

TAVR Durability: Is the Current Data Enough?

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 @Equipemangione

TAVR – Balloon Expandable *Technological Development*



Sapien



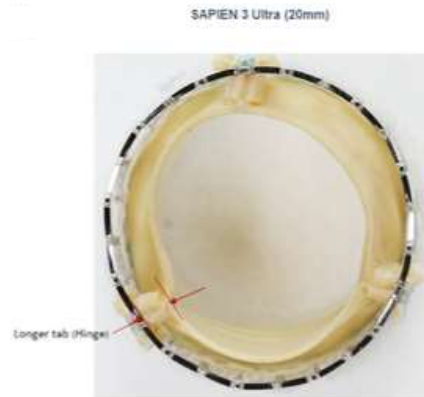
Sapien XT



Sapien 3



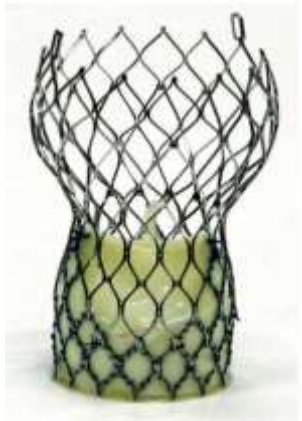
Sapien 3 Ultra



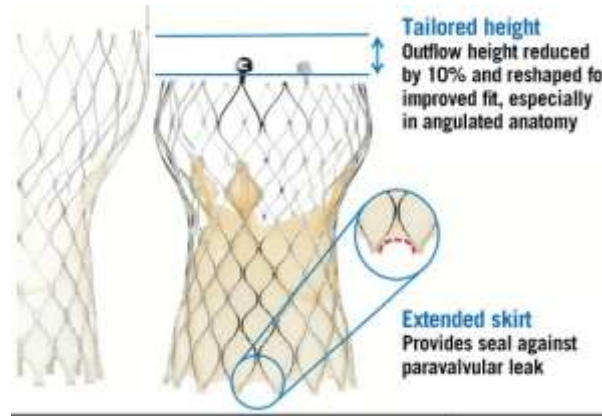
RESILIA tissue technology
 permanently caps the
 calcium-attracting free
 aldehydes to prevent future
 calcification

5^a Generation - Sapien 3 Ultra Resilia

TAVR – Self-Expandable *Technological Development*



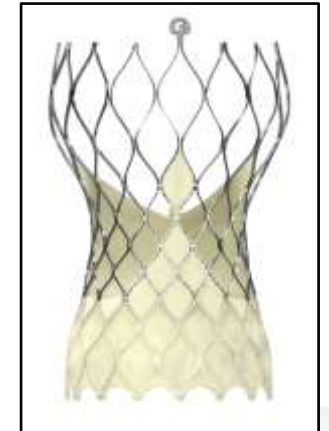
CoreValve



Evolut R



Evolut Pro



Evolut Pro+

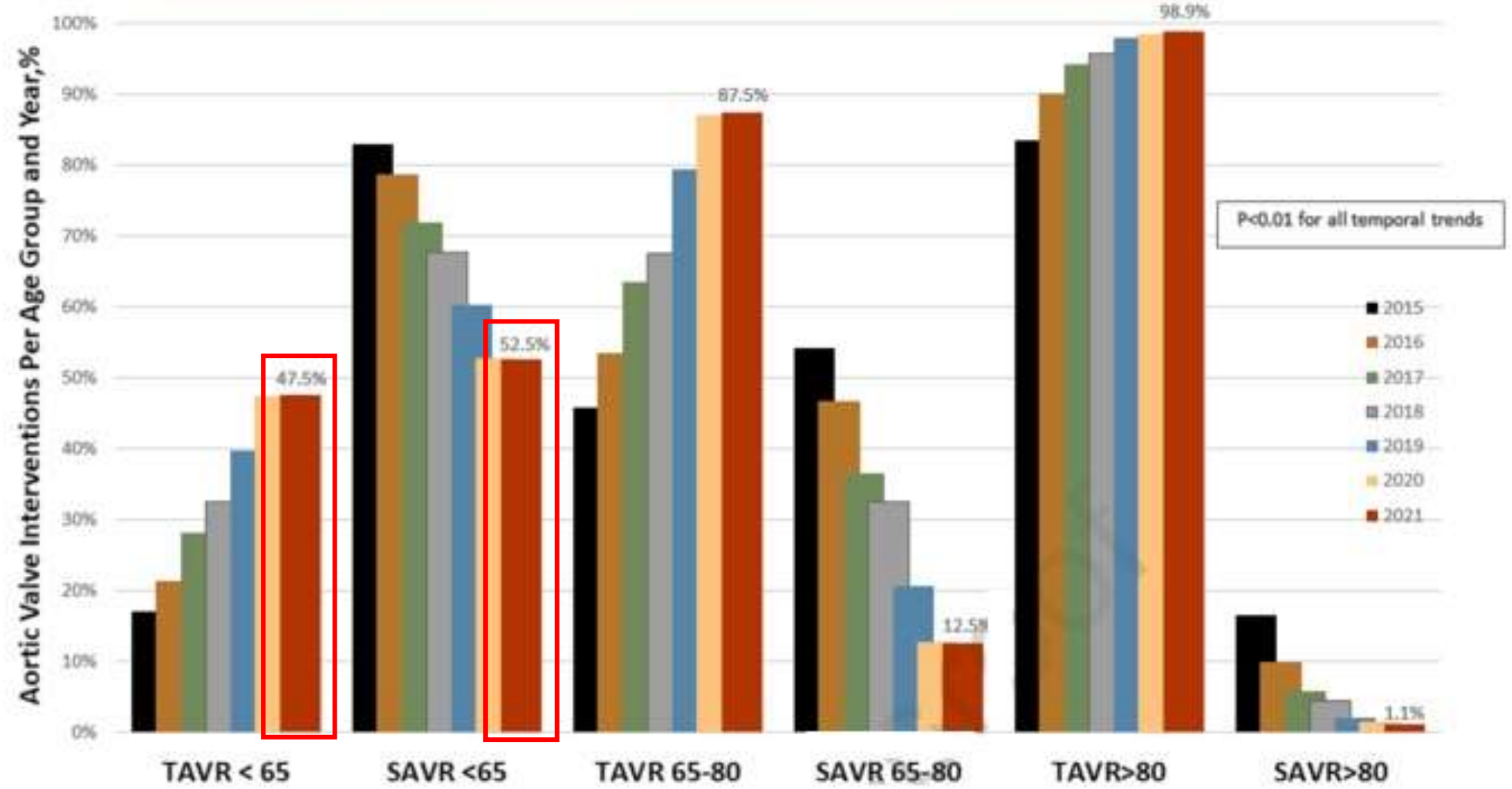


Evolut Fx



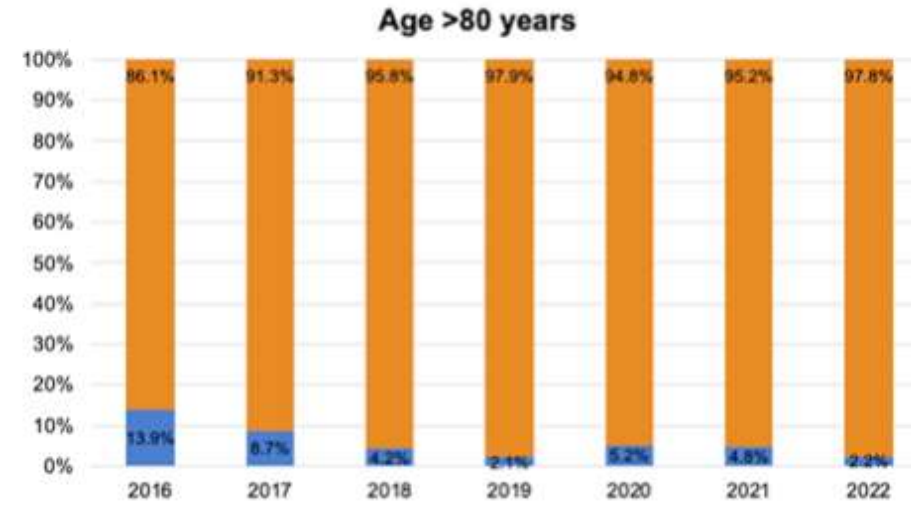
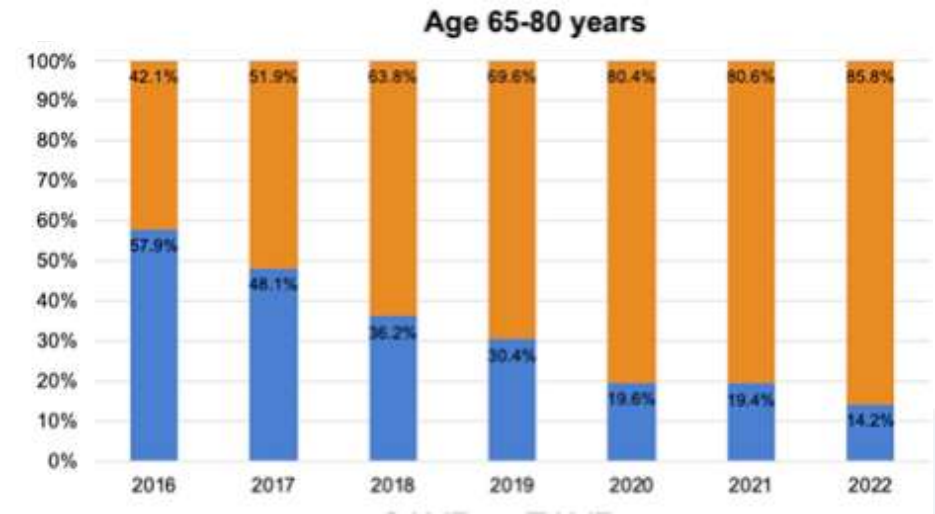
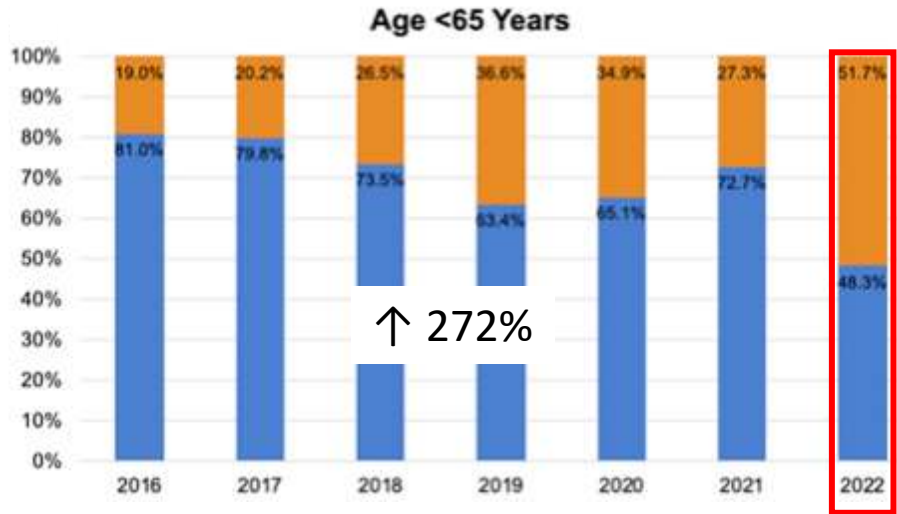
6ª Generation Evolut Fx+

Trends in TAVR vs SAVR Stratified by Guideline Recommended Age Groups



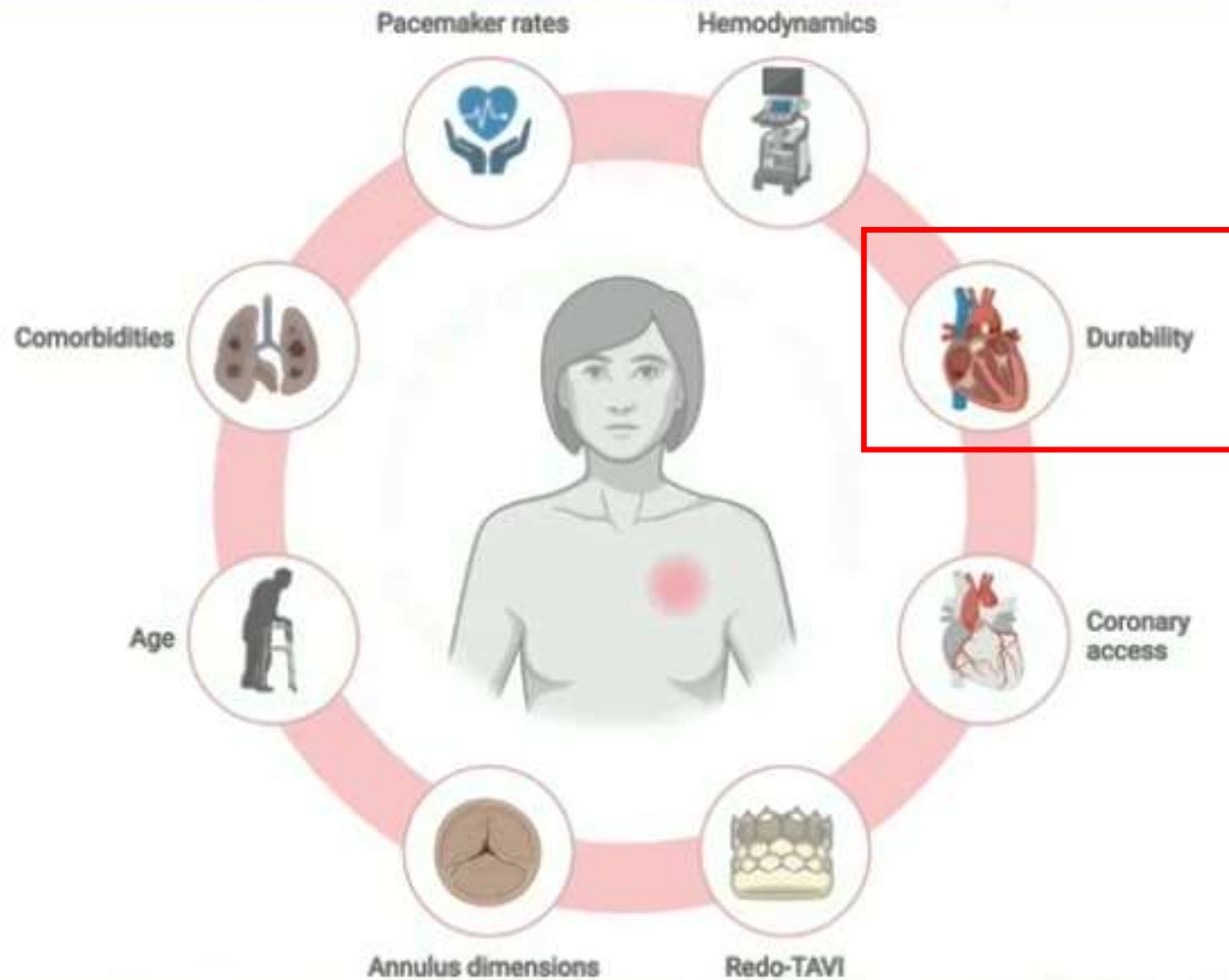
Temporal Trends in Transcatheter Aortic Valve Replacement for Isolated Severe Aortic Stenosis

