease Program*

LVOT Calcification & TAVR: Annular Rupture

"Among a total of 1000 TAVI procedures, 6 patients (0.6%) had a rupture of the device landing zone:
4 Supraannular Ruptures, 1 Annular Rupture and 1 Subannular Rupture."



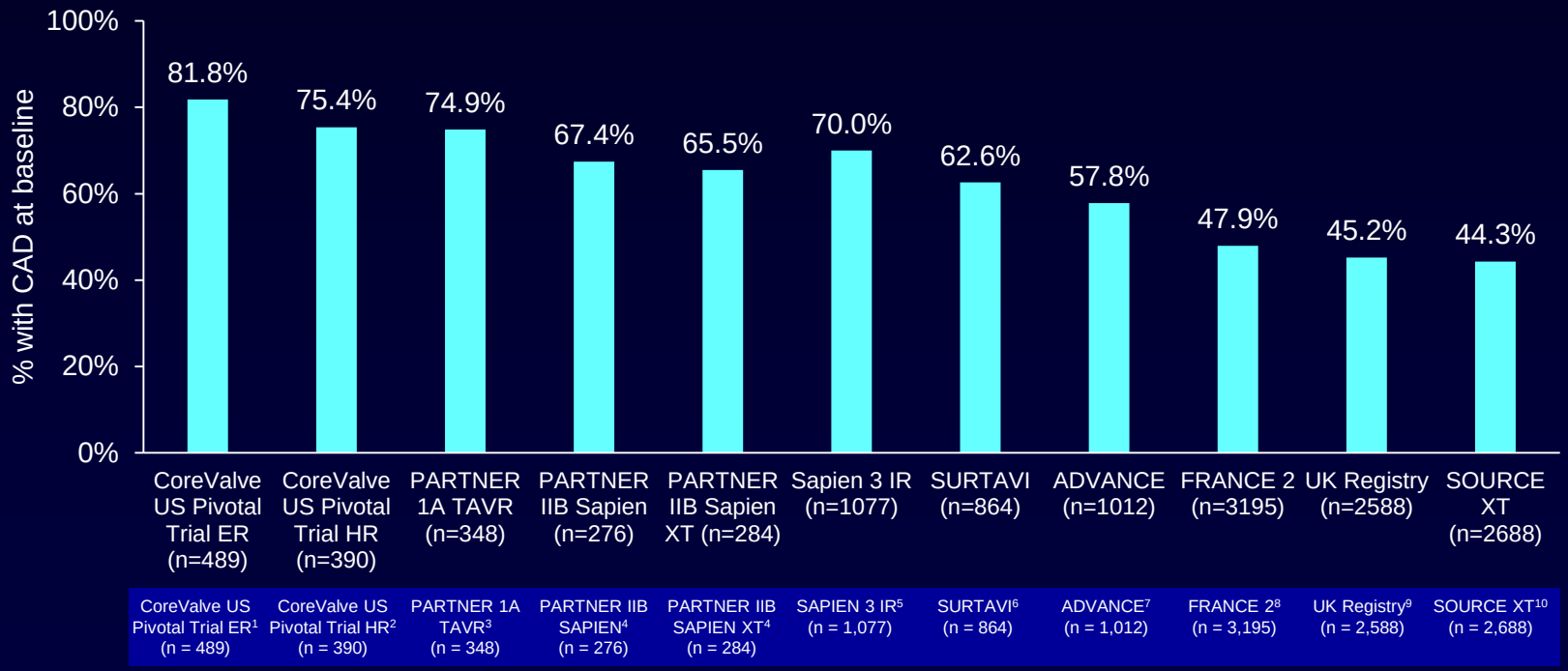
Risk factors for „Annular Rupture"

- Supraannular: Flat Sinuses of Valsalva and severe calcifications of the Aortic Cusps
- Annular: Ellipsoid Annulus and bulky calcifications of the Annulus
- Subannular: Narrow LVOT and bulky calcification of the LVOT

Schymik G et al. Clin Res Cardiol 2014; 103: 912-920

Coronary Artery Disease Prevalence in TAVI Patients

- It is important to maintain access to the coronaries to treat coronary artery disease (CAD) long-term post-TAVI.
- CAD is highly prevalent in the TAVR population, possibly affecting 80% of the cohort.

