

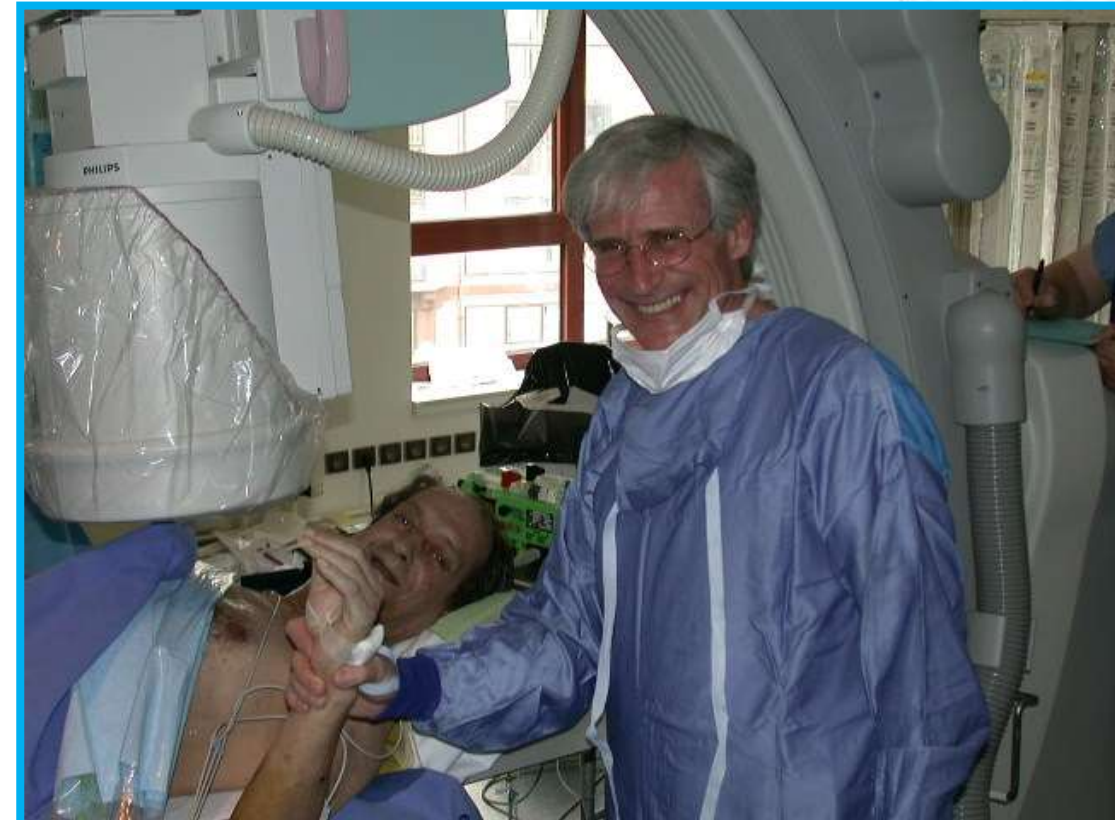
How to Optimize 1st Valve Choice Matter for Future

Jung-Min Ahn, MD.

Division of Cardiology, Asan Medical Center,
University of Ulsan College of Medicine, Seoul, Korea

Rouen, France on 16th, April 2002.

First-In-Man TAVR

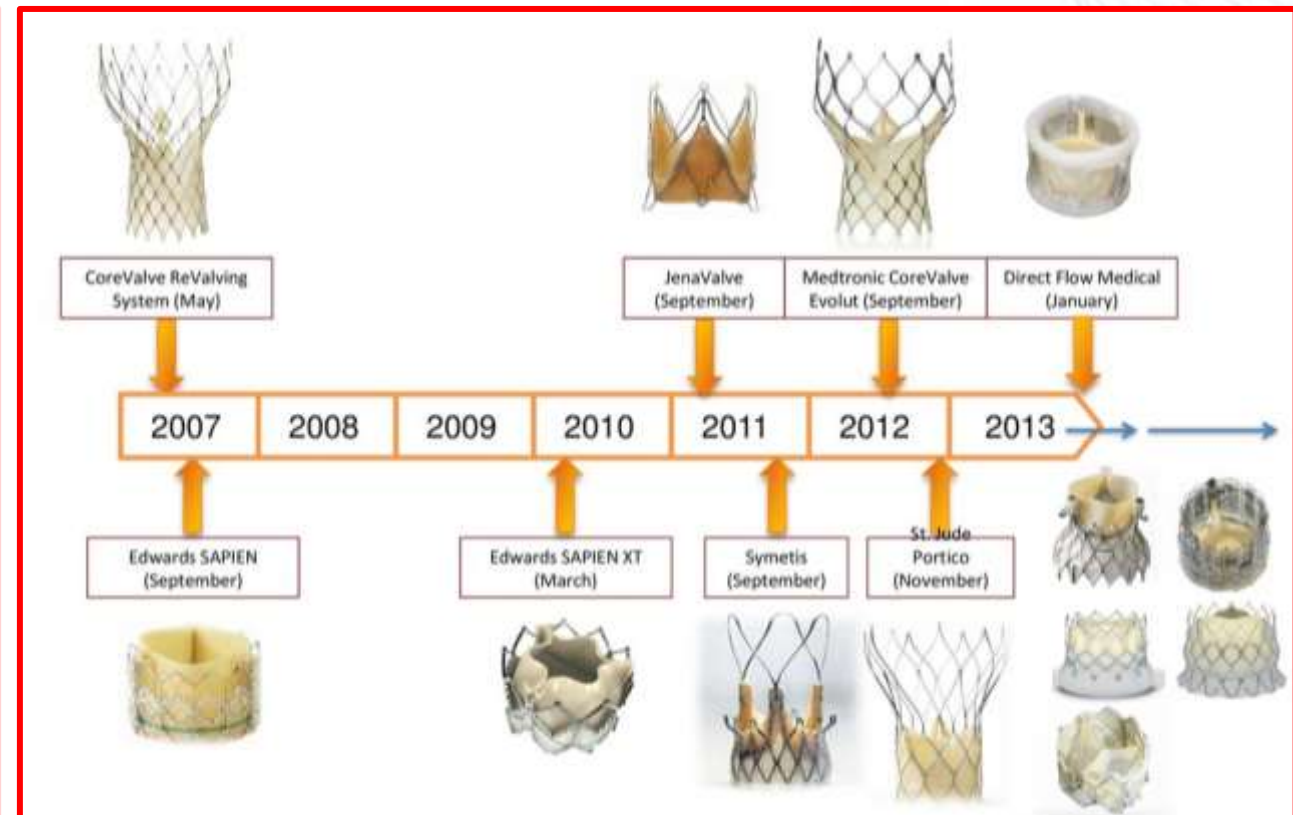
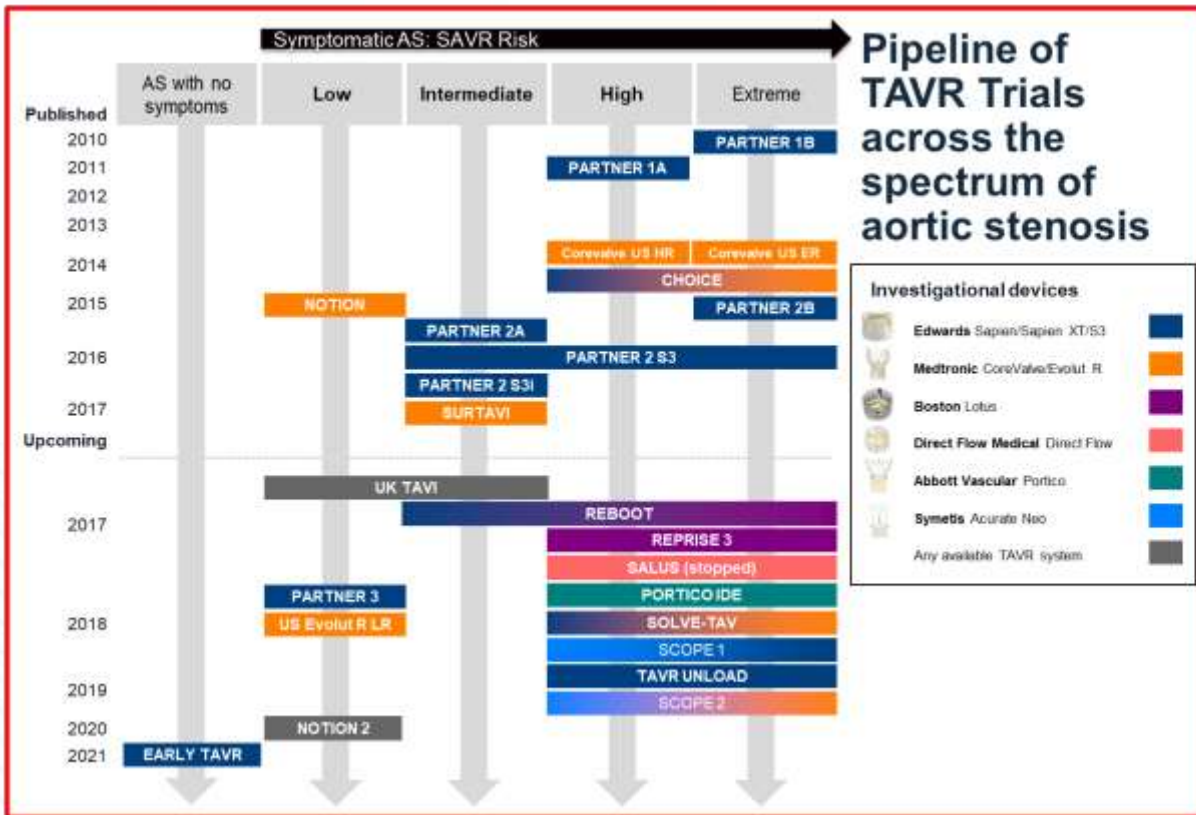


Cribier A, et al. Circulation. 2002;106:3006-3008

PCR Online: 20 years of TAVI - Revolutionising medicine since 2002

Clinical Trials

Evolution of TAVR Technology



Capodanno D, Leon MB. EuroIntervention 2016

Dr. Alain Cribier at TCTAP 2016

My prediction on the future of TAVR

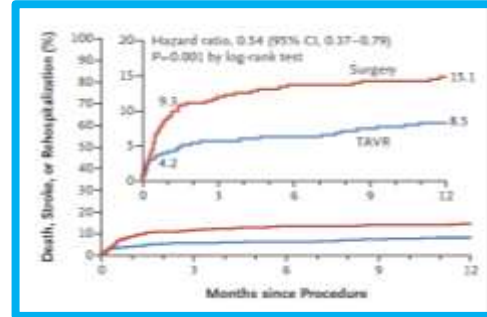
2016 TAVI is indicated in patients who are not optimal candidates to surgery



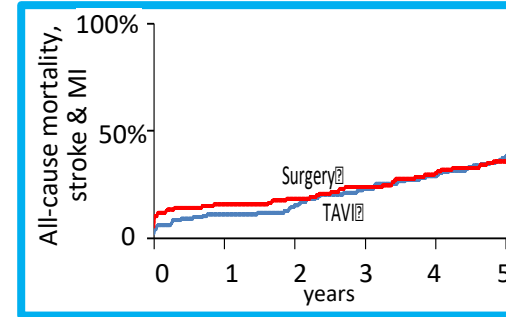
2020 SAVR is indicated in patients who are not optimal candidates to TAVR !

His Dream Comes True, Today

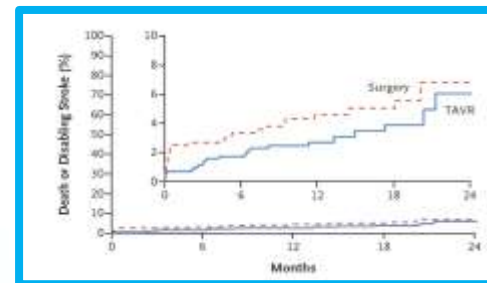
TAVR Low-Risk Trials (4 RCTs - 3,661 patients)



