

How Can We Tackle Small Annulus?



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Disclosure

- Consulting:
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- Proctoring:
 - Medtronic, Edwards

What is Small Aortic Annulus?

- No clear consensus regarding the cutoff value for defining SAA
- Annular diameter ≤ 23 mm
- Surgical prosthesis ≤ 21 mm
- Annular area < 400 mm² or perimeter < 72 mm

⇒ *Prevalence 22~44% of the SVR cases*

⇒ *More common in southern Europe and Asia*

⇒ *Women make up ~90% of the small annulus population*

⇒ *Frequent in patients undergoing TAVR in SAV*

Problems Associated with TAVR in Small Aortic Annulus

- Patient prosthesis mismatch
 - => increased mortality & morbidity
 - => linked to an increase in structural valve deterioration (SVD)
- Potential risk of procedural complications
 - Annular rupture
 - Coronary obstruction
 - AV conduction disturbance/PPI

Patient-Prosthesis Mismatch

- When the effective orifice area (EOA) of a prosthetic valve is too small in relation to body size.
- Unable to meet the patient's cardiac output requirements
- Lower cut point values for obese patients (BMI ≥ 30 kg/m²) because the indexed EOA may overestimate the severity of PPM.

TABLE 3 Definitions for Prosthesis-Patient Mismatch

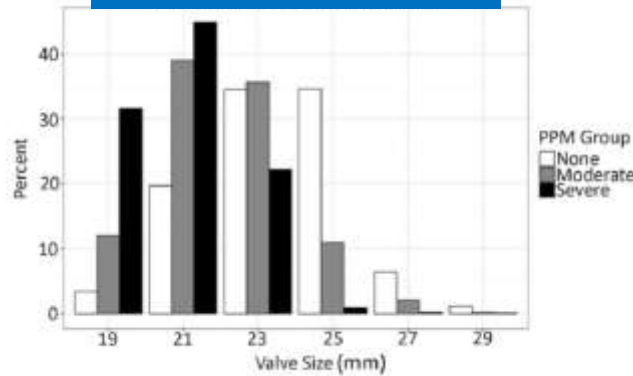
	Severe, cm ² /m ²	Moderate, cm ² /m ²
ASE guidelines ²⁶	<0.65	0.65-0.85
VARC-2 ¹⁰⁵	<0.65	0.65-0.85
BMI ≥ 30 kg/m ²	<0.60	0.60-0.70
EACVI recommendations ⁸⁰	<0.65	0.65-0.85
BMI ≥ 30 kg/m ²	<0.55	0.55-0.70
VARC 3 ⁶	≤ 0.65	0.66-0.85
BMI ≥ 30 kg/m ²	<0.55	0.55-0.70

PPM is characterized by

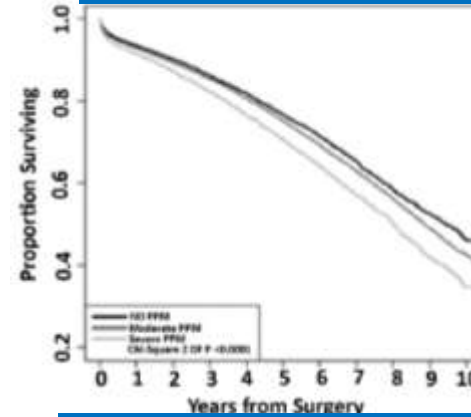
- high transprosthetic velocity and gradients
- normal EOA
- small indexed EOA
- normal leaflet morphology and mobility

PPM after AVR Decreased Long-term Survival and Increased Readmission Rates for HF and Re-OP

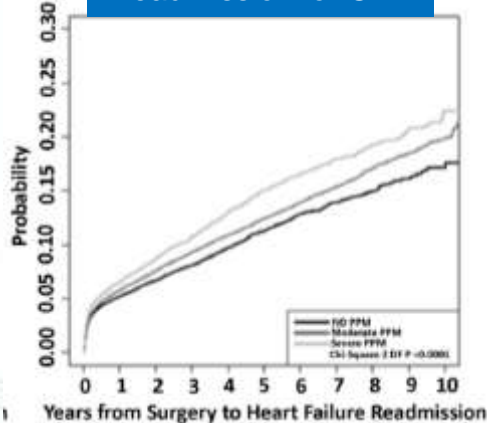
Prevalence of PPM



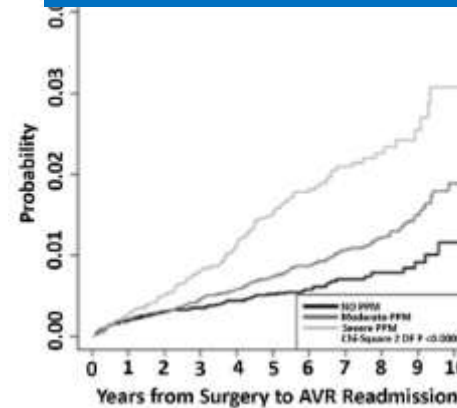
Survival



Readmission for CHF



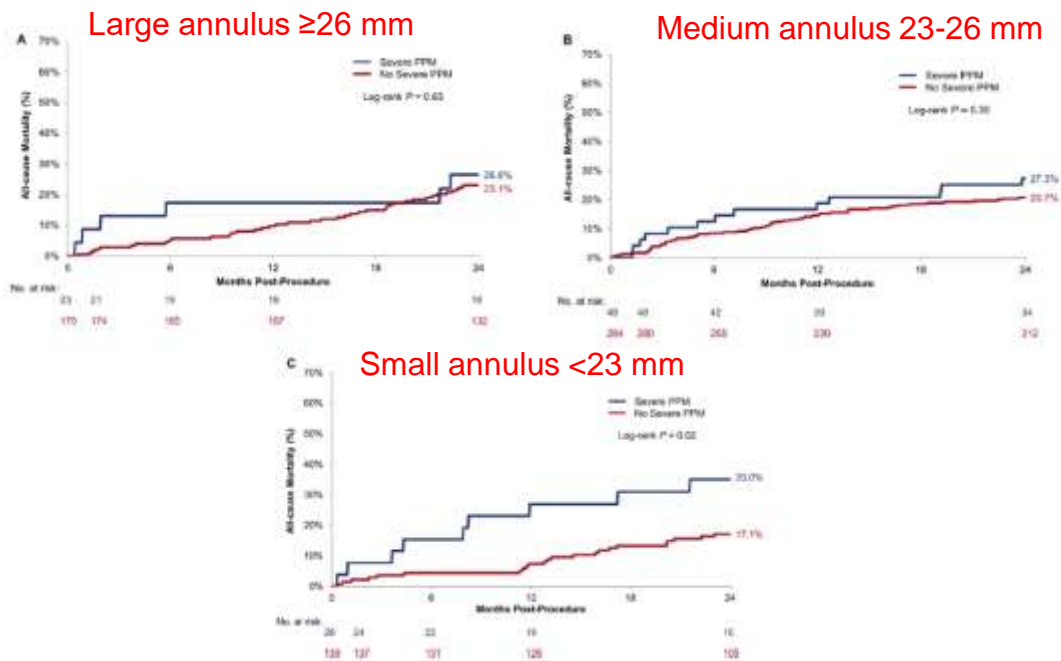
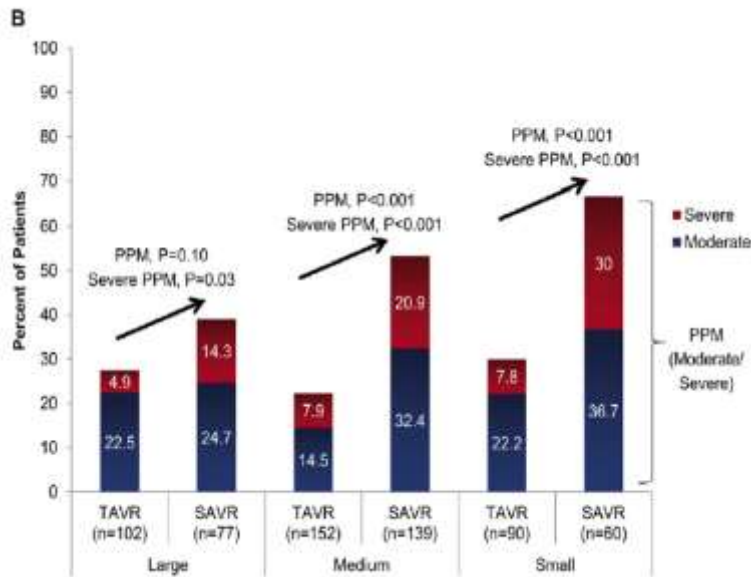
Readmission for Re-do AVR



