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Evolución y desafíos de la TAVI



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Conflictos de interes

- Evolut Proctor
- Acurate Proctor



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Edwards SAPIEN	SAPIEN XT	SAPIEN 3	SAPIEN Ultra	Centera	CoreValve	Evolut-R	Evolut Pro	Portico	JenaValve

Acurate Neo	Direct Flow	Lotus	LOTUS Edge	Allegra	Venus A	Venus A-Plus	J-Valve	VitaFlow	Myval	Colibri
Boston Scientific	Direct Flow Medical	Boston Scientific	Boston Scientific	New Valve Technology	Venus Medtech	Venus Medtech	JC Medical Technology	Shanghai MicroPort	Meril Life Sciences	Colibri Heart Valve



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2017 ESC/EACTS Guidelines for the management of valvular heart disease



August, 2017

Table 7 Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk (see Table of Recommendations in section 5.2.)

B) Choice of intervention in symptomatic aortic stenosis		
Aortic valve interventions should only be performed in centres with both departments of cardiology and cardiac surgery on site and with structured collaboration between the two, including a Heart Team (heart valve centres).	I	C
The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in Table 7). In addition, the local expertise and outcomes data for the given intervention must be taken into account.	I	C
SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II < 4% or logistic EuroSCORE I < 10% ^d and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation). ⁹³	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team. ^{91,94}	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10% ^d or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see Table 7), with TAVI being favoured in elderly patients suitable for transfemoral access. ^{91,94–102}	I	B
Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients or in patients with symptomatic severe aortic stenosis who require urgent major non-cardiac surgery.	IIb	C
Balloon aortic valvotomy may be considered as a diagnostic means in patients with severe aortic stenosis or other potential causes for symptoms (i.e. lung disease) and in patients with severe myocardial dysfunction, pre-renal insufficiency or other organ dysfunction that may be reversible with balloon aortic valvotomy when performed in centres that can escalate to TAVI.	IIb	C

	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II < 4% (logistic EuroSCORE I < 10%) ^a		+
STS/EuroSCORE II ≥ 4% (logistic EuroSCORE I ≥ 10%) ^a	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age < 75 years		+
Age ≥ 75 years	+	
Previous cardiac surgery	+	
Frailty ^b	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+