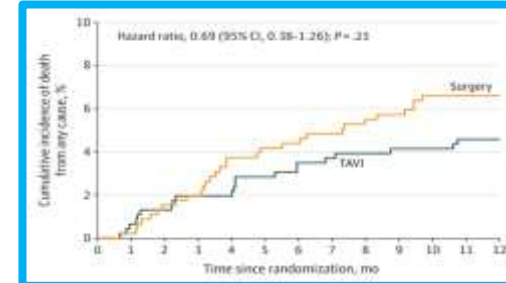
PARTNER 3



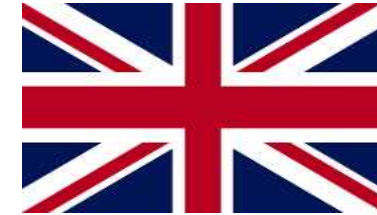
NOTION



Evolut Low Risk

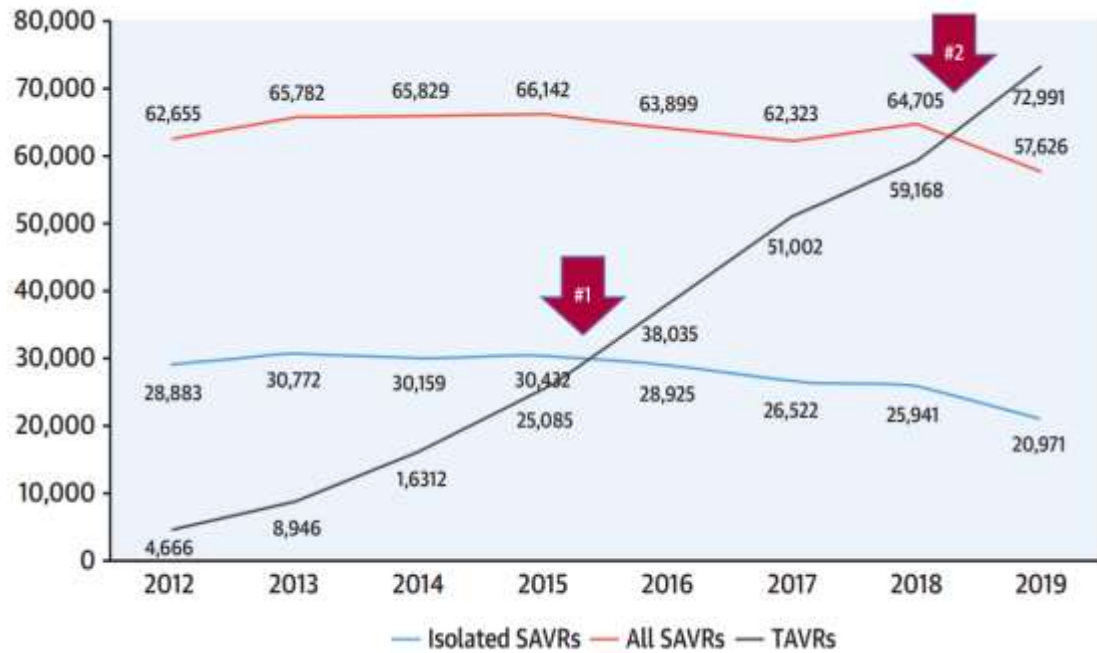


UK-TAVI



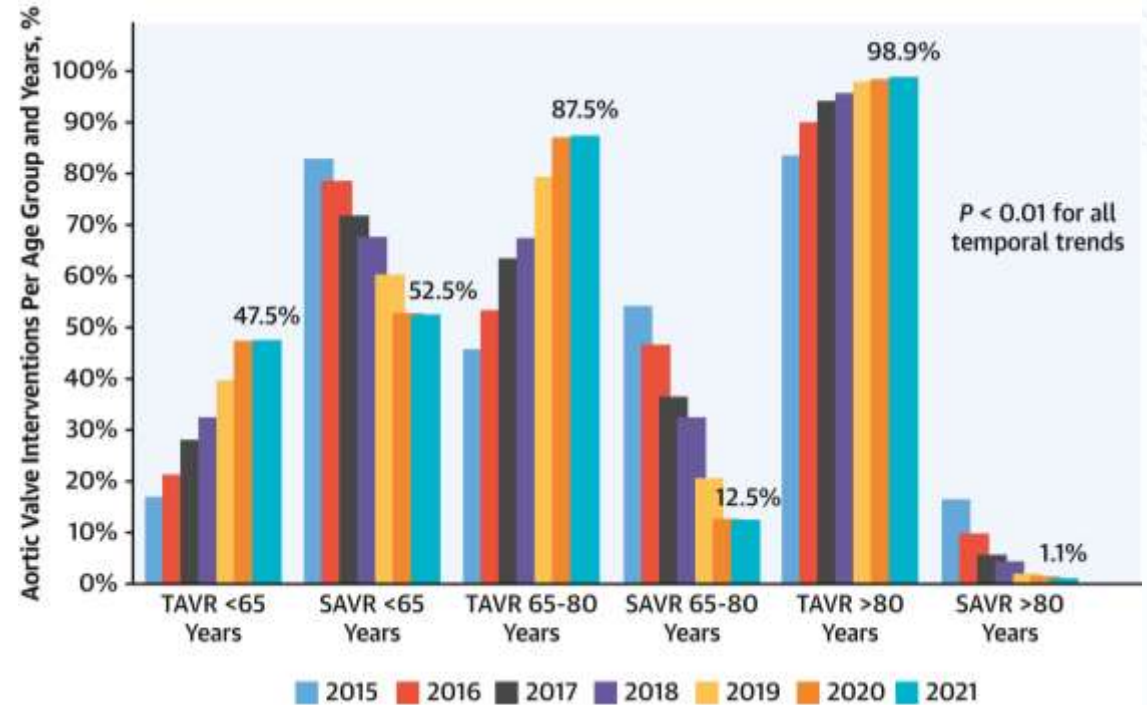
Current Status of TAVR in US

STS-ACC TVT Registry



J Am Coll Cardiol 2020;76:2492–516

The Vizient Clinical Data Base



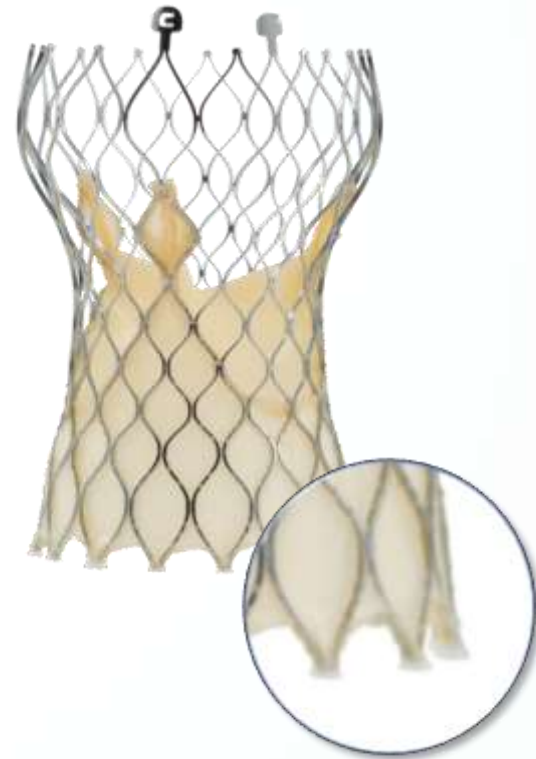
JACC 2022 Nov 22;80(21):2054-2056

Standard TAVR Device

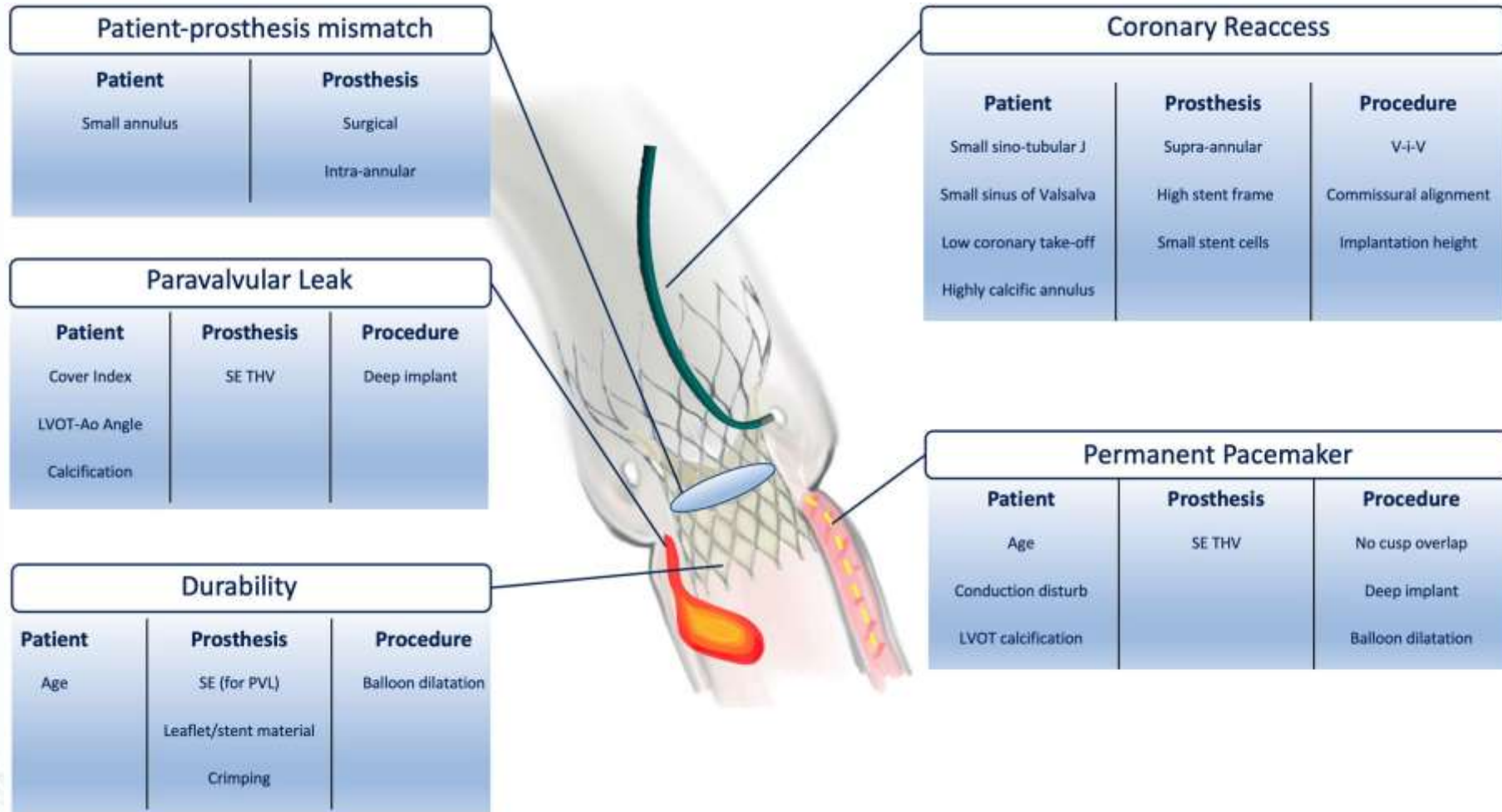
Edwards Sapien 3 (Ultra)



MDT Evolut R (PRO+)



Current Open Issues and Challenges for TAVR



Current Open Issues and Challenges for TAVR

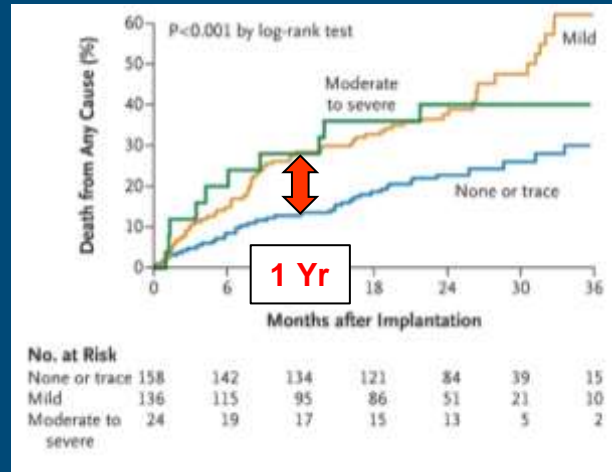
TAVR Valve Choice Considerations

	Balloon-expandable	Self-expanding
Paravalvular Leakage	?	?
Permanent Pacemaker Implantation	?	?
Coronary Obstruction (Acute/Late)	?	?
Coronary Access	?	?
Patient-Prosthesis Mismatch	?	?
Bicuspid Aortic Valve	?	?
Durability	?	?
Overall Outcomes	?	?

Parvalvular Leakage

PARTNER I Trial

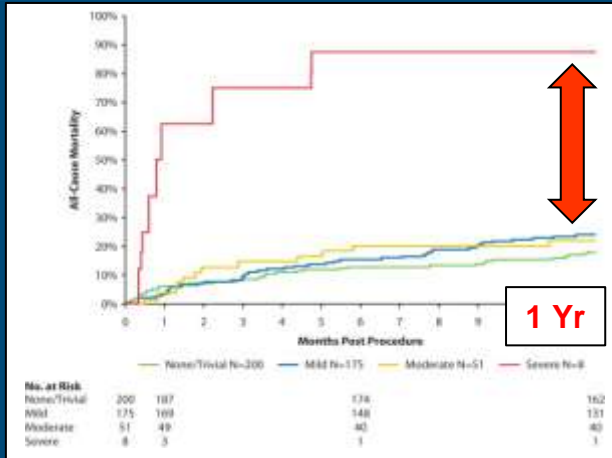
Kodali SK et al. N Engl J Med. 2012;366(18):1686-1695.



≥ Mild PVL: Mortality ↑

US CoreValve Pivotal Trial

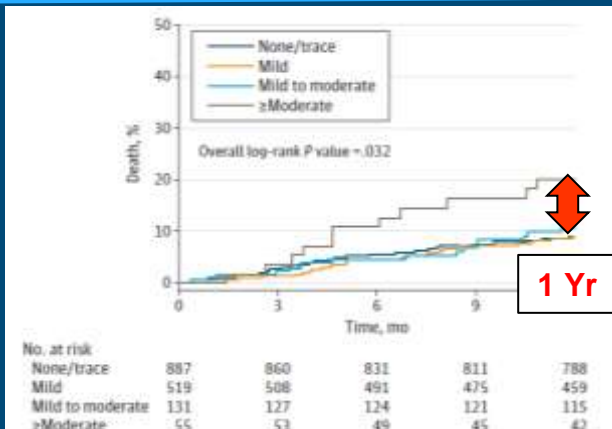
Pompa JJ et al. J Am Coll Cardiol. 2014;63(19):1972-1981.



Severe PVL: Mortality ↑

PARTNER II - SAPIEN 3

Pibarot P, et al. JAMA Cardiol 2017;2(11):1208-1216



≥ Moderate PVL: Mortality ↑

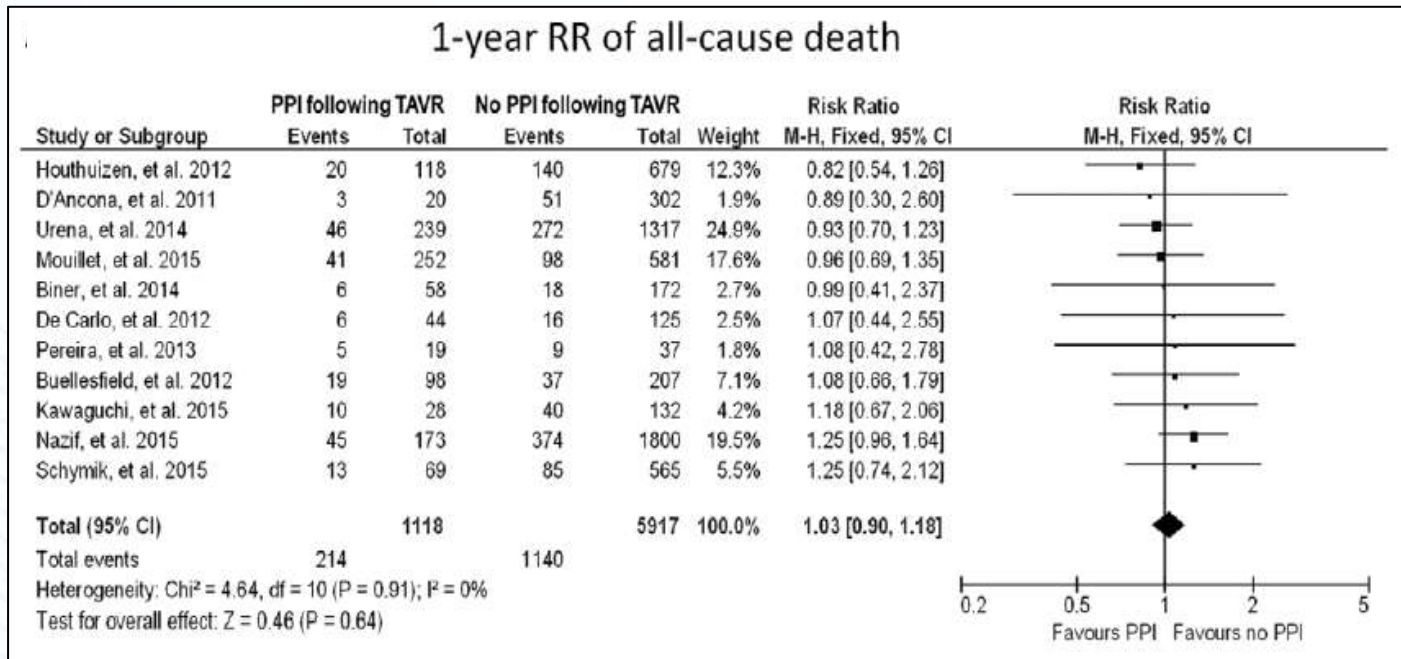
Rate of Significant PVL

	SAPIEN 3	SE Valve
Partner 3 trial vs. Evolut low-risk trial Moderate-Severe PVL 30-days	0.8%	3.4%
Partner 3 trial vs. Evolut low-risk trial Moderate-severe PVL 1-year	0.6%	3.6%
France TAVI (propensity matched analysis) PVR >moderate 2-year	5.7%	14.8%
OCEAN TAVI registry data SAPIEN 3 vs. Evolut R \geq Moderate PVL 4-year	1.2%	7.5%
SAPIEN 3 Ultra Moderate-severe PVL 30-days TVT registry propensity matched data n=1324 vs. Evolut Pro TVT registry data n=2065	0.2%	2.8%
PORTICO IDE Data Moderate or greater PVL 30-days	1.3%	7.6%

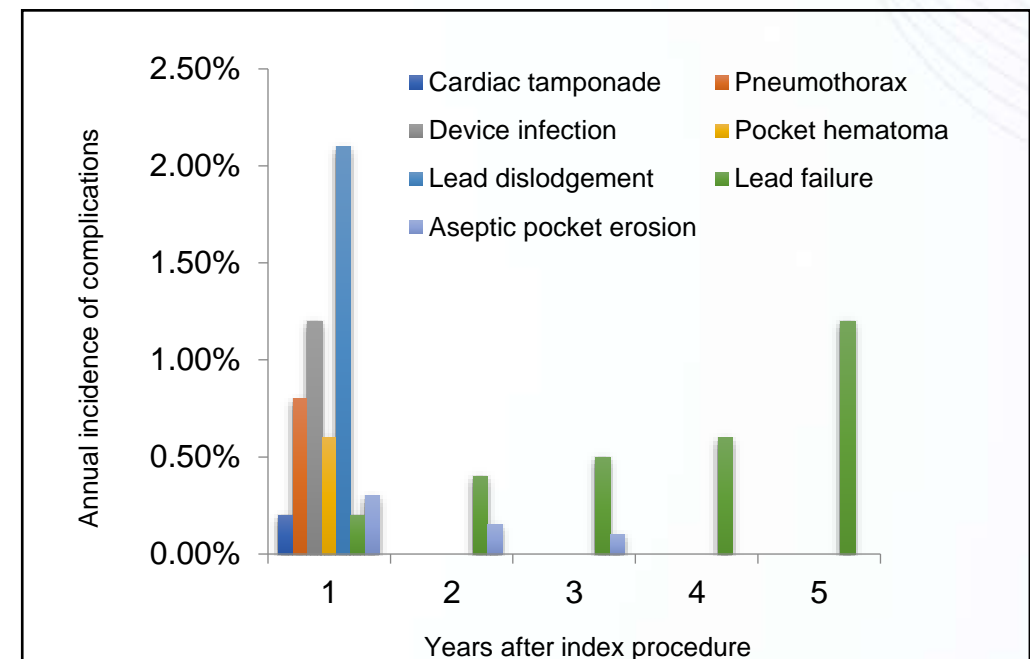
Permanent Pacemaker

Clinical Impact of Permanent Pacemaker after TAVR

No Impact of Mortality



Small But Significant Complications



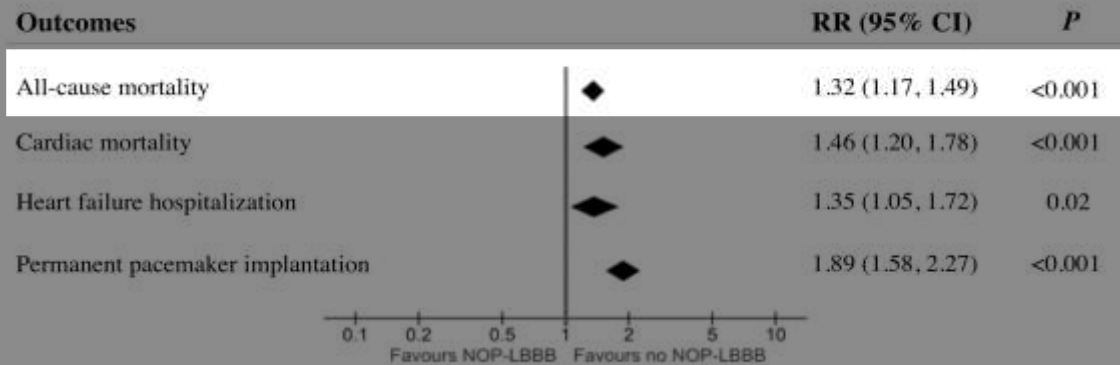
Rigueiro, A, et al. Circ Cardiovas Interv 2016;9:e003635

Palmisano P, et al., Europace. 2013 Apr;15(4):531-40.

