

11th
AP VALVES & 2022
STRUCTURAL HEART



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Latest Clinical Evidence and How It Impact My Practice

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Disclosure

- 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

Clinical Proctor/Speaking honorarium

COMPANY

- Abbott
- Boston Scientific
- Medtronic

Background

- Transcatheter aortic valve implantation (TAVI) is an established treatment for severe aortic stenosis (AS) in patients of all risk levels
- Younger, low risk patients with increasingly long expected survivals are being offered TAVI
- The **lifetime management** of these patient is very important

Archilles of TAVI in younger low risk patients

1. Durability
2. Feasibility of TAV-in-TAV
3. Conduction disturbance
4. Feasibility of future coronary access



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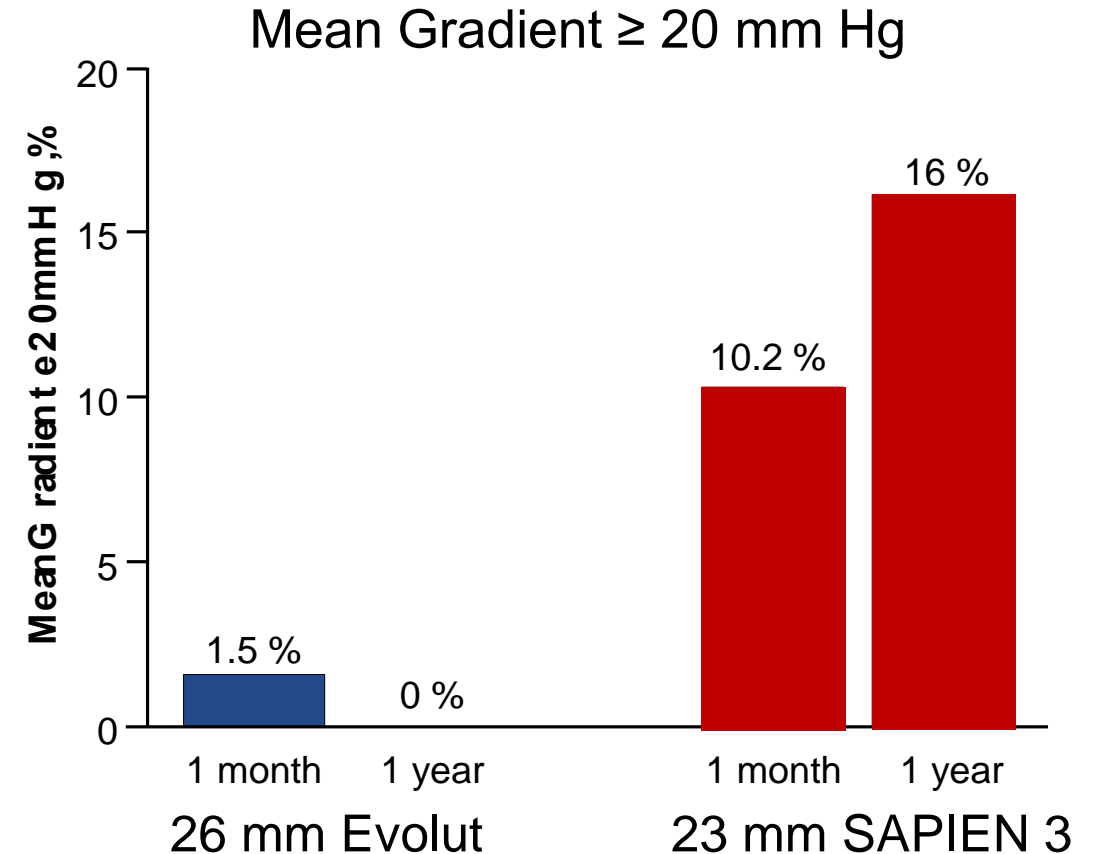
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Hemodynamic Profile and Durability

Supra-annular Design, porcine valve

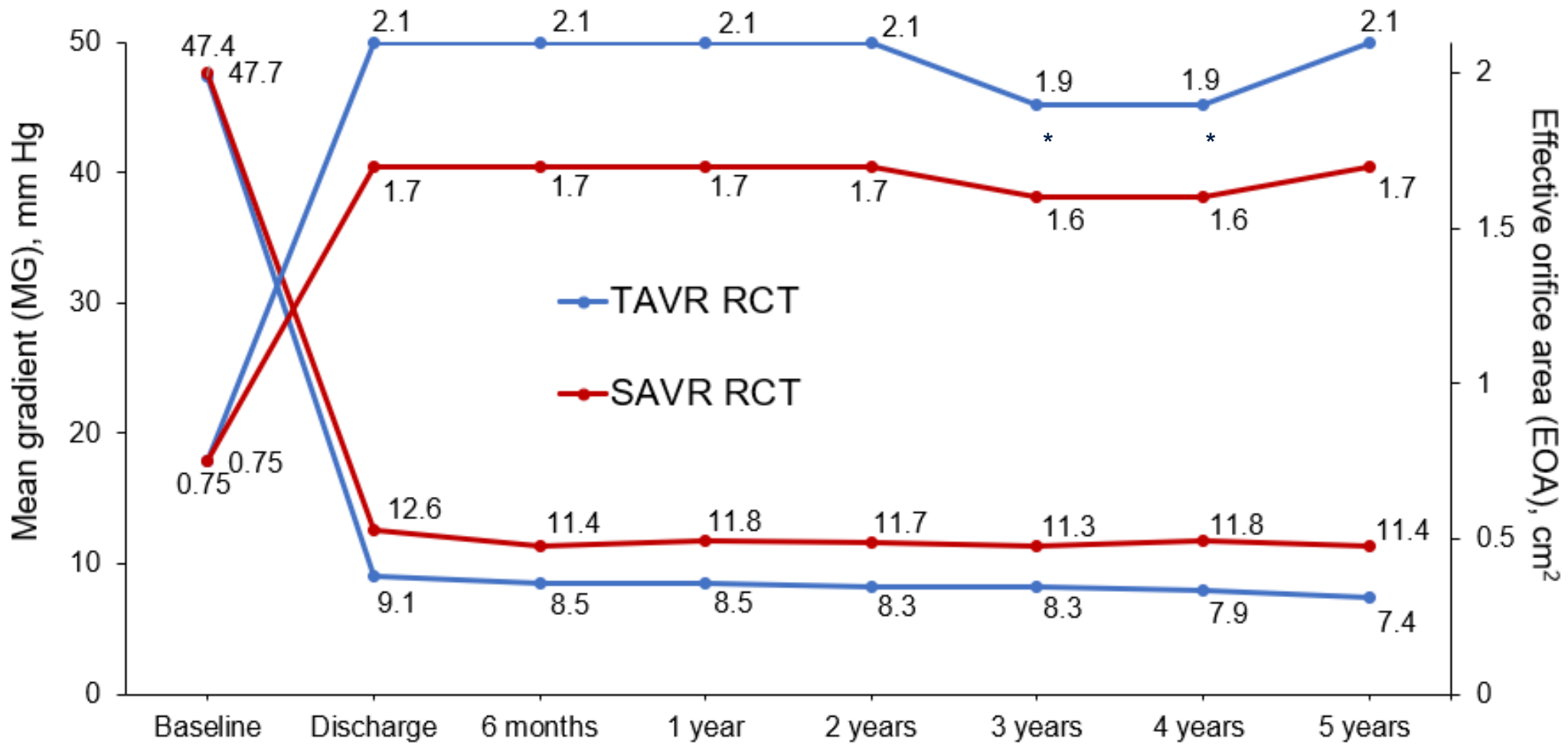
Comparison of 30-Day and 1-Year Gradients

1 Month Echo	23 mm Sapien3 (N = 522)	26 mm Evolut (n = 133)	p-value
Mean Gradient ± SD (mm Hg)	13.2 ± 4.7	7.7 ± 3.9	< 0.001
Pts with Mean Gradient ≥ 20 mm Hg, N (%)	53 (10.1%)	2 (1.5%)	0.001
Moderate/Severe AI, N (%)	8 (1.5%)	3 (2.2%)	0.475
1 Year Echo	(N = 368)	(N = 77)	p-value
Mean Gradient ± SD (mm Hg)	14.5 ± 5.6	8.2 ± 3.8	< 0.001
Pts with Mean Gradient ≥ 20 mm Hg, N (%)	59 (16.0%)	0 (0.0%)	< 0.001
Moderate/Severe AI, N (%)	12 (3.3%)	0 (0.0%)	0.234



Source: Ring ME, et al. *J Am Coll Cardiol.* 2020;75(11_Supplement_1):1266.