Impact of Annular Size on Outcomes After Surgical or Transcatheter AVR

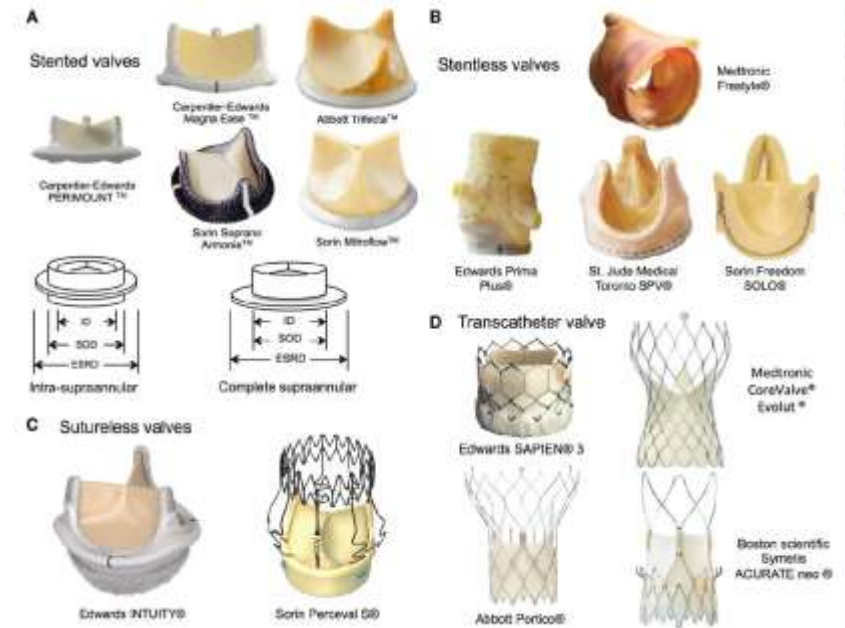
Study population
from CoreValve US Pivotal High Risk Trial

All-cause mortality



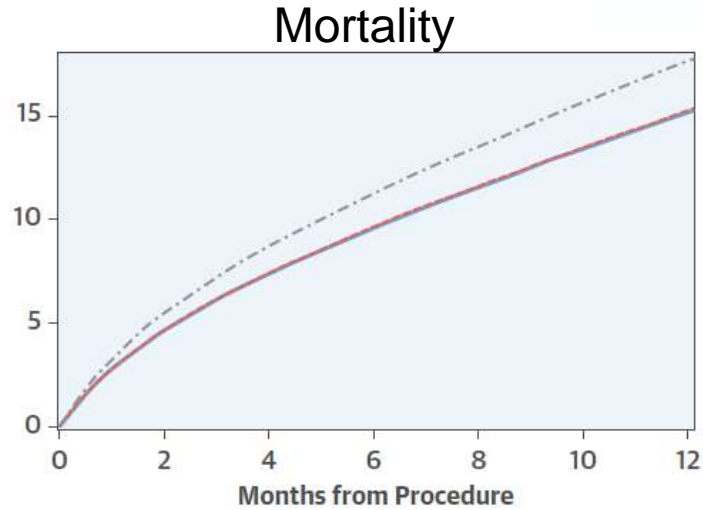
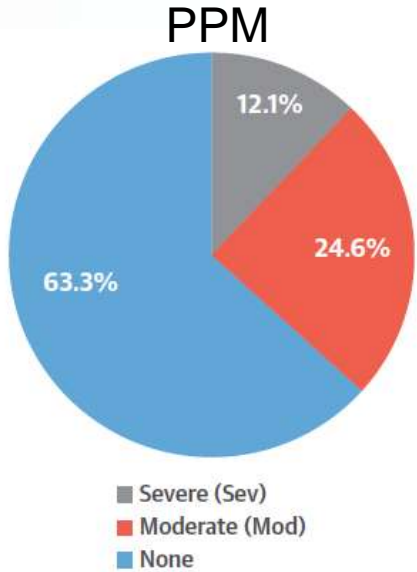
Superior Hemodynamic Profile with TAVR vs SAVR

- Systematic transcatheter valve oversizing
 - ~20% for self-expanding valves
 - ~10% for balloon-expanding valves
- Absence of a sewing ring
- Thin struts