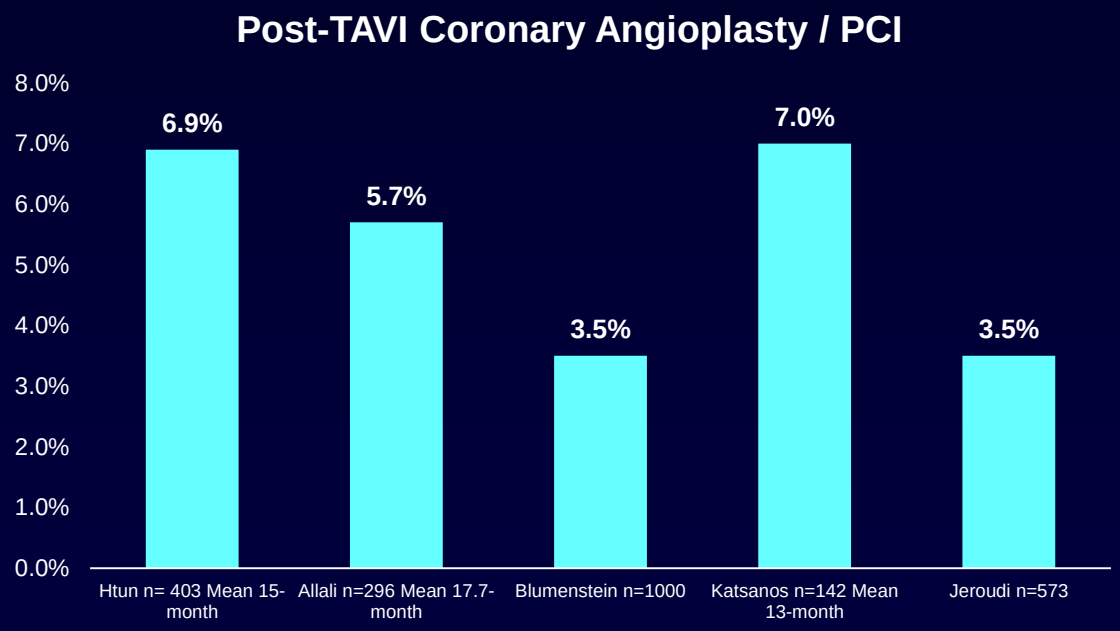


CoreValve US Pivotal Trial ER[1] (n = 489)	CoreValve US Pivotal Trial HR[2] (n = 390)	PARTNER 1A TAVR[3] (n = 348)	PARTNER IIB SAPIEN[4] (n = 276)	PARTNER IIB SAPIEN XT[4] (n = 284)	SAPIEN 3 IR[5] (n = 1,077)	SURTAVI[6] (n = 864)	ADVANCE[7] (n = 1,012)	FRANCE 2[8] (n = 3,195)	UK Registry[9] (n = 2,588)	SOURCE XT[10] (n = 2,688)

[1] Popma JJ, et al. *J Am Coll Cardiol*. 2014;63:1972-1981.
[2] Adams DH, et al. *N Engl J Med.* 2014;370:1790-1798.
[3] Smith CR, et al. *N Engl J Med.* 2011;364:2187-2198.
[4] Webb JG, et al. *JACC Cardiovasc Interv*. 2015;8:1797-1806.
[5] Thourani VH, et al. *Lancet*. 2016;387:2218-2225.
[6] Reardon MJ, et al. *N Engl J Med*. 2017;376:1321-1331.
[7] Bosmans J, et al. *J Am Coll Cardiol.* 2015;66:209-217.
[8] Gilard M, et al. *N Engl J Med.* 2012;366:1705-1715.
[9] Snow TM, et al. *Int J Cardiol.* 2015;199:253-260.
[10] Schymik G, et al. *JACC Cardiovasc Interv*. 2015;8:657-669.

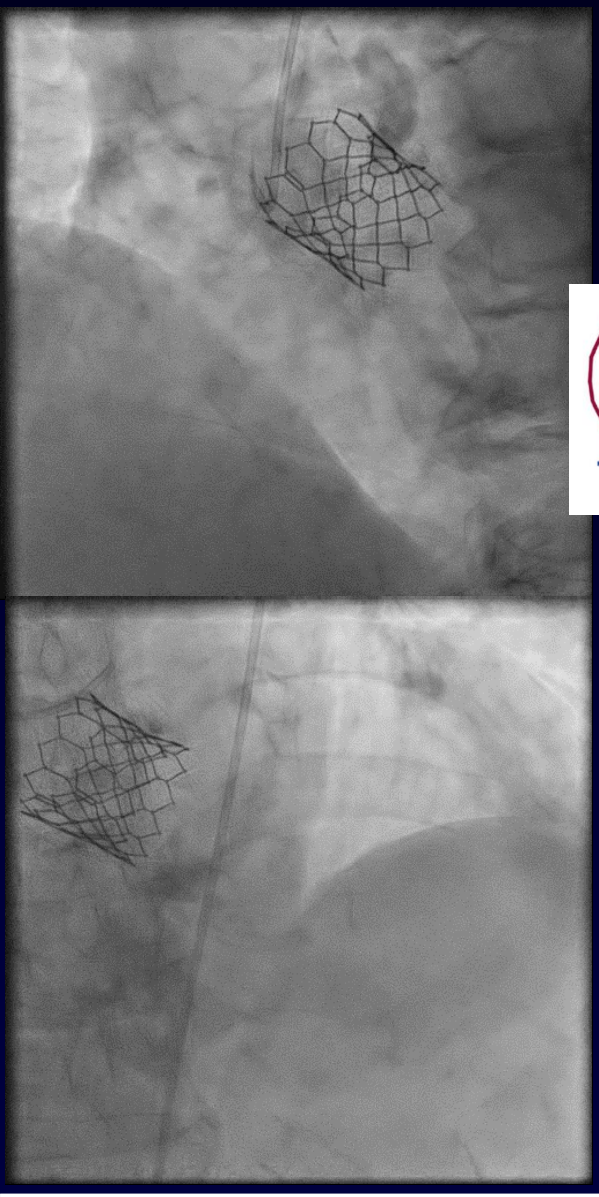
Recent studies have shown that with current indications, PCI after TAVI is already required for at least 3.5-7% of patients