Valve Performance to Five Years (TAVR → SEV)

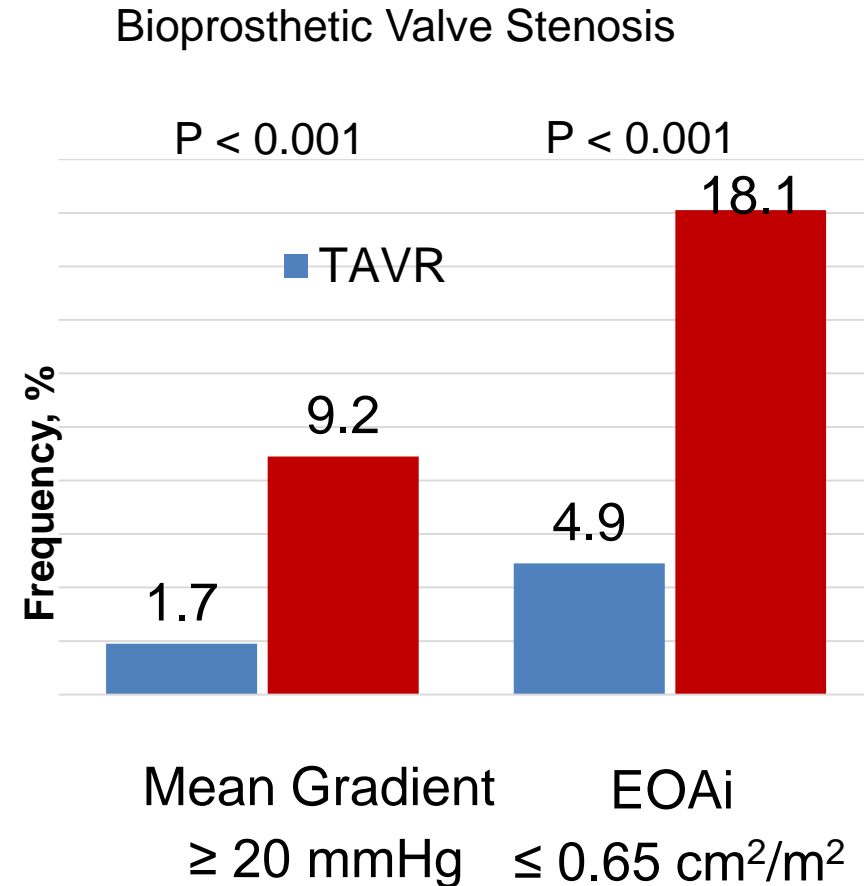


O'Hair D, et al. Presented at ACC2021

* Core lab to site-reported echo data

Small Differences in Mean Gradient Translate into Larger Difference in BVS

MEAN GRADIENT AND PROSTHETIC VALVE STENOSIS

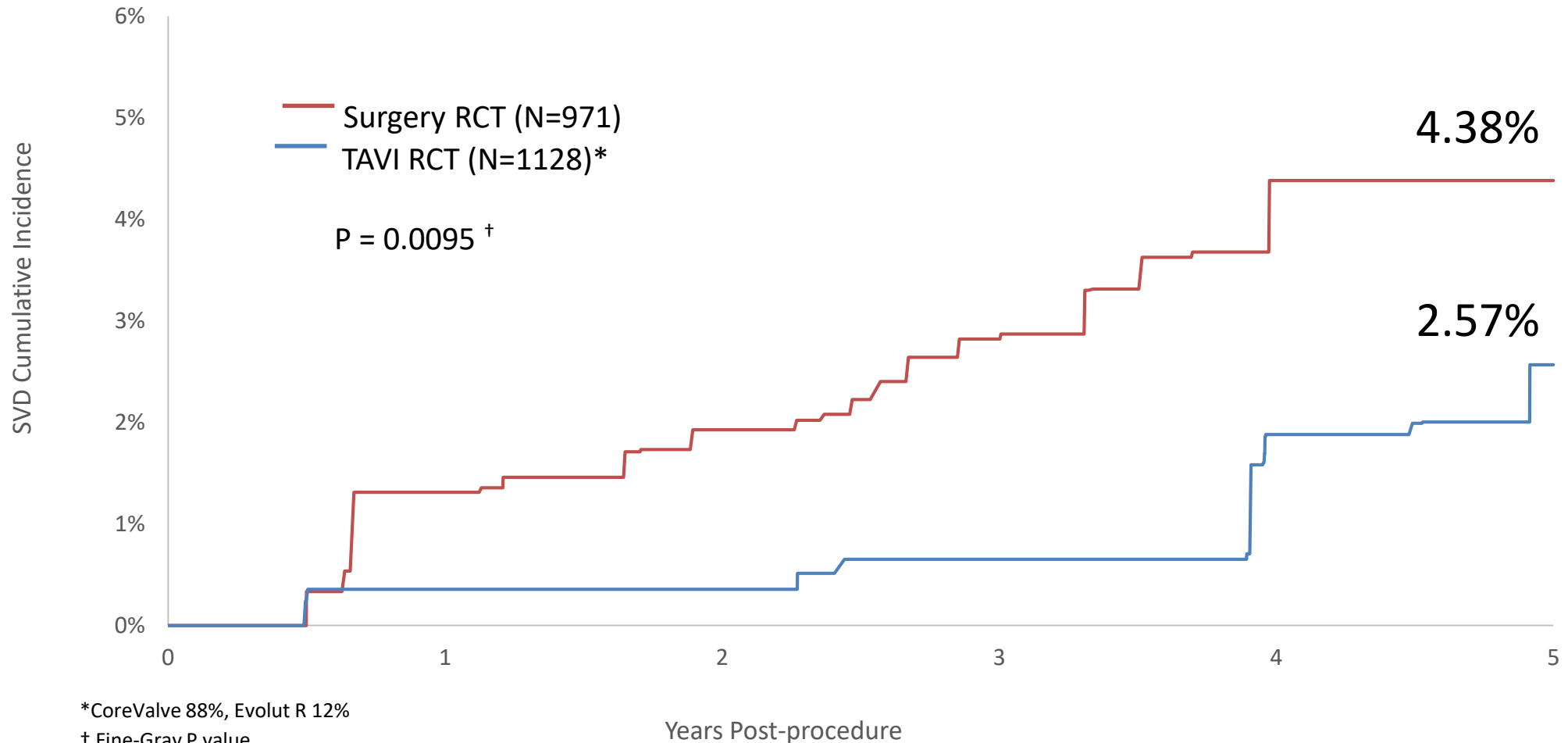


Source: Rovin Abstract Presentation CRT2021

Corevalve Evolut Pooled Analysis

- 5-Year SVD Adjusted For Competing Risk of Mortality

Significantly lower rate of SVD with TAVI vs. Surgery through 5 years



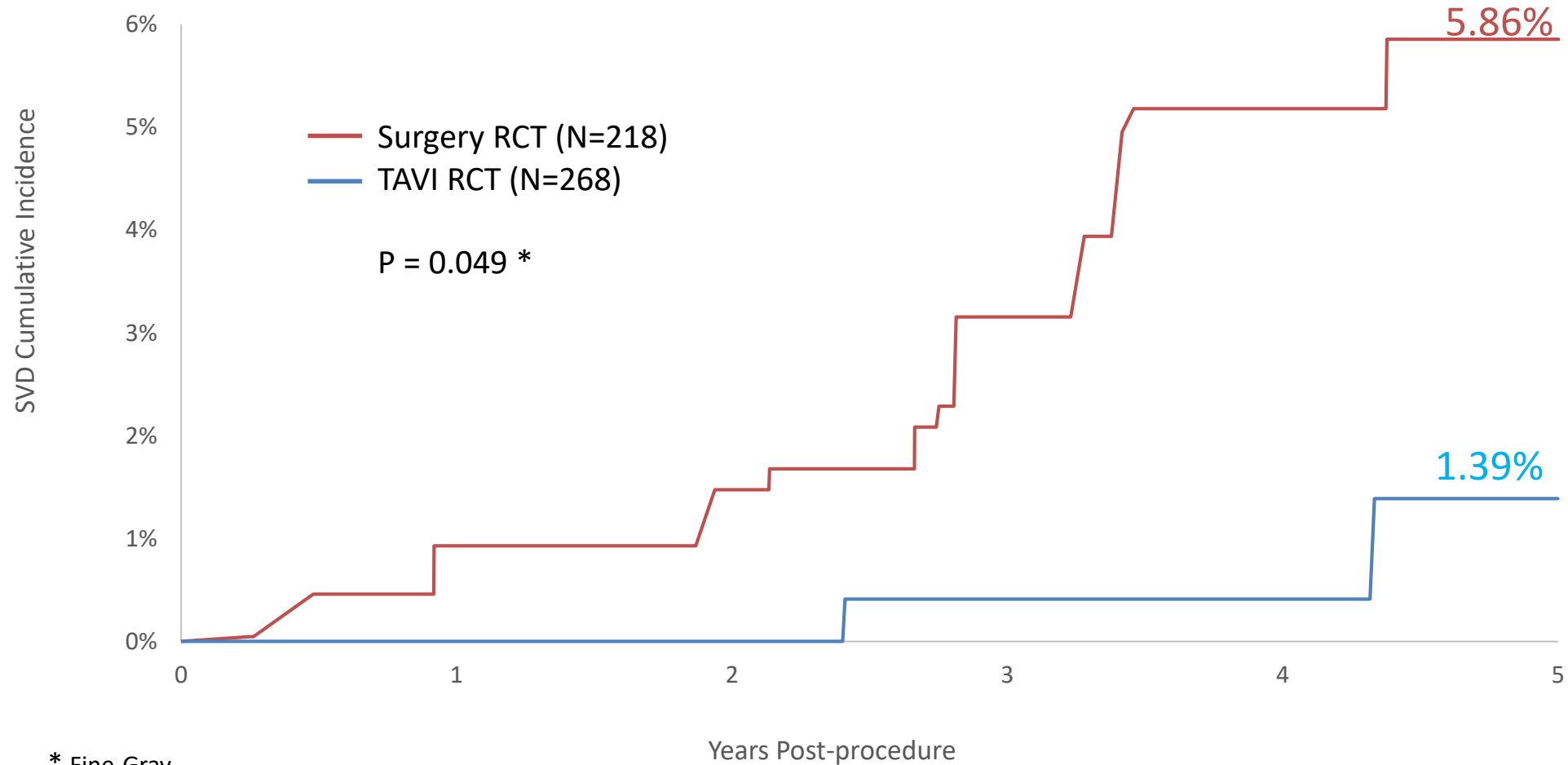
*CoreValve 88%, Evolut R 12%

† Fine-Gray P value

Corevalve Evolut Pooled Analysis