TVT Registry: Incidence and Effect on Survival of Severe PPM After TAVR

PPM was associated with higher mortality and HF rehospitalization

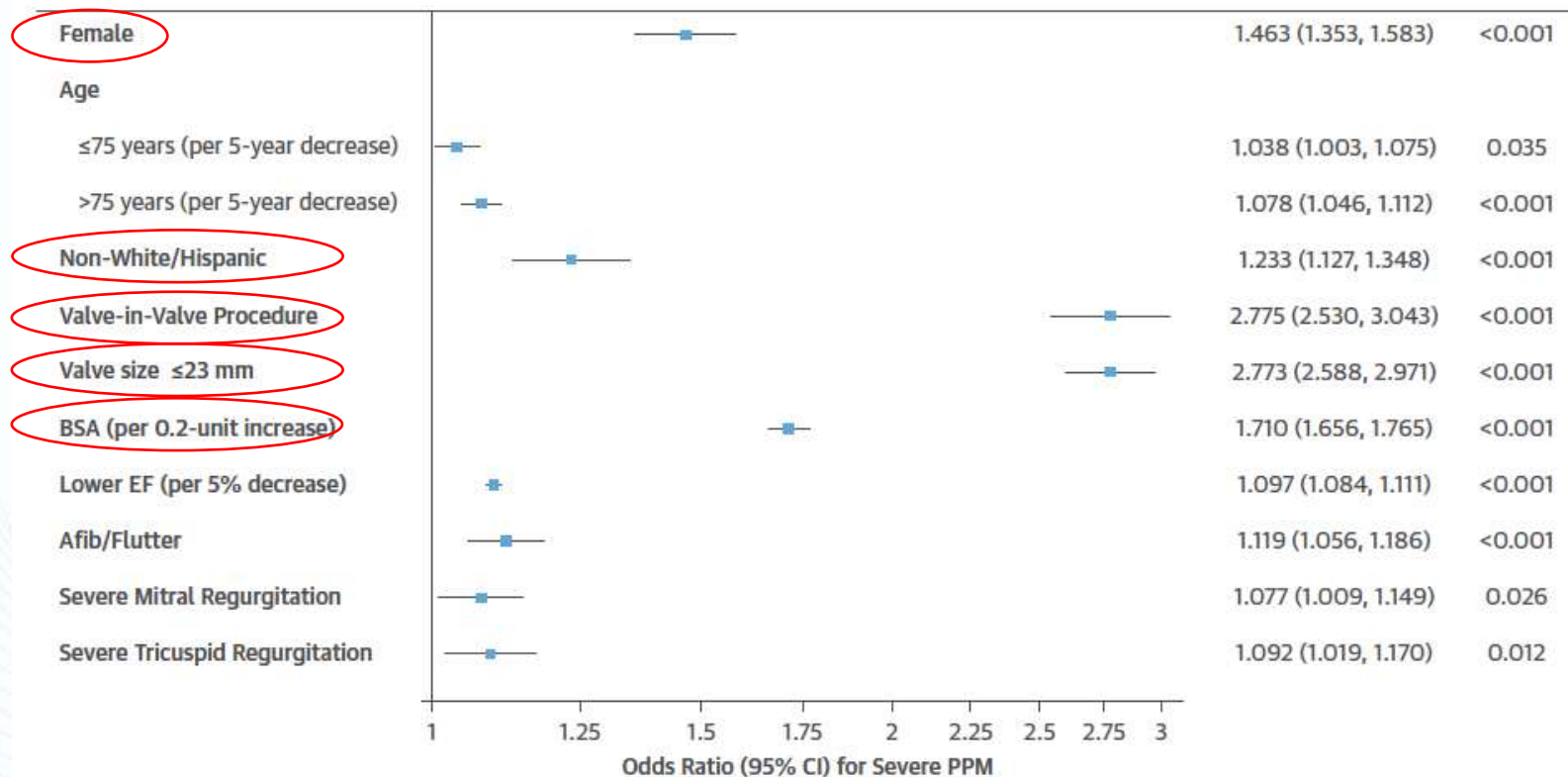


--- Sev PPM (EOAi <0.65 cm²/m²) — Mod PPM (EOAi 0.65-0.85 cm²/m²)
 — No PPM (EOAi >0.85 cm²/m²)

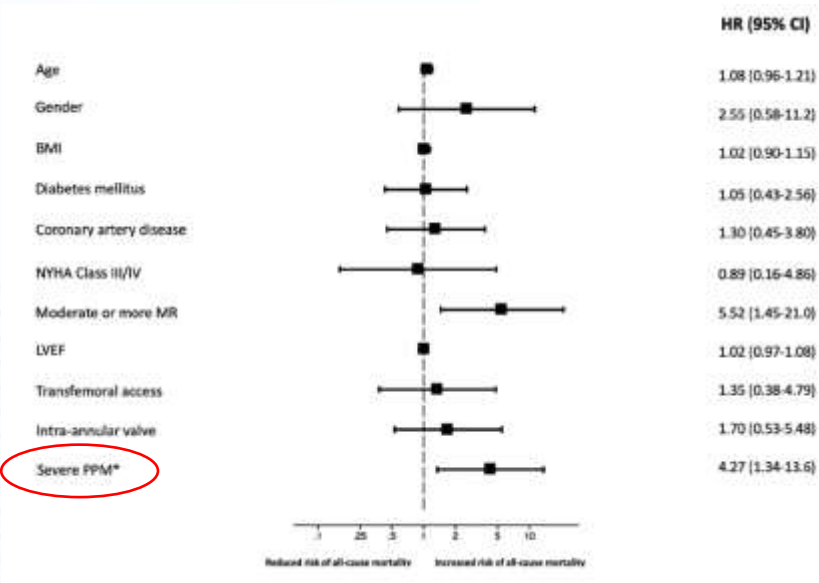
Number at Risk Adjusting for Baseline Covariates:

	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

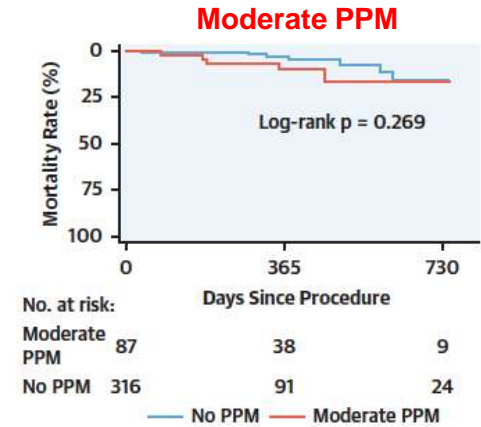
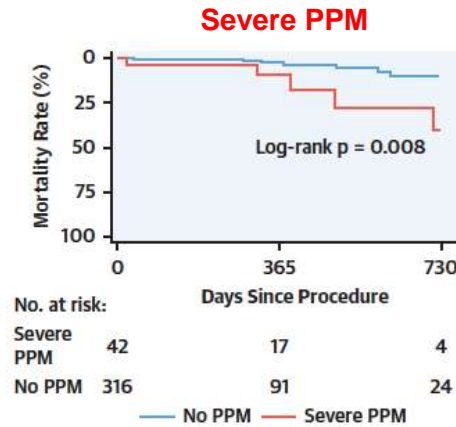
Predictors of Severe PPM