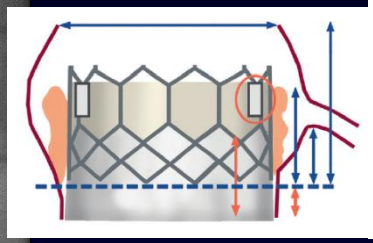
Frequency of need for PCI after TAVI

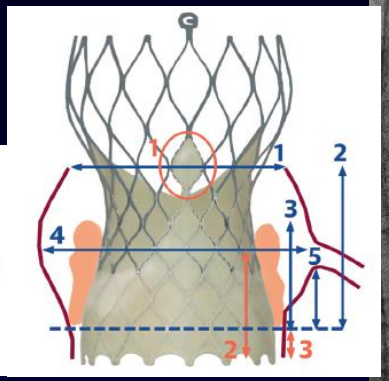


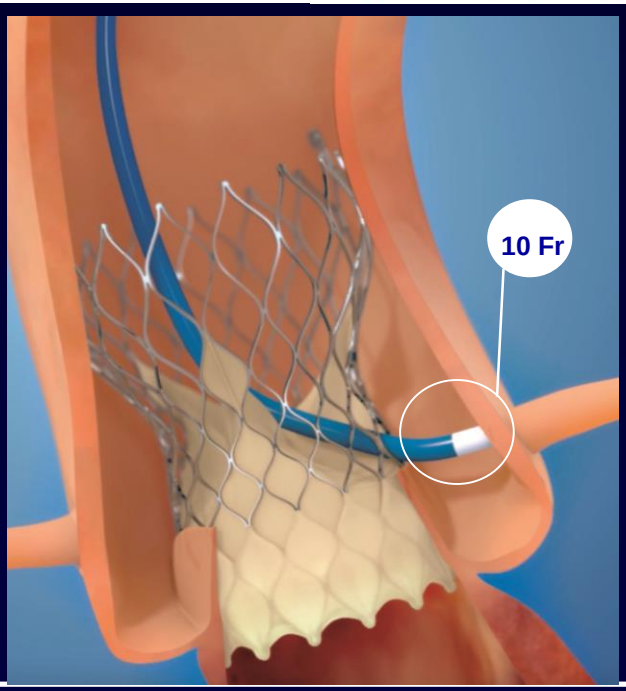
- Single center retrospective studies report 3.5% to 7% within 13 to 18 months.
- The authors from the various studies report TAVI patients who are treated post-TAVI for progressive CAD in their centers.
- **The overall number of post-TAVI intervention could be therefore higher since patients may receive treatment in other centers.**