N = 6.728 Northern New England Cardiovascular Disease Group Consortium (Maine, New Hampshire and Vermont)



■ SAVR ■ TAVR

Lifetime Management



VARC 3 CRITERIA

Structural Valve Deterioration

Intrinsic permanent changes to the prosthetic valve, including wear and tear, leaflet disruption, flail leaflet, leaflet fibrosis and/or calcification, strut fracture

Are there hemodynamic changes?

NO

YES

Parameters:

1. Aortic Valve Morphology
2. Mean gradients
3. Effective Orifice Area
4. Doppler Velocity Index

Stage 1

Morphological Valve Deterioration:

Intrinsic permanent changes to the prosthetic valve, including leaflet tear, disruption, flail leaflet, leaflet fibrosis and/or calcification, strut fracture without significant hemodynamic changes.

Stage 2

Moderate hemodynamic valve deterioration (HVD):

Increase in mean transvalvular gradient ≥ 10 mmHg resulting in mean gradient ≥ 20 mmHg† with concomitant decrease in EOA ≥ 0.3 cm² or $\geq 25\%$ and/or decrease in Doppler velocity index ≥ 0.1 or $\geq 20\%$ compared to echocardiographic assessment performed 1 to 3 months post-procedure,
OR
New occurrence or increase of ≥ 1 grade of intraprosthetic AR resulting in \geq moderate AR.

Stage 3

Severe HVD:

Increase in mean transvalvular gradient ≥ 20 mmHg resulting in mean gradient ≥ 30 mmHg† with concomitant decrease in EOA ≥ 0.6 cm² or $\geq 50\%$ and/or decrease in Doppler velocity index ≥ 0.2 or $\geq 40\%$ compared to echocardiographic assessment performed 1 to 3 months post-procedure,
OR
New occurrence, or increase of ≥ 2 grades, of intraprosthetic AR resulting in \geq severe AR.

Follow-up:

1. Change in parameters
2. Absolute measurements

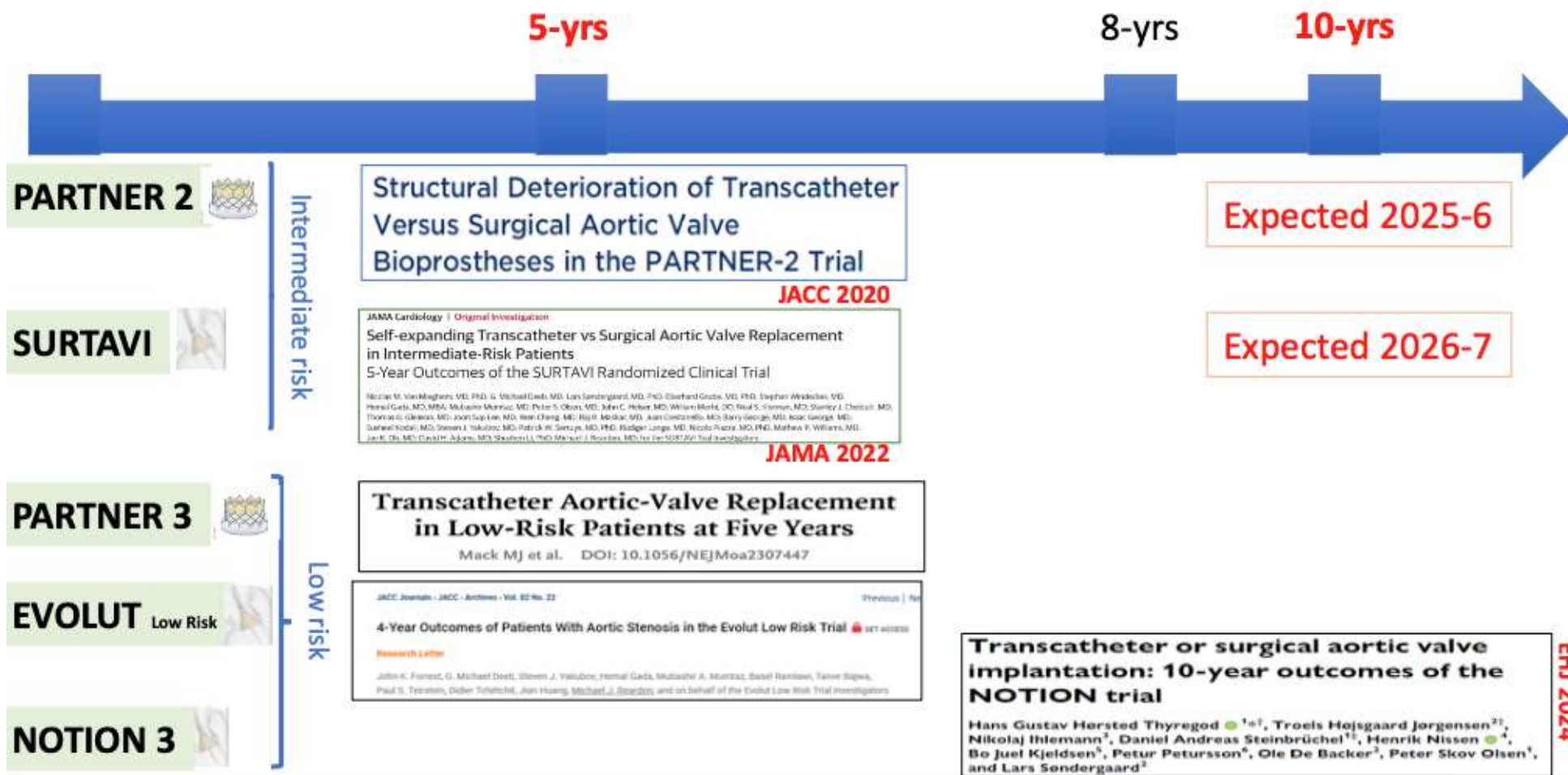
Bioprosthetic Valve Failure (BVF)

Stage 1: Any bioprosthetic valve dysfunction with clinically expressive criteria (new-onset or worsening symptoms, LV dilation/hypertrophy/dysfunction, or pulmonary hypertension) or irreversible Stage 3 HVD

Stage 2: Aortic valve reintervention

Stage 3: Valve-related death

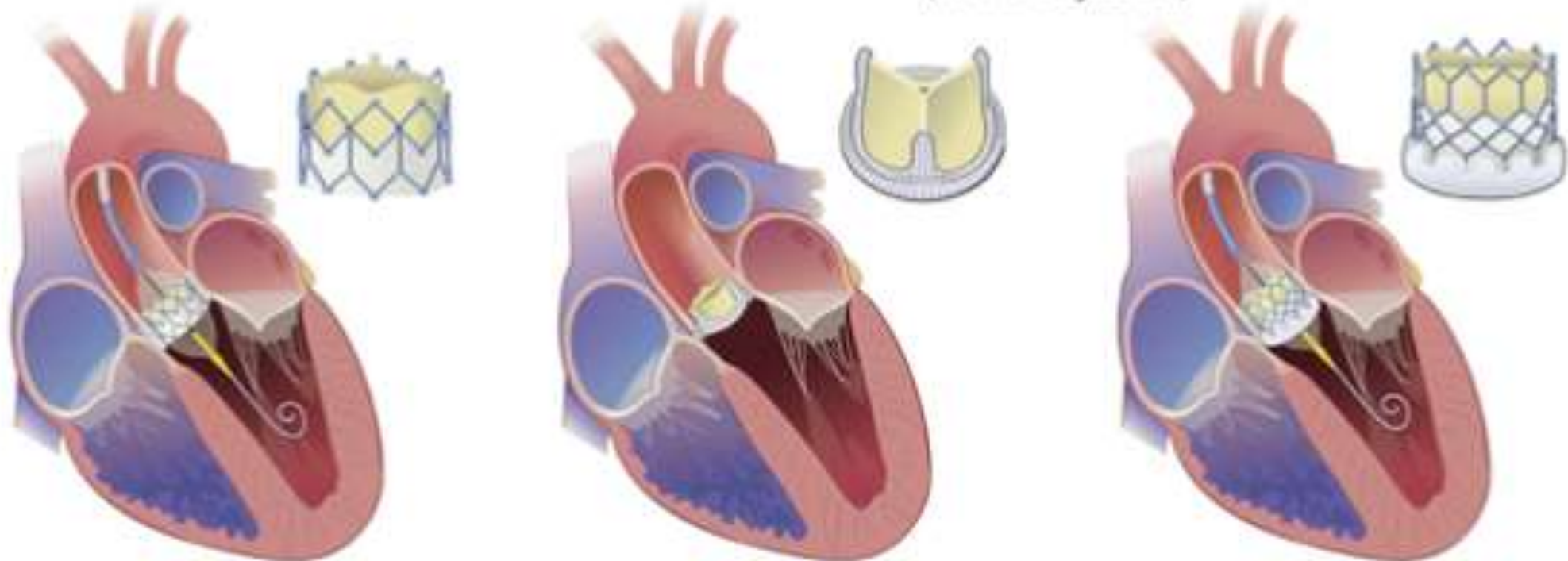
Current data from randomised trials TAVI vs. Surgery



PARTNER 2 INTERMEDIATE RISK TRIAL AND REGISRY

Partner 2 Trial N = 1.438

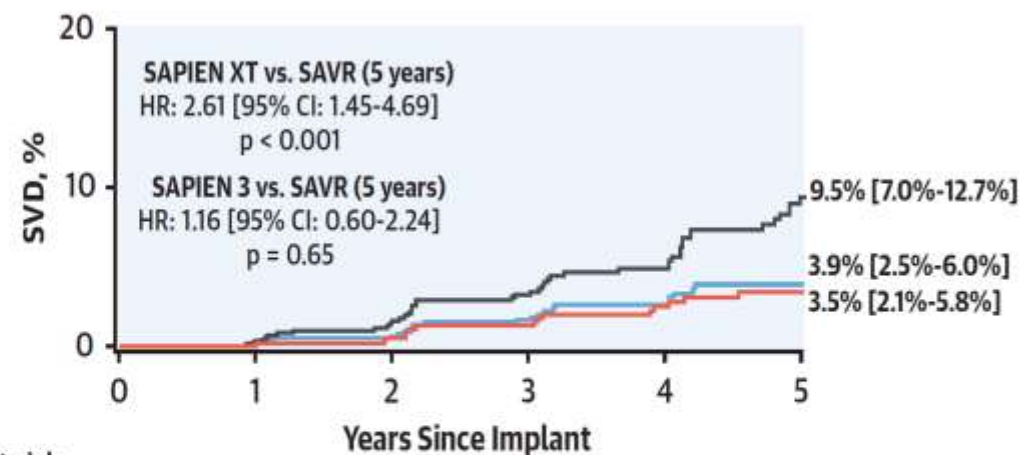
Partner 2 Sapien 3 Registry N = 891



PARTNER 2 TRIAL AND REGISTRY

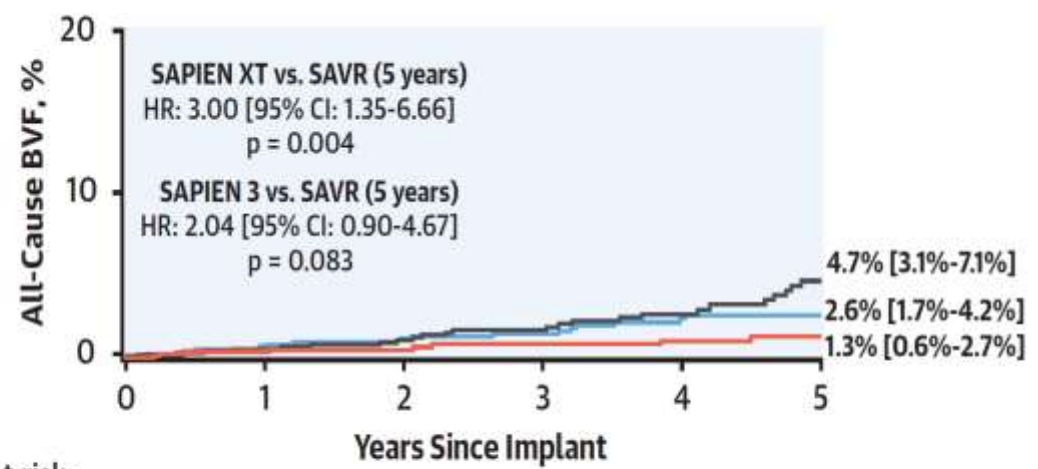
VARC 3 Definition

- SVD (Structural Valve Deterioration) ≥ Stage 2
 - BVF (Bioprosthetic Valve Failure)