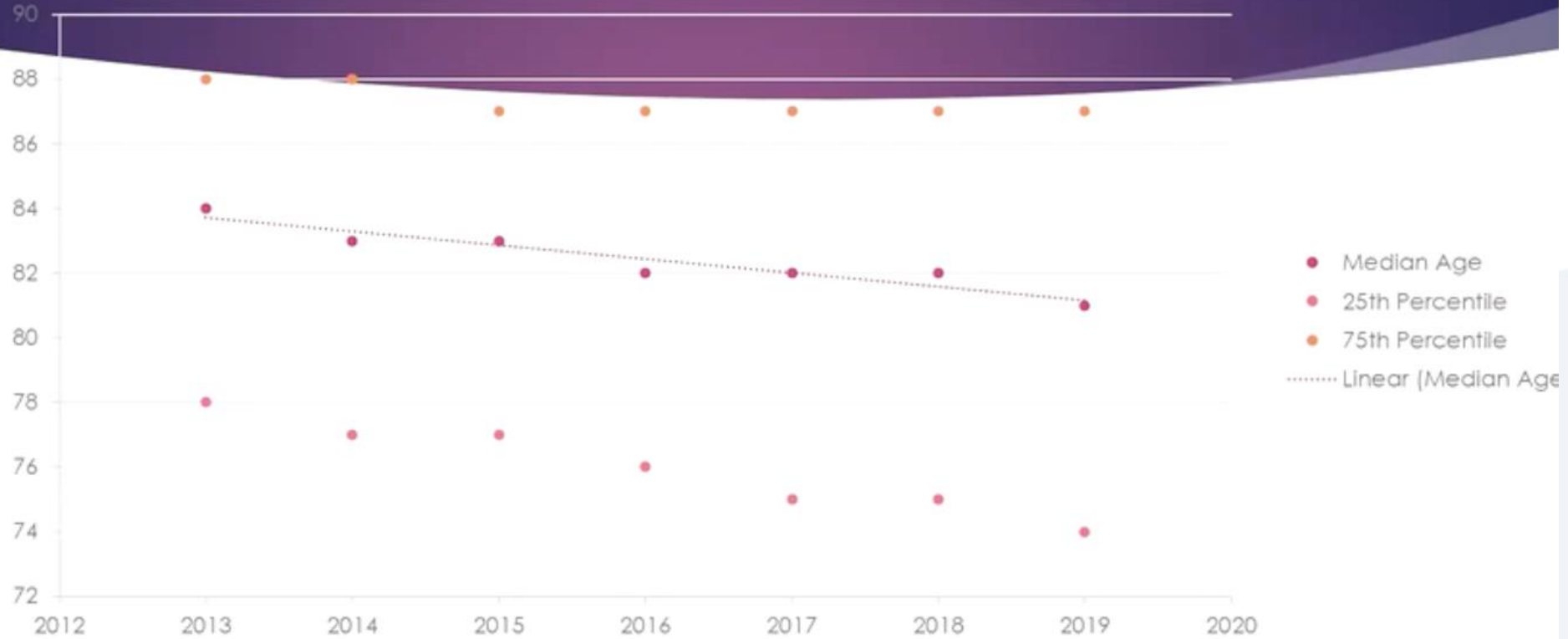


Figure 3 Rates of TAVR and SAVR From 2012 to 2019





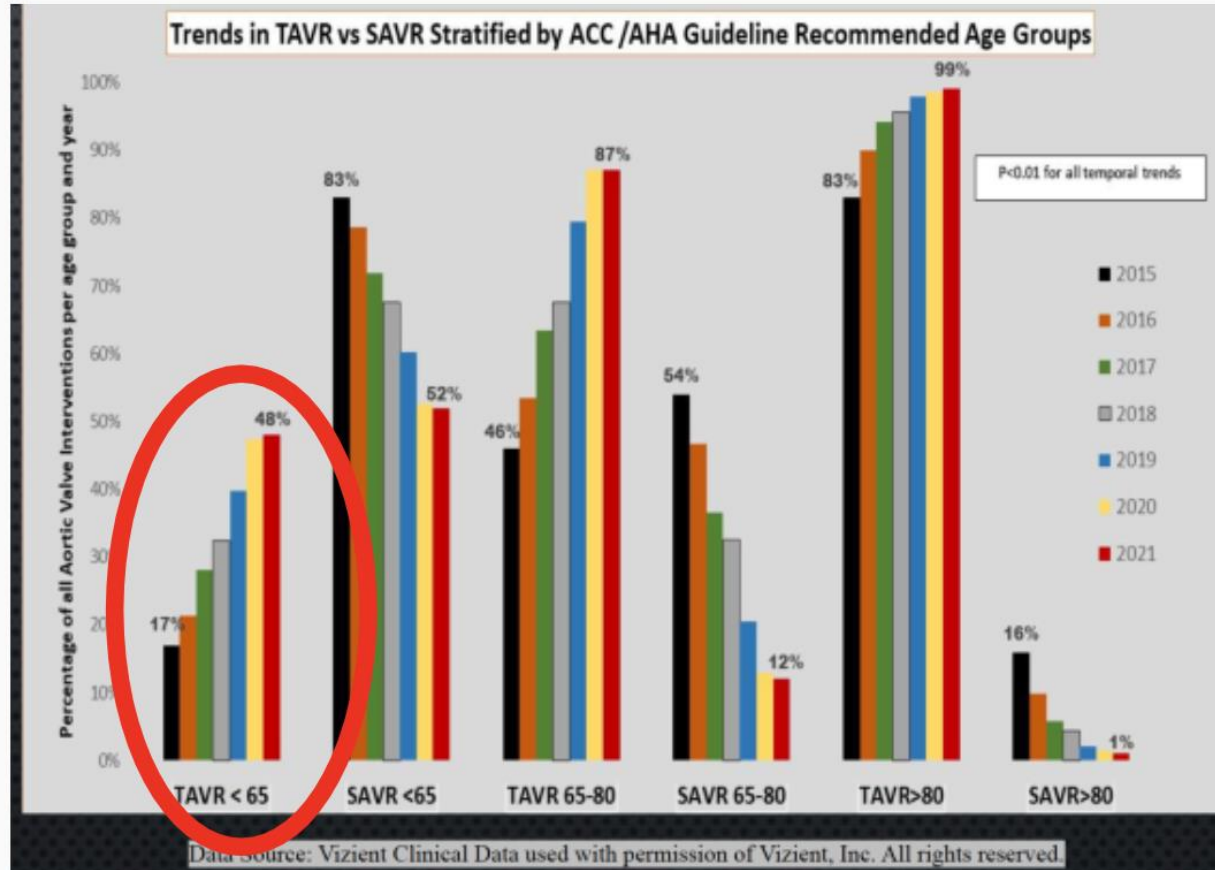
Mean age of TAVR patients in the US



Carroll J, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. The Annals of Thoracic Surgery. 2021: 111(2)