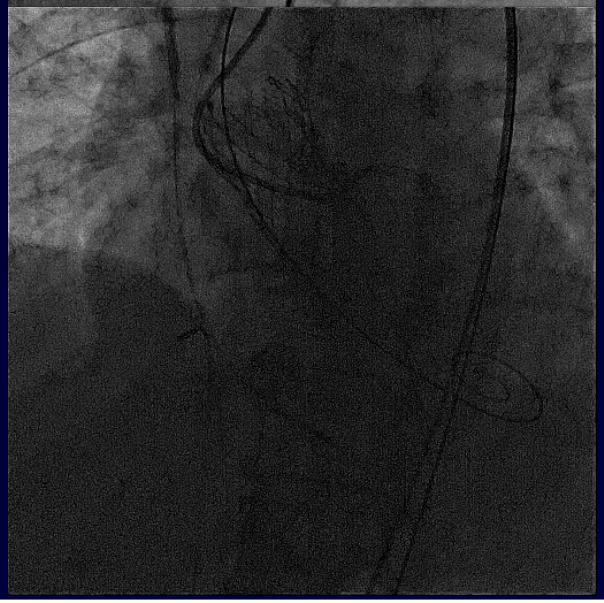
Engagement of CA



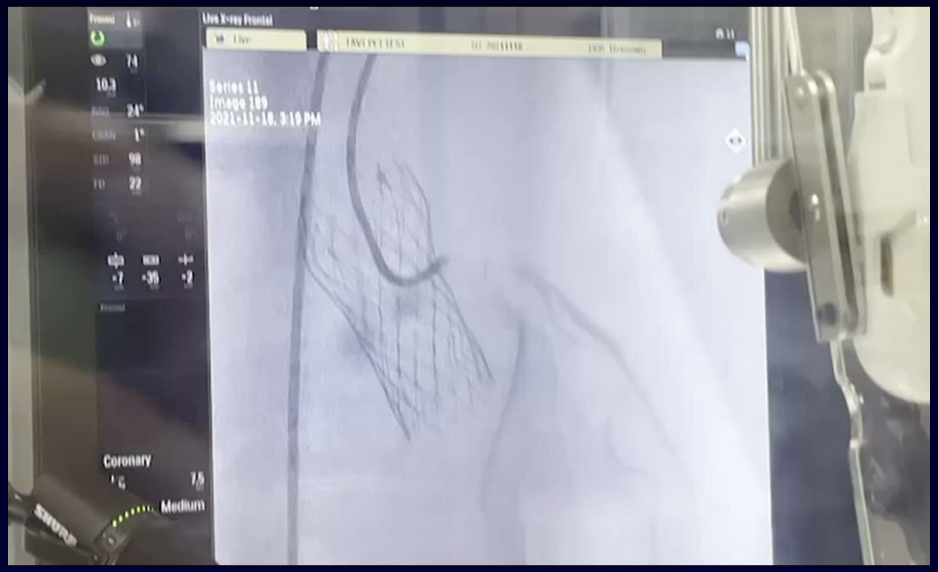


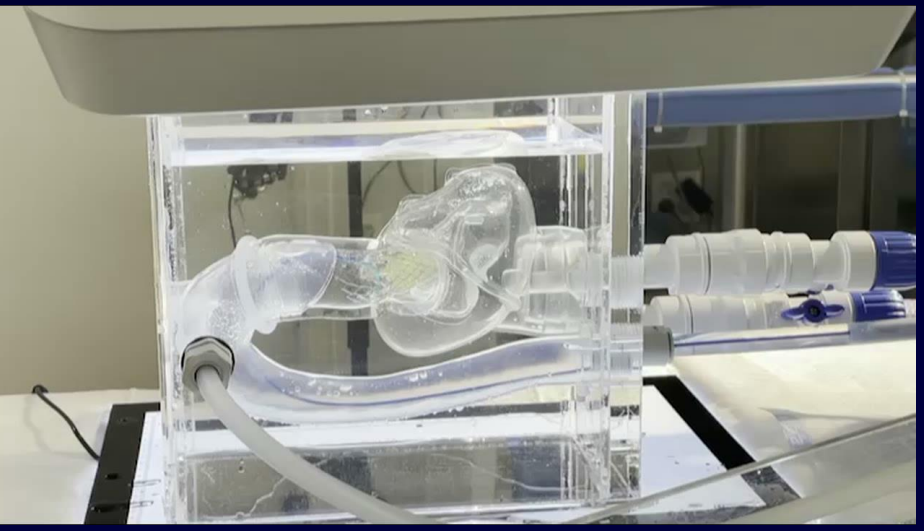


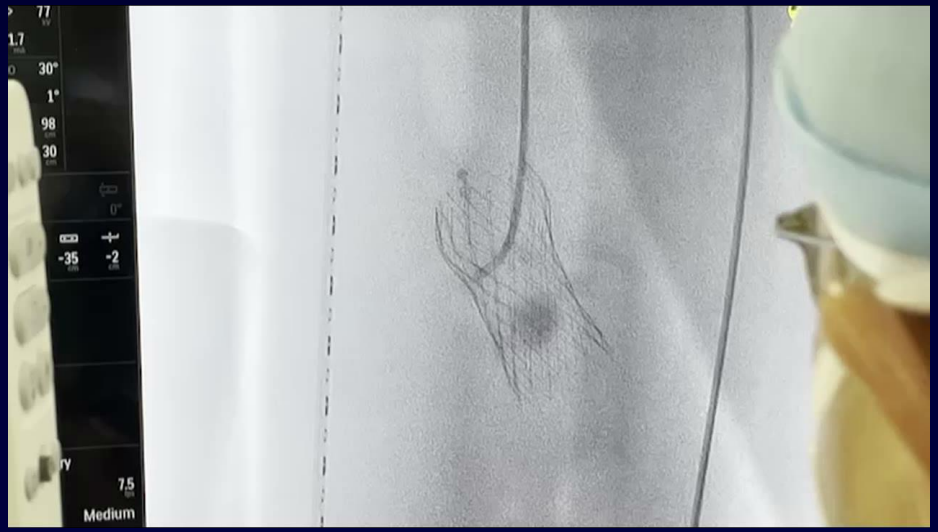




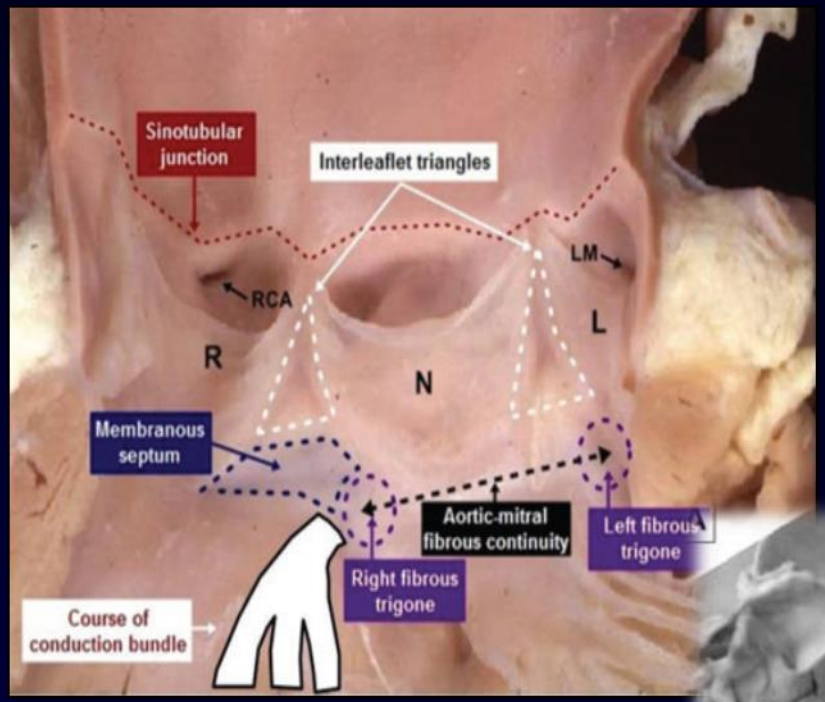
Training Heartroid



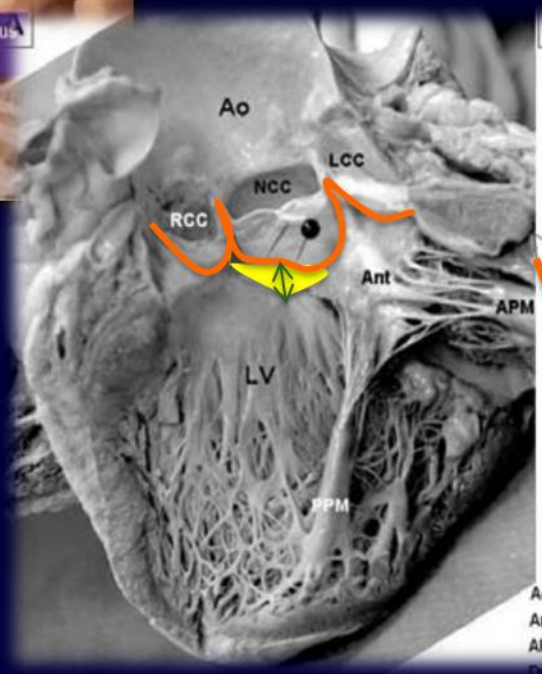