No. at risk:

SAVR	664	625	538	449	346	265
SAPIEN XT	774	733	622	505	368	297
SAPIEN 3	891	827	705	581	412	283

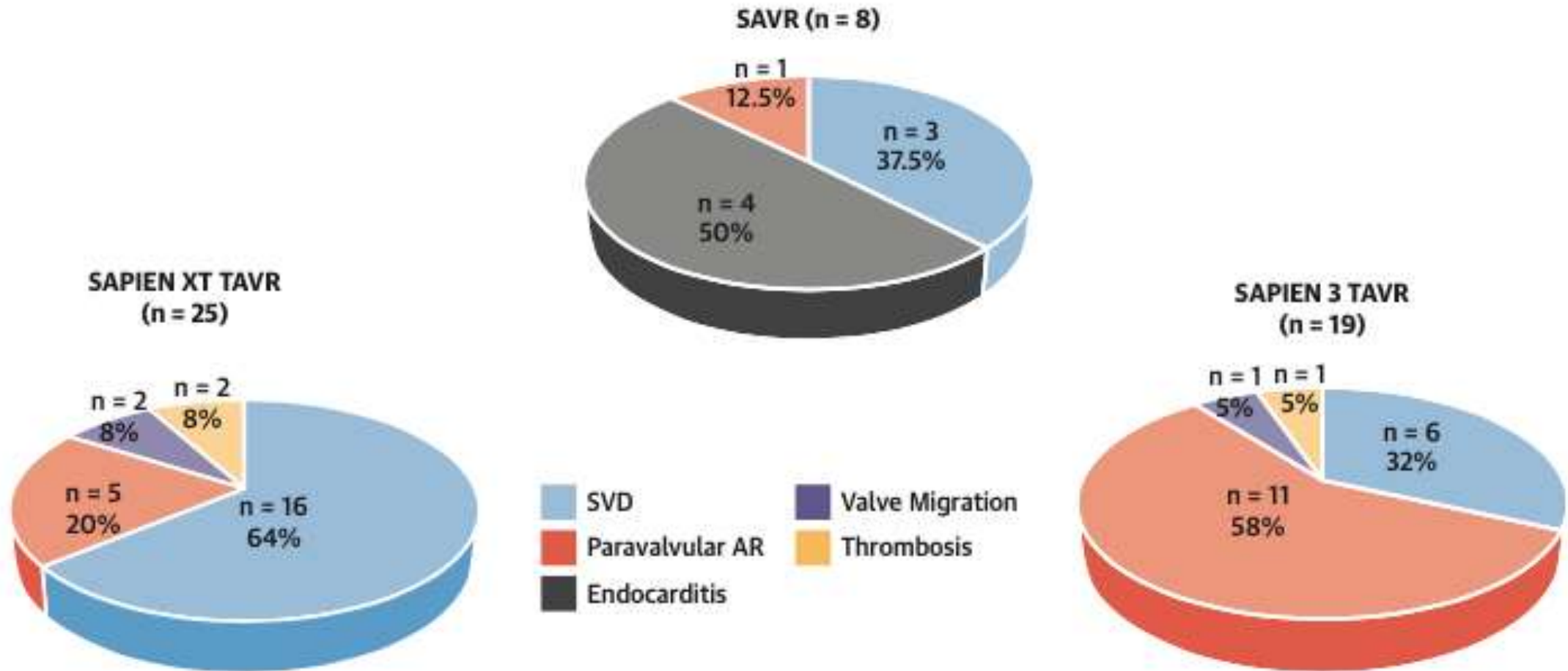


No. at risk:

SAVR	936	762	643	536	423	321
SAPIEN XT	974	813	689	556	406	326
SAPIEN 3	1,069	909	764	628	451	312

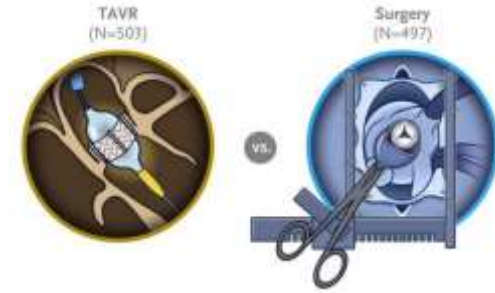
PARTNER 2 TRIAL AND REGISTRY

Causes of BVF



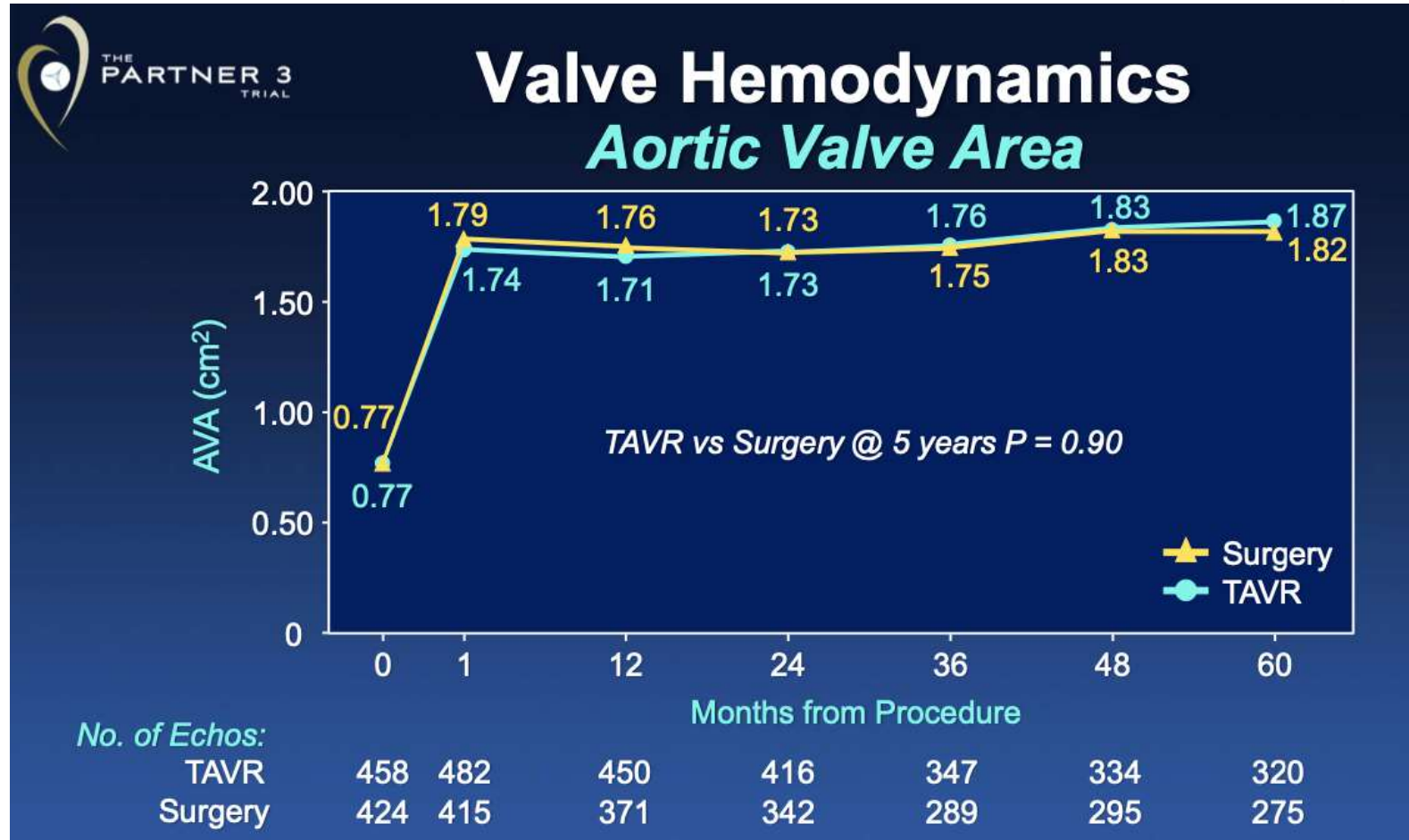
PARTNER 3

Low Risk Trial



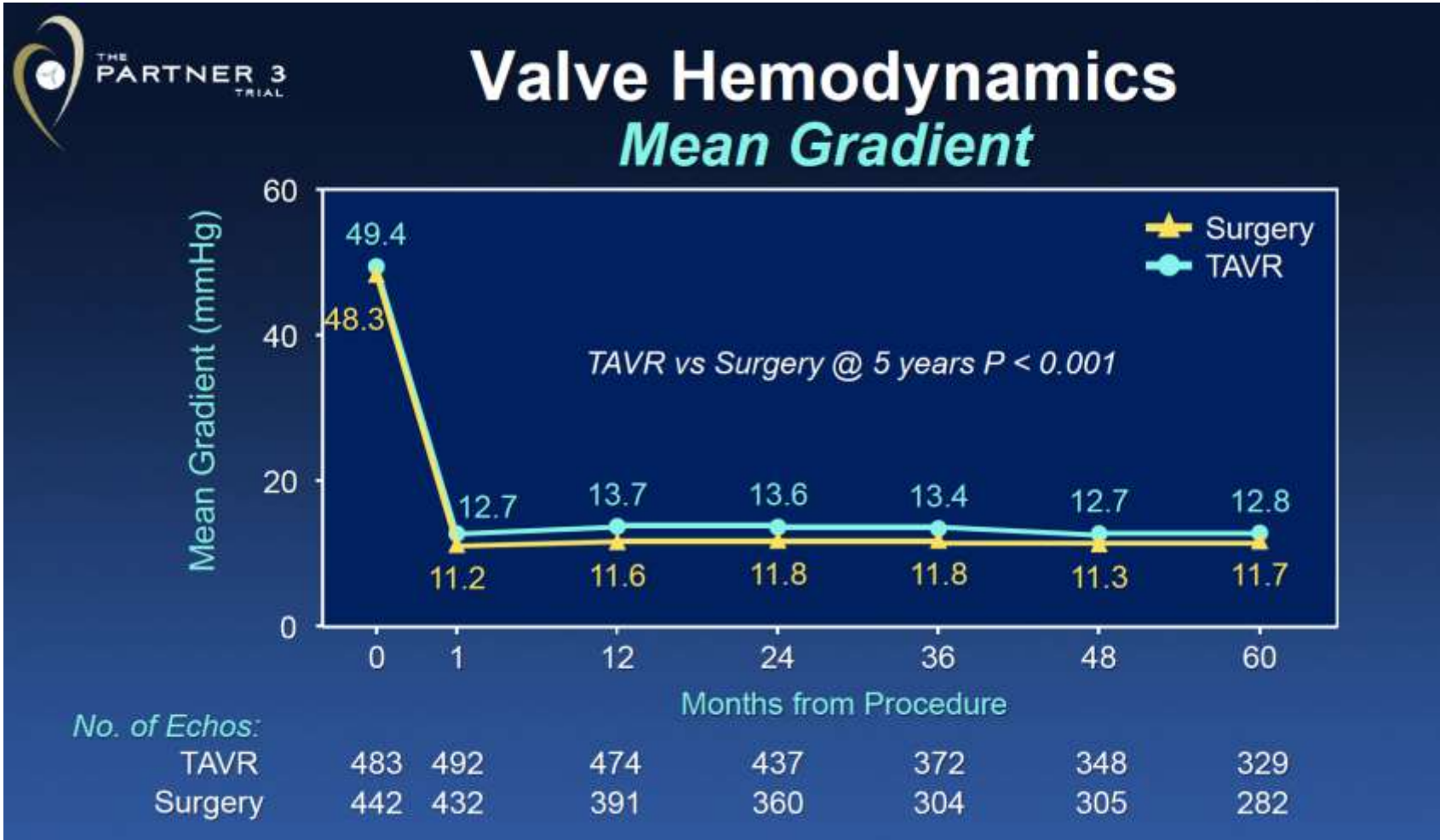
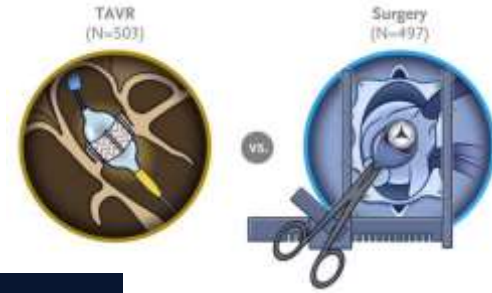
Sapien 3