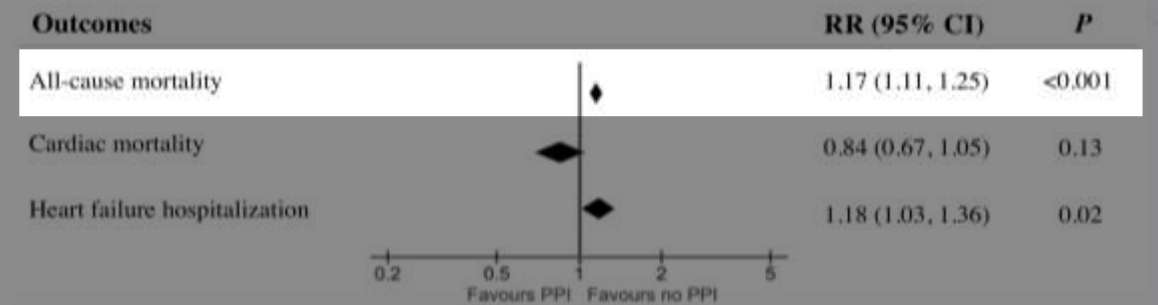
Meta-analysis

New Onset Persistent LBBB and Permanent Pacemaker Increase the Mortality

New Onset Persistent LBBB

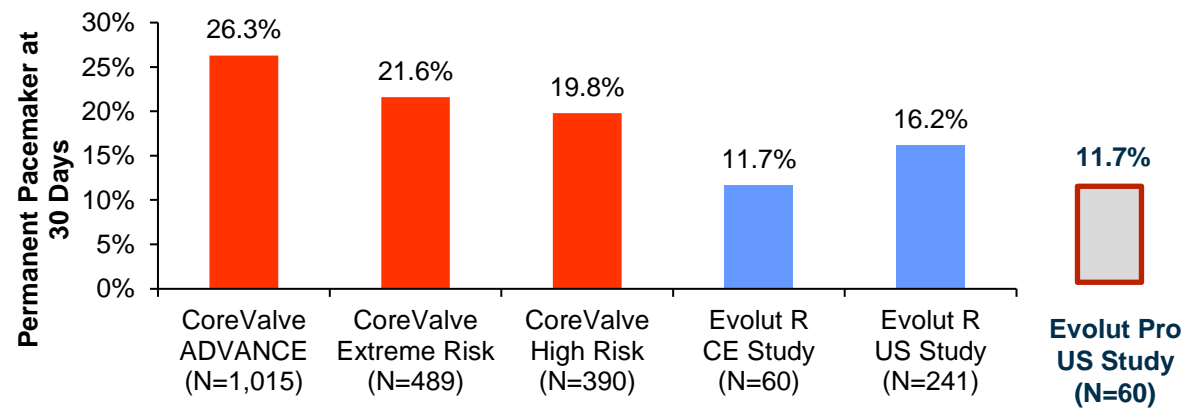
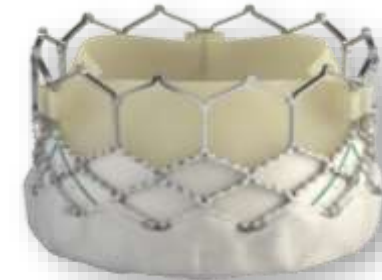
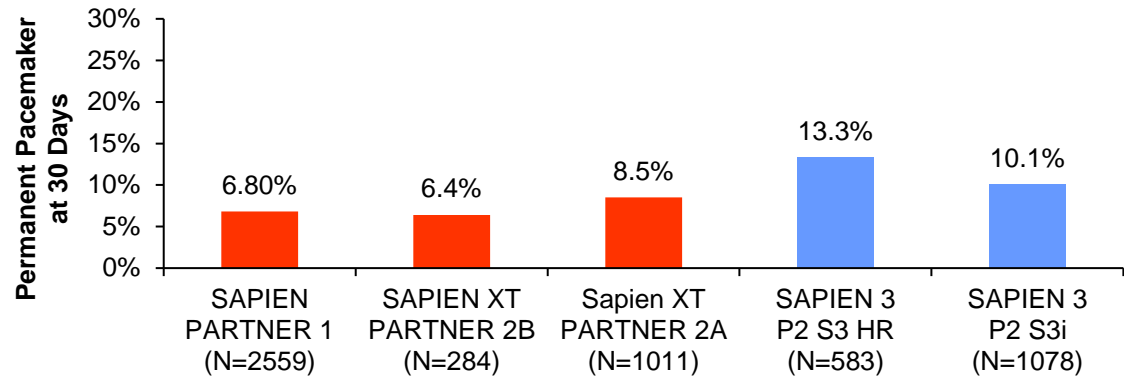


Permanent Pacemaker



Data from 30 studies, including 7792 patients (12 studies) and 42 927 patients (21 studies) for the evaluation of the impact of NOP-LBBB and PPI after TAVR were sourced

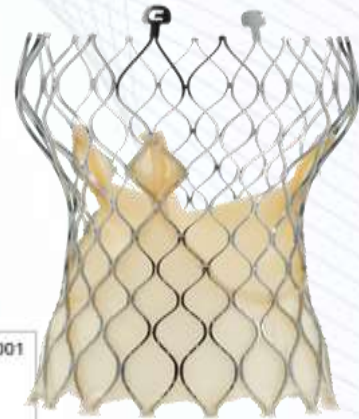
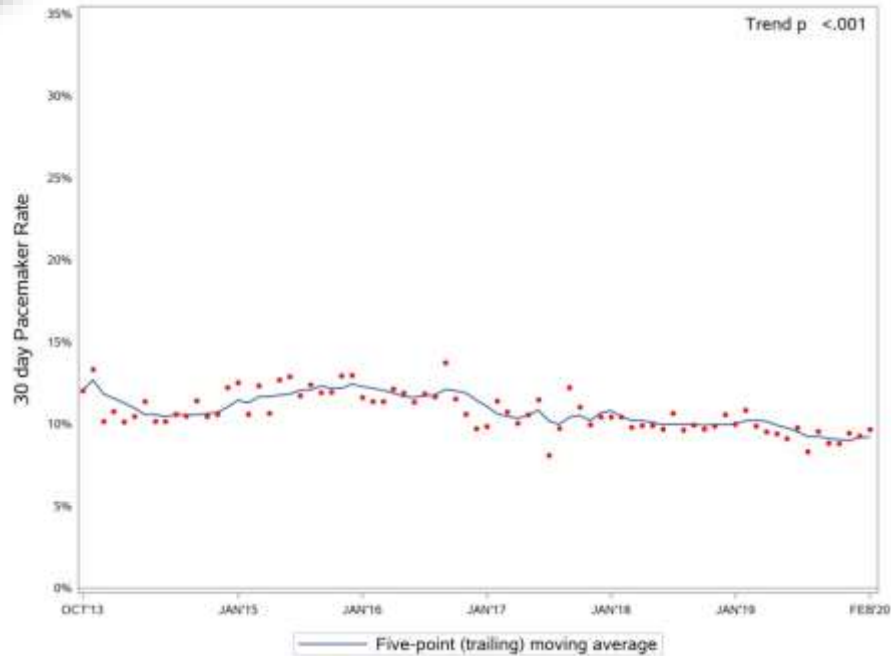
The Rate of Permanent Pacemaker After TAVR



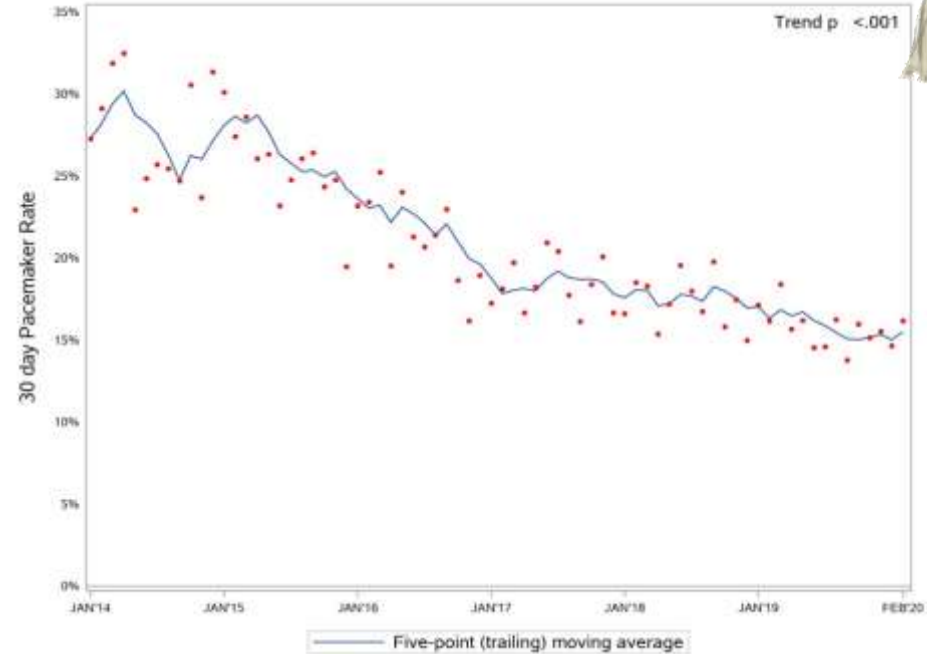
30-day PPM in the TVT Registry 2013-2020



BEV (N=144,042)



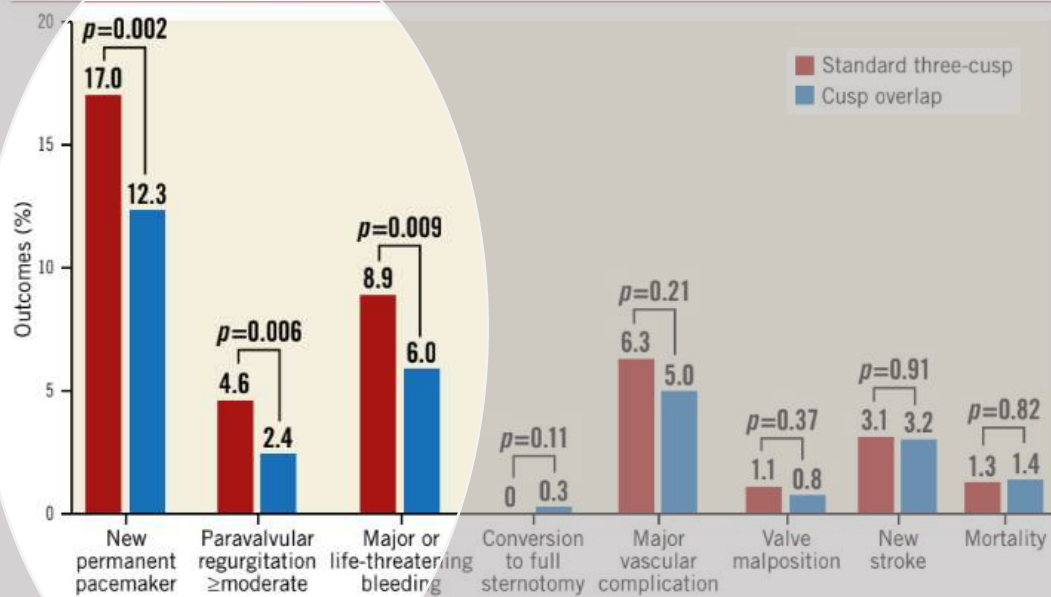
SEV (N=52,965)