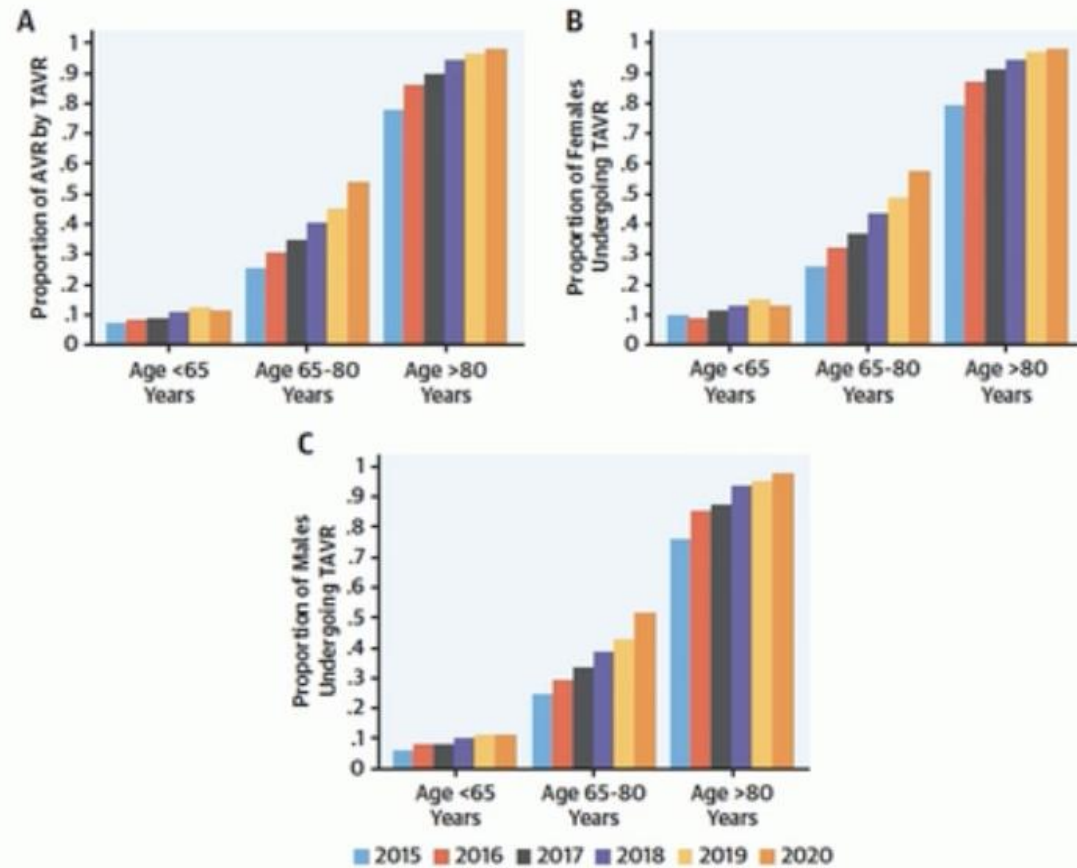
The real world



- US national database
- 279,066 patients
- Isolated AVR
- 48% of patients under 65 years had TAVI