N = 1.000
71 Centers

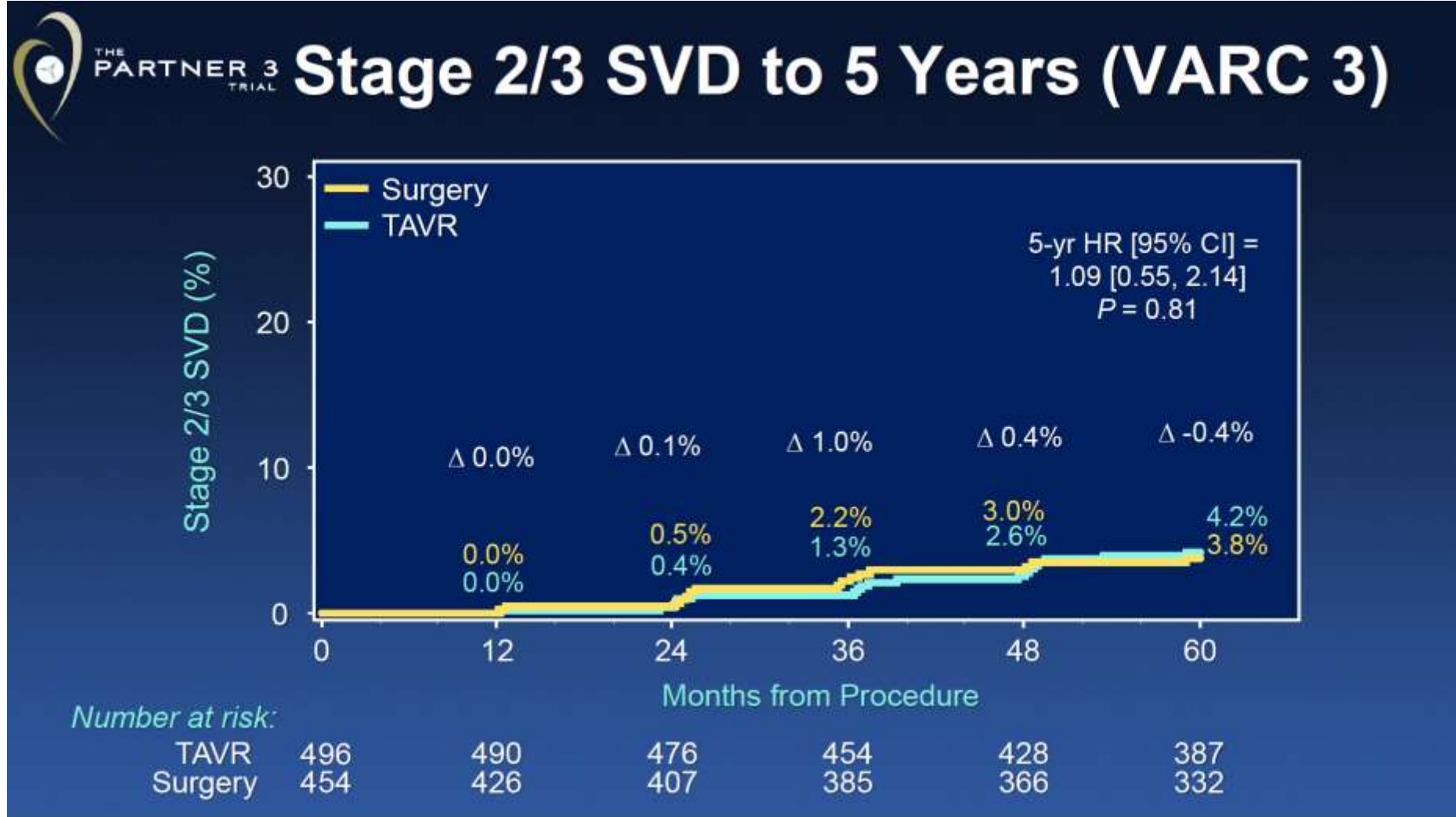


PARTNER 3

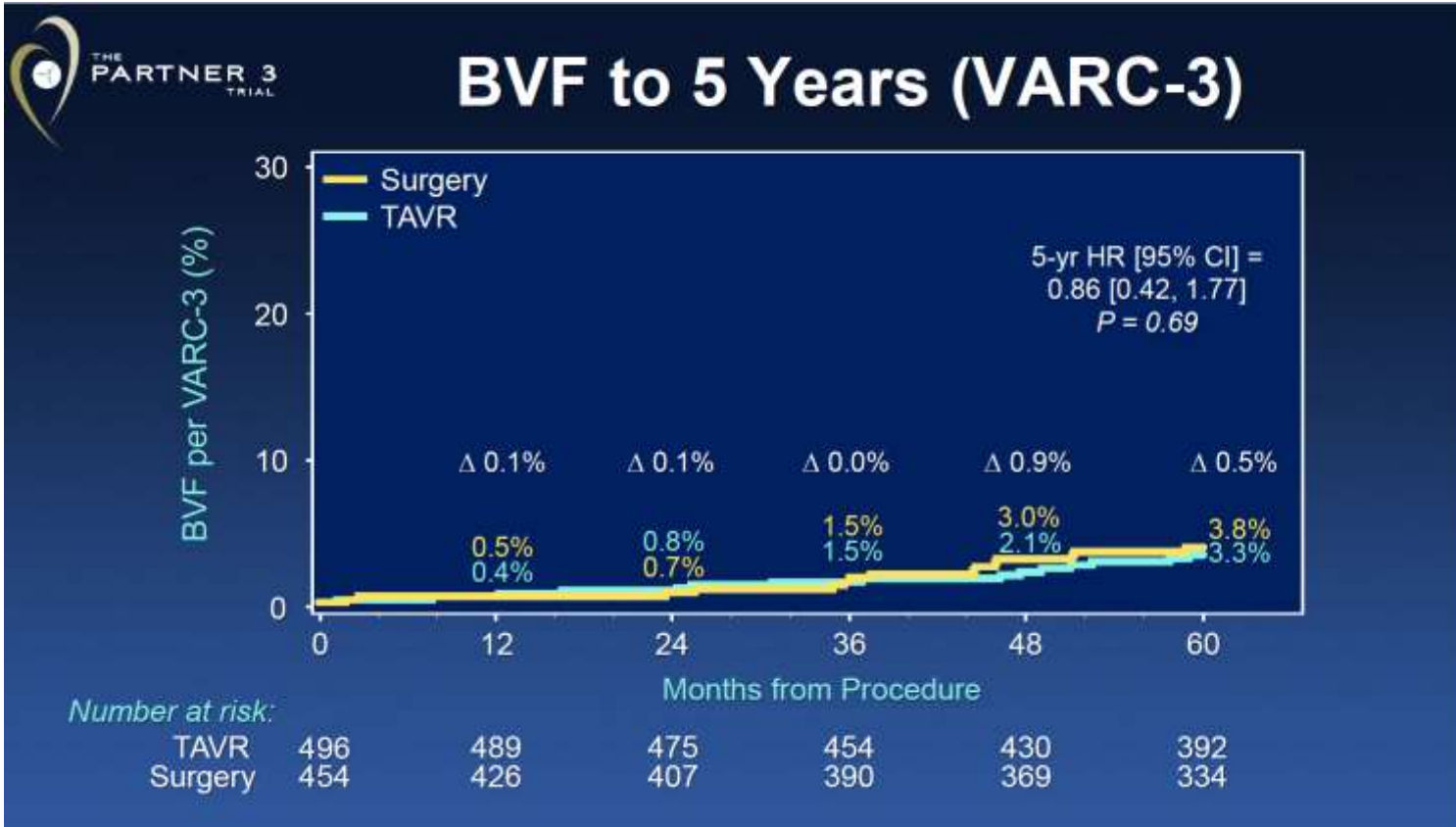
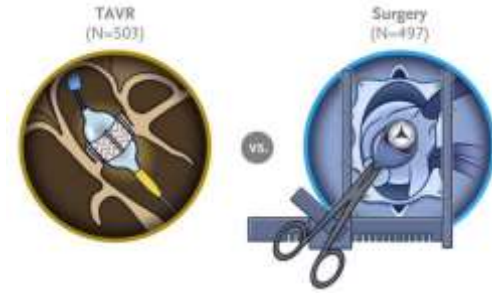
Low Risk Trial