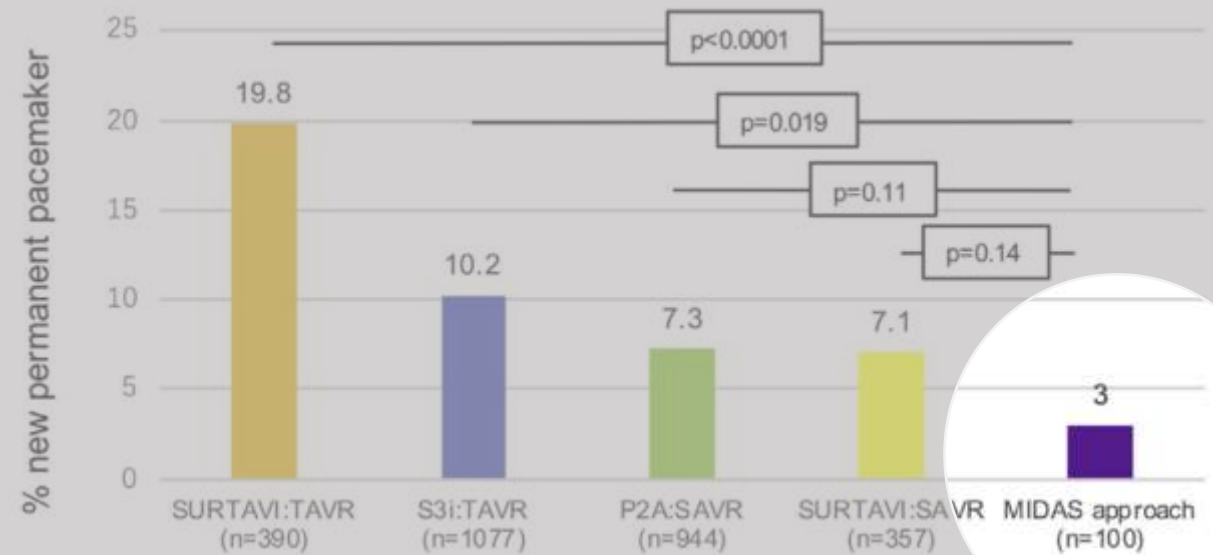
Chau, K. et al. TVT 2021

Effort to Lower PPM: Self Expandable Device

Cusp Overlap Technique



Minimizing Depth According to the membranous Septum (MIDAS) Approach



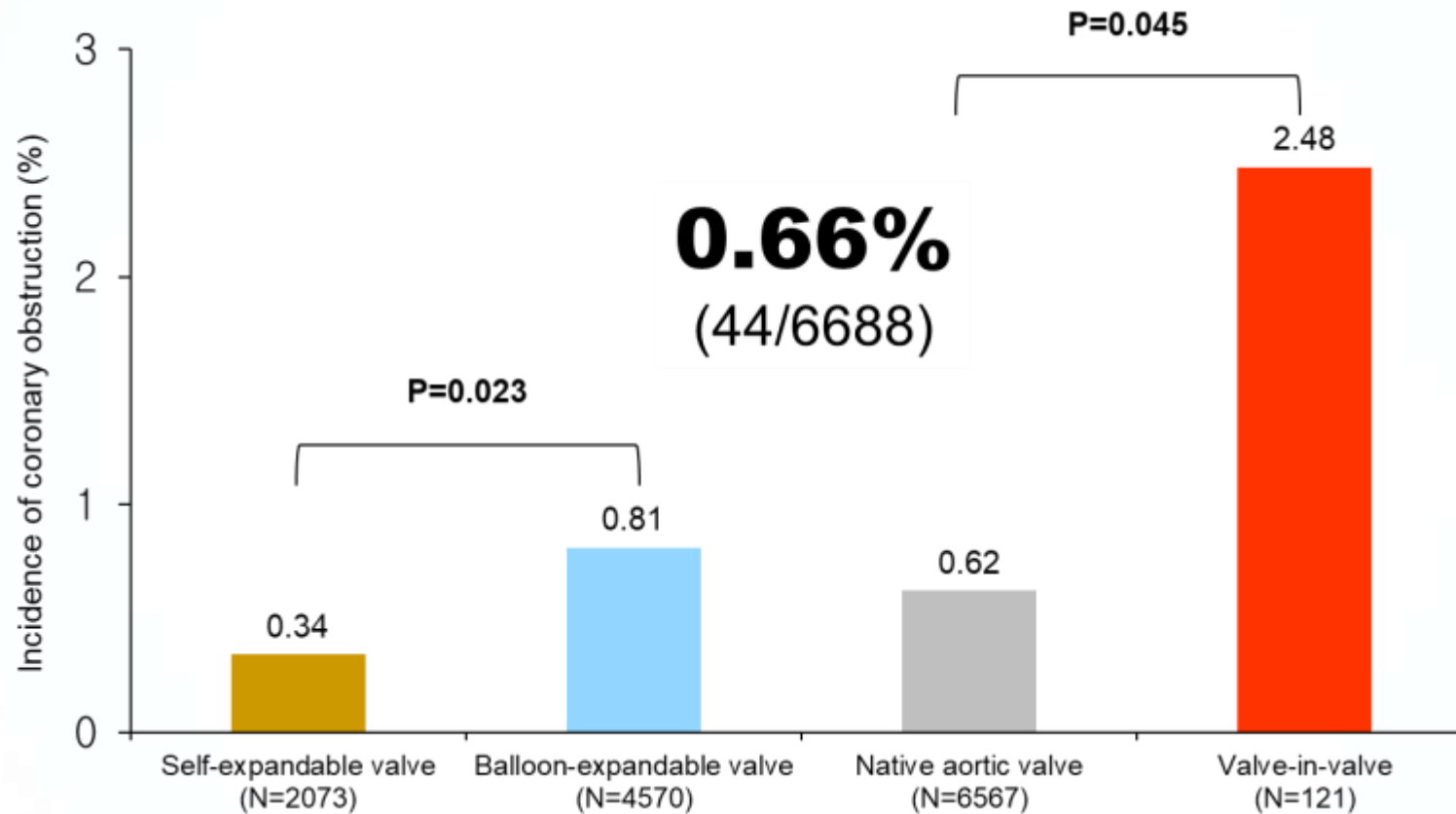
<https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-22-01030>

J Am Coll Cardiol Intv 2019;12:1796–807

A blue diamond shape with a black outline, centered on the page. Inside the diamond, the text "Coronary Obstruction and Access" is written in white, sans-serif font.