- 5-Year SVD in Smaller ($\leq 23\text{mm}$) Annular Diameter

Significantly lower rate of SVD with TAVI vs. Surgery through 5 years in small annuli

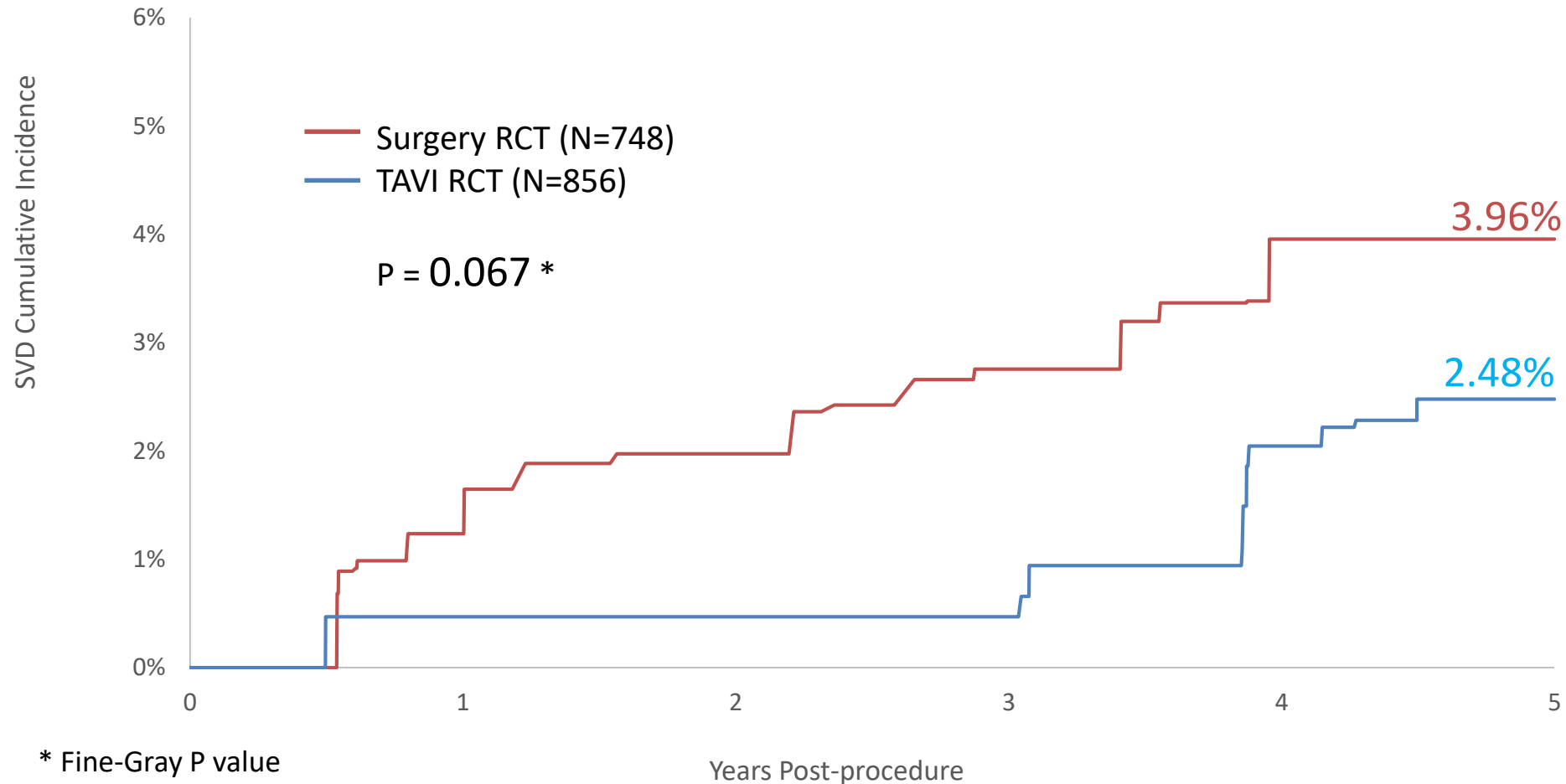


* Fine-Gray

Corevalve Evolut Pooled Analysis

- 5-Year SVD in Larger ($\geq 23\text{mm}$) Annular Diameter

Trend towards a lower rate of SVD with TAVI vs. Surgery through 5 years in larger annuli



Superior hemodynamic → Durability

1. Superior Acute Valve Performance in usual anatomy, additional benefit in
 - V-in-V
 - Small Annuli (<430 mm²) → Asian/women
2. Long Term Valve Integrity
 - Better gradient, larger EOA
 - Less SVD



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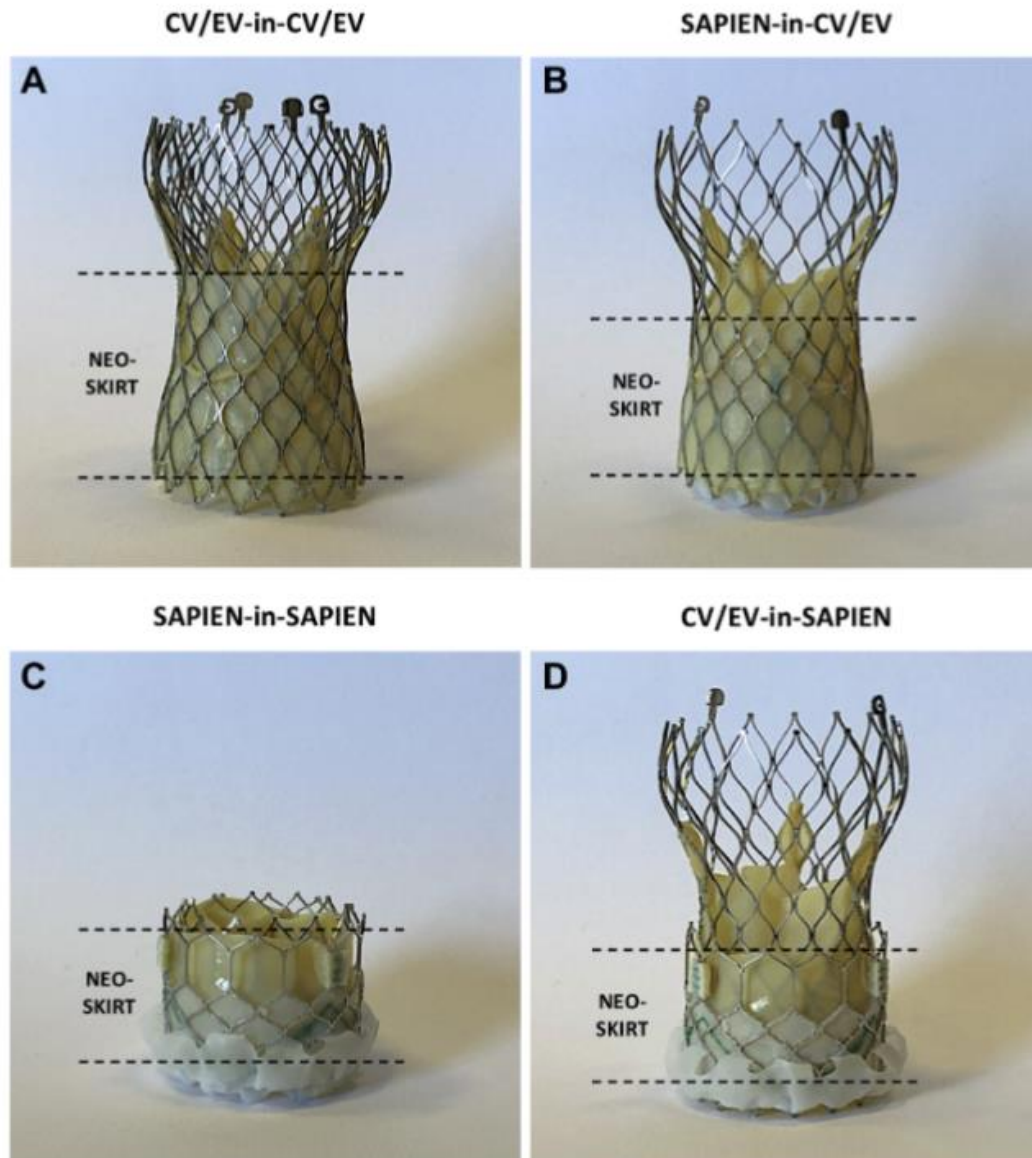