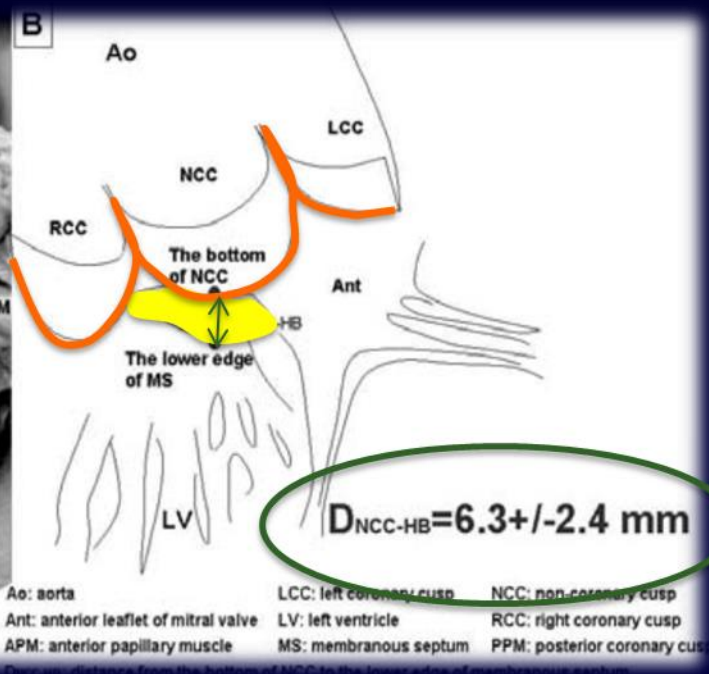


PPM: Length of MS



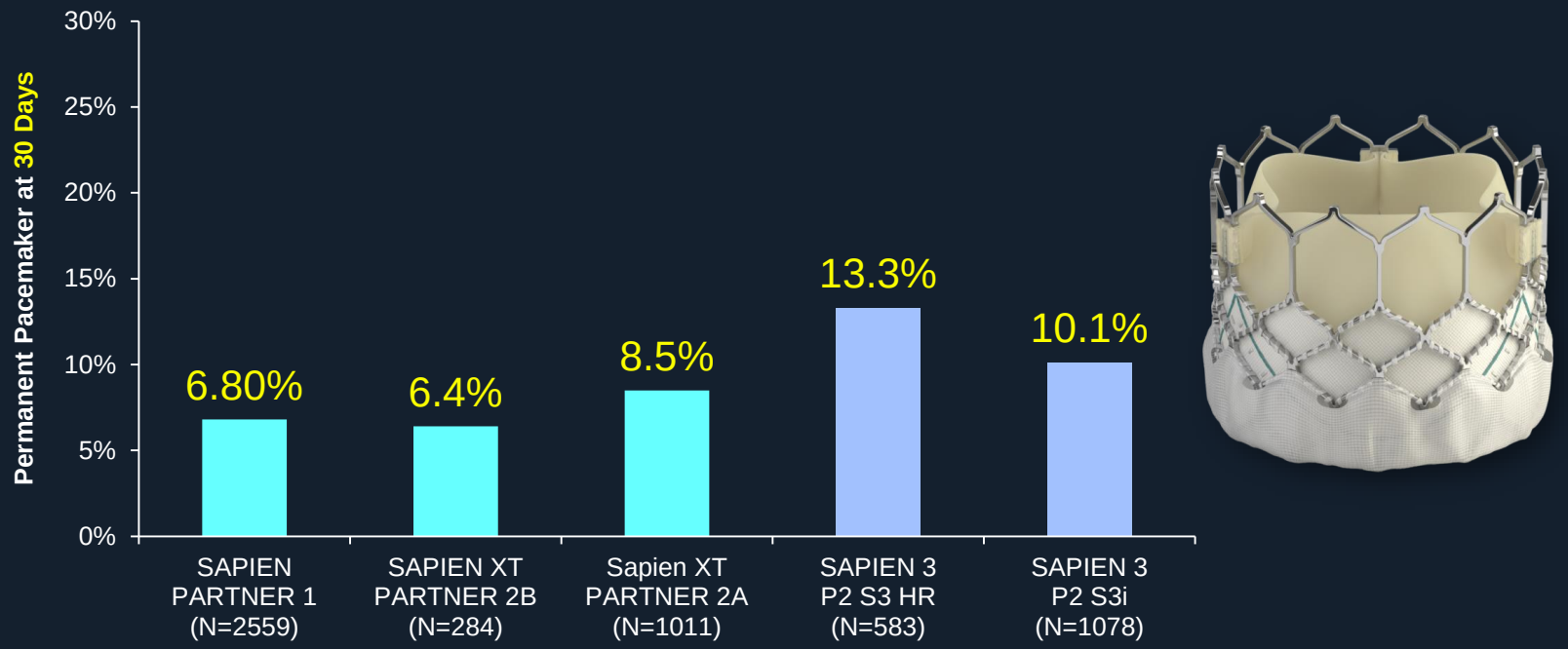
- Close proximity of the aortic valve to the cardiac conduction system[1]
- Distance between non-coronary cusp and His-bundle: on average, 6.3 mm
- Distance varies among individuals, but is usually <10 mm