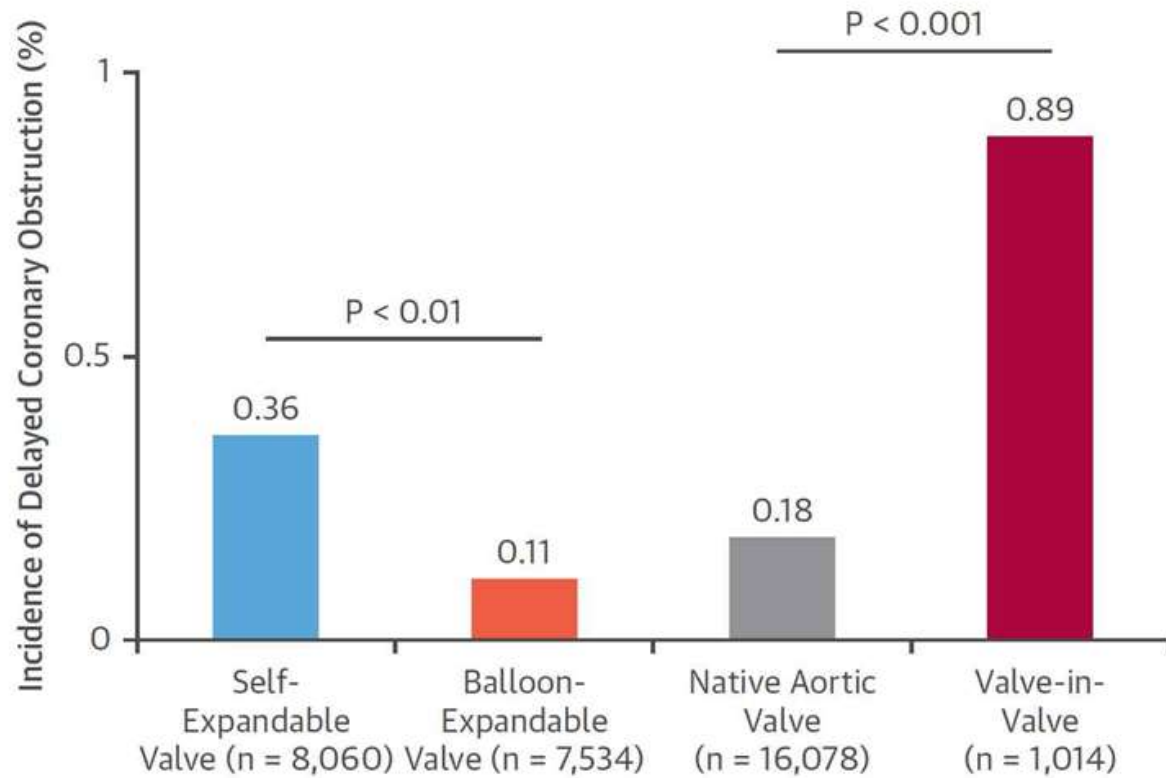
Coronary Obstruction and Access

Acute Coronary Obstruction

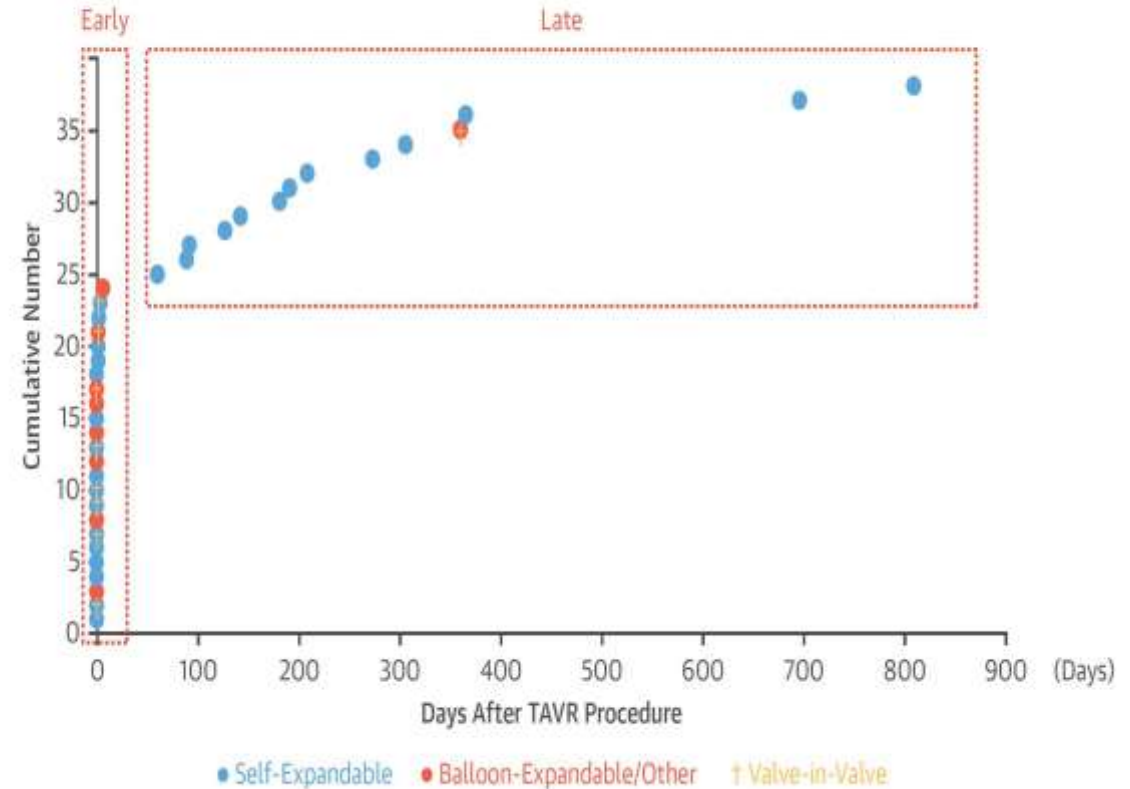


Riberiro HB, et al. J Am Coll Cardiol. 2013 Oct 22;62(17):1552-62

Delayed Coronary Obstruction

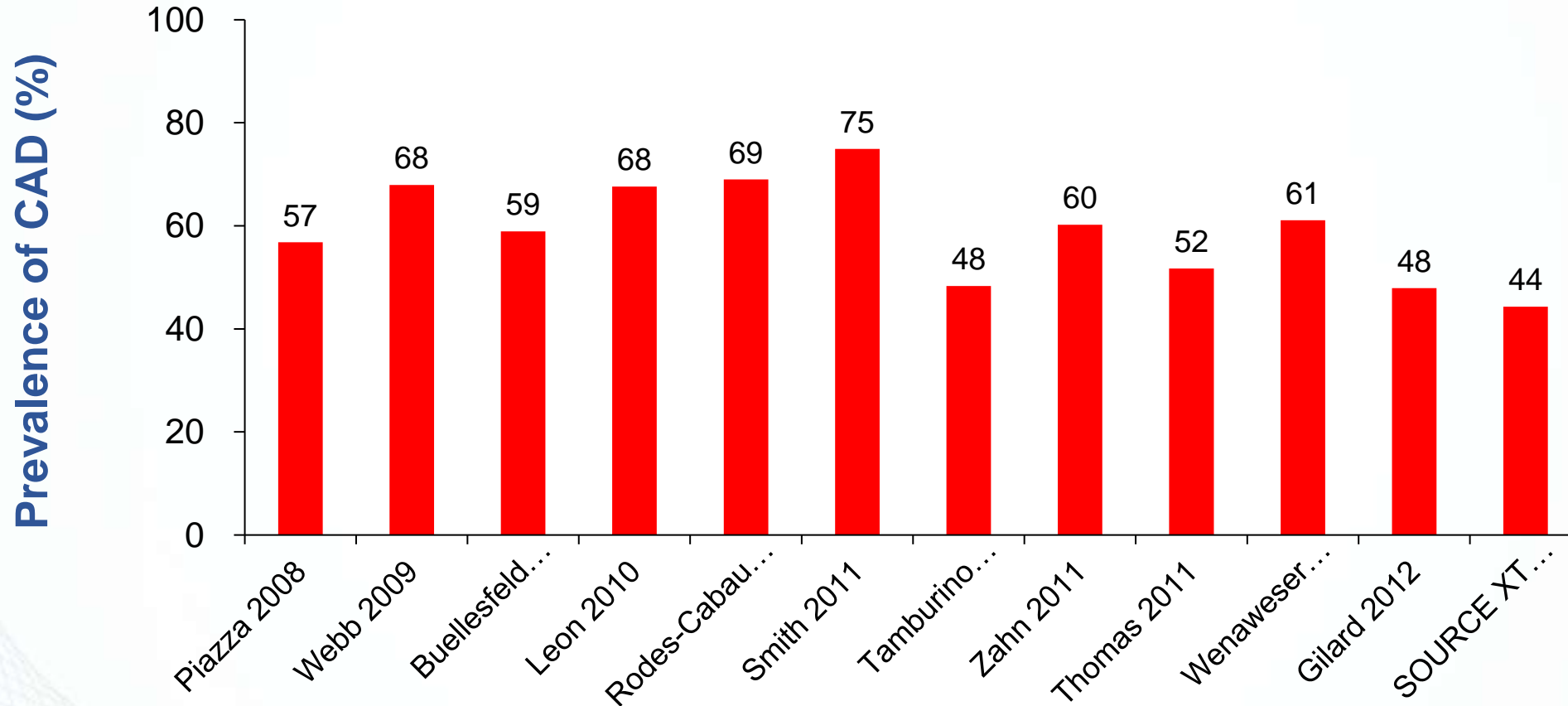


Timing



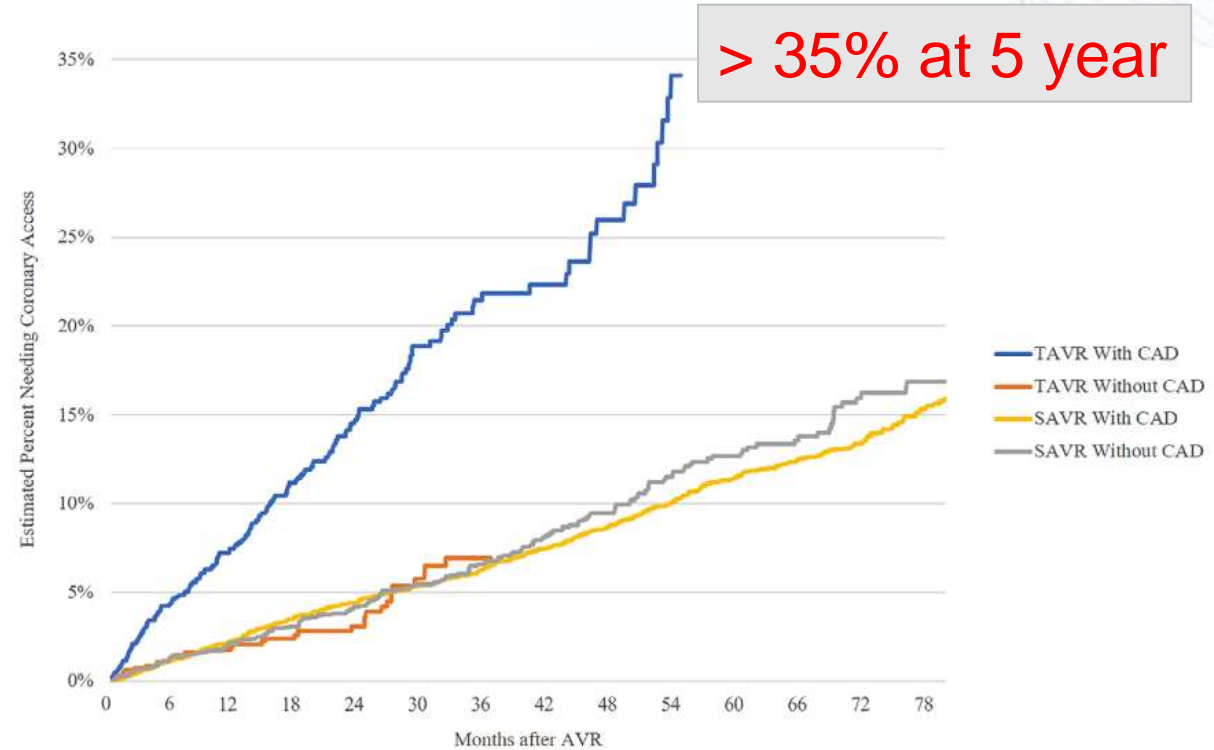
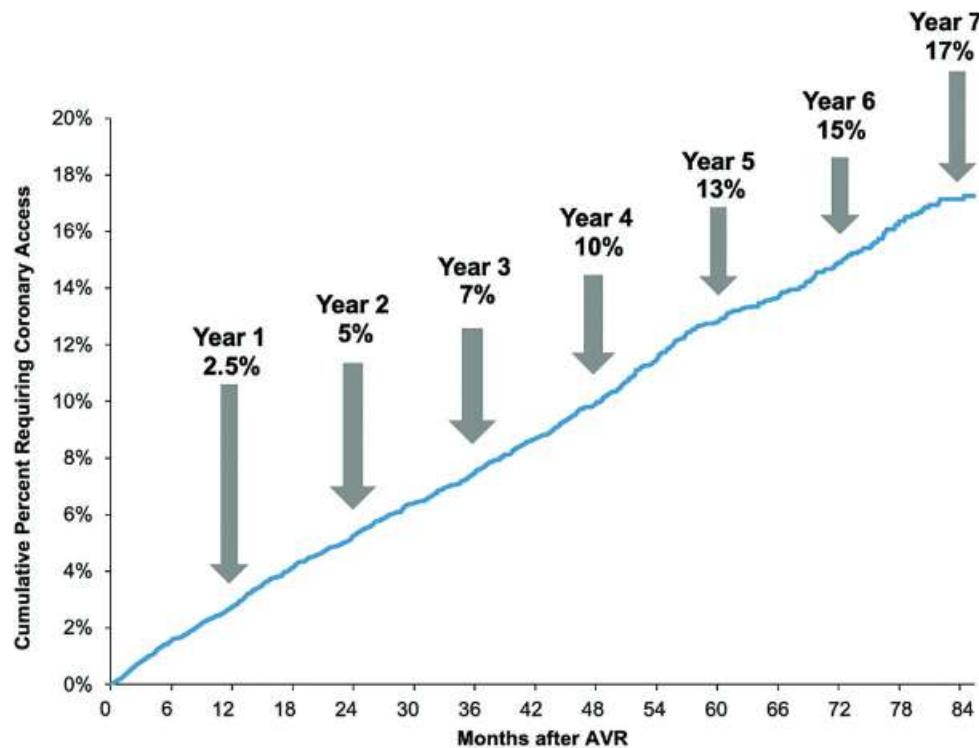
Jabbour RJ et al. J Am Coll Cardiol 2018;71:1513–24

Incidence of CAD in TAVR Patients



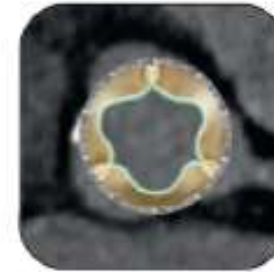
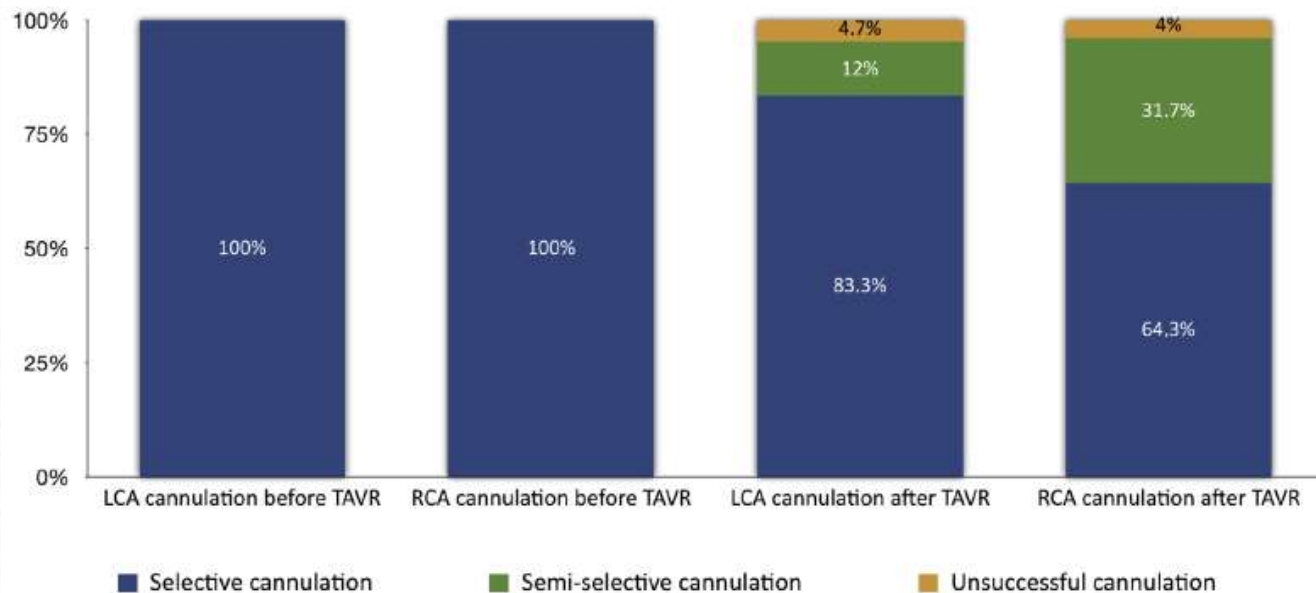
Stefanini GG et al, Eurointervention. 2013;9:S63-S68

The Need for Future Coronary Access after TAVR or SAVR



Coronary Access after TAVR

RE-ACCESS Single-Center Registry (N=300)



**Transcatheter Aortic Valve/
Sinuses of Valsalva Relation**
Odds Ratio 1.1;
95% CI: 1.0-1.2; $p < 0.01$

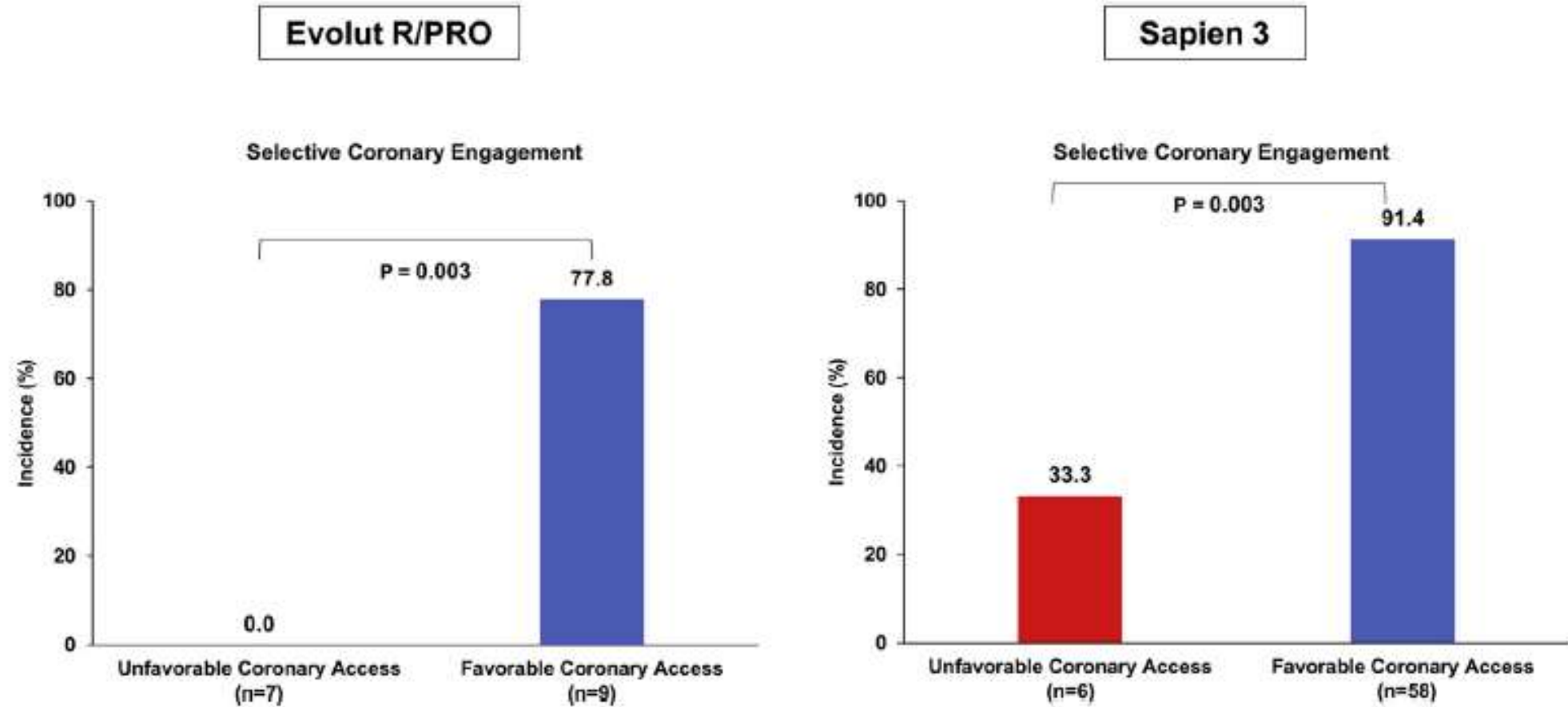


Transcatheter Aortic Valve Implant Depth
Odds Ratio 1.7;
95% CI: 1.3-2.3; $p < 0.01$



Evolut Transcatheter Aortic Valve
Odds Ratio 29.6;
95% CI: 2.6-335.0; $p < 0.01$

Unfavorable Coronary Access After TAVR Can be Identified by CT



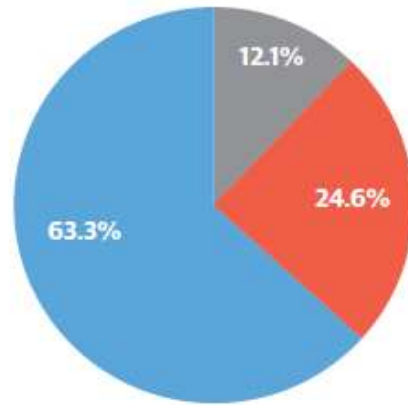
A blue diamond shape with a black outline, centered on the slide. The text "Patient-Prosthesis Mismatch" is written in white inside the diamond.

Patient-Prosthesis Mismatch

The STS/ACC TVT Registry

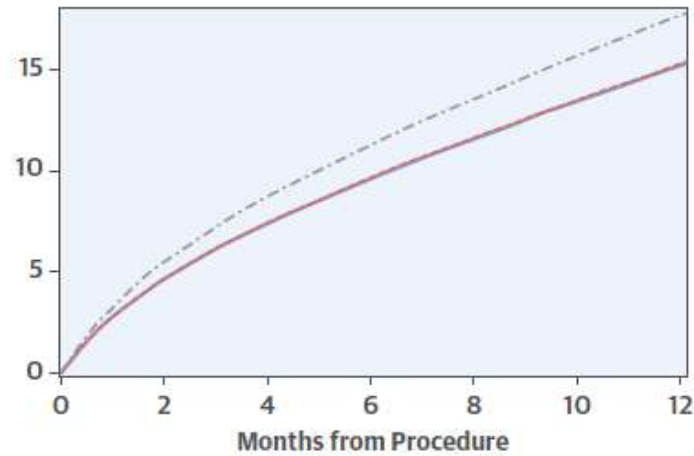
CENTRAL ILLUSTRATION Incidence and Effect on Survival of Severe Prosthesis-Patient Mismatch After Transcatheter Aortic Valve Replacement

Prosthesis-Patient Mismatch (PPM)



■ Severe (Sev)
 ■ Moderate (Mod)
 ■ None

Mortality (%)



PPM
 --- Sev PPM (EOAi < 0.65 cm²/m²) — Mod PPM (EOAi 0.65-0.85 cm²/m²)
 — No PPM (EOAi > 0.85 cm²/m²)

Number at Risk Adjusting for Baseline Covariates:

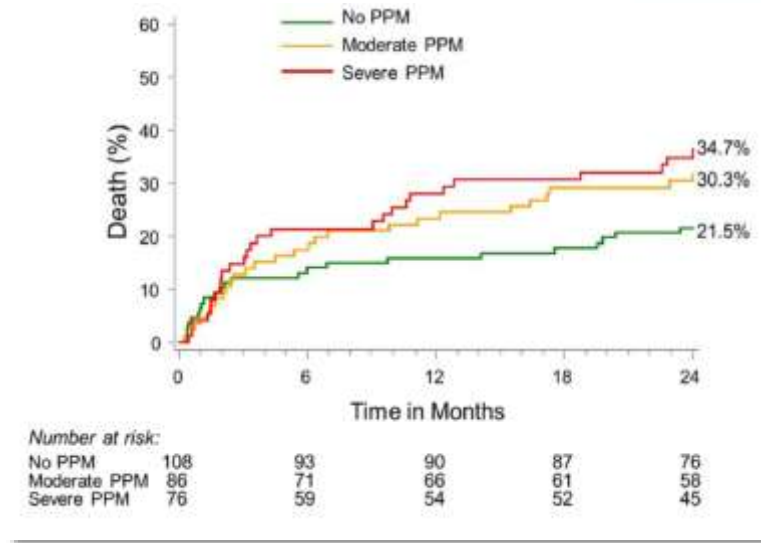
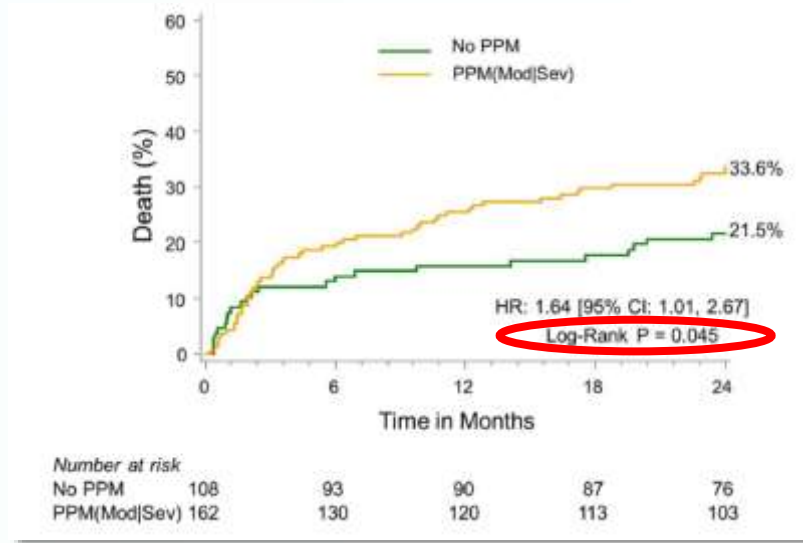
	Day 0	Month 4	Month 8	Month 12
No PPM	23,635	21,080	16,734	13,136
Mod PPM	8,983	7,995	6,277	4,831
Sev PPM	4,152	3,626	2,976	2,130

Herrmann, H.C. et al. *J Am Coll Cardiol.* 2018;72(22):2701-11.

This figure shows the incidence of PPM in the entire study population (N = 62,125) and the adjusted 1-year mortality for 37,470 patients with Centers for Medicare & Medicaid Services Medicare claims linkage. It demonstrates that severe PPM is common after TAVR and is associated with greater 1-year mortality (hazard ratio: 1.19). Further investigation is warranted into prevention of severe PPM in patients undergoing TAVR. EOAI = effective orifice area index; TAVR = transcatheter aortic valve replacement.