TAVI-Small Registry (SEV): Predictors of Mortality after TAVR

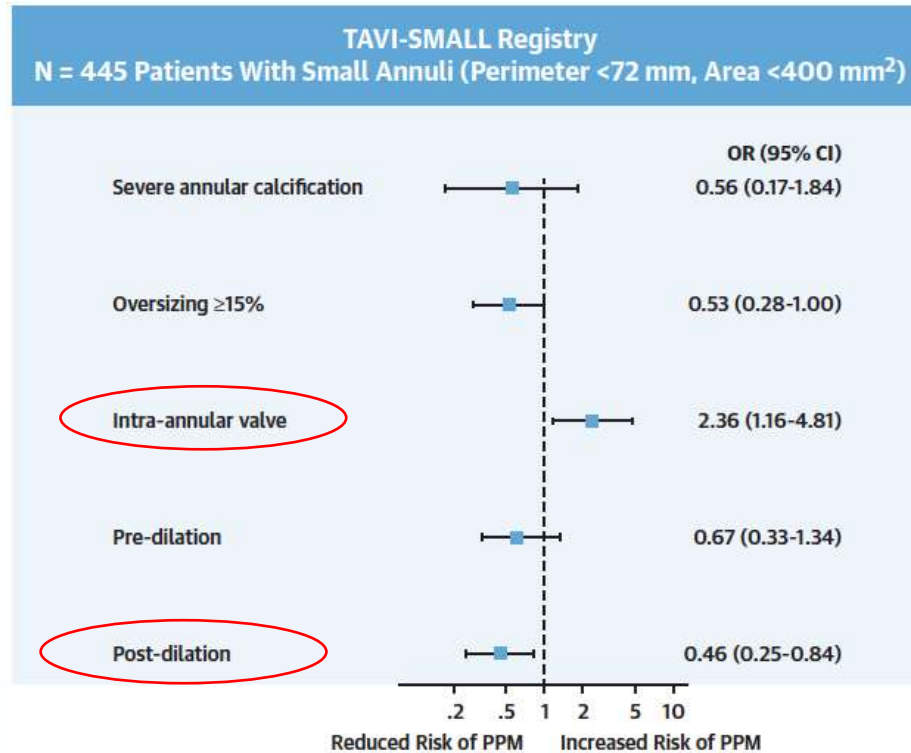


Mortality



Leone PP, JACC Intv. 2021;14:1218

TAVI-Small Registry: Predictors of PPM for Self-expanding Valves

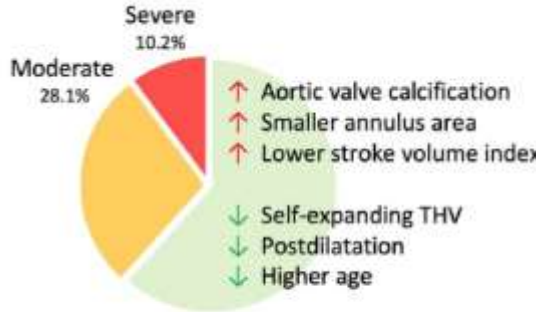


Leone PP, JACC Intv. 2021;14:1218

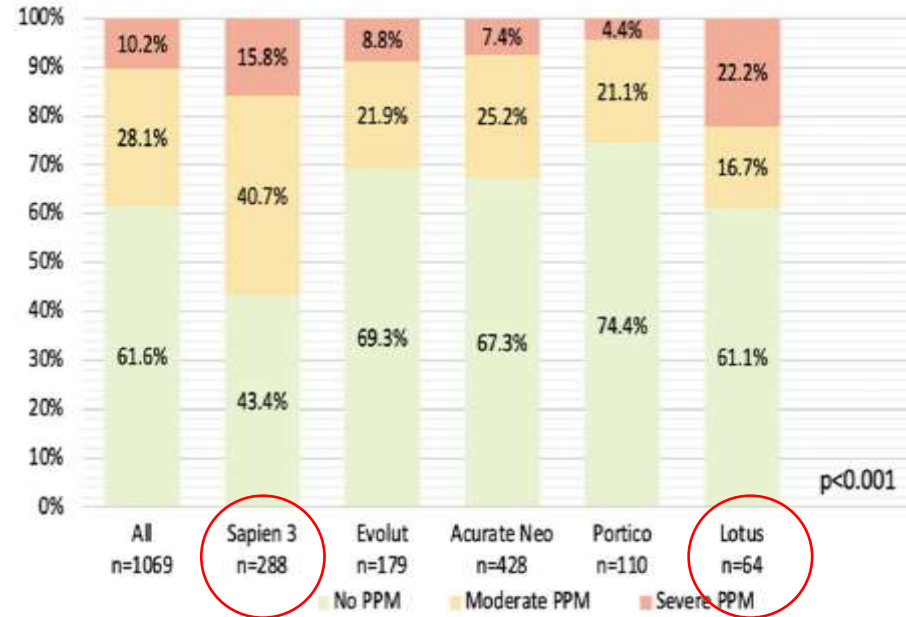
Risk Factors of PPM after TAVR

N=8411, from 4 German centers

Small aortic annulus in 12.7% of patients



38.3% with prosthesis-patient mismatch after TAVI



Voigtlaender L, Clin Res Cardio 2021;110:1957

Balloon-Expandable (Sapien XT) vs. Self-Expanding (CoreValve) Valves: CHOICE Randomized Clinical Trial

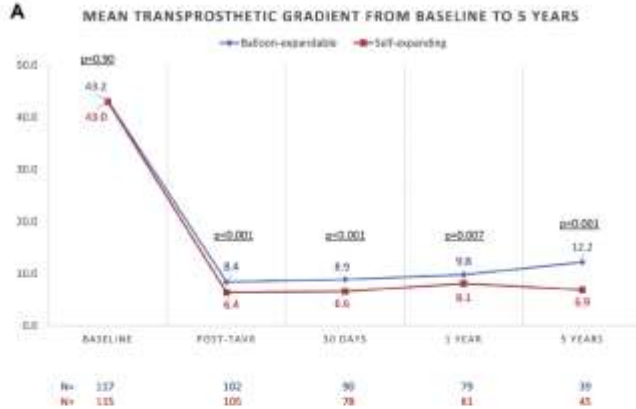
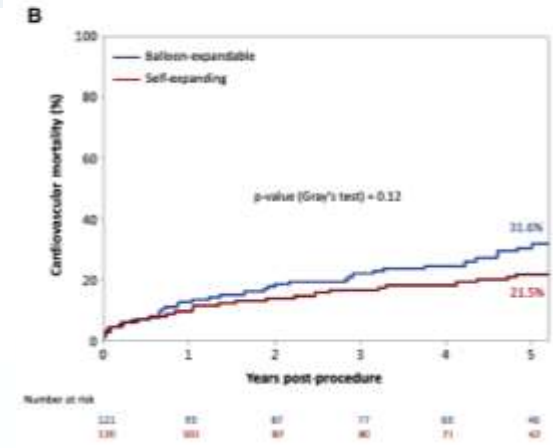
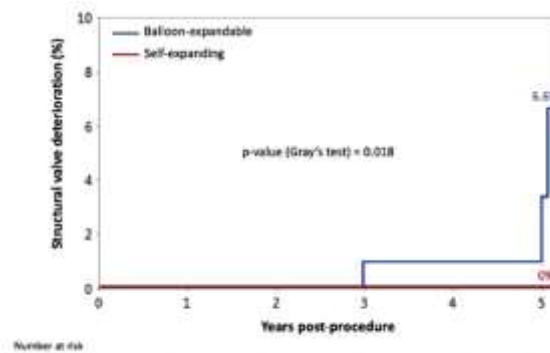
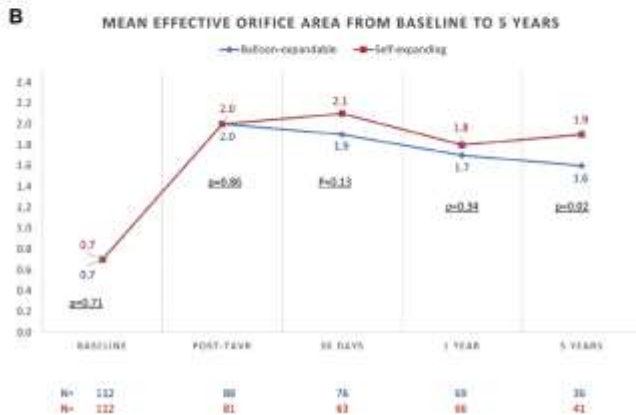
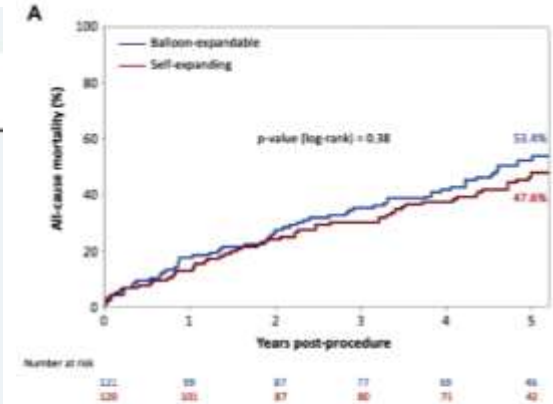