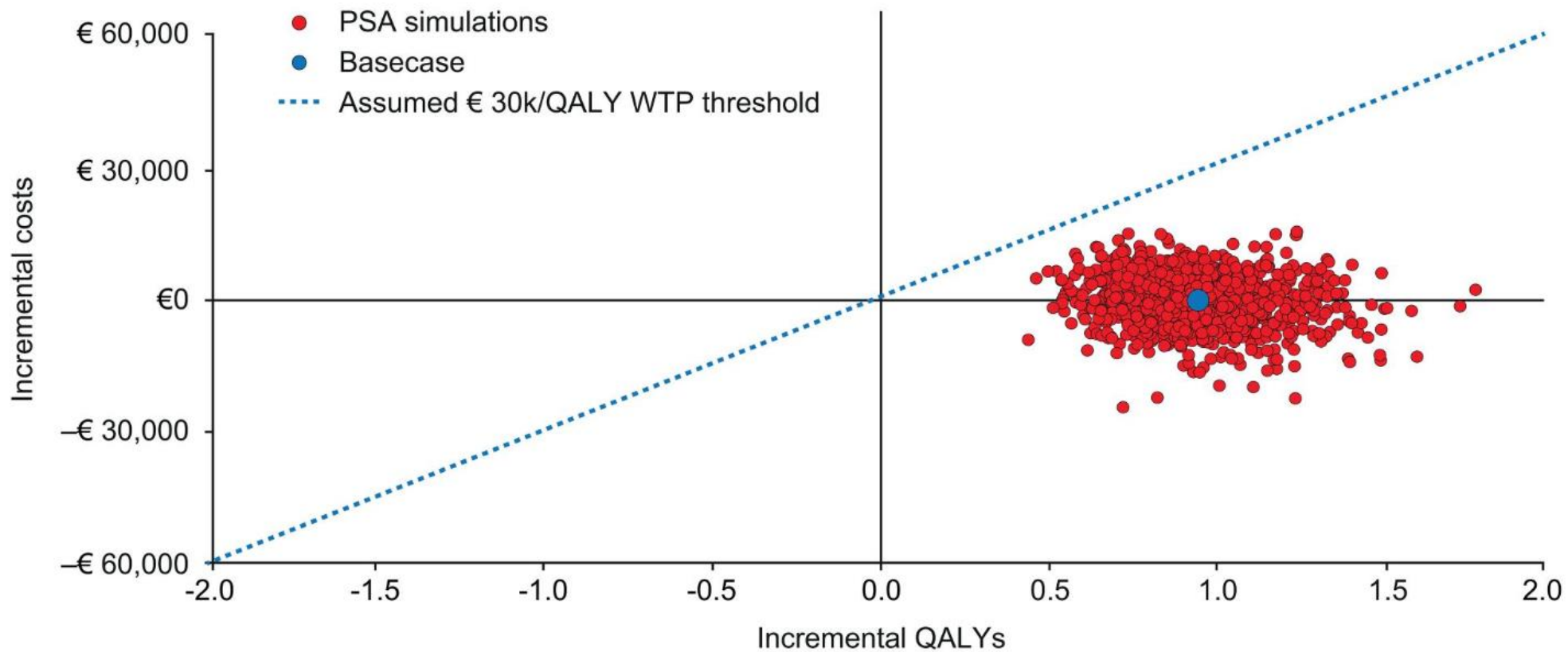


FIGURE 2 Proportion of Patients Undergoing Transcatheter Aortic Valve Replacement



Proportion of transcatheter aortic valve replacement patients within each age group (<65, 65-80, and >80 years of age), (A) overall, (B) in females, and (C) in males showing the greatest relative growth in patients >80 years of age and relative reduction in patients <65 years of age.

Transcatheter aortic valve implantation versus surgical aortic valve replacement in severe aortic stenosis patients at low surgical mortality risk: a cost-effectiveness analysis in Belgium





Traditional Focus: Immediate Cure



Typically Patient 80+
Limited Functional
Capacity
Typical Tri-leaflet Anatomy



Mortality Rate



Stroke Risk



Pacemaker Need

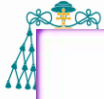


Quality of Life

TAVI IN 2024

- 1% in-patient mortality
- 2% stroke
- 3% vascular complications
- 1 hour procedure (max.)
- Conscious sedation/LA
- 48 hr hospital stay (max.)

- Growing demand



We forgot one thing.....