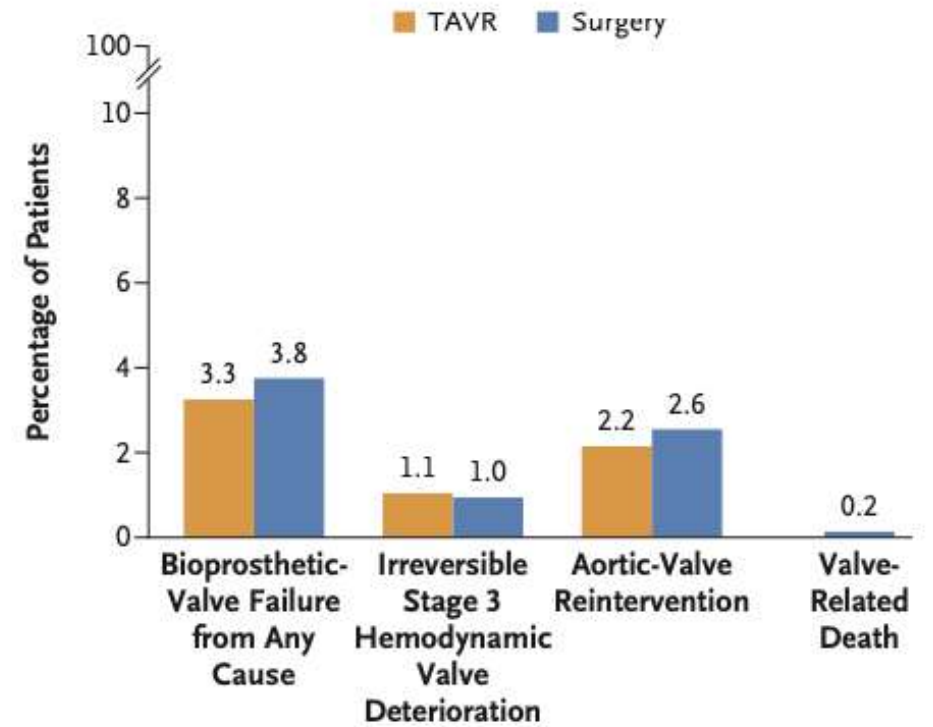
PARTNER 3 *Low Risk Trial*



PARTNER 3 Low Risk Trial

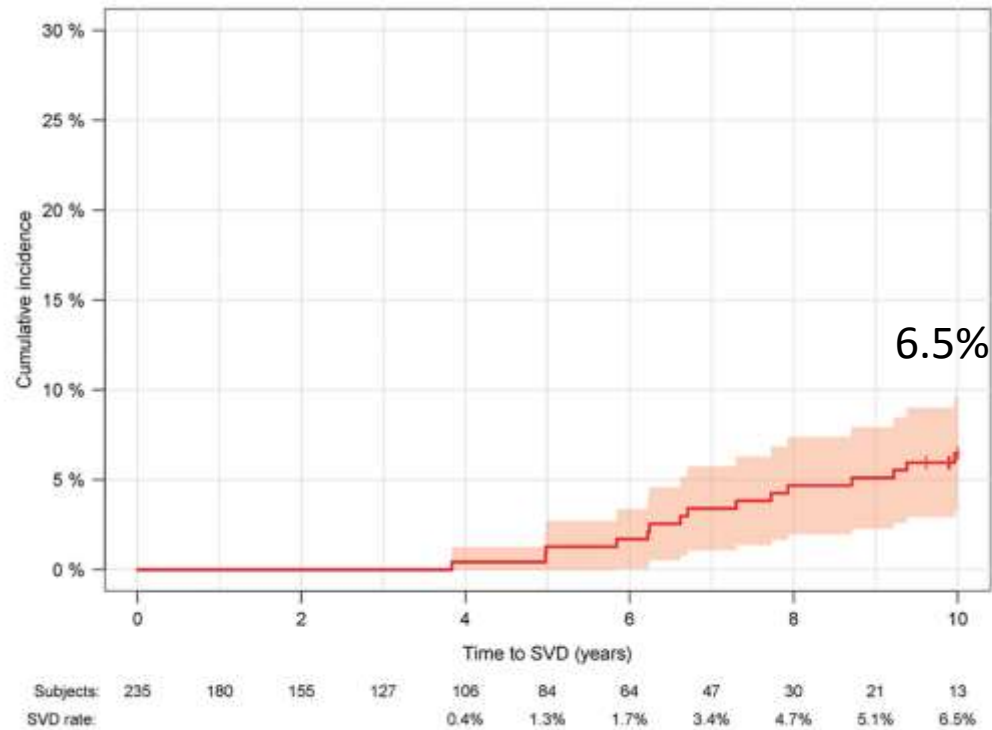


Bioprosthetic-Valve Failure and Components at 5 Yr



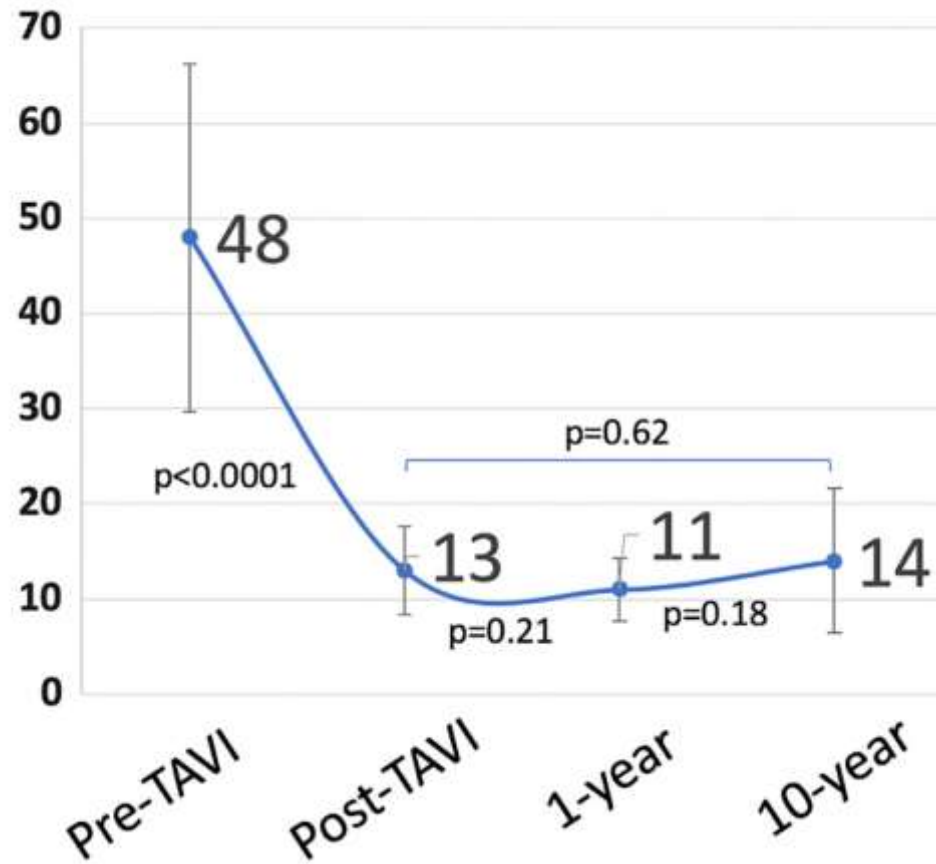
Ten year follow-up of high-risk patients treated during the early experience with transcatheter aortic valve replacement

N = 235 St Paul's Hospital Vancouver - Canada Mean age – 82.3± 7.9 yo 10 years follow-up
 Cribier-Edwards – 20.9% Edwards Sapien – 77.4% CoreValve – 1.7%

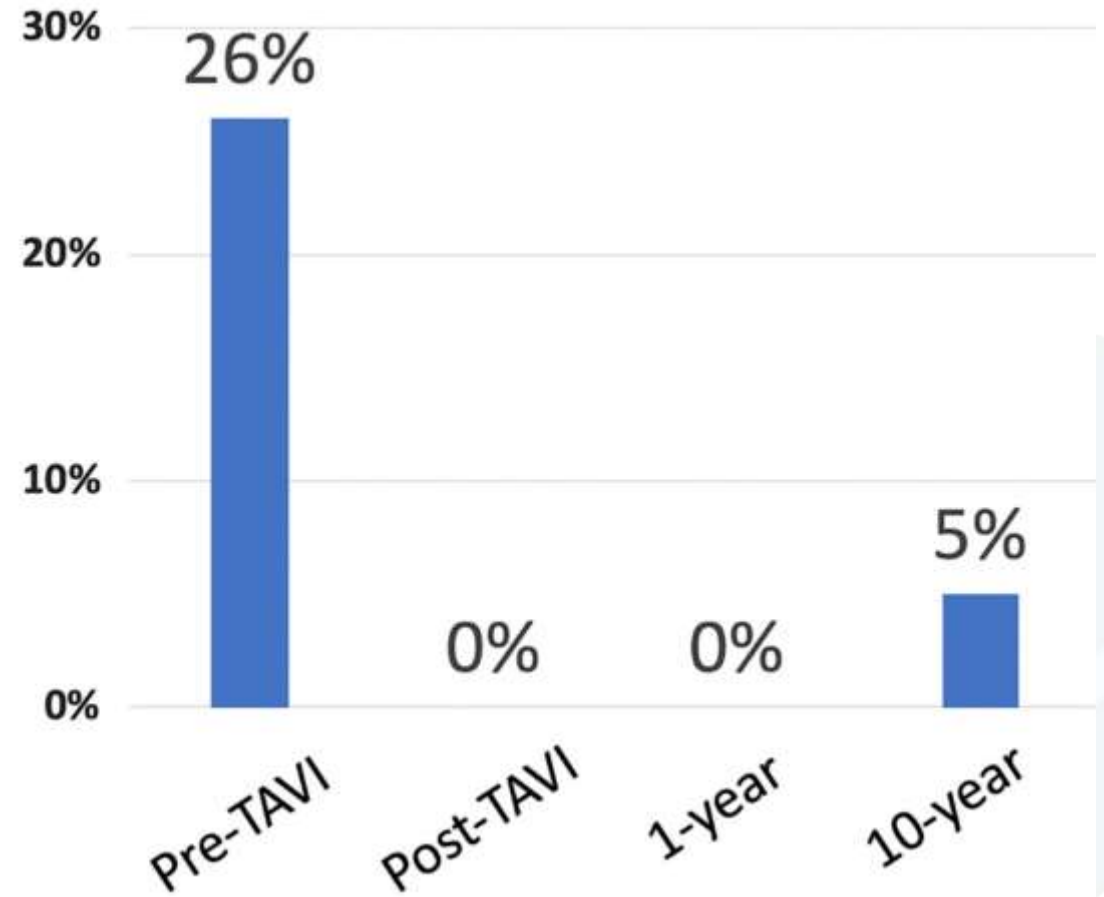


EAPCI Definition - SVD/BVF

Ten year follow-up of high-risk patients treated during the early experience with transcatheter aortic valve replacement



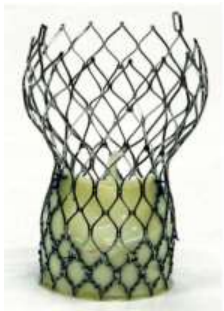
Mean Gradient (mmHg)



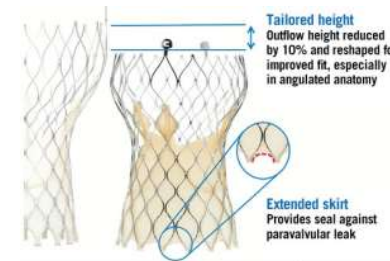
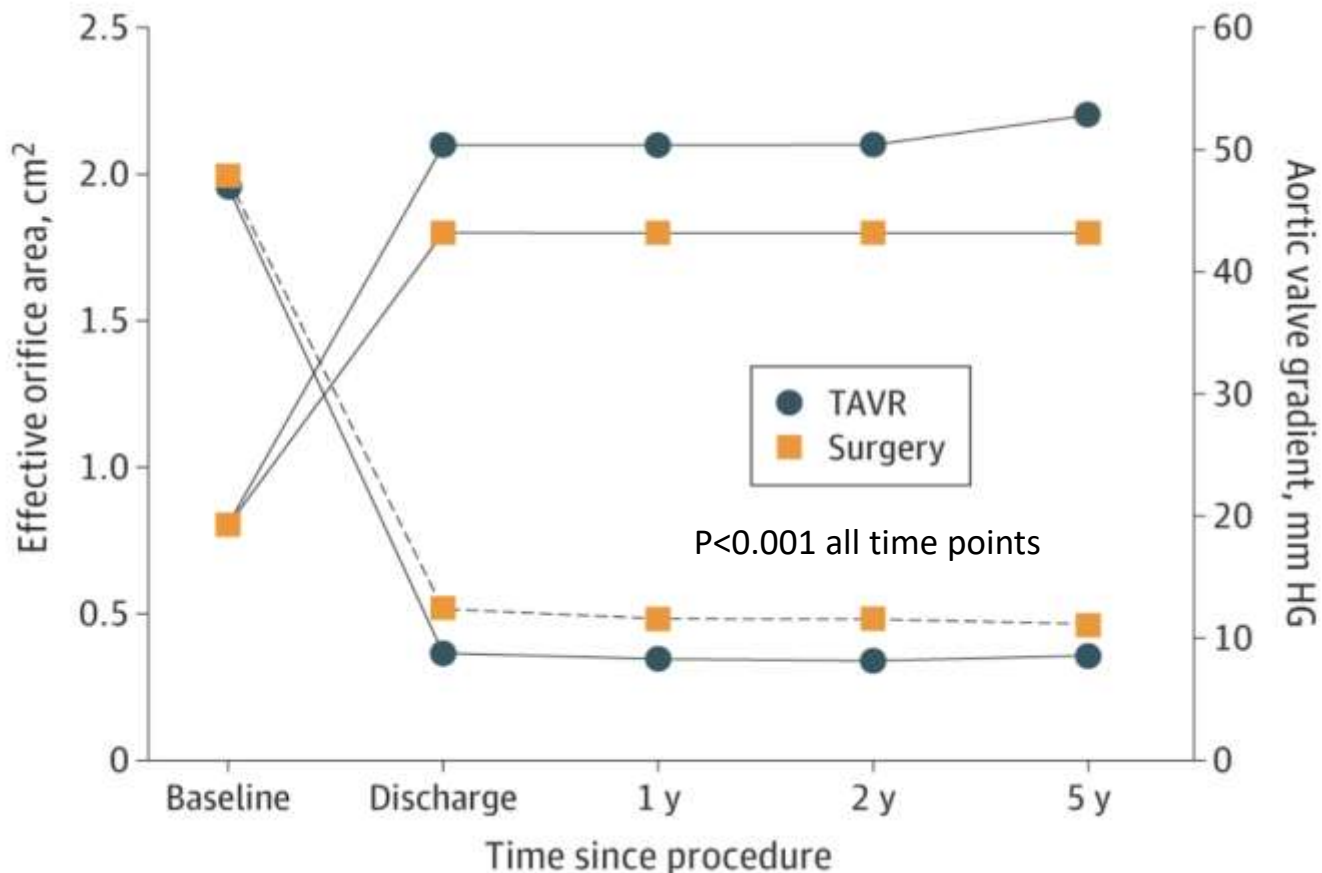
≥ moderate intra-prosthetic regurgitation

Self-expanding Transcatheter vs Surgical Aortic Valve Replacement in Intermediate-Risk Patients

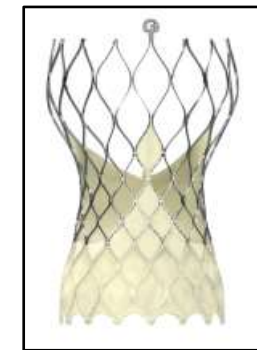
5-Year Outcomes of the SURTAVI Randomized Clinical Trial



N = 1.660
87 Centers
CoreValve (84%)
Evolut R (16%)

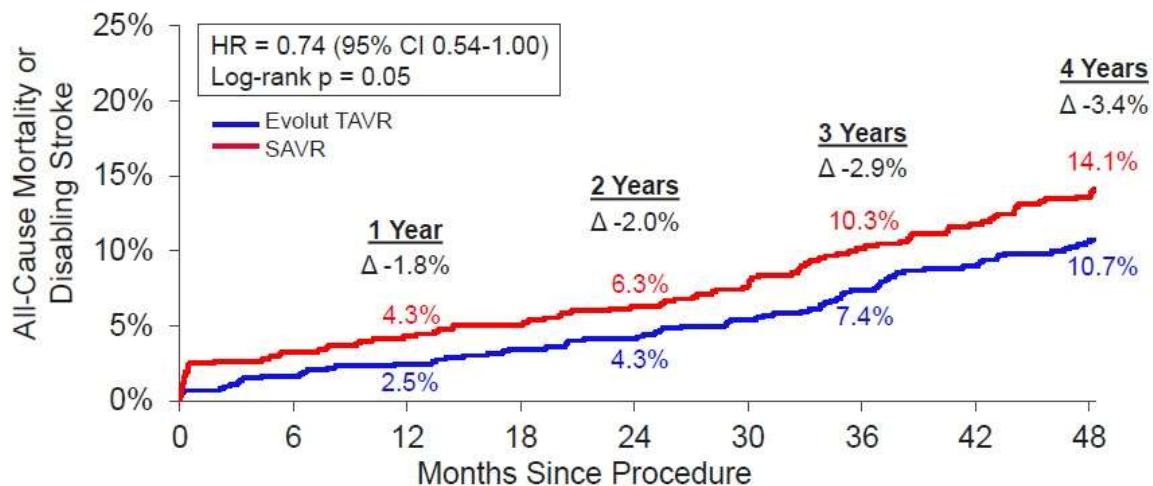


Evolut Low Risk 4 Years results

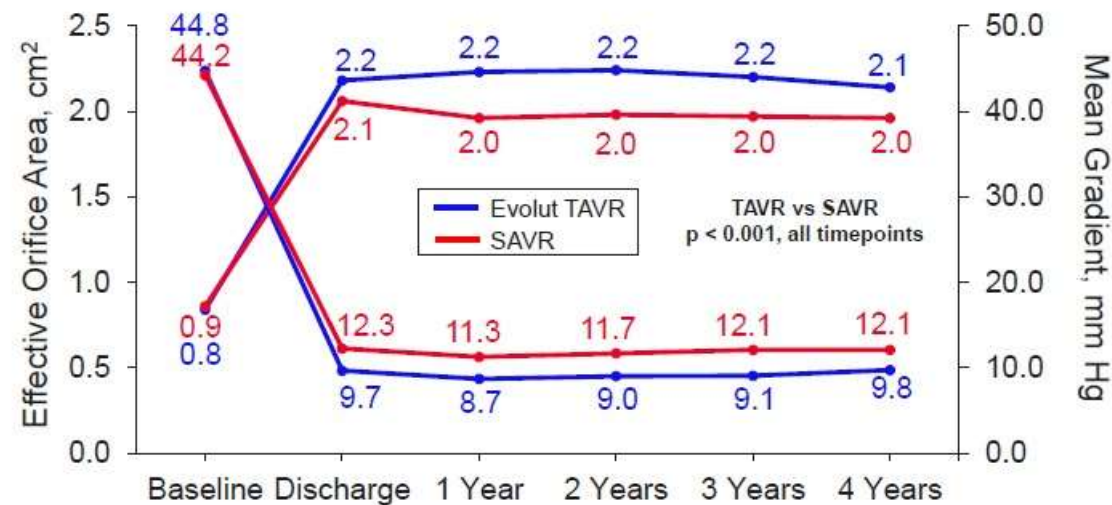


n = 1.468 Mean age – 74 yo STS – 1.9% ± 0.7
 CoreValve – 3.6% Evolut R – 74.1% Evolut Pro – 2.3%