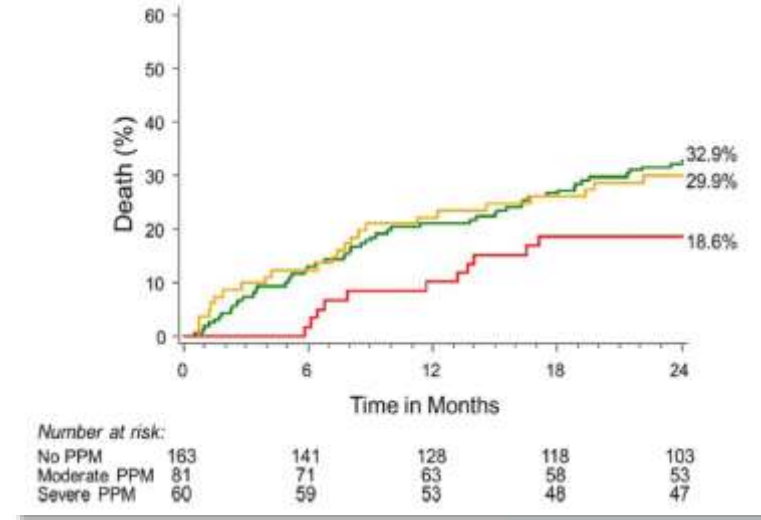
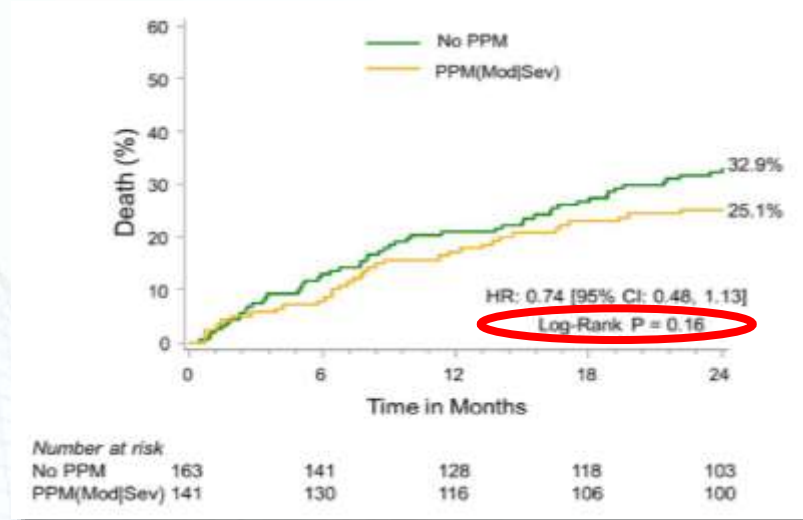
PPM, a Predictor of Mortality in SAVR but Not TAVR

SAVR-RCT



PARTNER Trial

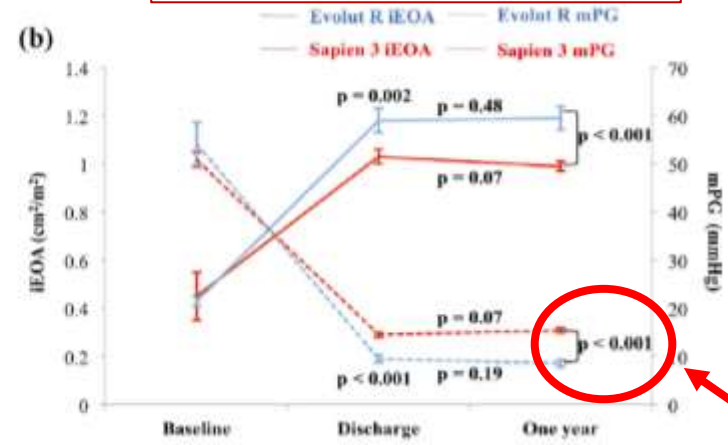
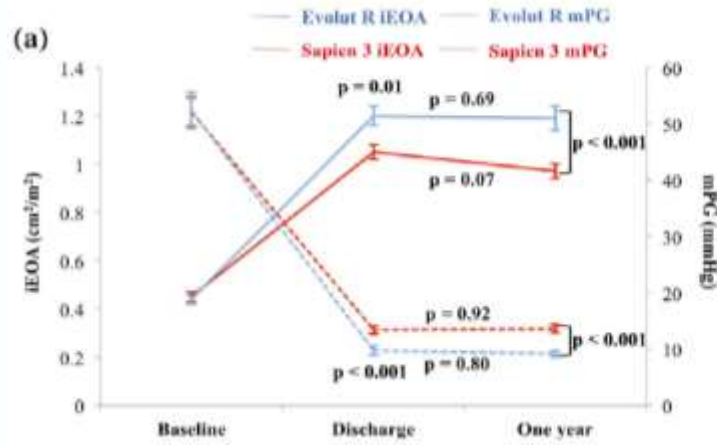
TAVR-RCT



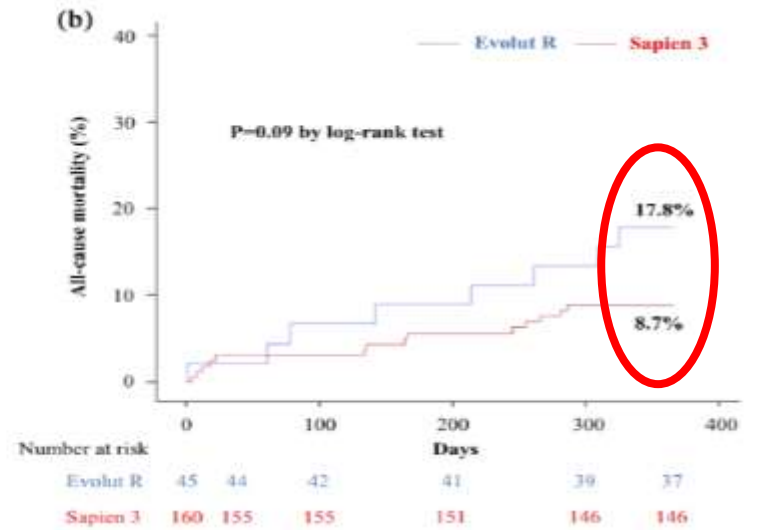
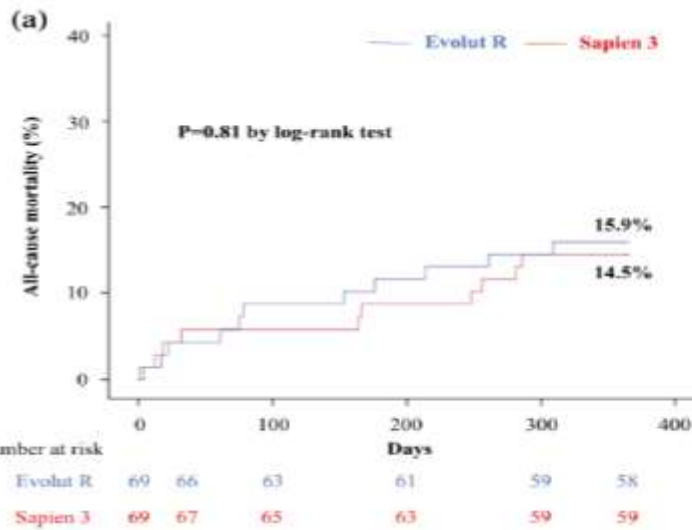
Ocean TAVI Registry

Aortic Annulus $\leq 23\text{mm}$

Aortic Annulus $\leq 21\text{mm}$

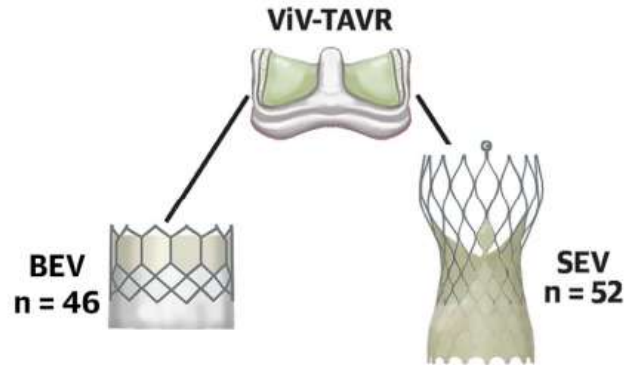


In small annuli despite better echo derived gradients with Evolut R...



...mortality was doubled at 400 days compared to SAPIEN 3

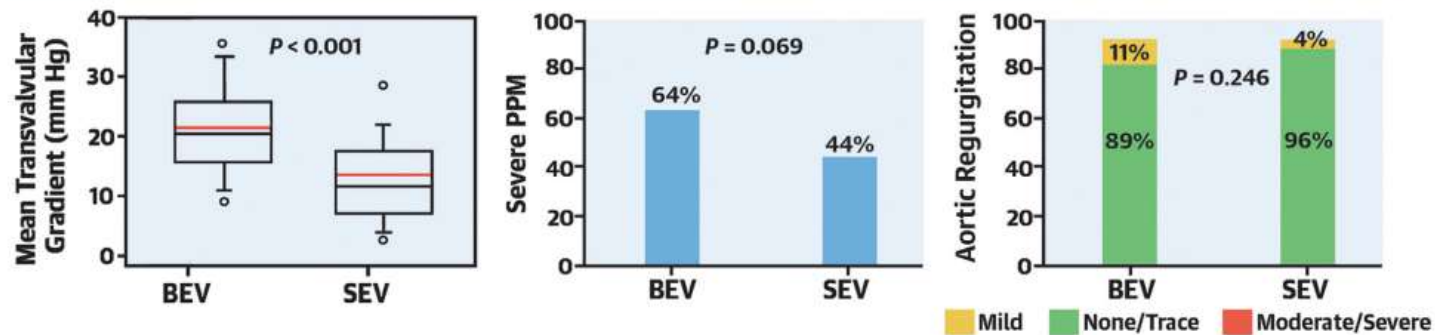
The 'LYTEN' Trial



- There were no differences between groups in intraprocedural invasive valve hemodynamics and 30-day clinical outcomes

No differences in clinical outcomes at 30 days
No death or stroke events at 30 days

Valve Hemodynamics as Evaluated by Doppler-Echocardiography at 30-Day Follow-Up (Primary Endpoint)

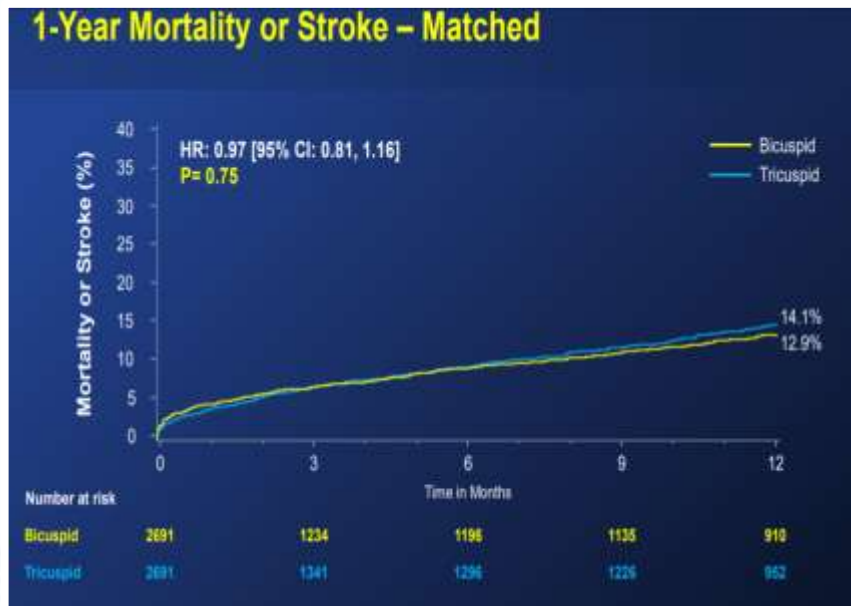


Doppler Assessment

Bicuspid Aortic Valve

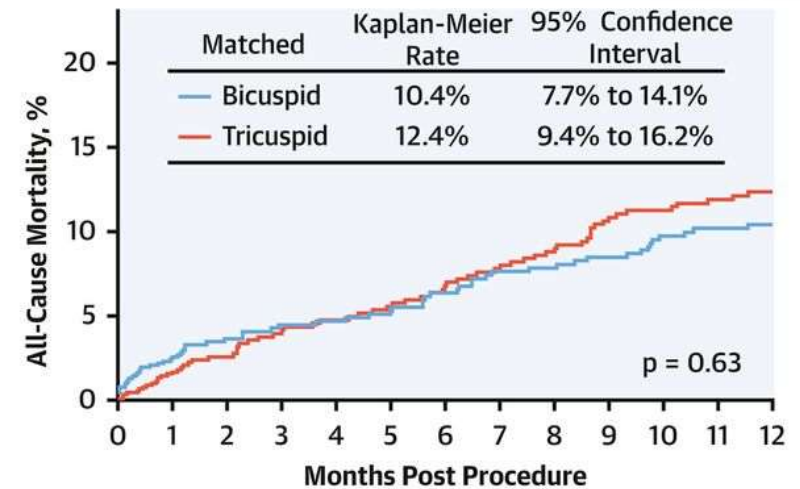
STS/ACC TVT Registry

Sapien 3



JAMA 2019 Jun 11;321(22):2193-2202

Evolut R

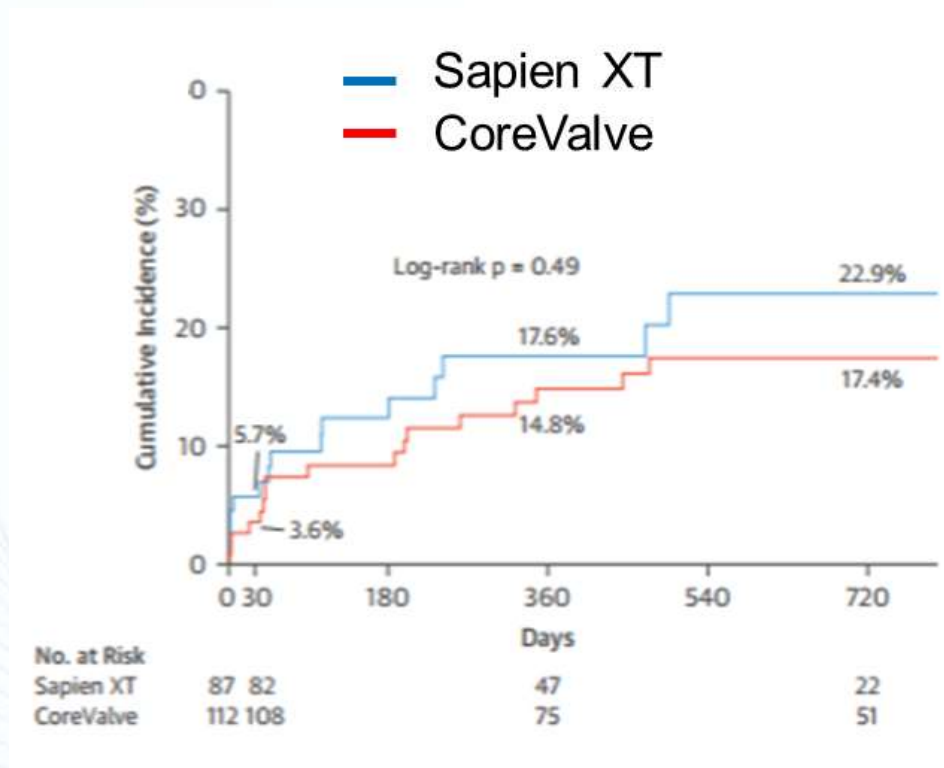


		No. at Risk												
		0	1	2	3	4	5	6	7	8	9	10	11	12
—	Bicuspid	929	791	496	456	445	437	425	321					
—	Tricuspid	929	796	508	474	463	449	432	314					