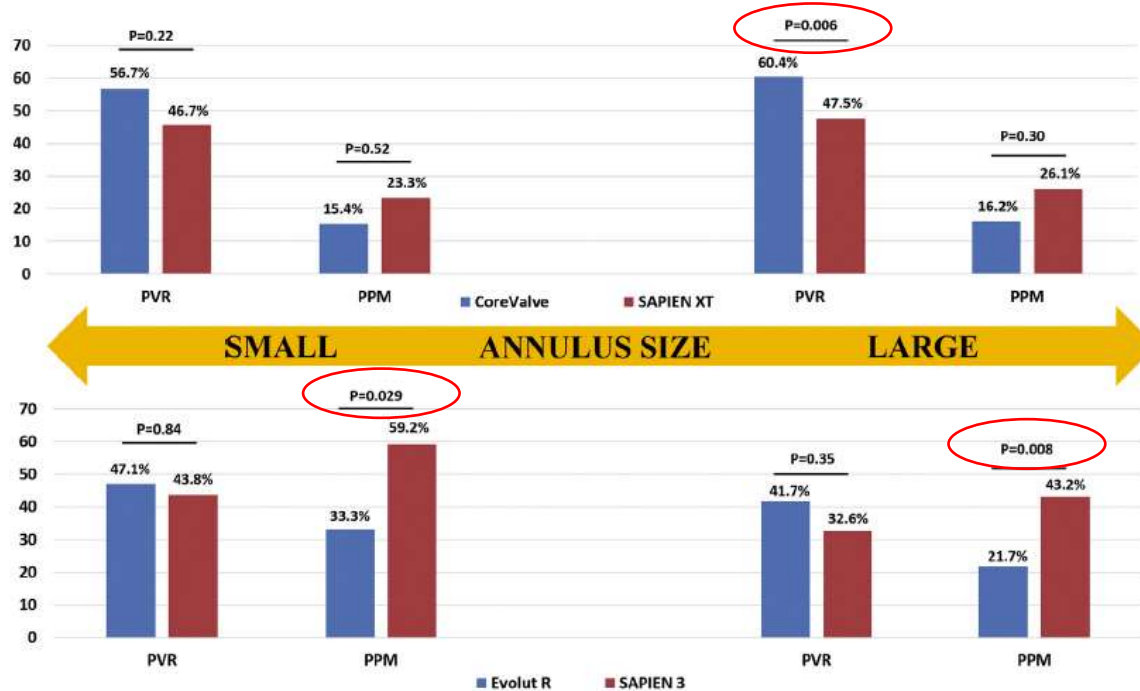
TABLE 3 BVD and Its Components Through 5 Years

	Balloon-Expandable Valve (n = 121)	Self-Expanding Valve (n = 120)	p Value
Bioprosthetic valve dysfunction	28 (22.5)	26 (20.9)	0.91
Components:			
SVD	6 (6.6)	0 (0.0)	0.018
Moderate SVD	4 (5.6)	0 (0.0)	0.047
Severe SVD	2 (0.9)	0 (0.0)	0.20
NSVD	17 (17.8)	23 (26.7)	0.20
Moderate/severe PPM	14 (15.9)	13 (16.0)	1.0
Moderate/severe PVL	3 (2.5)	10 (8.5)	0.08
Valve thrombosis	6 (7.3)	1 (0.8)	0.06
Endocarditis	2 (1.6)	4 (3.4)	0.39



Rates of PVR and PPM According to Aortic Annulus Size

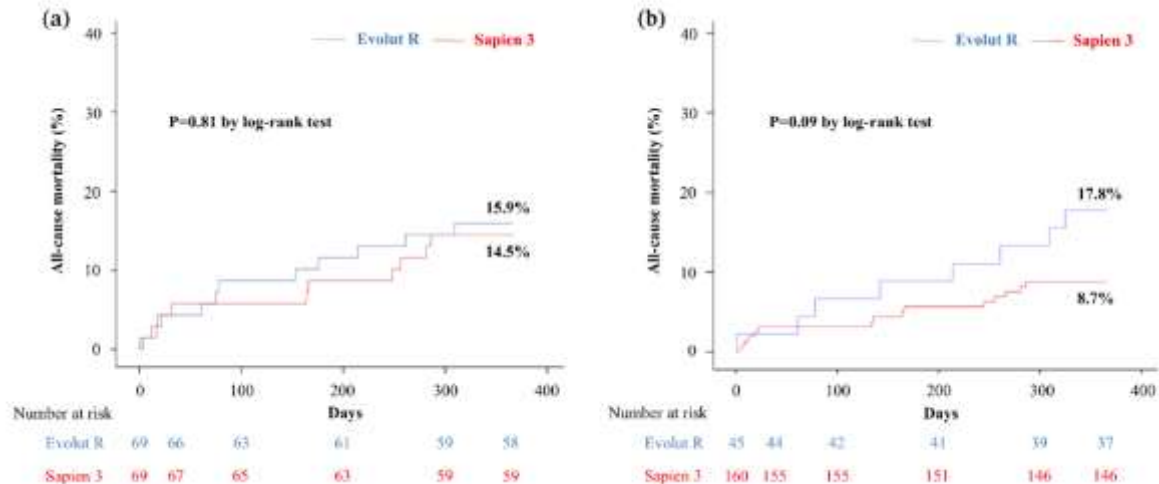
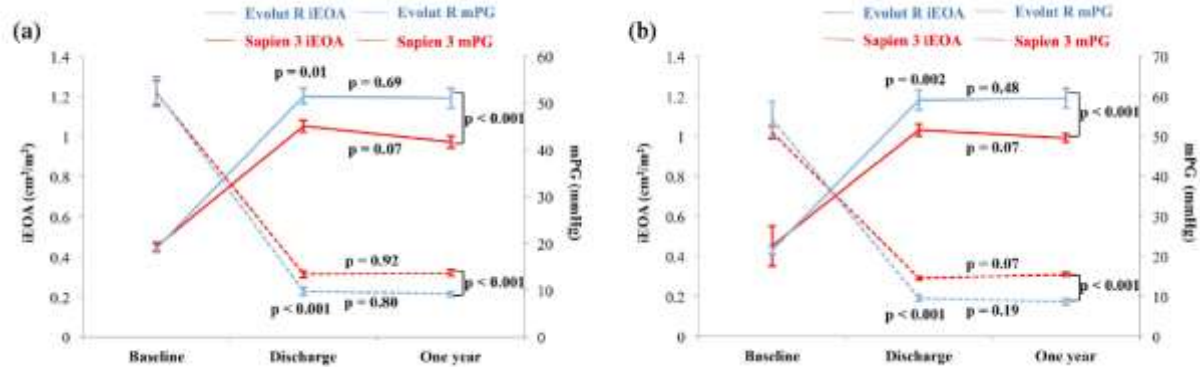
Second Generation THVs - Randomized CHOICE Trial