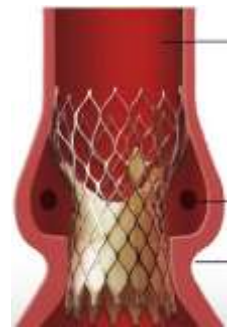
26% Relative Reduction in Hazard for Death or Disabling Stroke (p = 0.05) with Evolut TAVR vs SAVR and the Curves Continue to Separate Over Time



Significantly Better Hemodynamics with Evolut TAVR vs SAVR

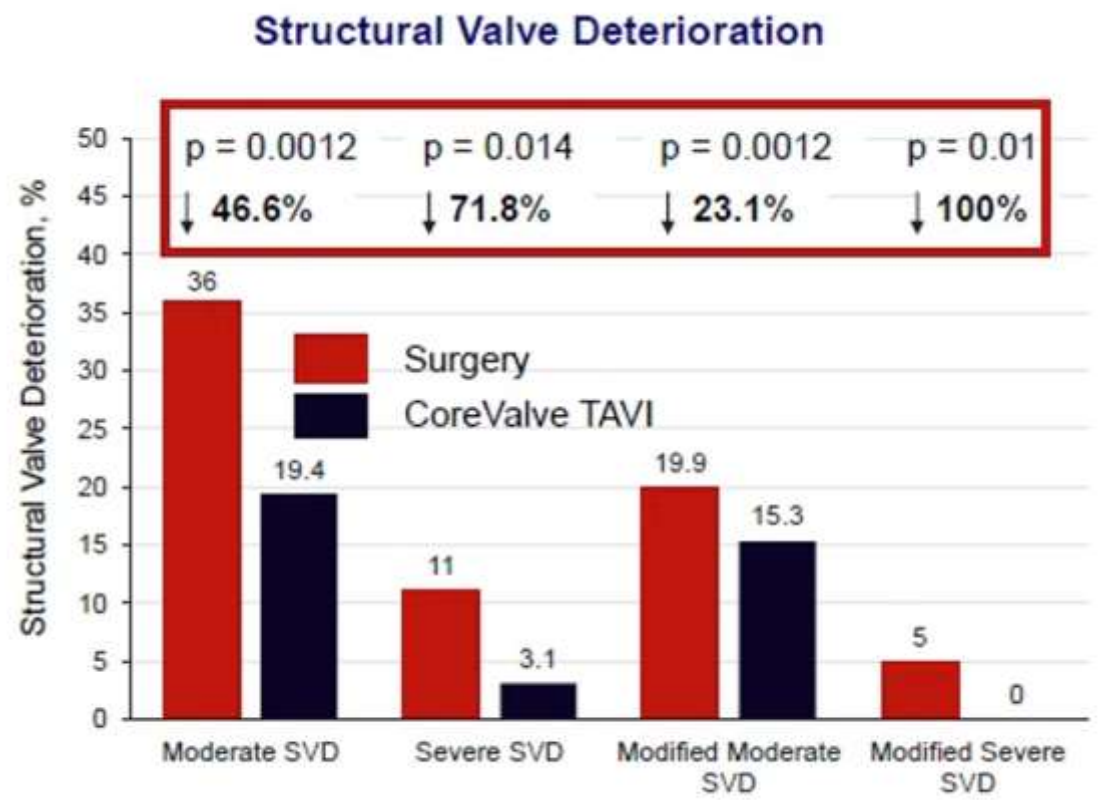
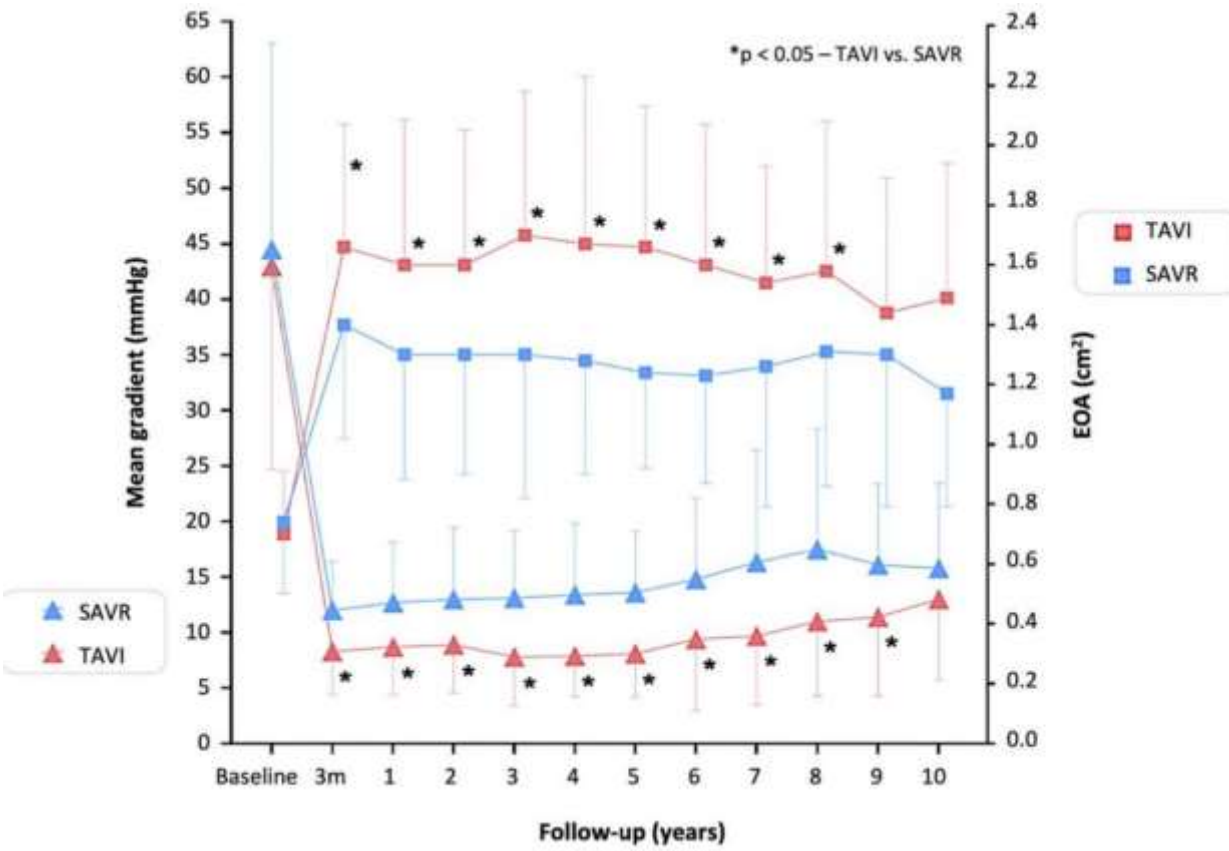


NOTION TRIAL - 10 years



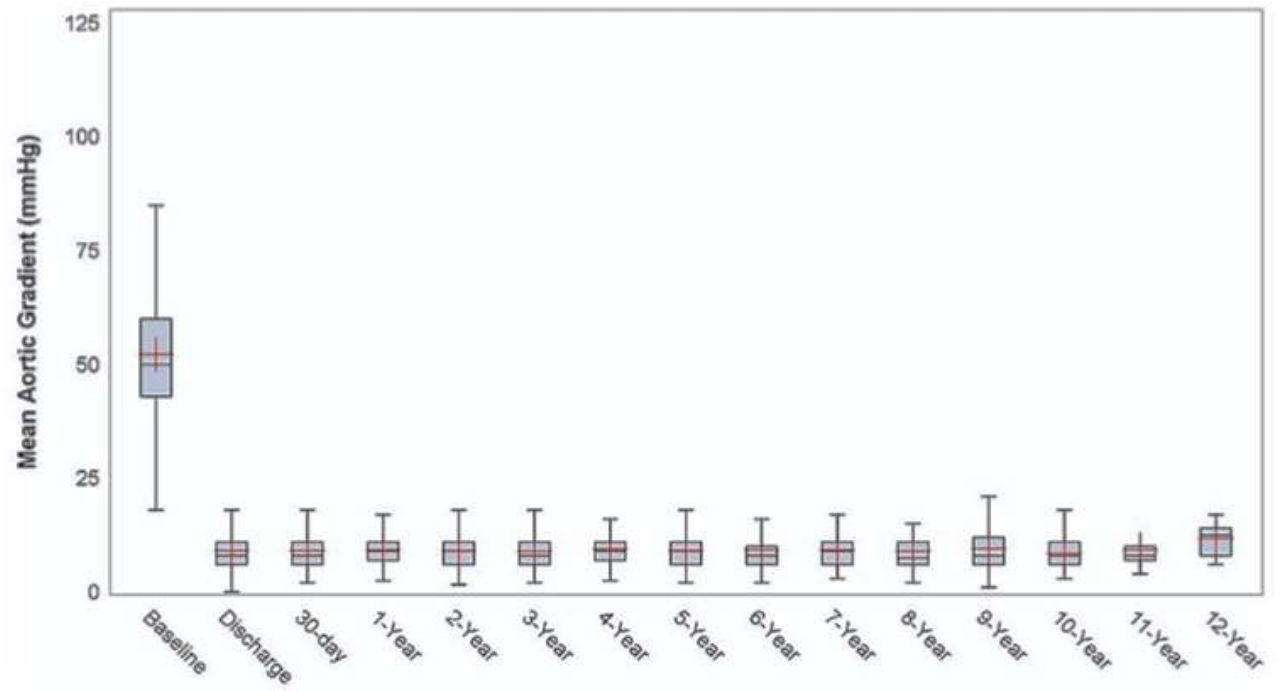
Randomized Trial 3 centers (Dinamarca e Suécia) n = 280

Self-Expandable Corevalve Mean age- 79 yo STS score – 3.0%

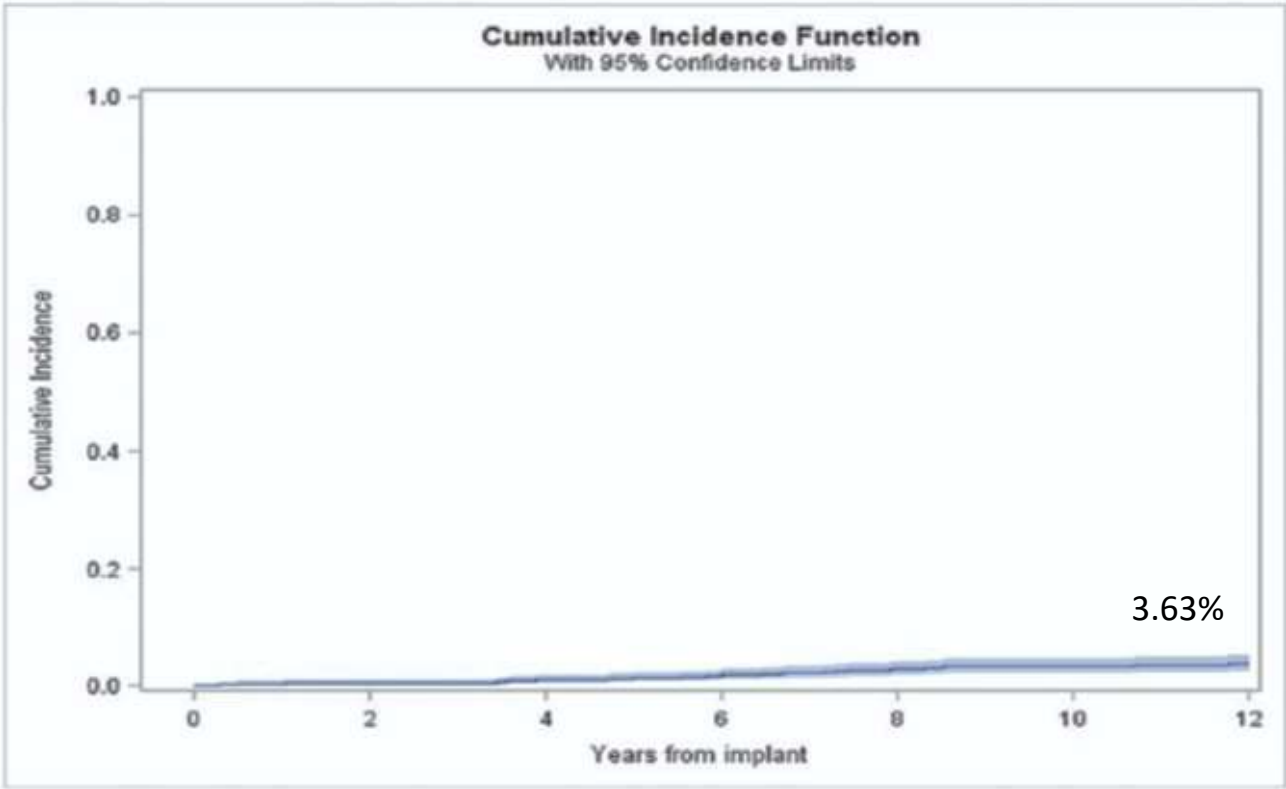


Transcatheter aortic valve replacement with corevalve self-expanding bioprosthesis: Clinical and durability data up to 12 years