JACC CVI 2020 May 23;S1936-8798(20)30763-9

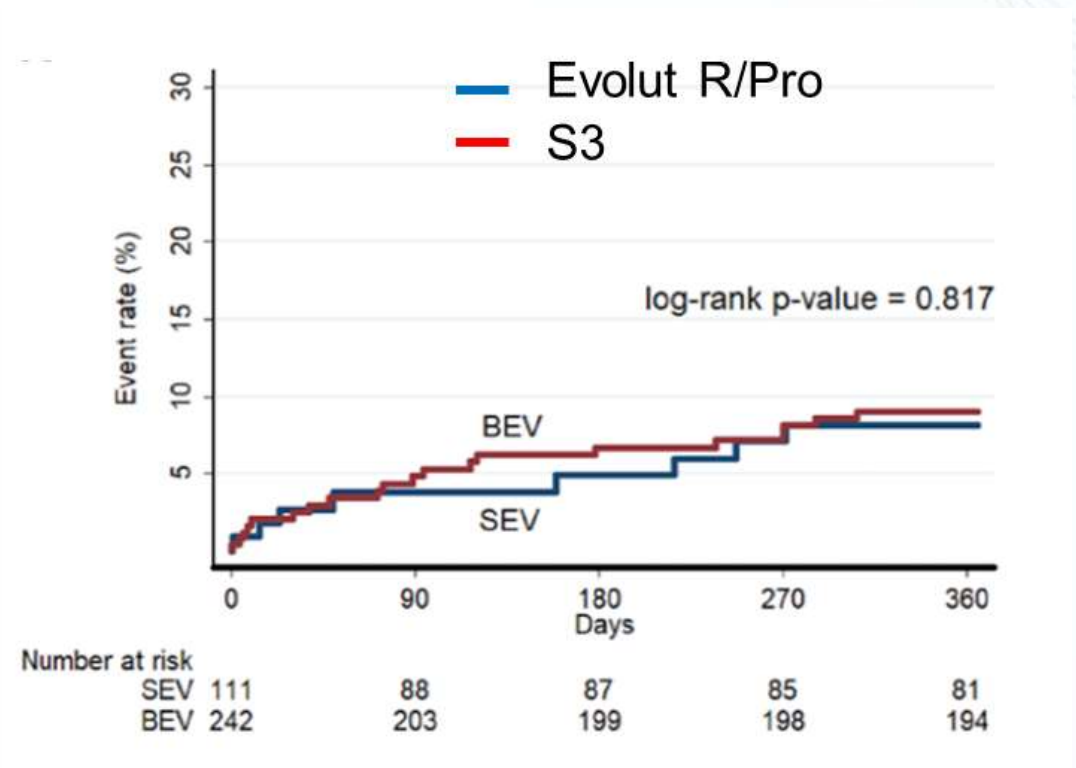
SEV vs. BEV

The Bicuspid TAVR Registry



J Am Coll Cardiol 2016;68:1195–205

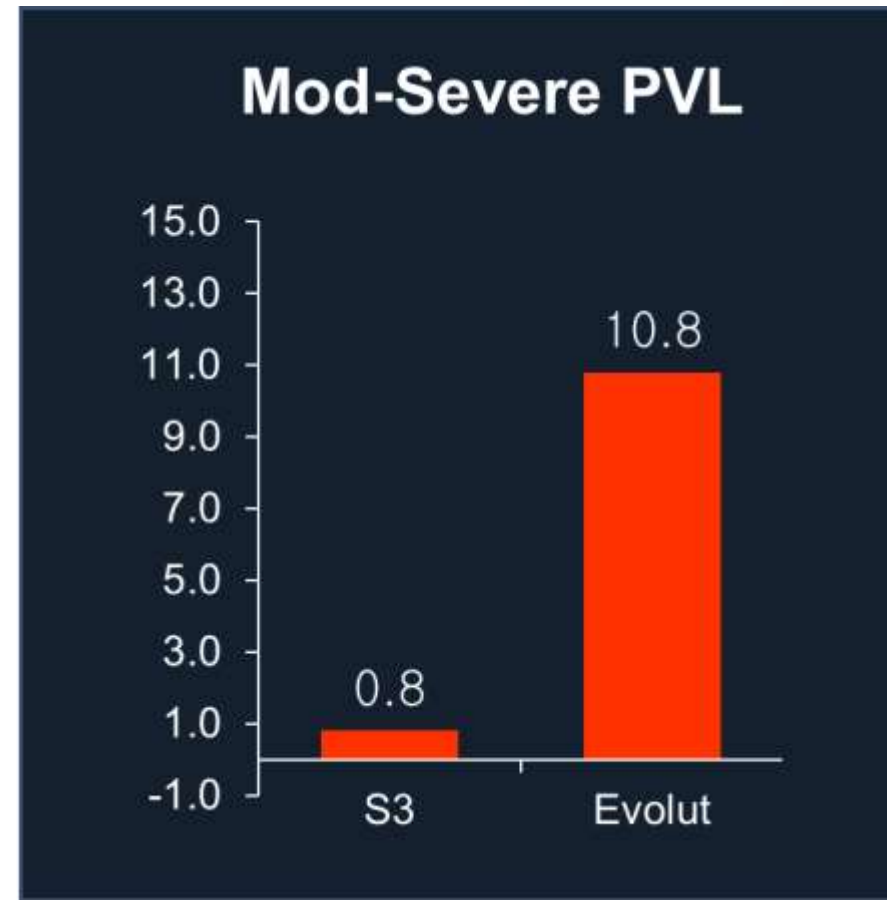
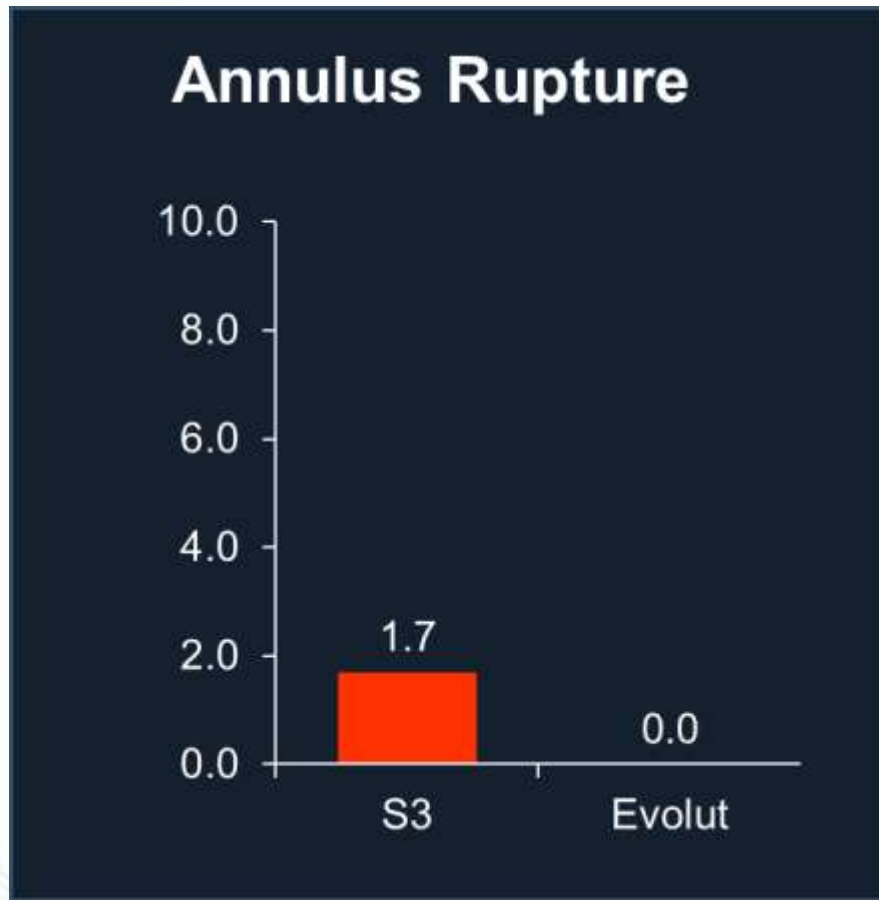
The BEAT Registry



Circ Cardiovasc Interv. 2020;13:e008714

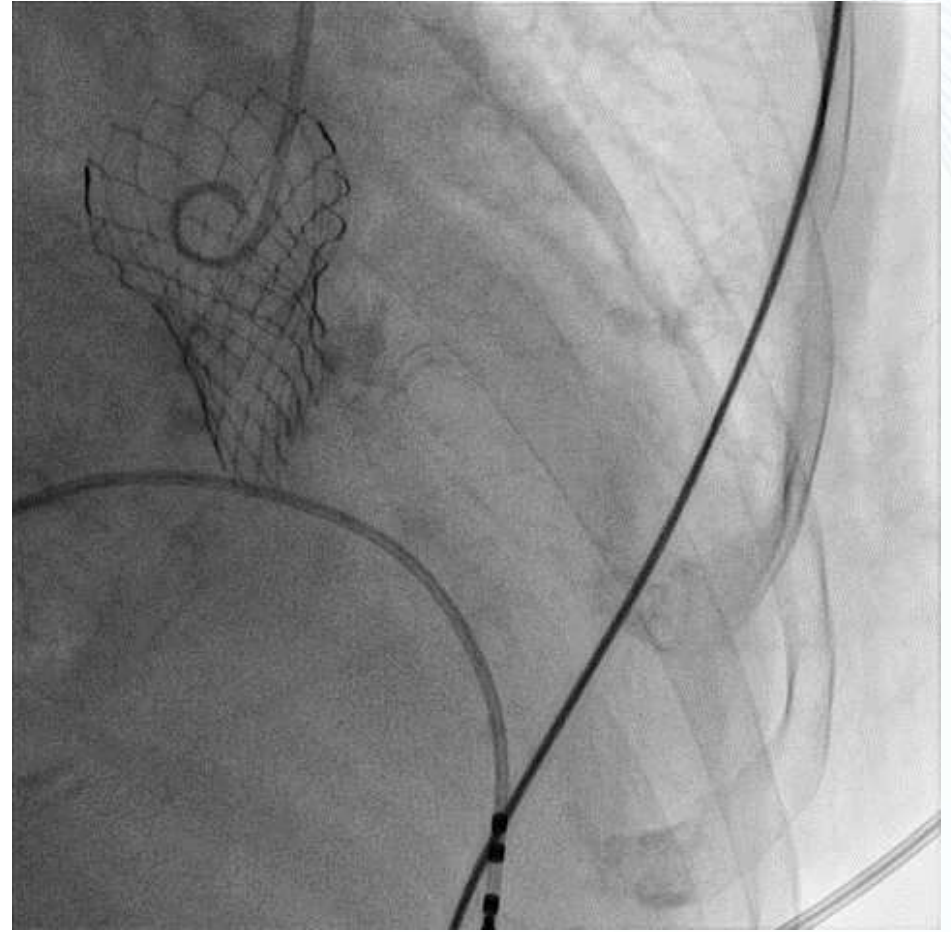
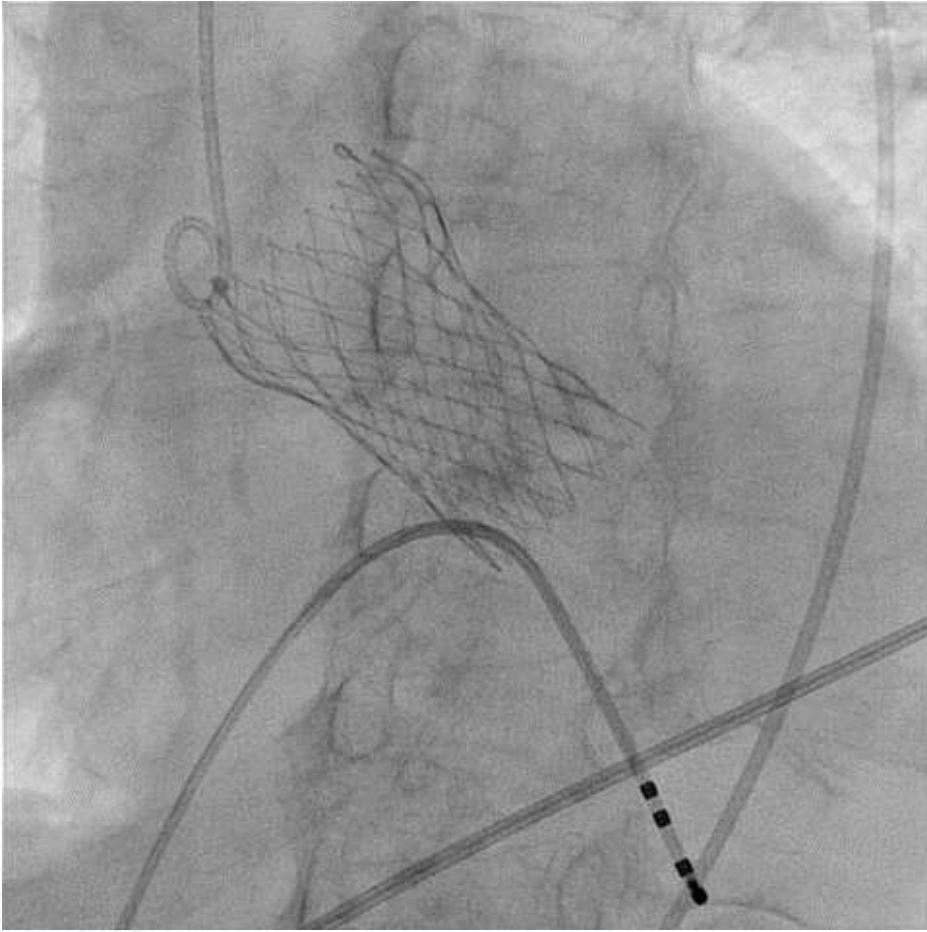
S3 vs. Evolut R/PRO

The BEAT Registry



Circ Cardiovasc Interv. 2020;13:e008714

Check Two Projection



Device Used in Bicuspid Registry

TVT Registry

- S. Halim
- TVT Registry
- n=5,412
- STS=3.8%

73% SAPIEN 3 valve

Low-Risk TAVR Trial

- R. Waksman
- Investigator-Initiated Study
- n=61
- STS=1.5%

74% SAPIEN 3 valve

International Bicuspid Registry

- SH. Yoon
- BAV TAVR International Registry
- n=1,034
- STS=3.7%

72% SAPIEN 3 valve

BAVARD Registry

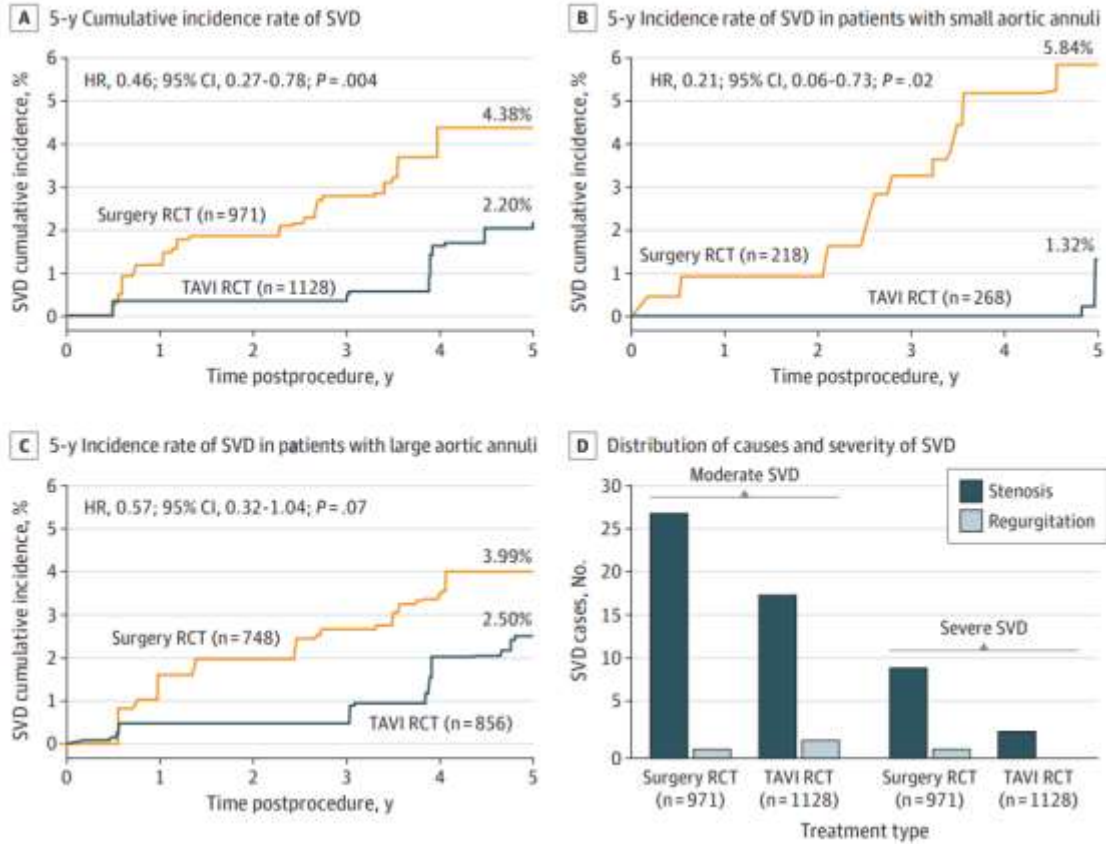
- D. Tchétché
- BAVARD Multicenter Registry
- n=101
- STS=11.3%