Third Generation THVs - Non-Randomized CHOICE-Extend Registry

Evolut R vs. Sapien 3 in Japanese patients with a small aortic annulus: The OCEAN-TAVI registry

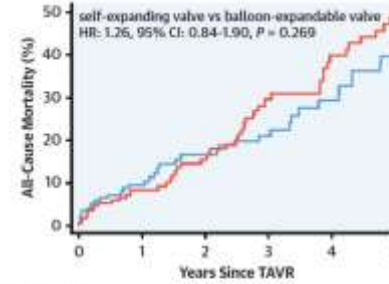
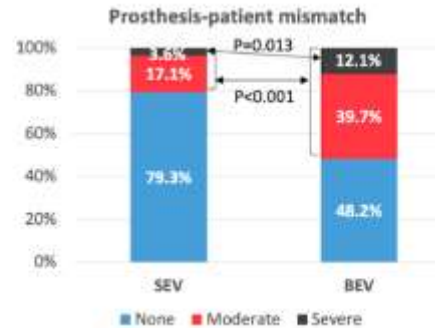
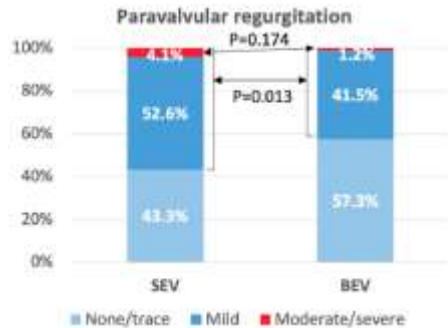
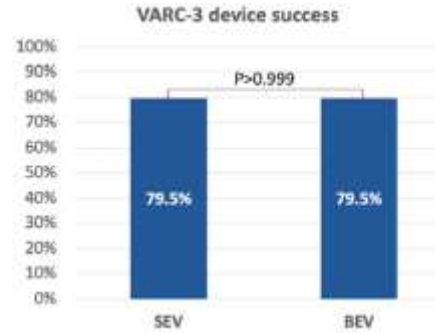
a) small annulus ≤ 23 mm matched cohort, b) small annulus ≤ 21 mm cohort



Hase H,
Catheter Cardiovasc Interv.
2021;97:E875

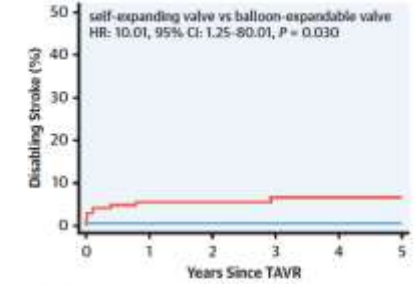
BEV vs. SEV in Patients with Small Annuli

Matched cohort from Bern TAVI registry



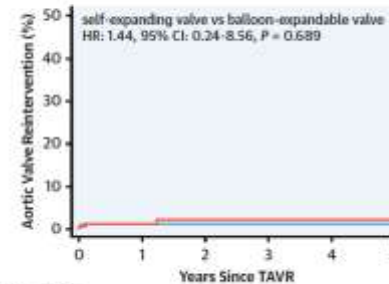
No. at risk:

Years Since TAVR	0	1	2	3	4	5
BEV	171	130	78	68	41	26
SEV	171	136	95	75	41	27



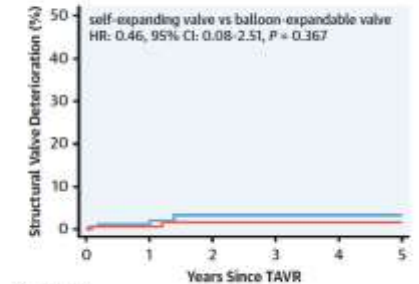
No. at risk:

Years Since TAVR	0	1	2	3	4	5
BEV	171	130	78	68	41	26
SEV	171	129	92	71	38	25



No. at risk:

Years Since TAVR	0	1	2	3	4	5
BEV	171	129	78	68	41	26
SEV	171	135	93	73	40	26



No. at risk:

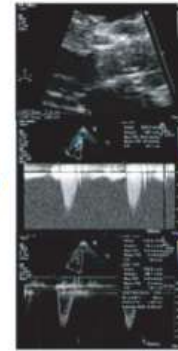
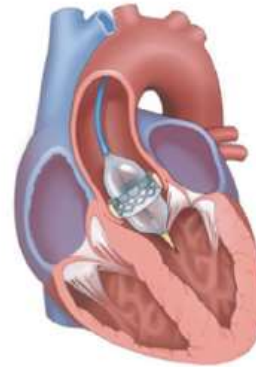
Years Since TAVR	0	1	2	3	4	5
BEV	171	129	76	66	40	26
SEV	171	136	94	74	41	27

PPM: Asian vs. Non-Asian

N=1,101
from Asan
medical center
& 2 US centers



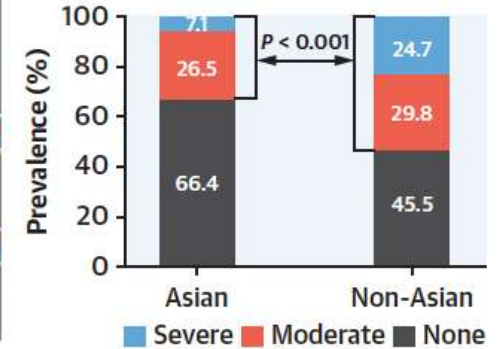
TAVR



Annulus perimeter: 75.7 vs. 78.4 mm
Annulus area: 441 vs. 461 mm²

Prosthesis-Patient Mismatch

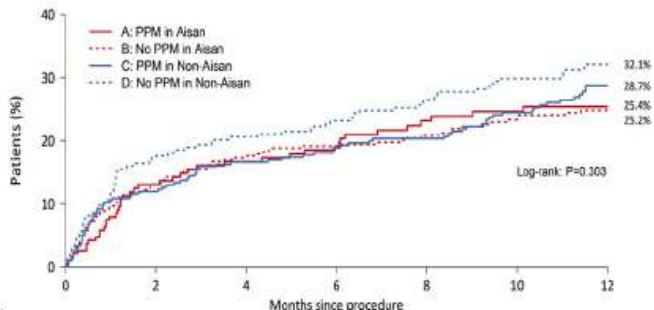
EOA $1.50 \pm 0.37 \text{ cm}^2$
Indexed EOA $0.94 \pm 0.22 \text{ cm}^2/\text{m}^2$