[1] Igawa O. *Circ J* 2009; 73 Suppl I: S5-7.

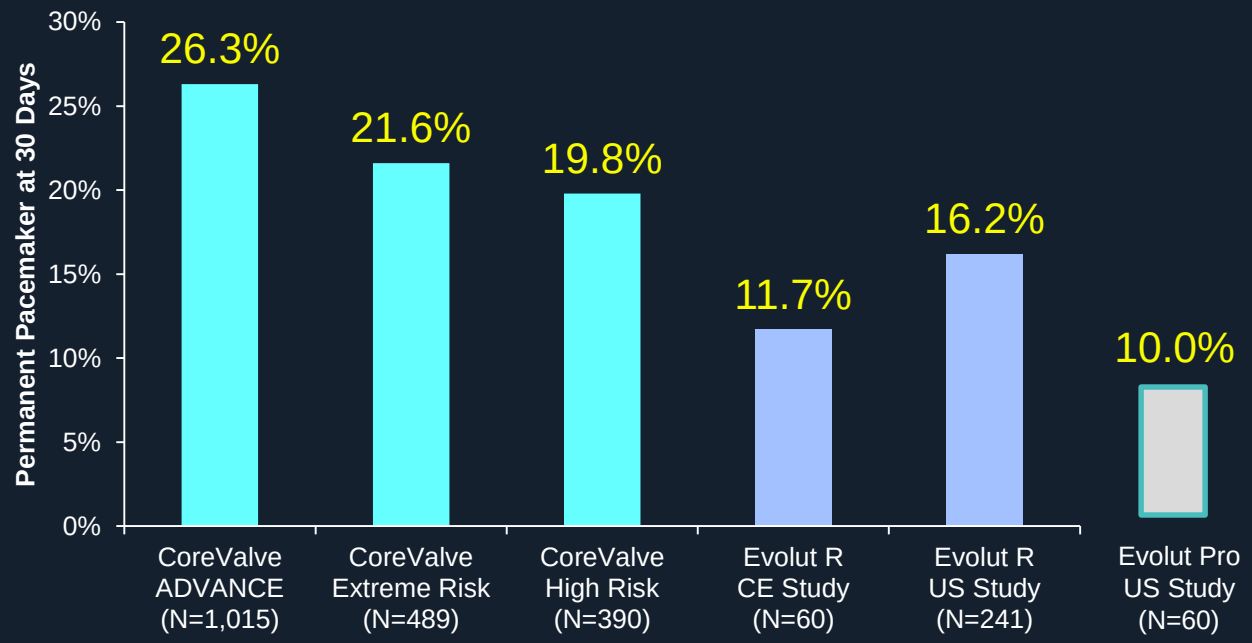
Pacemaker: Edwards SAPIEN 3



Nazif TM. *J Am Coll Cardiol Intv* 2015;8:60-9.; Webb JG. *J Am Coll Cardiol Intv 2015;8:1797-806.*; Leon MB. *N Engl J Med* 2016;374:1609-20.; Kodali S. Eur Heart J. 2016;37:2252-62