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TAV-in-TAV

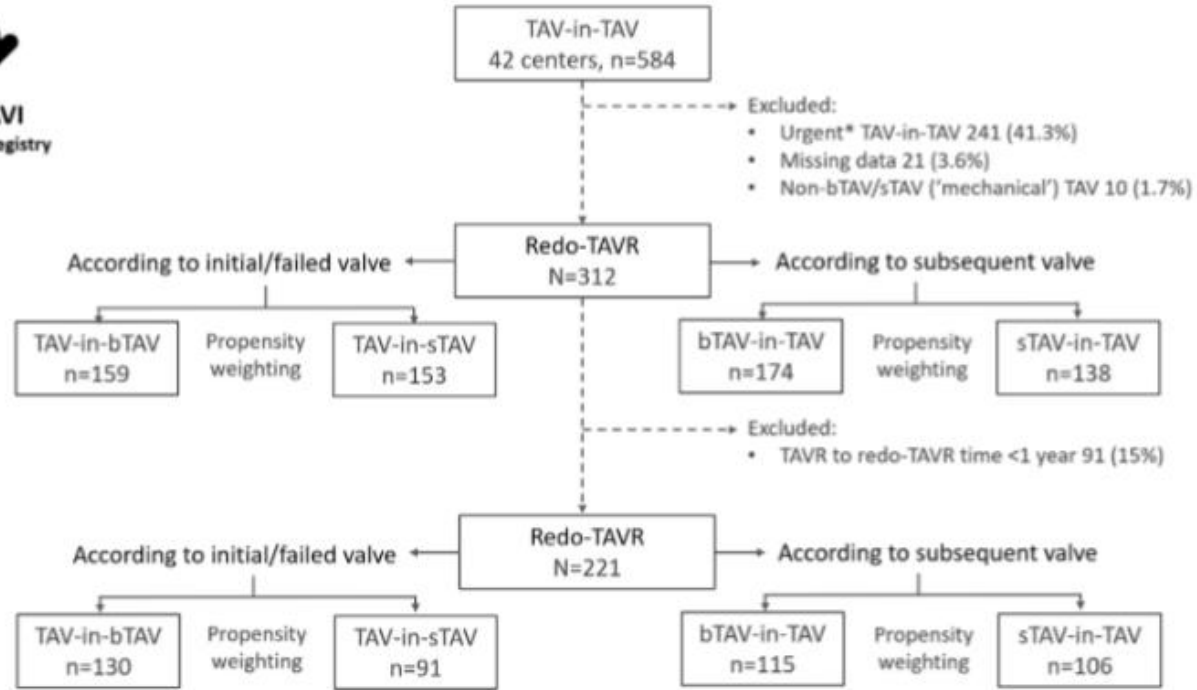
Feasibility

FIGURE 1 TAVR-in-TAVR



- Feasibility of TAV in SEV?
- Supra-annular, tall valve frame design
→ Risk of coronary occlusion
- First valve choice?

FIGURE 1 Patient Flowchart



A total of 584 consecutive patients who underwent transcatheter aortic valve (TAV)-in-TAV implantation were identified at the 42 participating centers. *As a single procedure with the native valve transcatheter aortic valve replacement (TAVR) and not as a repeated procedure. bTAV = balloon-expandable transcatheter aortic valve; sTAV = self-expanding transcatheter aortic valve.

42 centers
International Redo-TAVI
registry
Propensity score matched
analysis

TABLE 2 Redo TAVR Outcomes (30 Days)

	According to Initial Valve Type			According to Subsequent Valve Type		
	TAV-in-bTAV	TAV-in-sTAV	P Value	bTAV-in-TAV	sTAV-in-TAV	P Value
Device success ^a	91 (71.0)	67 (71.4)	0.952	68 (64.3)	74 (77.2)	0.045
Early safety ^b	93 (72.6)	67 (71.2)	0.817	78 (73.2)	73 (76.5)	0.590
Mortality	2 (2.3)	0	0.499	1 (1.7)	1 (1.0)	0.612
Stroke	0 (0.0)	3 (3.0)	0.047	0 (0.0)	1 (0.7)	0.384
Myocardial infarction	1 (0.5)	0 (0.0)	0.506	1 (0.6)	0	0.452
Valve malposition/embolization	0 (0.0)	2 (1.8)	0.126	0	1 (0.7)	0.443
Coronary obstruction	1 (0.5)	0 (0.0)	0.506	1 (0.6)	0	0.452
Annular rupture	0	0	NA	0	0	NA
Cardiac tamponade	0	0	NA	0	0	NA
Conversion to open heart surgery	0	0	NA	0	0	NA
Major vascular complication	8 (6.0)	11 (11.3)	0.155	10 (9.1)	9 (9.2)	0.984
Major bleeding	9 (7.2)	9 (9.8)	0.488	14 (13.0)	6 (6.4)	0.116
Acute kidney injury	6 (4.9)	2 (1.7)	0.207	2 (2.1)	2 (1.8)	0.903
New permanent pacemaker	8 (6.1)	6 (5.9)	0.946	7 (6.8)	8 (8.6)	0.641
30-d reintervention	0	0	NA	0	0	NA
High residual mean gradient ^c	25 (19.3)	11 (11.2)	0.104	25 (23.6)	10 (11.0)	0.018
Aortic regurgitation moderate or greater	12 (9.1)	4 (4.4)	0.176	6 (5.7)	5 (5.7)	0.987