EOA $1.52 \pm 0.49 \text{ cm}^2$
Indexed EOA $0.80 \pm 0.25 \text{ cm}^2/\text{m}^2$

Clinical Outcomes According to PPM and Race

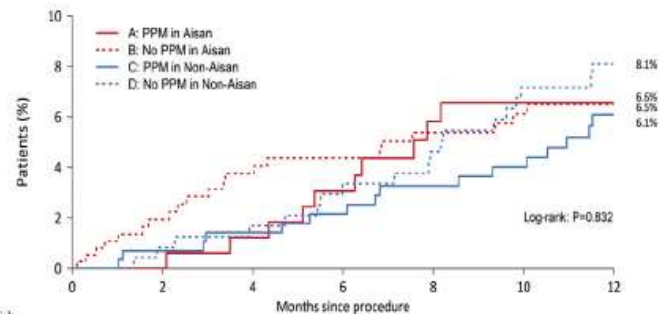
A Primary outcome
: A composite of death, stroke or rehospitalization



Number at risk

	0	2	4	6	8	10	12
A	189	146	139	134	104	102	100
B	373	291	276	269	224	211	189
C	294	246	230	220	215	201	159
D	245	198	190	184	175	167	147

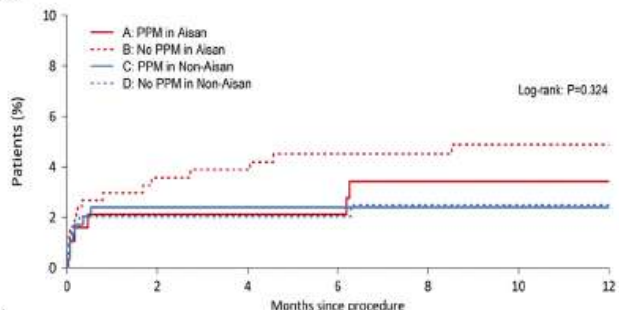
B Death



Number at risk

	0	2	4	6	8	10	12
A	189	189	163	159	128	127	127
B	373	330	319	316	269	256	255
C	294	285	273	268	262	255	210
D	245	238	235	231	226	219	199

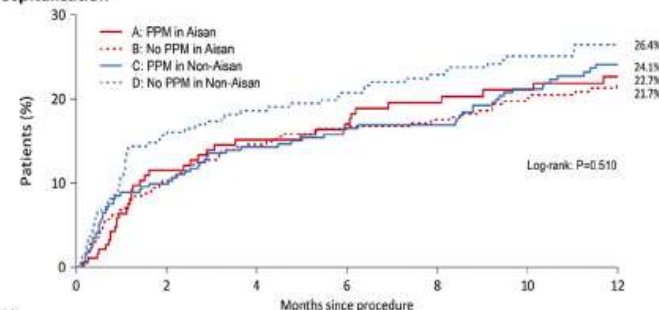
C Stroke



Number at risk

	0	2	4	6	8	10	12
A	189	185	185	185	149	149	149
B	373	318	312	305	305	252	252
C	294	288	288	288	288	288	288
D	245	241	241	241	225	225	225

D Rehospitalization



Number at risk

	0	2	4	6	8	10	12
A	189	149	141	136	118	103	96
B	373	296	279	271	225	212	189
C	294	251	235	224	221	204	162
D	245	201	193	197	189	171	162

Bioprosthetic AV Hemodynamic: Evidence Gaps

Bioprosthetic Aortic Valve Hemodynamics: Definitions, Outcomes, and Evidence Gaps

JACC State-of-the-Art Review

TABLE 2 Summary of Reasons for Discordance Between Echocardiographic and Invasive Hemodynamic Measurement of Bioprosthetic Valve Function

Echocardiographic

- Failure to align Doppler sector parallel to maximal velocity
- Simplified Bernoulli equation fails to account for
 - a. Laminar/average flow with lower velocity adjacent to vessel wall
 - b. Proximal LV velocity
 - c. Variability of contraction coefficient
 - d. Nonconvective forces of flow acceleration, viscosity, and convective acceleration
- Not corrected for pressure recovery

Invasive hemodynamic

- Inaccuracies introduced by
 - a. Fluid-filled catheters
 - b. Use of pigtail instead of end-hole catheters
 - c. Improper positioning within LV and aorta
- Timing of measurements immediately post-TAVR

TABLE 4 Summary of Reasons for Discrepancy in Effects of Severe PPM on Outcomes

Reasons why the reported incidence of PPM varies after AVR

- Method of EOA calculation (measured vs predicted)
- Correction or not for obesity
- Timing of measurement (immediate vs later)
- Effect of underlying flow state
- Method of gradient determination (echocardiographic vs hemodynamic)

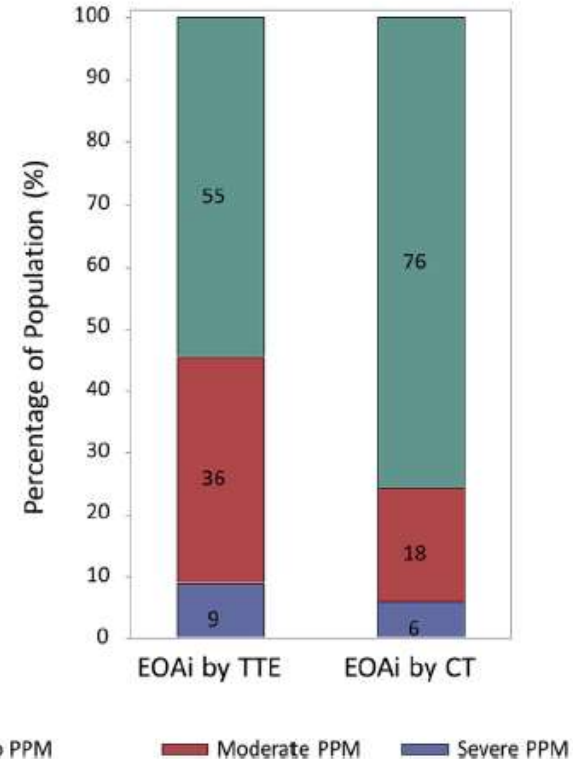
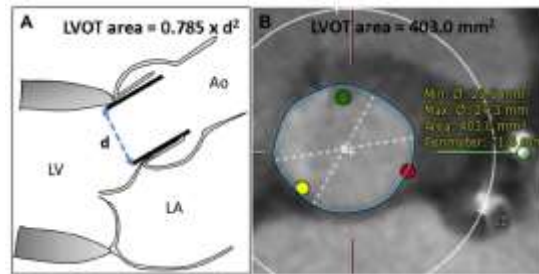
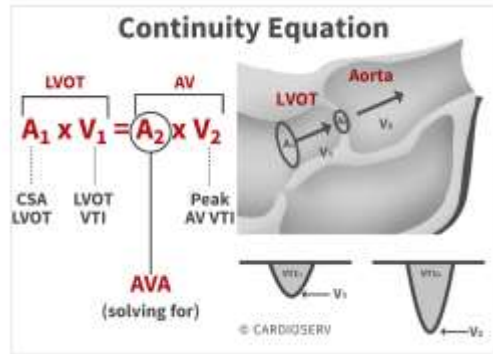
Reasons why the effects of severe PPM on outcomes are conflicting