Adapted from Nazif T. TVT 2017

Pacemaker: Medtronic Evolut-R



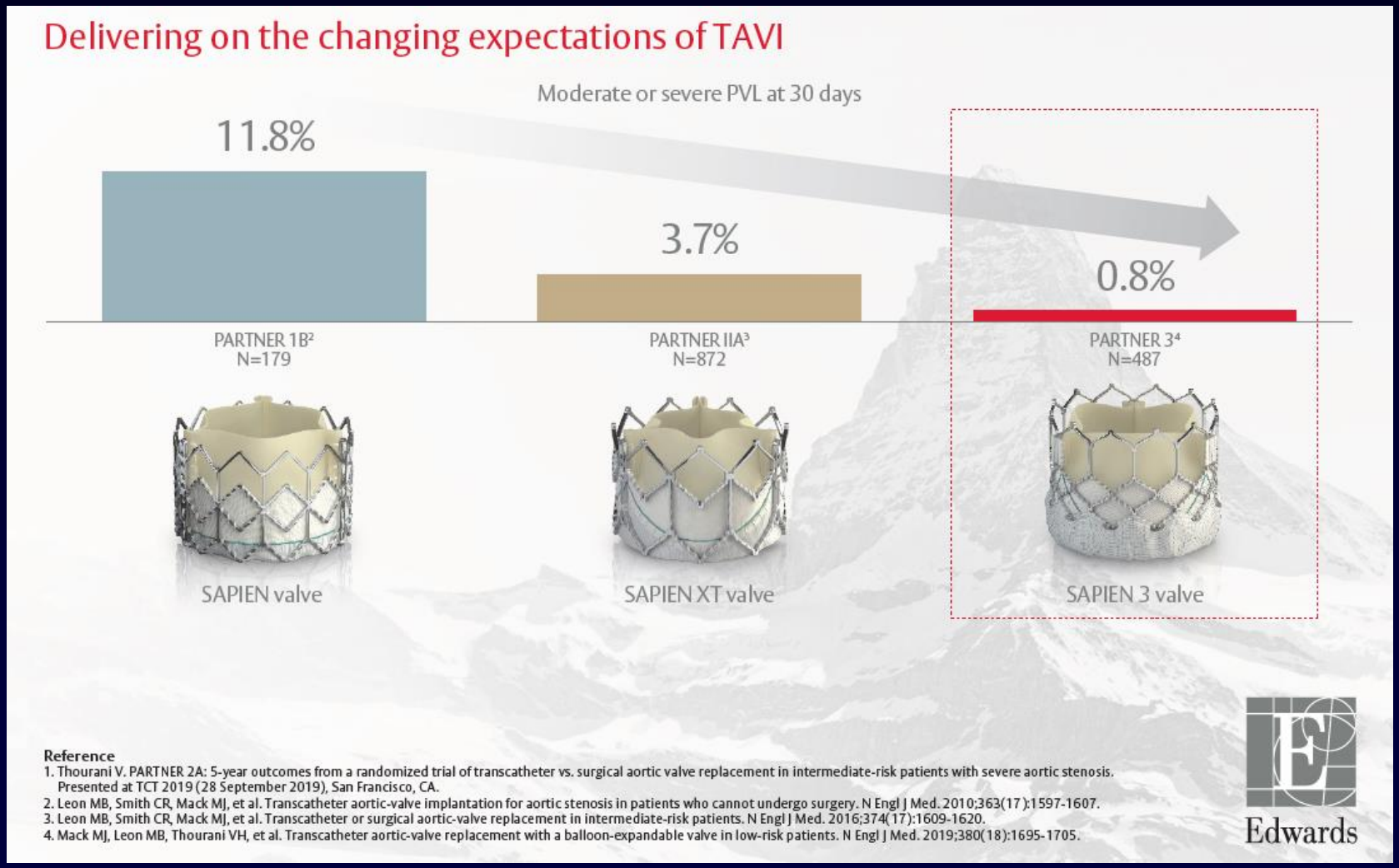
Linke A. *Eur Heart J* 2014;35:2672-84; Popma J. *J Am Coll Cardiol* 2014;63:1972-81; Adams D. *N Engl J Med* 2014;370:1790-8; Manoharan G. *J Am Coll Cardiol Intv* 2015;8:1359-67; Williams MR presented at ACC 2016, Forrest J presented at ACC 2017