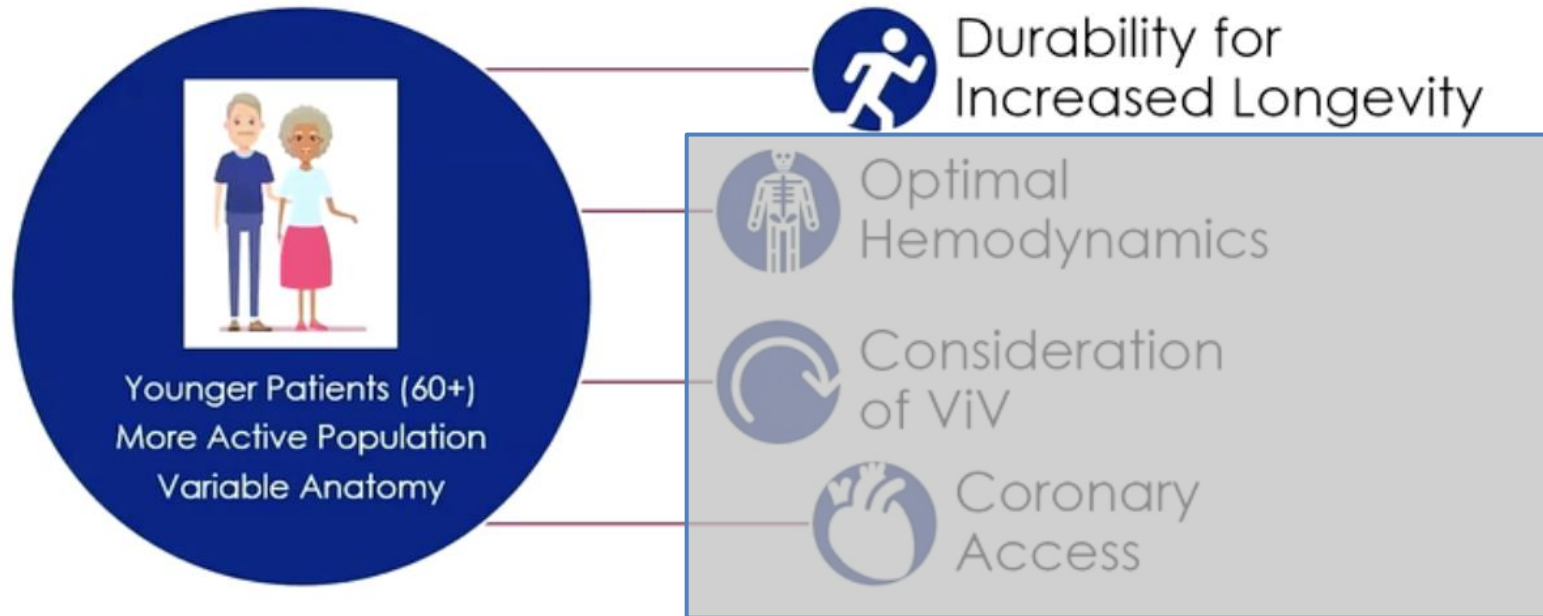


Redo-TAVR: An Emerging Epidemic

- Cuando implantamos una TAVI en la década de 2010, quedábamos muy satisfechos si el paciente salía bien de Hemodinámica, ese ya no puede ser el objetivo
- El objetivo ahora es ¿Qué vamos a hacer cuando el paciente vuelva son SVF?
- Si implantamos una válvula de un modelo no adecuado, muy alta, muy grande en relación con los senos etc. Será imposible repetir el procedimiento y habrá que remitir el paciente a cirugía.



Evolution of Focus: Lifetime Management





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Lifetime Management of Aortic Disease in 2023

Bioprosthetic Valve Durability



Hemodynamic
Deterioration

Degeneration

Failure



Longest Follow-up of Landmark Trials of TAVR versus SAVR



10 years

5 years

4 years

1 year

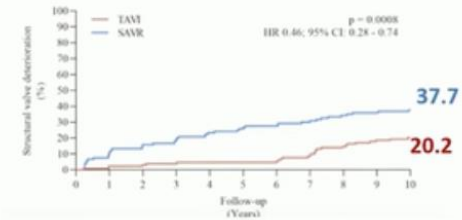
• **Notion** *ESC Congress 2023*

- **PARTNER 1A**
- **Corevalve High risk**
- **PARTNER 2A**
- **SURTAVI**
- **PARTNER 3**
- **Evolut Low-Risk**