- Measurements and calculations differ as above
- Incomplete correction for confounding and competing outcome variables
 - Paravalvular aortic regurgitation
 - Low flow state
 - Older patients or other survival limitations
- Underpowered analyses
- Limited follow-up (1 year may not be sufficient)

CT-Defined Prosthesis–Patient Mismatch Downgrades Frequency and Severity of PPM

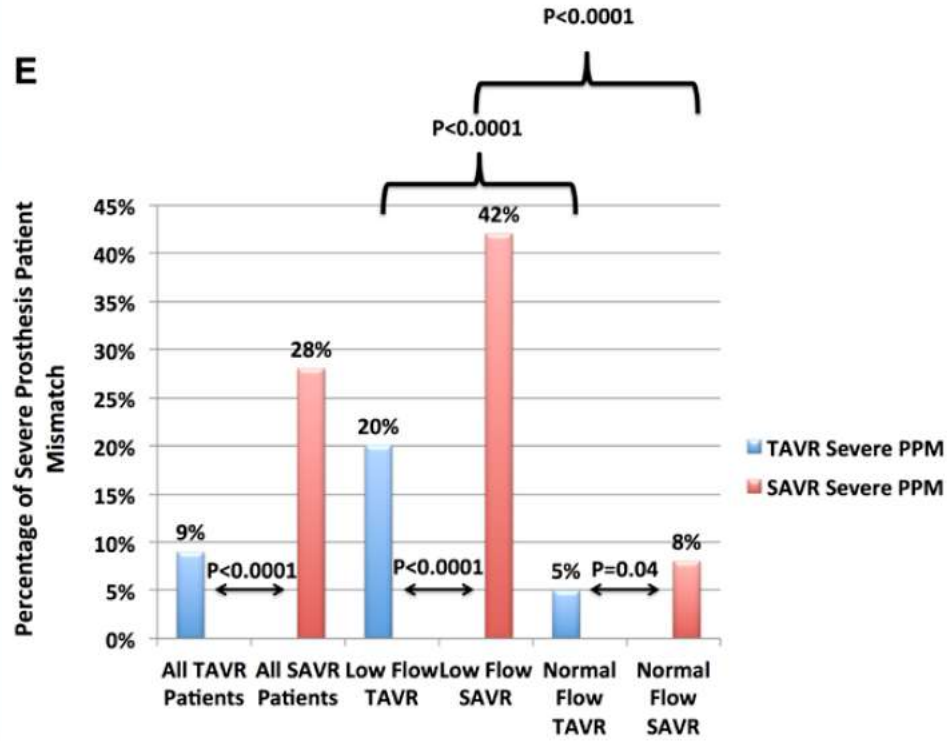
Continuity equation errors by 2D echo

$$AVA = \frac{\pi(\text{radius LVOT})^2 \times (V_{\text{maxLVOT}})}{(V_{\text{maxAV}})}$$



Mooney J, JACC Intv 2017;10:1578

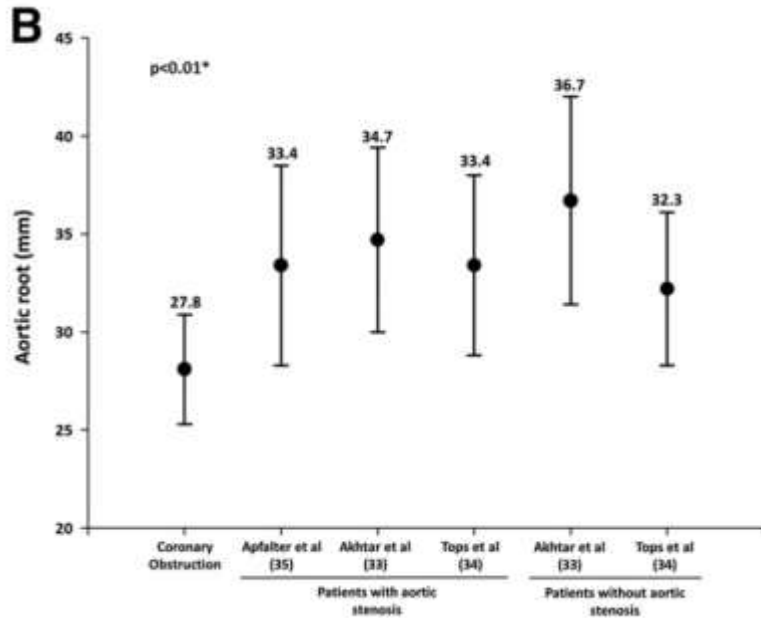
Impact of Flow on PPM Following TAVR and SAVR



Abbas AE, *Circ Cardiovasc Imaging* 2021;14:e012364

Rare Complications Related to Small Annulus

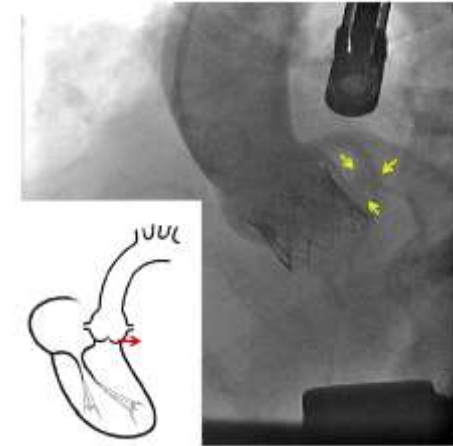
Coronary Obstruction



Ribeiro HB,
JACC Cardiovasc Interv. 2013;6:452

Annular Rupture

- Oversized ballooning
- Especially when calcified



Pasic M,
JACC Cardiovasc Interv. 2015;8:1

Take Home Messages

- Small aortic annulus is prone to develop PPM after TAVR or SAVR.
- Diagnosis of PPM based on TTE is often inaccurate.
- Self-expanding valves especially with supra-annular design show superior hemodynamics than balloon-expanding valves .
- However, the impact of PPM on clinical outcomes after TAVR appears to be inconsistent.
- If severe PPM is expected after TAVR, self-expanding valves need to be preferred in cases of young and physically active patients and patients with low LVEF, severe LVH, or significant MR.
- Otherwise, selection of valves for small annuli doesn't need to be different than for large annuli.