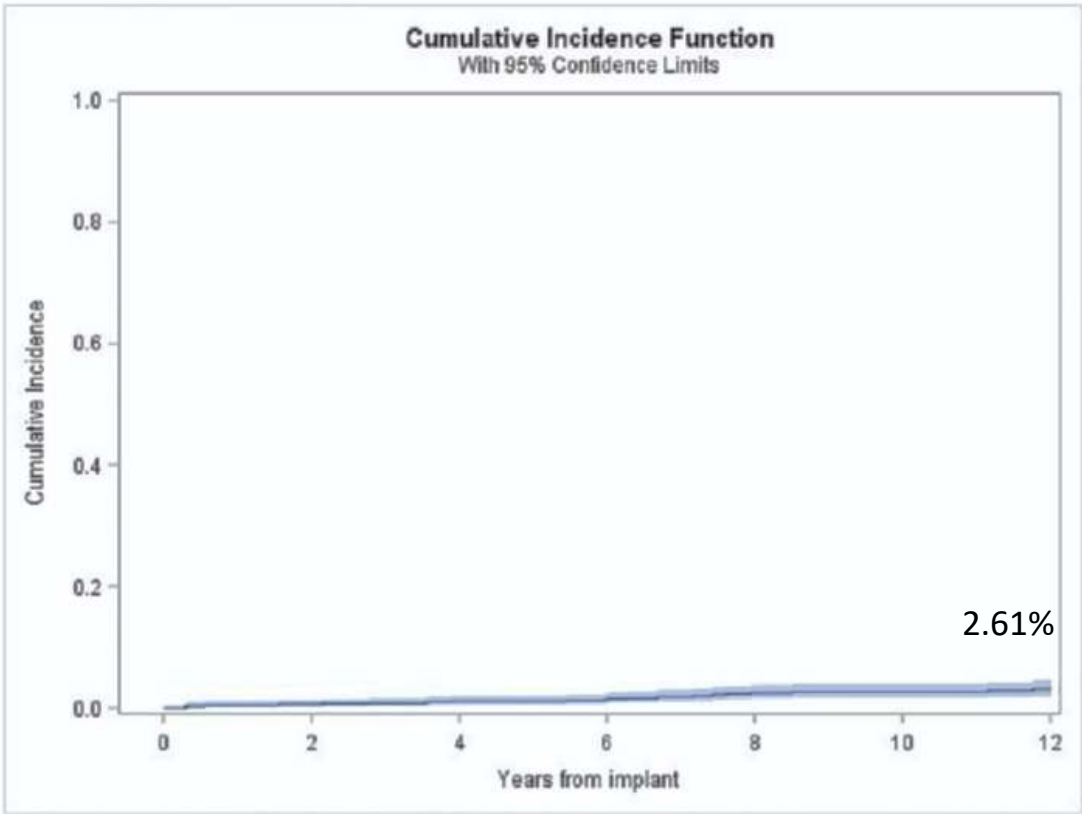
N = 882 Inoperable or High-Risk Patients Mean age – 83.3±6 yo CoreValve 8 Italian Centers



Transcatheter aortic valve replacement with corevalve self-expanding bioprosthesis: Clinical and durability data up to 12 years



SVD



BVF

Trial design



Prospective, randomized controlled, post-market trial
conducted at 83 international sites
All-comer trial with all surgical risk categories
including bicuspid patients

Key eligibility

- Symptomatic severe AS[†]
- Small aortic annulus (< 430 mm² by MDCT)

Randomization

1:1 stratified by site & sex

Medtronic (N=355)
Evolut PRO/PRO+/FX

716
patients treated

Edwards (N=361)
SAPIEN 3/SAPIEN 3 Ultra

**Co-Primary Endpoints
at 1 year with planned
5-year follow-up**

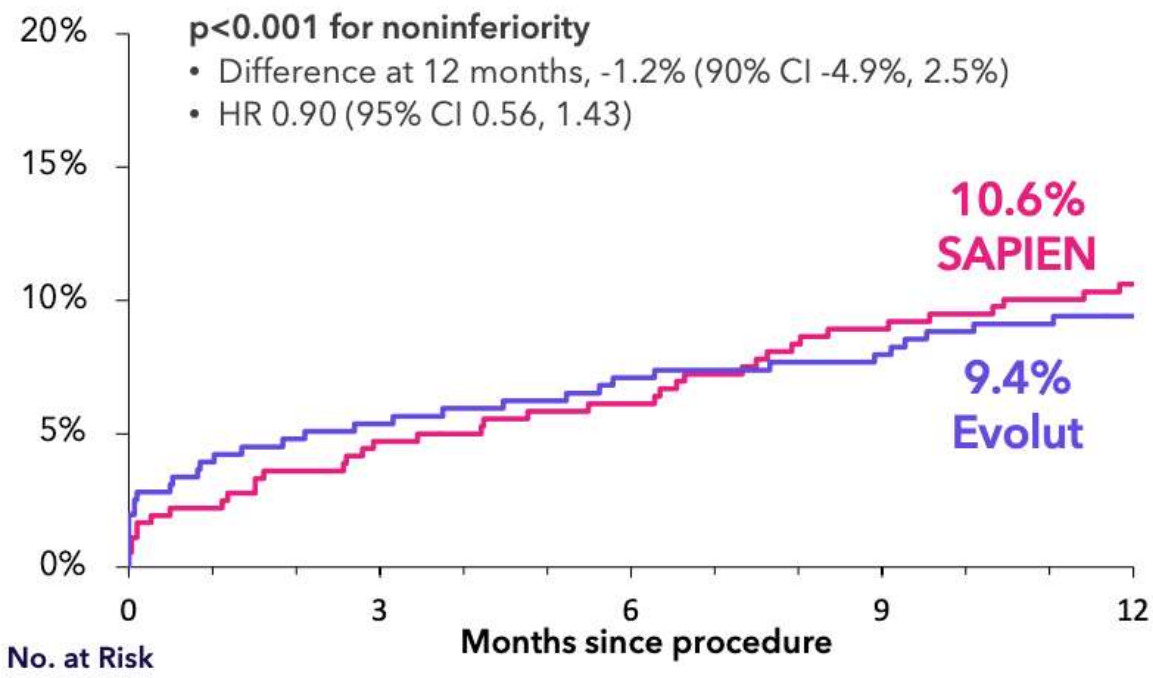
Co-Primary Endpoint 1:
Composite of mortality,
disabling stroke, or heart failure
rehospitalization through 12 months

Co-Primary Endpoint 2:
Bioprosthetic valve dysfunction
through 12 months

Co-primary endpoint 1:

Clinical outcome composite through 12 months powered for noninferiority

Mortality, Disabling Stroke, or HF Rehospitalization

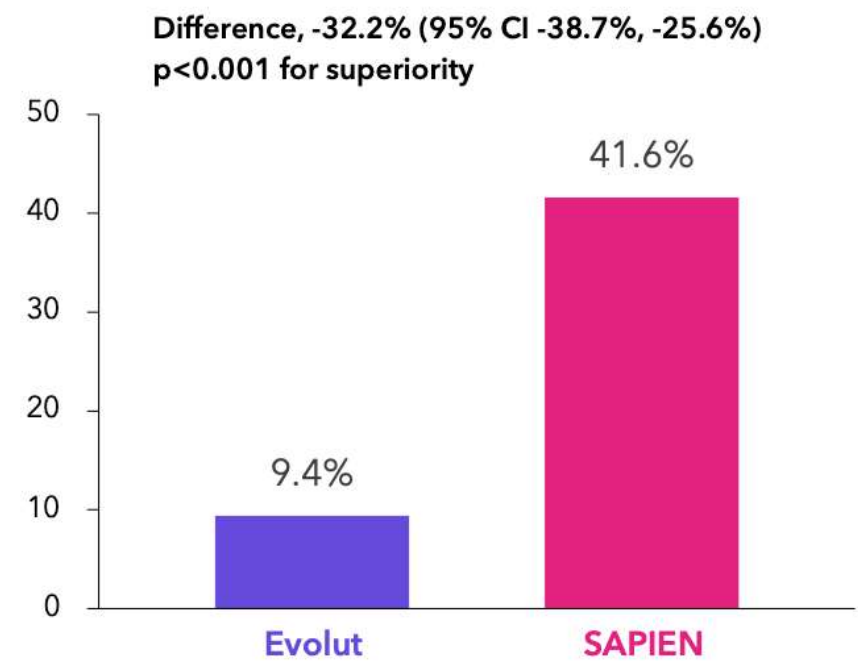


12 Months	Evolut (N=355)	SAPIEN (N=361)	HR (95% CI)
All-cause mortality	5.1%	5.9%	0.88 (0.47, 1.65)
Disabling stroke	3.1%	2.6%	1.26 (0.52, 3.03)
HF re hosp	3.8%	3.5%	1.11 (0.51, 2.44)



Co-primary endpoint 2:
 BVD through 12 months powered for superiority

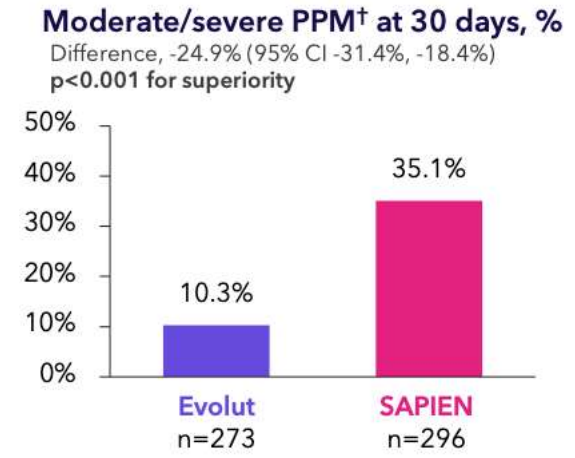
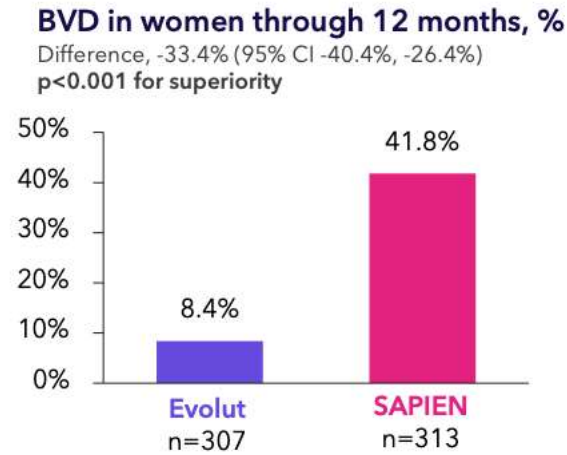
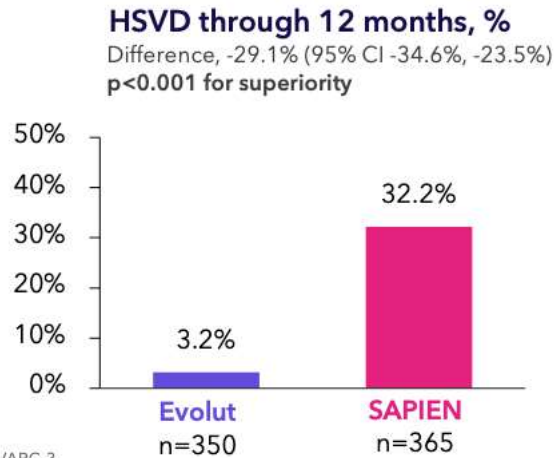
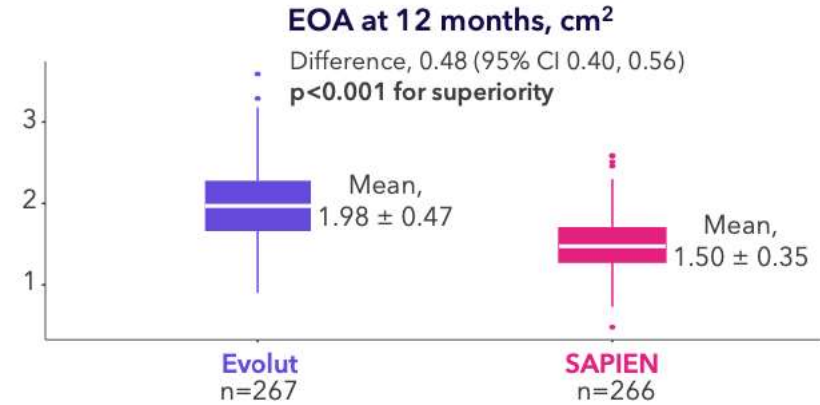
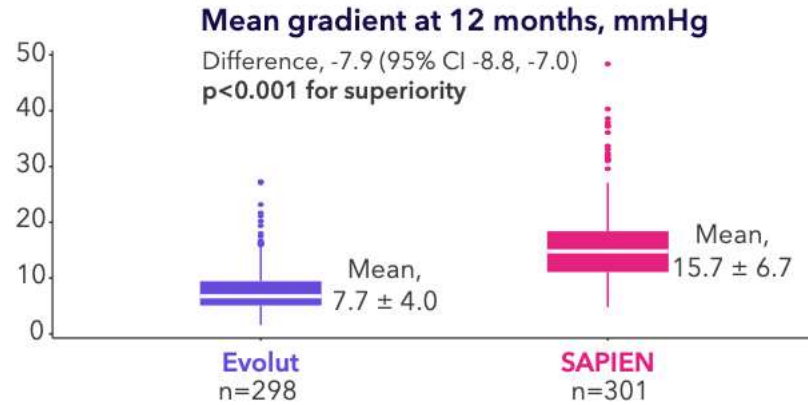
Bioprosthetic Valve Dysfunction through 12 months



	Evolut (N=350)	SAPIEN (N=365)	P Value
BVD composite	9.4%	41.6%	<0.001
HSVD	3.2%	32.2%	
NSVD	5.9%	18.2%	
Thrombosis (clinical)	0.3%	0.3%	
Endocarditis	0.6%	2.3%	
AV Reintervention	0.9%	0.6%	

HSVD = Mean gradient ≥ 20 mmHg
 NSVD = Severe PPM per VARC-3 or ≥ moderate total AR

Hypothesis-tested secondary endpoints



†VARC-3.