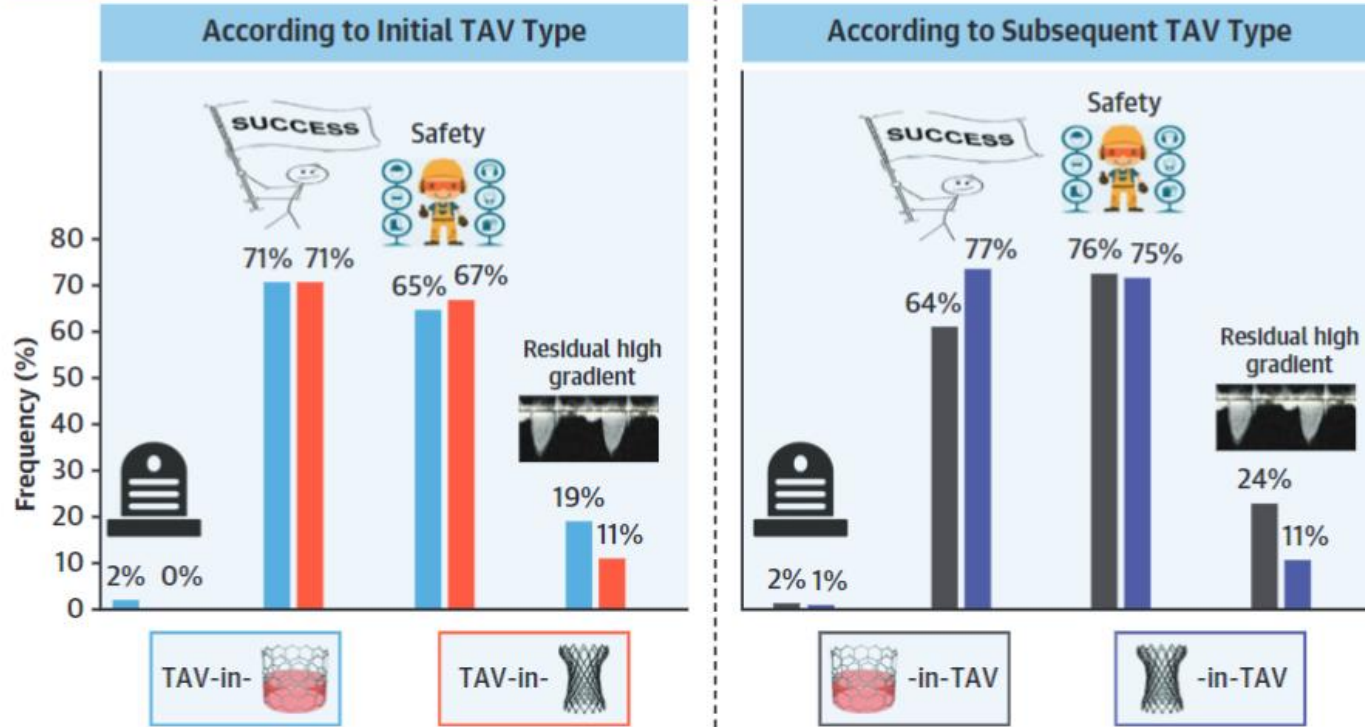
Values are n (%). Adjusted cohorts (using propensity weighting). Adjusted cohorts: after applying propensity weighting and excluding redo TAVR performed within 1 year of the initial TAVR. ^aComposite of freedom from all-cause mortality, freedom from intervention related to the device or to a major vascular or cardiac structural complication (coronary obstruction, annular rupture, or cardiac tamponade), and technical success with intended performance of the valve (mean gradient <20 mm Hg and less than moderate aortic regurgitation) at 30 days. ^bComposite of freedom from all-cause mortality, all stroke, major bleeding, major vascular complication or cardiac structural complication, acute kidney injury, moderate or severe aortic regurgitation, new permanent pacemaker, and surgery or intervention related to the device at 30 days. ^cHigh if ≥20 mmHg.

Abbreviations as in Table 1.



CENTRAL ILLUSTRATION Redo Transcatheter Aortic Valve Replacement Outcomes According to Initial and Subsequent Transcatheter Aortic Valve Type: Balloon Expandable vs Self-Expanding

30-Day Outcome of TAV-in-TAV From the Redo-TAVR Registry 2008-2021; N = 221



Landes U, et al. J Am Coll Cardiol Interv. 2022;15(15):1543-1554.

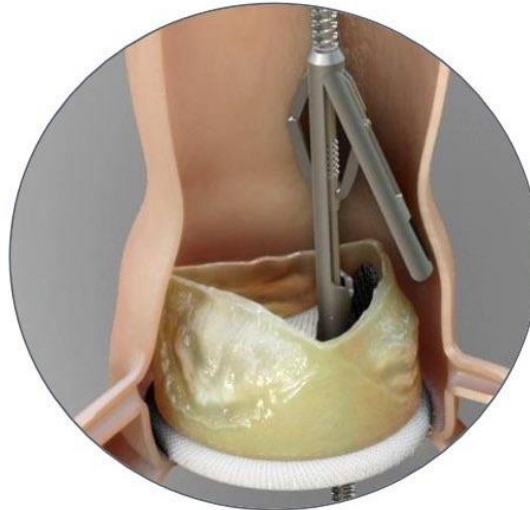
- Safety and mortality for redo TAVR were similar among patients with initial BEV and SEV
- Redo TAVR using a BEV vs an SEV for the redo procedure also had similar early safety and mortality rates
- SEV had higher device success, driven by a lower mean pressure gradient.
- Limitations:
 - Registry based
 - Did not include all patients requiring TAV-in-TAV

ShortCut™ Catheter

First dedicated transcatheter leaflet splitting device



Designed to **enable coronary access** and **prevent coronary obstruction** during TAVI



Complete **control over positioning** and **leaflet splitting location**



Allows for **safe, simple splitting** of **single or double leaflets**, with **short procedural times**



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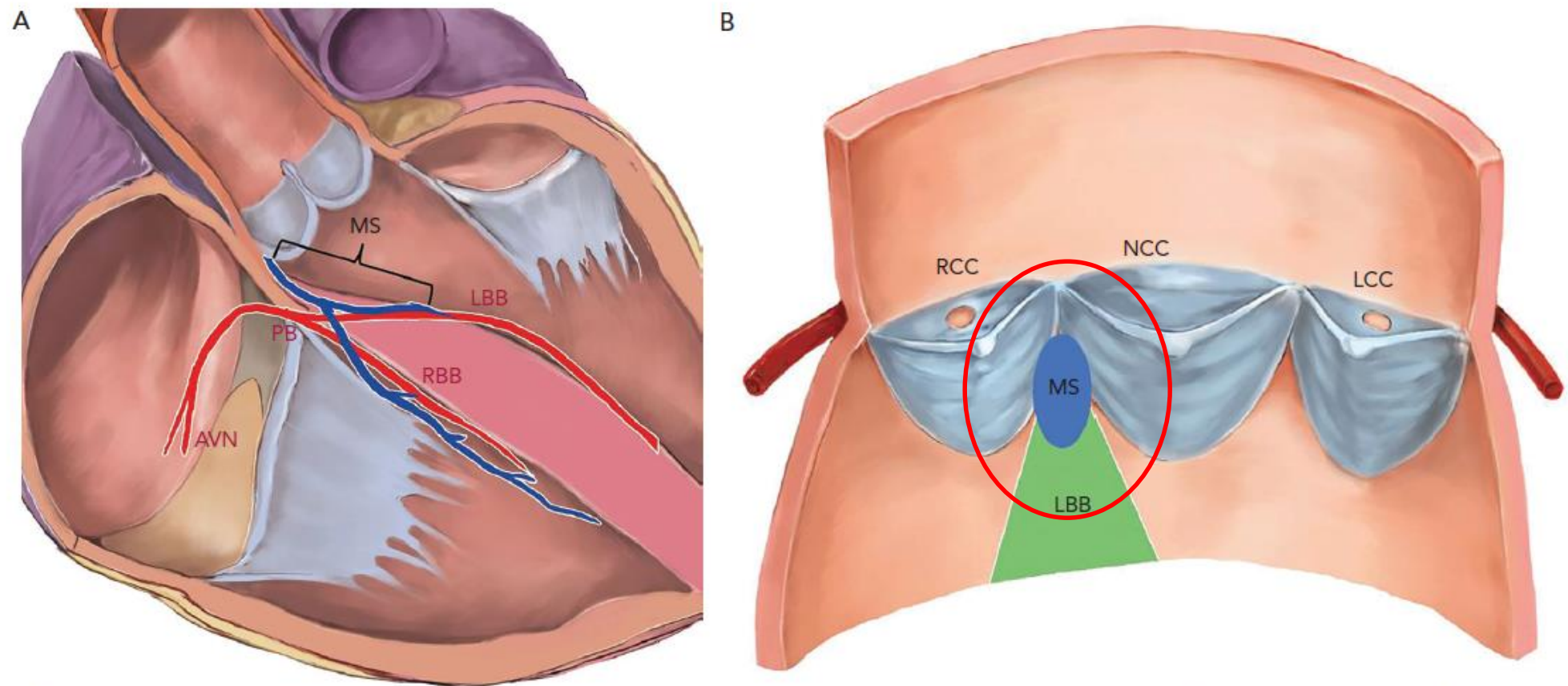


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Conduction disturbance and coronary access