Adapted from Nazif T. TVT 2017

Other clinical endpoints

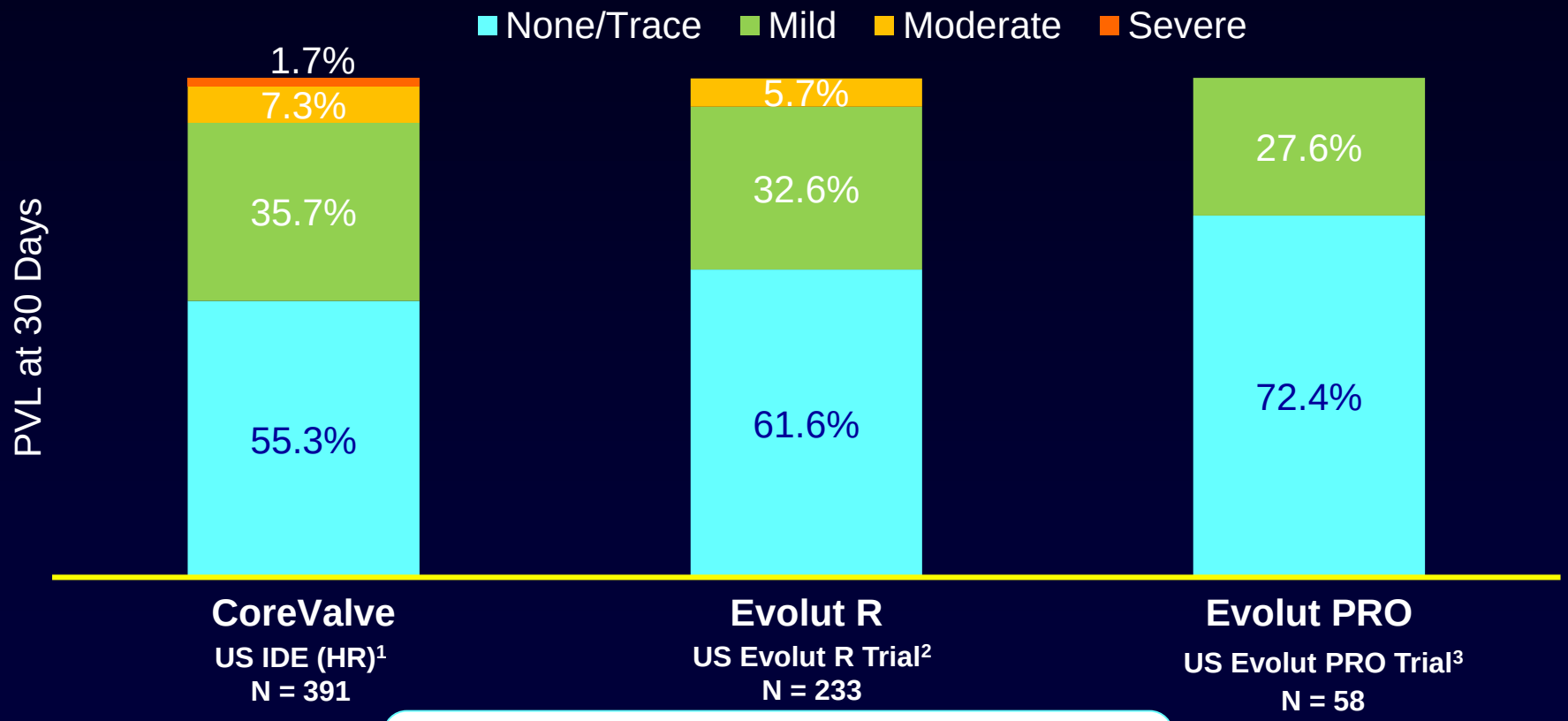
	Balloon-expandable valve (n=121)	Self-expanding valve (n=120)	p-value
Stroke	21 (17.5%)	19 (16.5%)	0.73
Repeat hospitalization for heart failure	30 (28.9%)	26 (22.5%)	0.75
Myocardial infarction	2 (1.6%)	7 (6.1%)	0.08
Bleeding			
Life threatening	21 (17.3%)	18 (16.2%)	0.77
Major	28 (26.3%)	20 (22.0%)	0.26
Minor	17 (14.3%)	12 (10.4%)	0.37
Vascular complications			
Major	14 (11.6%)	14 (12.1%)	0.89
Minor	5 (4.2%)	3 (2.6%)	0.51
New pacemaker	28 (25.4%)	40 (40.4%)	0.01

Paravalvular Leak I



Paravalvular Performance II

ADVANCED SEALING AT 30 DAYS



Evolut PRO PVL at 30 Days
0% Moderate & 0% Severe PVL[3]

1. CoreValve HR Data; Adams et al., ACC, 2014; 2. Popma, et al., JACC 2017; 3. Forrest, et al., ACC, 2017
NOTE: PVL performance data represent different device performance in different trials; comparison of results is for illustration purposes only and may not be indic ative of clinical performance.

YUHS

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Table 1. 임상 및 해부학적조건에 따른 경피적대동맥판막삽입술용 판막 종류의 선호도

Clinical and anatomical condition	 Choice between Evolut R/Pro vs Sapien 3 
Small or diseased transfemoral access route	>
Horizontal ascending aorta	<
Coronary artery obstruction	>
Coronary artery access	<
Heavy or unfavorable calcification of aortic valve	>
Small annulus	>
Small sinotubular junction	>
Risk of AV conduction	<
Valve-in-valve TAVR	>
Severe LV dysfunction	>
Valve size selection based on echocardiography	>

Conclusion

- The recent generation self-expandable and balloon-expandable valves were both effective and safe regarding clinical outcomes.
- The decision of the TAVR valve depends on the opinion and expeience of the heart team.
- It is recommended to select the type of valve in consideration of the patient's aortic valve, heart function, and the condition of the aorta and blood vessels in the access path before the procedure.

Thanks for your attention

Severance

With the Love of God, Free Humankind from Disease and Suffering