OCEAN-TAVI registry database

Latest consecutive data

S3UR n=618



S3UR n=618

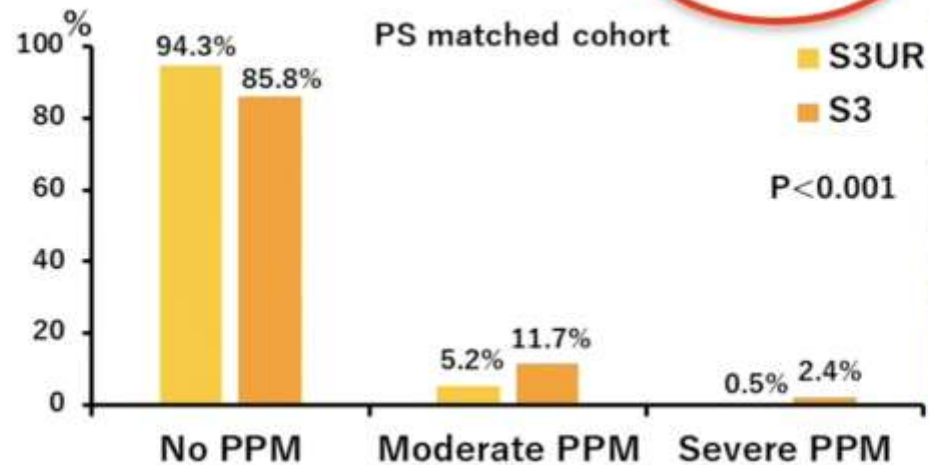
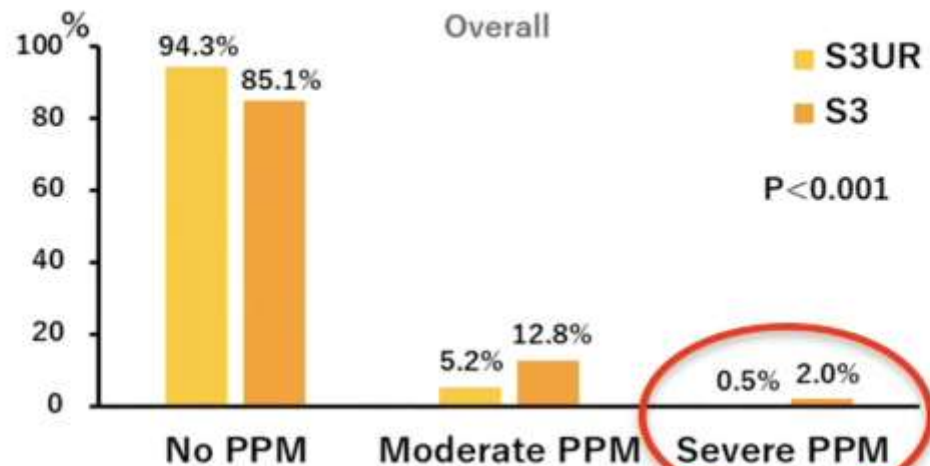
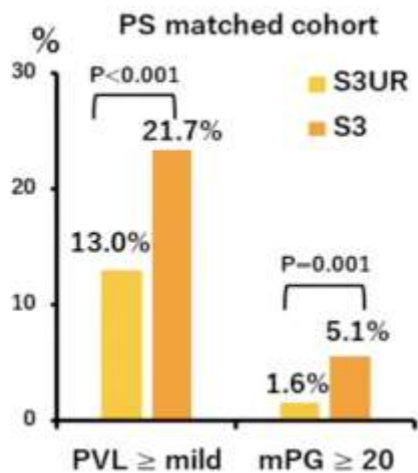
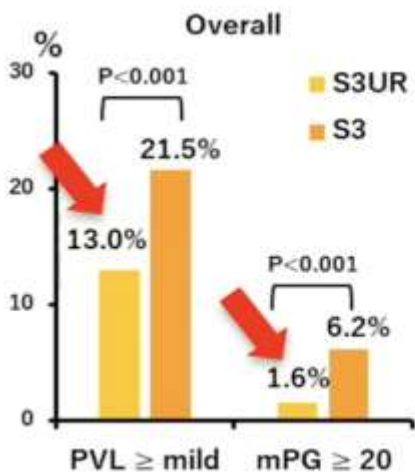
PS matched

Historical data

S3 n=8750



S3 n=618



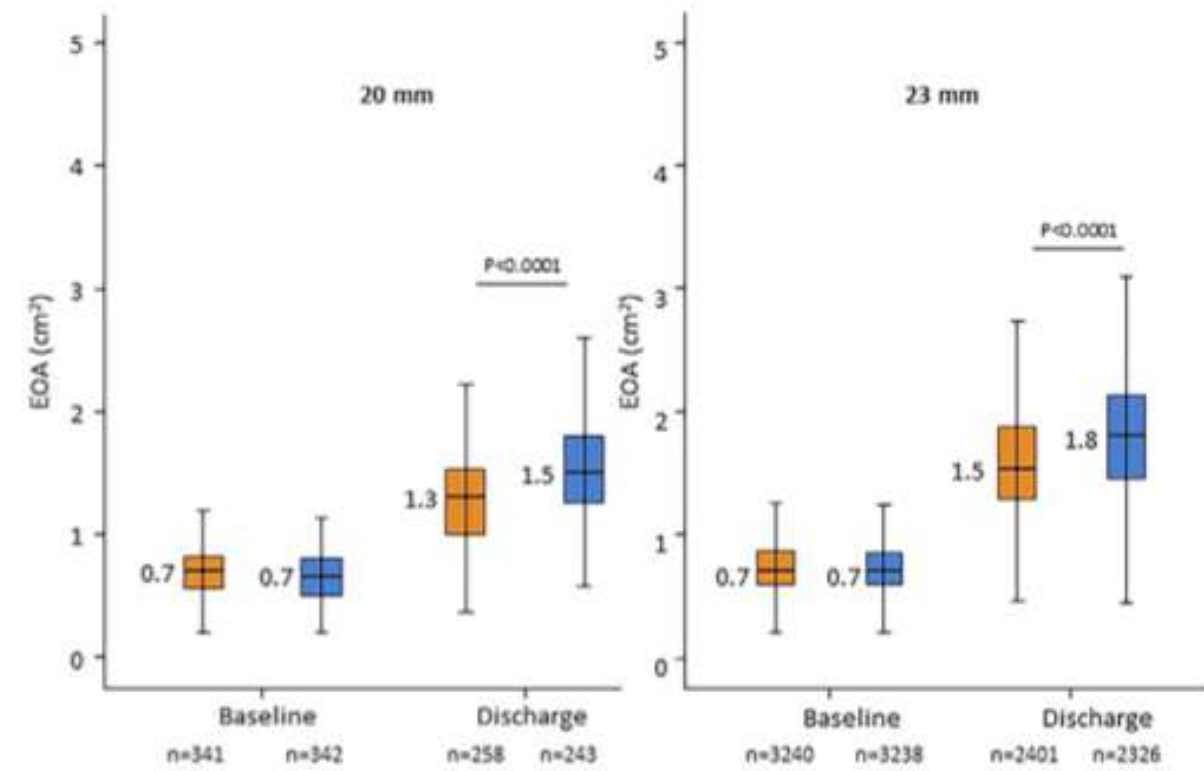
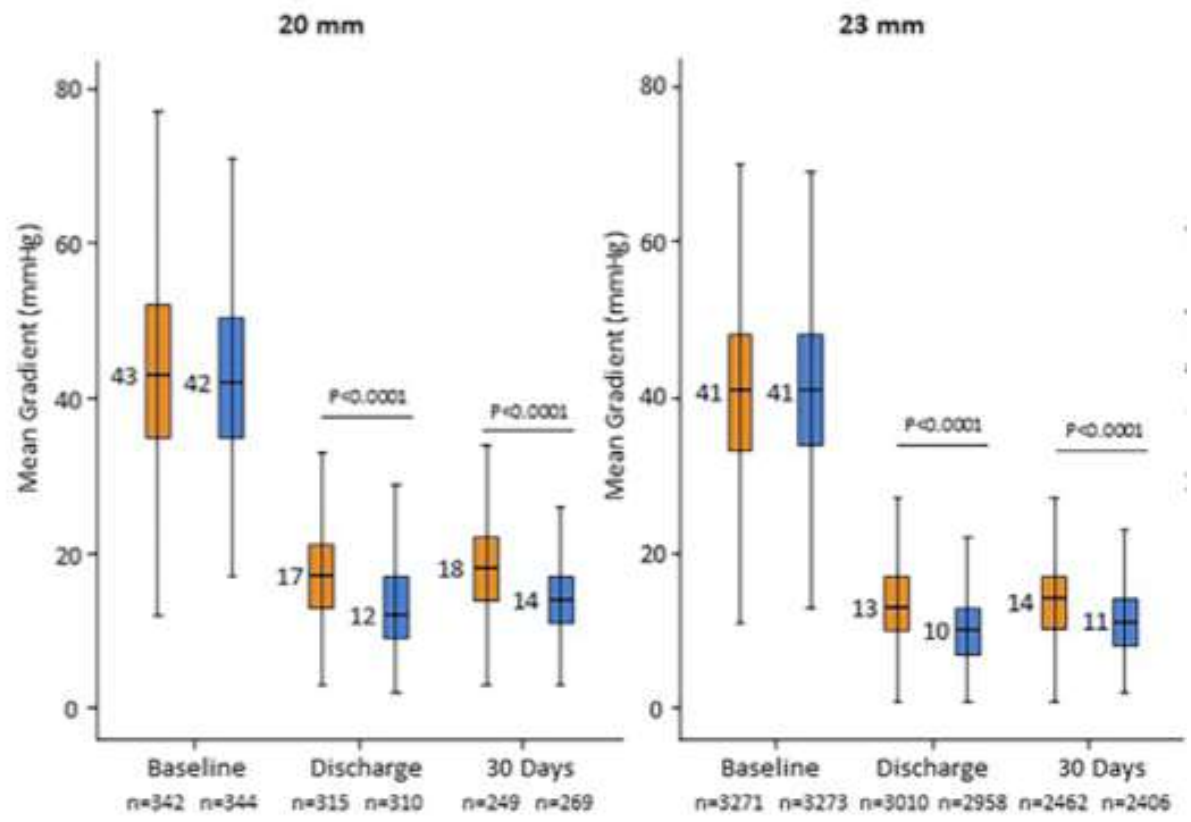


	Overall cohort		P value	Propensity-matched cohort		P value
	S3UR (n = 618)	S3 (n = 8750)		S3UR (n = 618)	S3 (n = 618)	
Patient number, n						
EOA, cm²	1.86 ± 0.47	1.67 ± 0.46	<0.001	1.86 ± 0.47	1.69 ± 0.47	<0.001
iEOA cm²/m²	1.26 ± 0.31	1.14 ± 0.30	<0.001	1.26 ± 0.31	1.14 ± 0.30	<0.001
Peak flow velocity, m/sec	2.05 ± 0.43	2.35 ± 0.44	<0.001	2.05 ± 0.43	2.34 ± 0.43	<0.001
Peak PG, mmHg	17.6 ± 7.3	22.8 ± 8.7	<0.001	17.6 ± 7.3	22.6 ± 8.2	<0.001
Mean PG, mmHg	9.0 ± 4.0	11.9 ± 4.8	<0.001	9.0 ± 4.0	11.8 ± 4.8	<0.001

Real-World Outcomes for the Fifth-Generation Balloon Expandable Transcatheter Heart Valve in the United States



TVT Registry S3UR n = 10.314 S3U/S3 n = 10.314 Propensity Matched



Conclusions

- Data on the durability of TAVR to date are promising. However, we should await the results of more studies with 10 years of follow-up.
- There seems to be an advantage in terms of durability with supra-annular platforms mainly in small annulus (Not yet demonstrated with S3UR)
- Long term durability data (>10 years) on contemporary devices is a challenge since technology is evolving very fast