Cusp overlap and commissural alignment

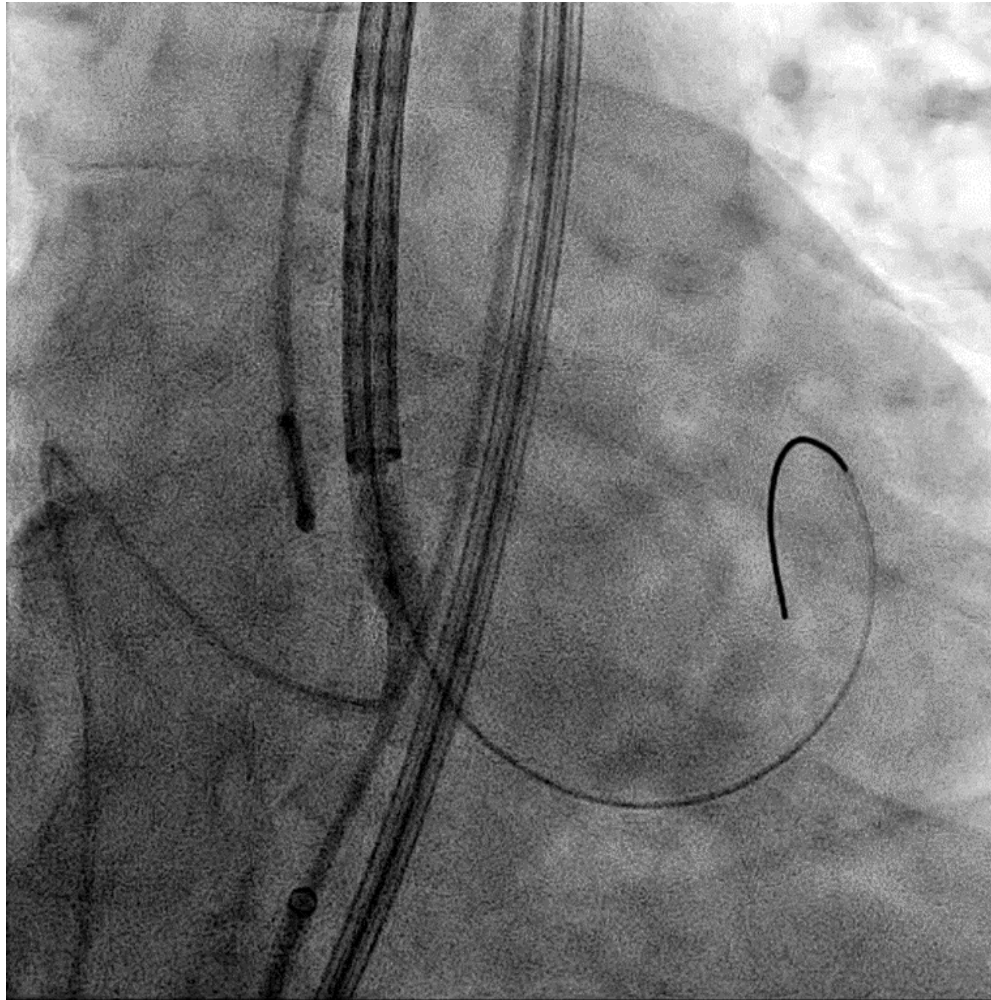
Figure 1: Anatomical Relationships Between the Aortic Cuspids, Membrane Septum and Conduction System



A: The penetrating bundle of His emerges at the surface of the left ventricular outflow tract beneath the membrane septum (MS). The length of the MS is equal to the distance between the aortic annulus and bundle of His. B: The left bundle branch emerges beneath the MS and is positioned between the right coronary cusp and non-coronary cusp. AVN = atrioventricular node; LBB = left bundle branch; LCC = left coronary cusp; PB = penetrating bundle; MS = membrane septum; NCC = non-coronary cusp; RBB = right bundle branch; RCC = right coronary cusp.

Principle – Cusp Overlap View for Valve Deployment

- To accurately assess and achieve target implant depth by isolating the NCC
- To allow valve to **descend** to target position to minimize the risk of interaction with the conduction system



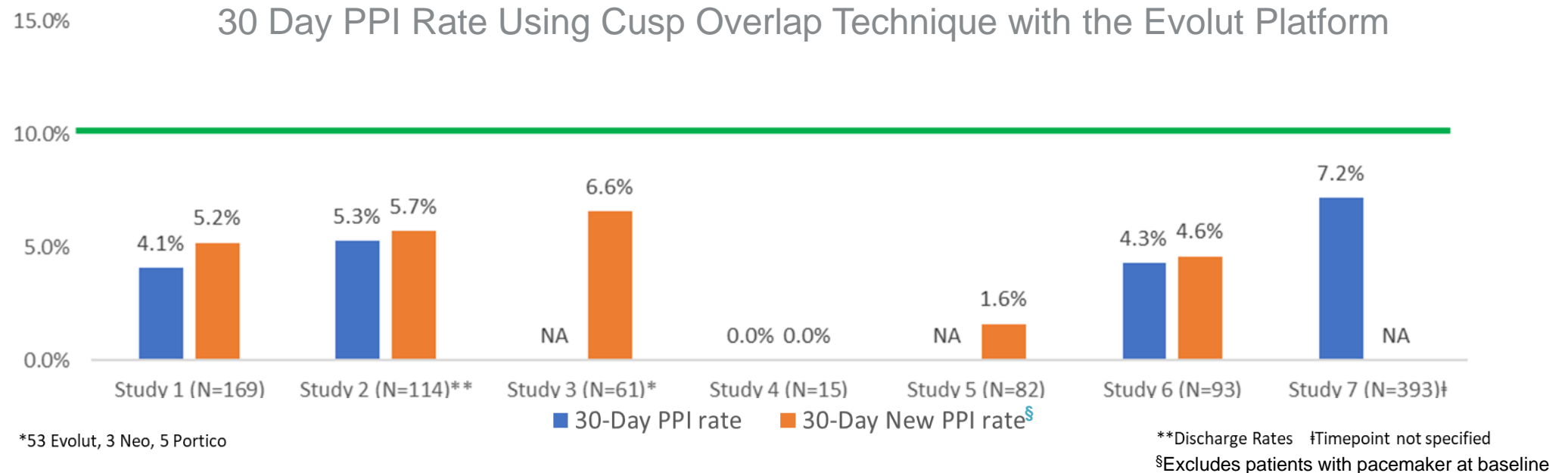
Deployment **starts above the annulus** in an effort to maintain valve position above the conduction system.

Slow valve release with the delivery catheter centered across the aortic valve helps with stability.

An accurate view provides confidence in targeting a **3 mm implant depth**.