65% SAPIEN 3 valve



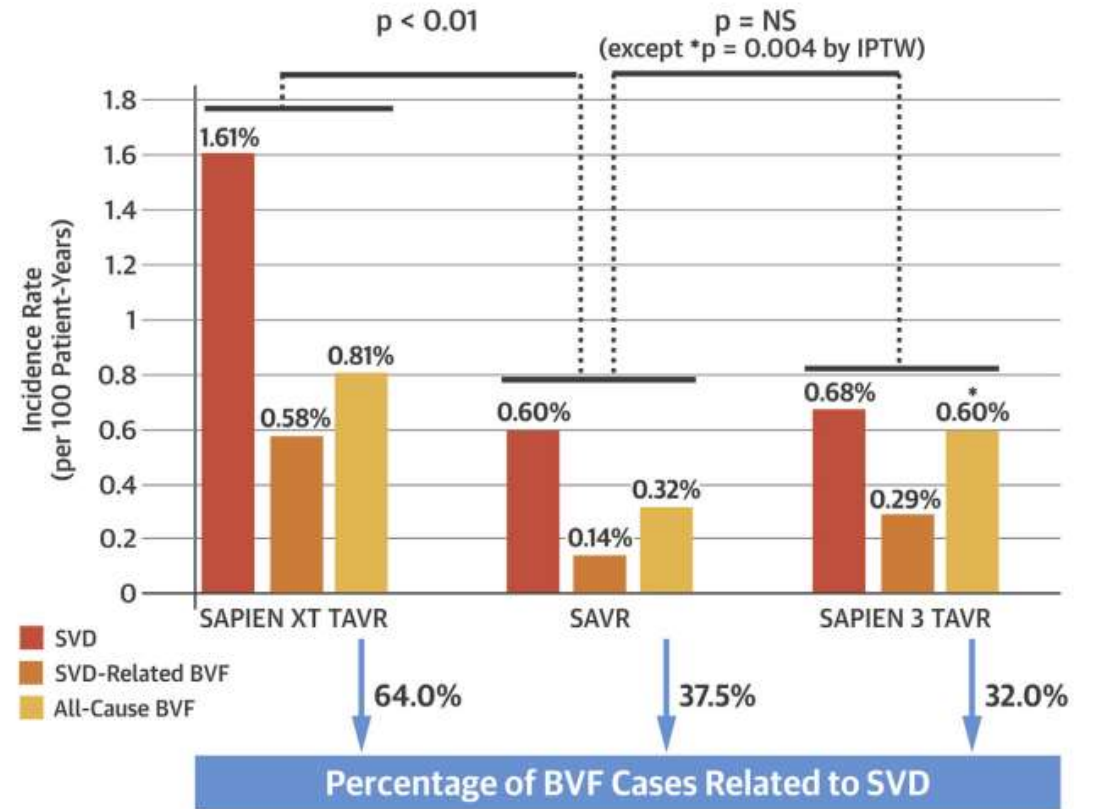
Durability

SURTAVI Trial



JAMA Cardiol. 2023;8(2):111-119

PARTNER II



J Am Coll Cardiol 2020;76(16):1830-43



Over-all Outcomes

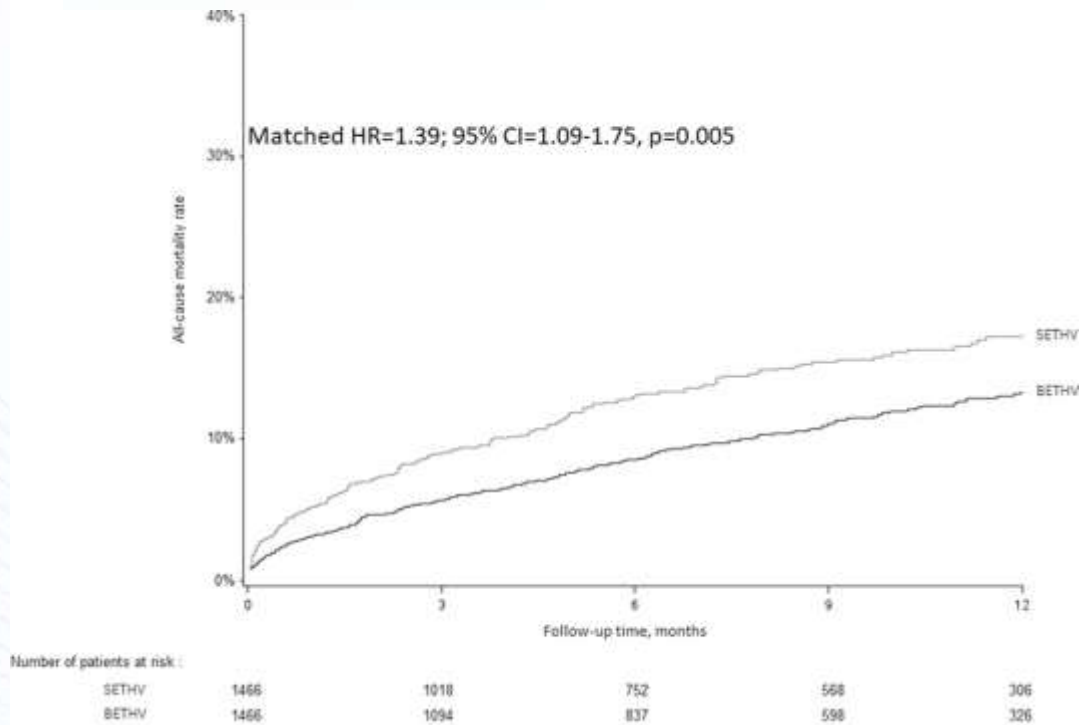
FRANCE-TAVI Registry: PS-Matched Cohort

Outcome	SE (n=1467)	BE (n=1467)	Effect Size (95%CI)	P-Value
Primary outcome (PVR>mod and/or intra-hospital mortality)	18%	8% ✓	2.10 (1.50 to 2.94)*	<0.001
PVR>moderate	14.8%	5.7% ✓	2.59 (1.92 to 3.49)*	<0.001
Intra-hospital mortality	3.9%	2.7% ✓	1.43 (0.92 to 2.24)*	0.11
Second THV	3.3%	0.6% ✓	6.05 (2.95 to 12.41)†	<0.001
Stroke	2.2%	1.5% ✓	1.50 (0.85 to 2.61)†	0.19
MI	0.2%	<0.1% ✓	Not estimable	-
Major or life-threatening bleeding	10.2%	7.6% ✓	1.19 (0.91 to 1.55)†	0.20
Vascular complications	7.6%	4.8% ✓	1.57 (1.10 to 2.22)†	0.01
Permanent pacemaker implantation	22.6%	12.6% ✓	1.86 (1.55 to 2.23)†	<0.001
Post-procedural mean gradient (mmHg)	8 (5-10) ✓	10 (8-14)	-0.26 (-0.31 to -0.22)‡	<0.001
Mean gradient >20mmHg	2.2% ✓	3.6%	0.61 (0.39 to 0.95)†	0.029

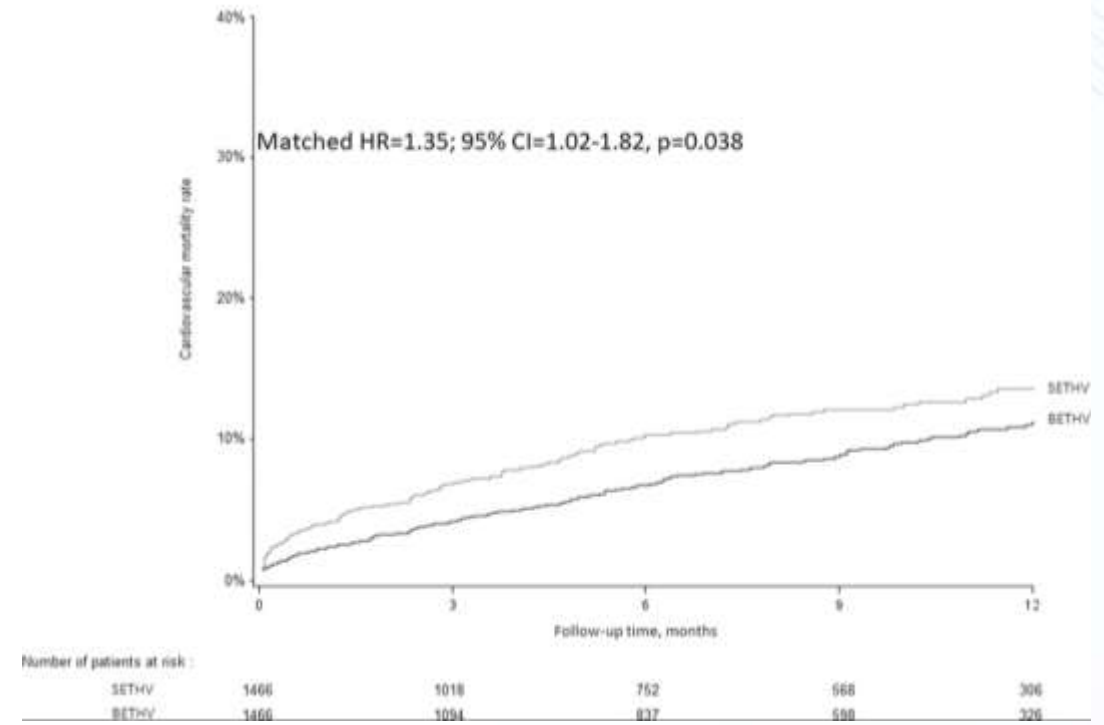
Van Belle, E et al. Circulation. 2020;141(4):243-259

FRANCE-TAVI Registry: PS-Matched Cohort

All-Cause Mortality



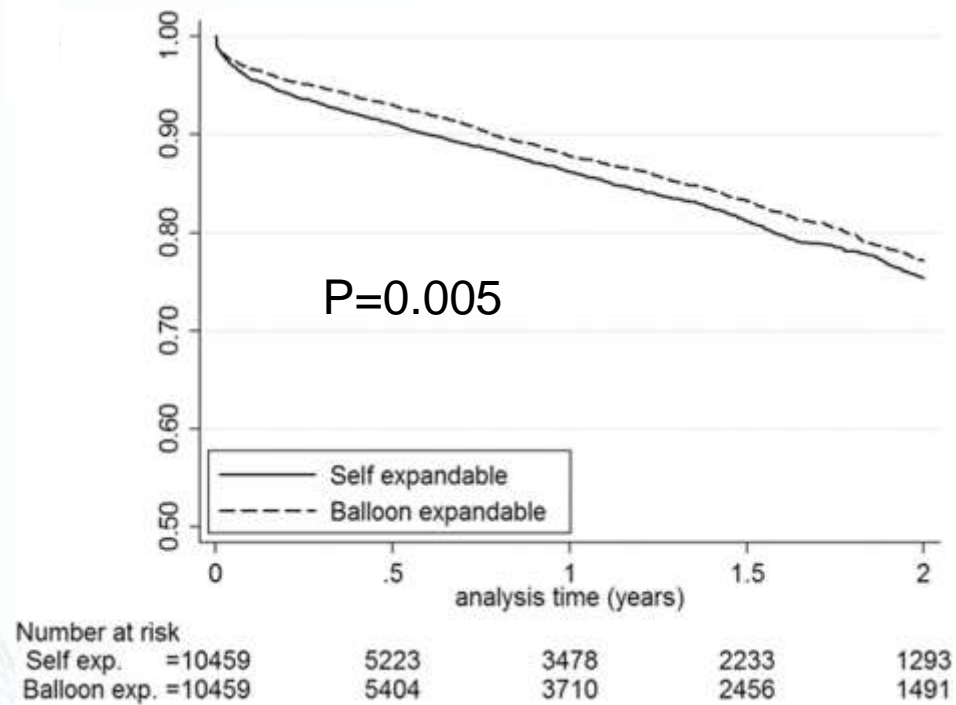
Cardiac Mortality



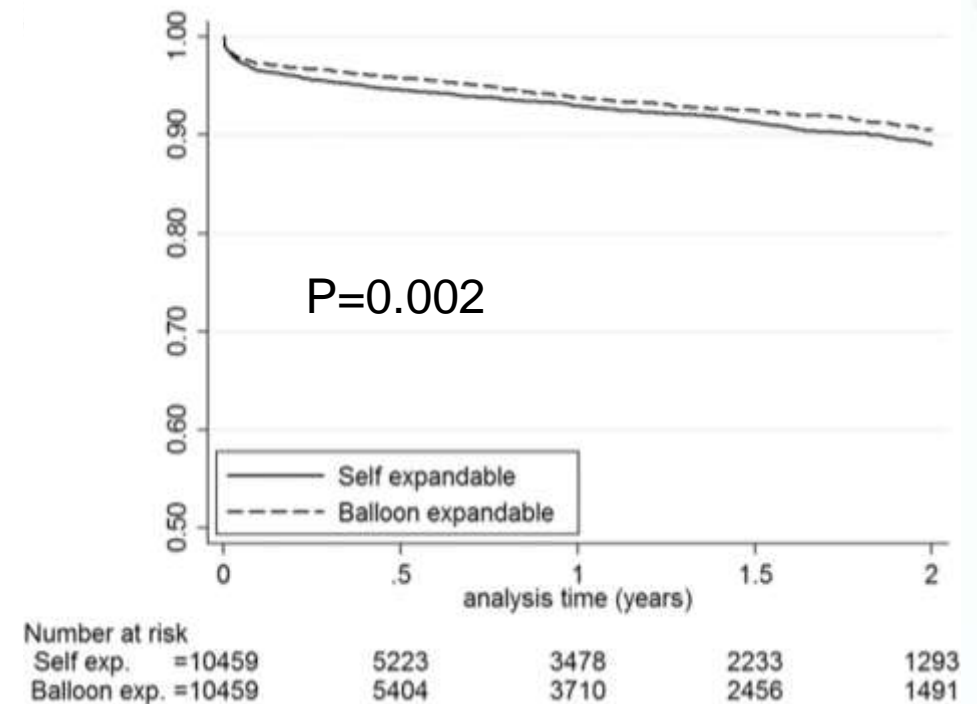
Van Belle, E et al. Circulation. 2020;141(4):243-259

French Administrative Hospital-Discharge Database

All-Cause Mortality



Cardiac Mortality



Deharo P et al. *Circulation*. 2020;141:260–268.

Current Open Issues and Challenges for TAVR

TAVR Valve Choice Considerations

	Balloon-expandable	Self-expanding
Paravalvular Leakage	+	
Permanent Pacemaker Implantation	+	
Coronary Obstruction (Acute/Late)		
Acute		+
Late	+	
Coronary Access	+	
Patient-Prosthesis Mismatch		+
Bicuspid Aortic Valve	+	+
Durability	+	++
Overall Outcomes	Need RCT	

+ : better

Conclusion

- Randomized trials have demonstrated that transcatheter aortic valve replacement (TAVR) with both balloon-expandable and self-expandable valves shows comparable or better clinical outcomes than surgical aortic valve replacement (SAVR).
- Balloon-expandable valves have shown lower risks of paravalvular leak (PVL) and permanent pacemaker implantation, as well as easier coronary access.
- Self-expandable valves, on the other hand, have demonstrated better hemodynamics and lower risks of structural valvular deterioration.
- Real-world data has shown lower mortality in patients who use balloon-expandable valves, but large randomized trials are needed to confirm or refute these observations.
- It is important to note that one device cannot fit all patients, and operators should understand the unique procedural and prognostic characteristics of both devices.