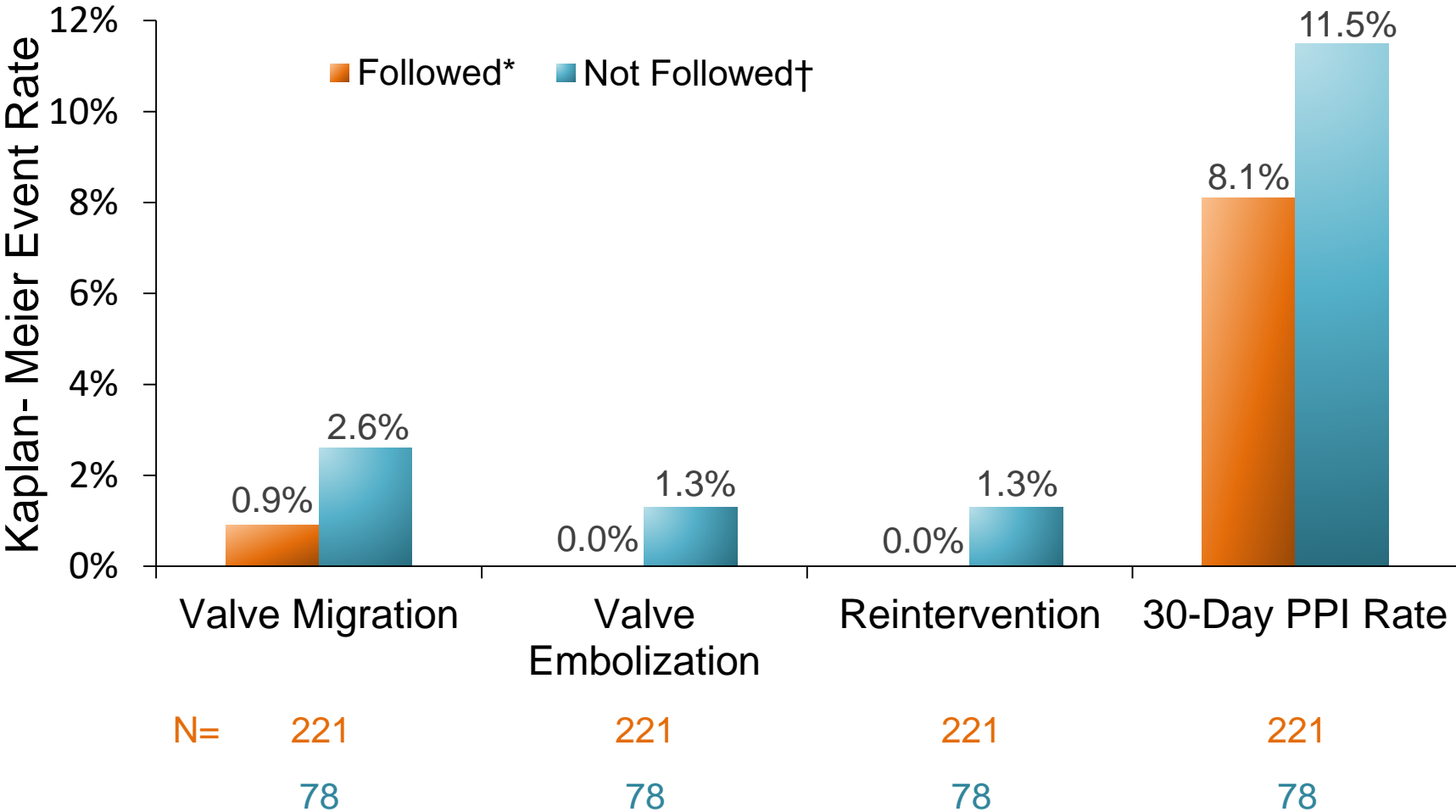
Cusp overlap data

Cusp overlap technique has been associated with single-digit pacemaker rates in several single center and multicenter clinical studies. Large, prospective studies are being performed to confirm the risks and benefits of this new implant strategy.



Study 1- Gada et al., presented at TCT 2020. *Reduction of rates of permanent pacemaker implantation with 34 mm Evolut R using cusp overlap technique*; **Study 2** - Gada et al., presented at TCT 2020. *Reproducibility of cusp overlap technique to reduce permanent pacemaker implantation with Evolut – the Latin American Experience*; **Study 3**- Mendiz et al., Presented at TCT 2020. *Cusp Overlapping Technique for TAVR Procedures with Self-Expandable Valves*; **Study 4**- Giuliani et al., presented at TCT 2020. *Impact of Cusp-Overlap technique on pacemaker requirement among transcatheter aortic valve replacement*; **Study 5**- Gada et al., presented at TCT 2019. *Site-level variation and predictors of post-TAVR permanent pacemaker implantation in the Evolut low Risk Trial*; **Study 6**- Pisaneillo et al., ACC 2020. *Implantation of self-expanding transcatheter heart valves in the annular plane is associated with low implant depths and pacemaker rates*; **Study 7**-Aljabbary et al., presented at CCC 2020. *Cusp Overlap Method for Self-Expanding Transcatheter Aortic Valve Replacement*.

Compliance with Key Cusp Overlap Steps (Main Cohort)



*Followed: all 6 steps are followed or "NOT APPLICABLE". †Not followed: at least one of the 6 steps was not followed.

EVOLUT COMMISSURAL ALIGNMENT

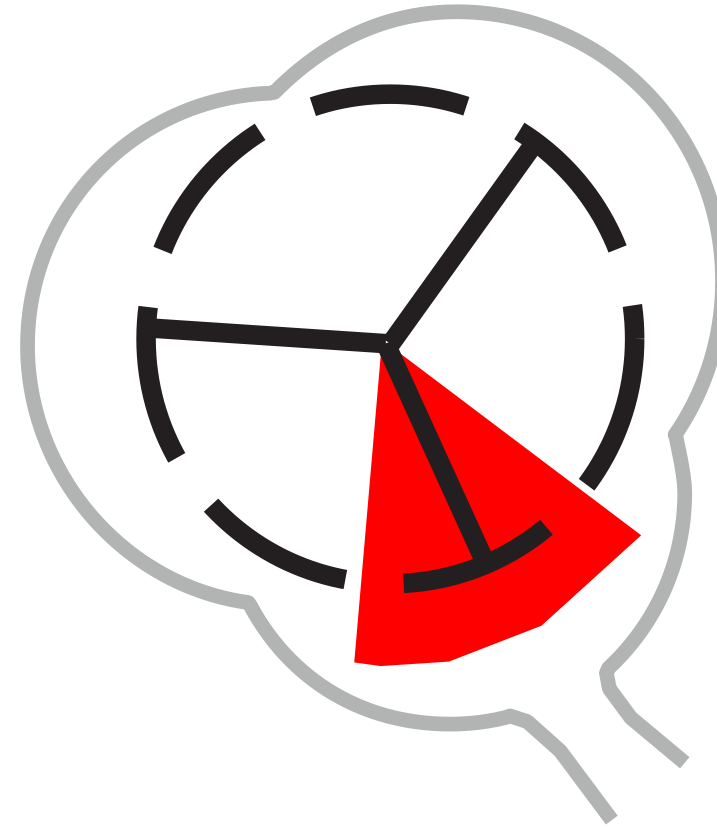
Commissural Post Orientation

Favorable Alignment



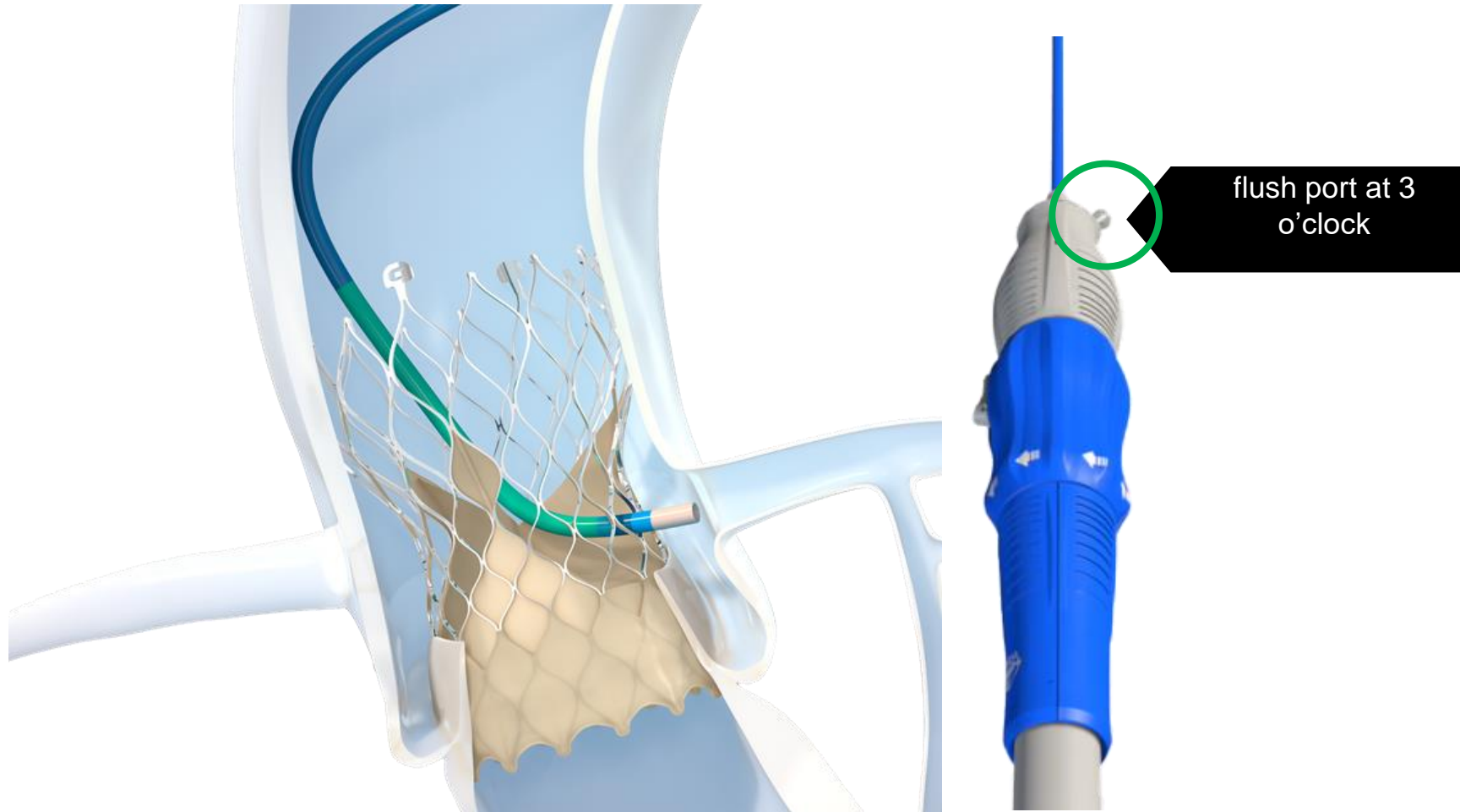
VS.

Unfavorable Alignment



Source: Rogers T. Small Annuli Symposium. Presented at TCT Connect 2020.

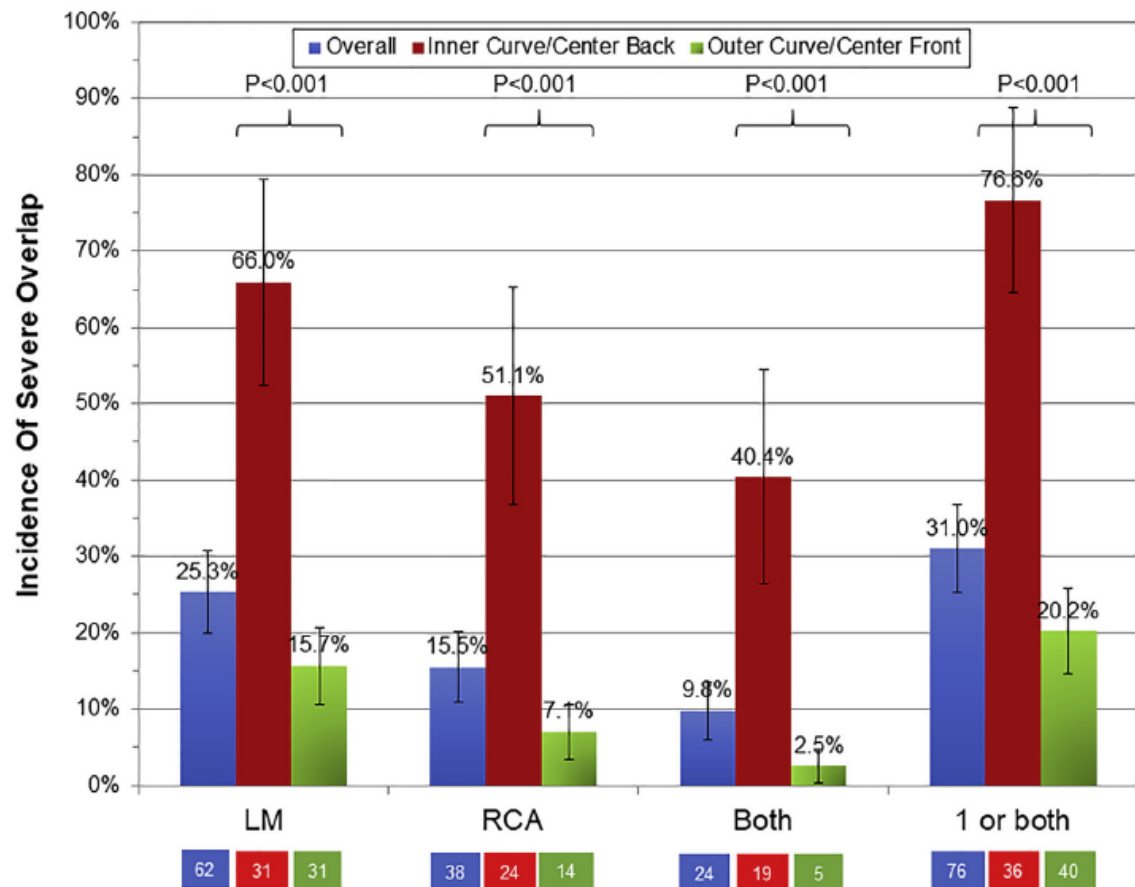
- Coronary Access



Positioning the flush port at 3 o'clock during sheath insertion to help achieve commissural alignment that may facilitate future coronary access.¹

1. Tang et al. JACC: Cardiovascular Interventions, 2020.

Initial Evolut "Hat" Marker Orientation on Coronary Overlap



Positioning the "Hat" marker at the outer curve or center front during initial deployment substantially reduced the incidence of severe coronary artery overlap with either the LM or the RCA, or both ($p < 0.001$). Abbreviations as in Figure 4.

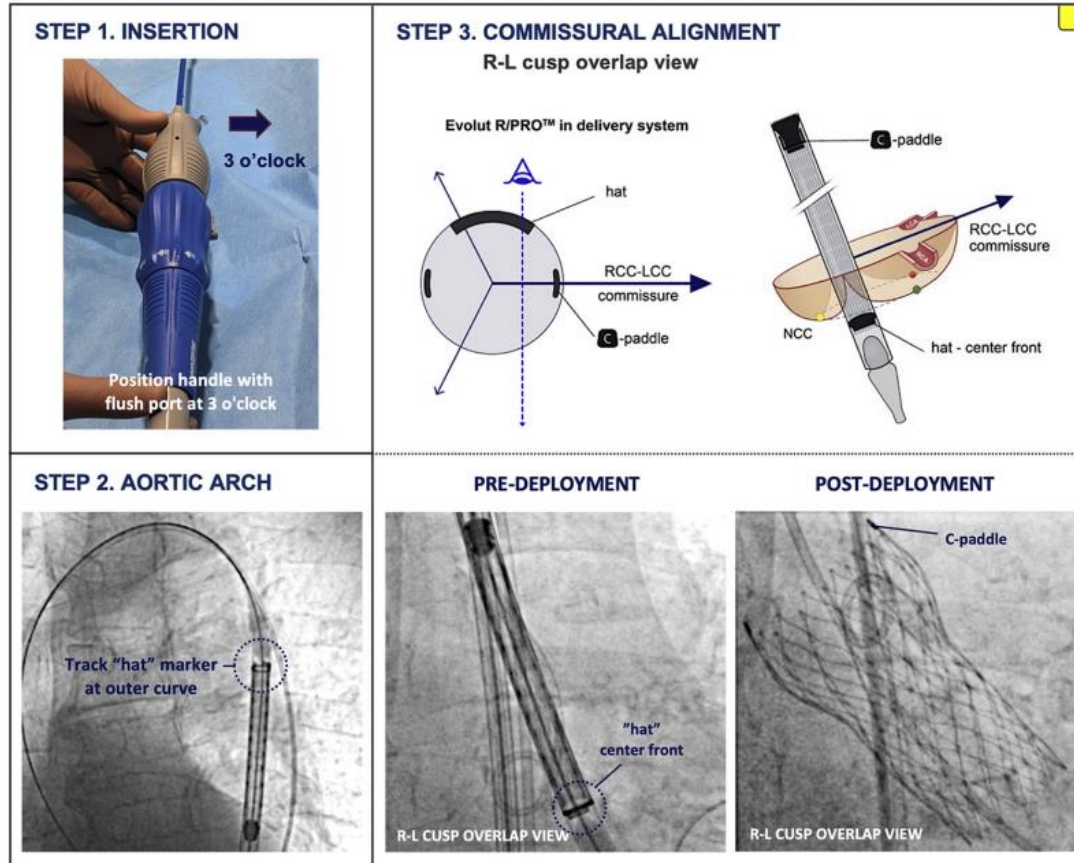
CENTRAL ILLUSTRATION Summary of the ALIGN TAVR Study on Transcatheter Valve Orientation and its Impact on Commissural Alignment and Coronary Artery Overlap

	Sapien 3	Evolut	ACURATE-neo
Method of Transcatheter Valve Orientation	1 commissure crimped at 3, 6, 9 and 12 o'clock	"Hat" marker position at initial deployment	Commissure position at initial deployment
Impact of Initial Deployment Orientation on Commissural Alignment	None	<ul style="list-style-type: none"> Insert catheter with flush port facing 3 o'clock Alignment improves when "Hat" at outer curve (OC)/center front (CF) 	<ul style="list-style-type: none"> Insert catheter with flush port facing 12 o'clock Alignment improves when commissure at center back (CB)/ inner curve (IC)
Severe Overlap With Left Main	32.7%-39.7%	15.7% (OC/CF) vs. 66.0%	0-7.1% (CB/IC) vs. 14.8%-75.9%
Severe Overlap With Right Coronary Artery	28.8%-51.6%	7.1% (OC/CF) vs. 51.1%	7.1%-12.5% (CB/IC) vs. 62.1%-74.1%

Tang, G.H.L. et al. J Am Coll Cardiol Interv. 2020;13(9):1030-42.

New Standard of Practice

FIGURE 6 Evolut Commissural Alignment Steps



Three procedural steps in order to increase the chances of obtaining commissural alignment with the Evolut system. Abbreviations as in [Figures 2 and 3](#).

Conclusion

- Lifetime management is important in younger/low risk AS patients
- Supra-annular SEV has superior hemodynamic profile, less SVD, potentially longer durability
- TAV-in-TAV is feasible in selected patients
- Cusp overlap implantation technique help reduce conduction disturbance
- Commissural alignment increases feasibility of future coronary access, *and facilitate future TAV-in-TAV*

Thank you



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