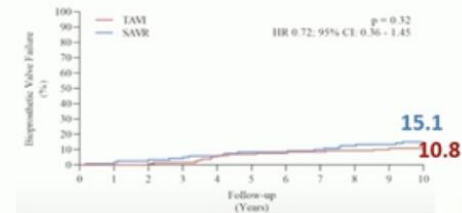
• **UK-TAVI (all THVs)**

Notion Trial – 10y

SVD - $p < 0.001$



BVF - $p = \text{NS}$

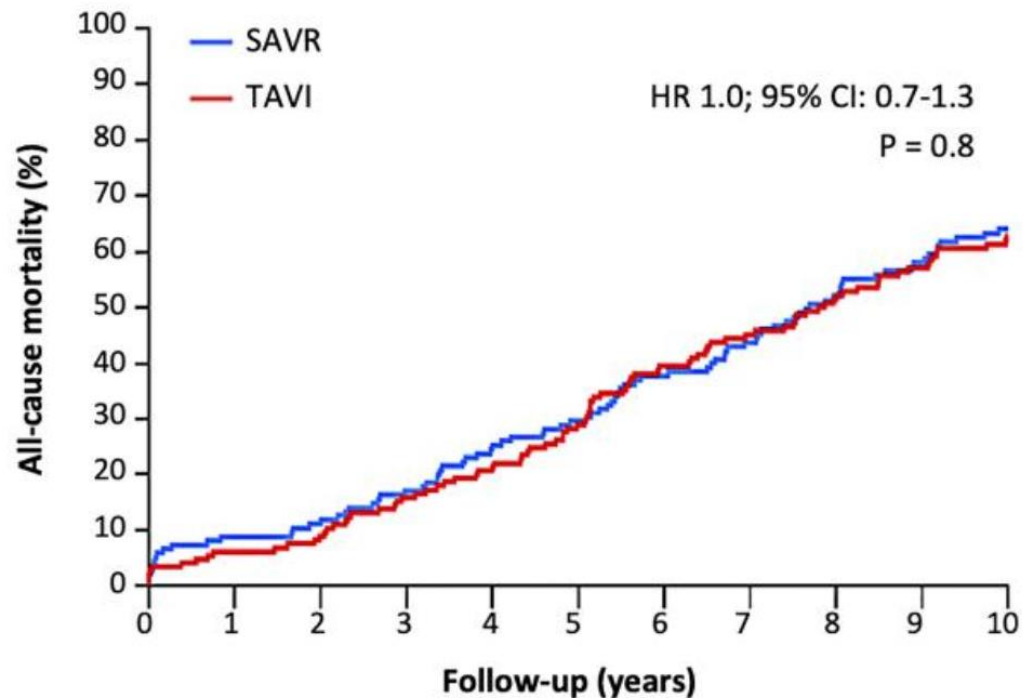




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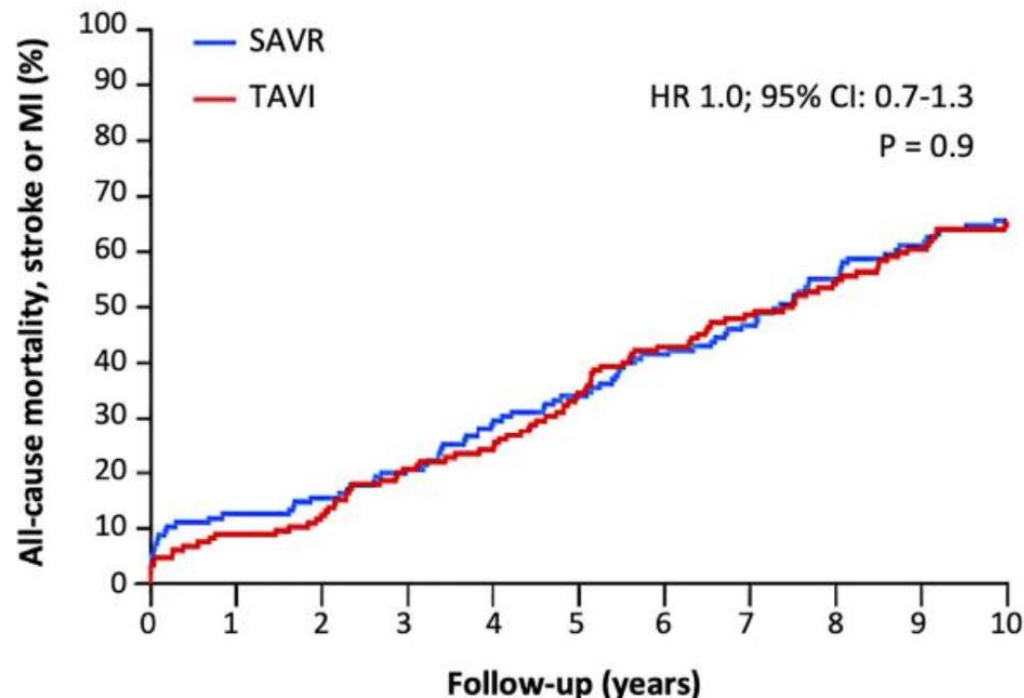


Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial



Patients at risk

TAVI	145	136	132	122	115	101	86	78	69	61	53
SAVR	135	123	120	112	102	95	83	75	64	56	48



Patients at risk

TAVI	145	133	128	116	110	93	81	73	65	56	49
SAVR	135	122	118	110	99	92	80	71	60	52	46

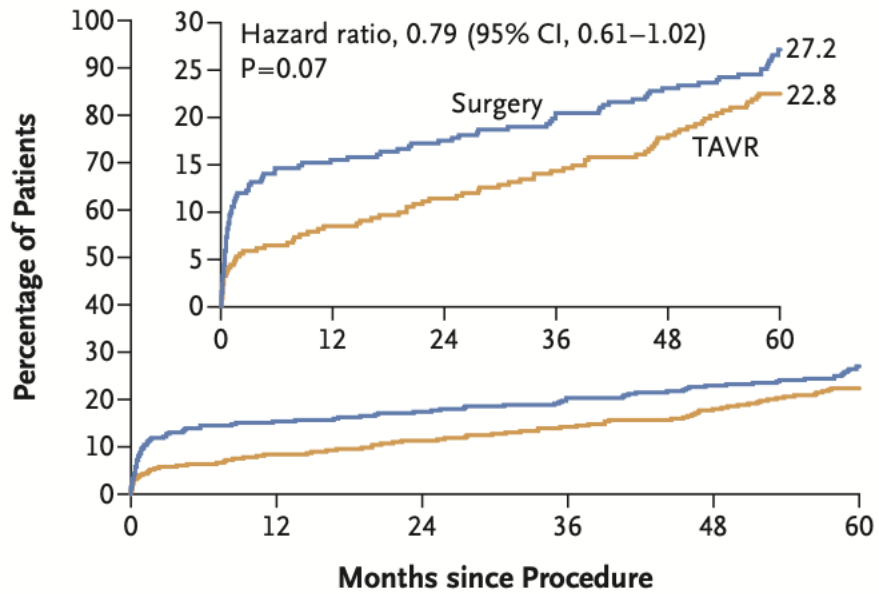
Figure 1 NOTION—clinical outcomes up to 10 years of follow-up: all-cause mortality and all-cause mortality, stroke, or myocardial infarction (MI). TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement; MI, myocardial infarction. Hazard ratio (HR); 95% confidence interval (CI); *P*-value was based on Cox regression



ORIGINAL ARTICLE

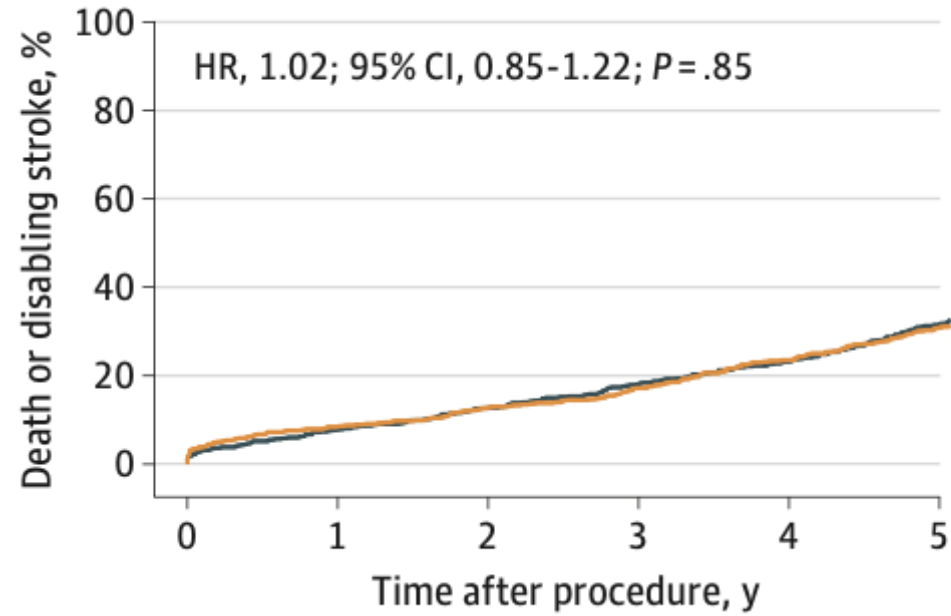
Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

Death from Any Cause, Stroke, or Rehospitalization



PARTNER 5 AÑOS

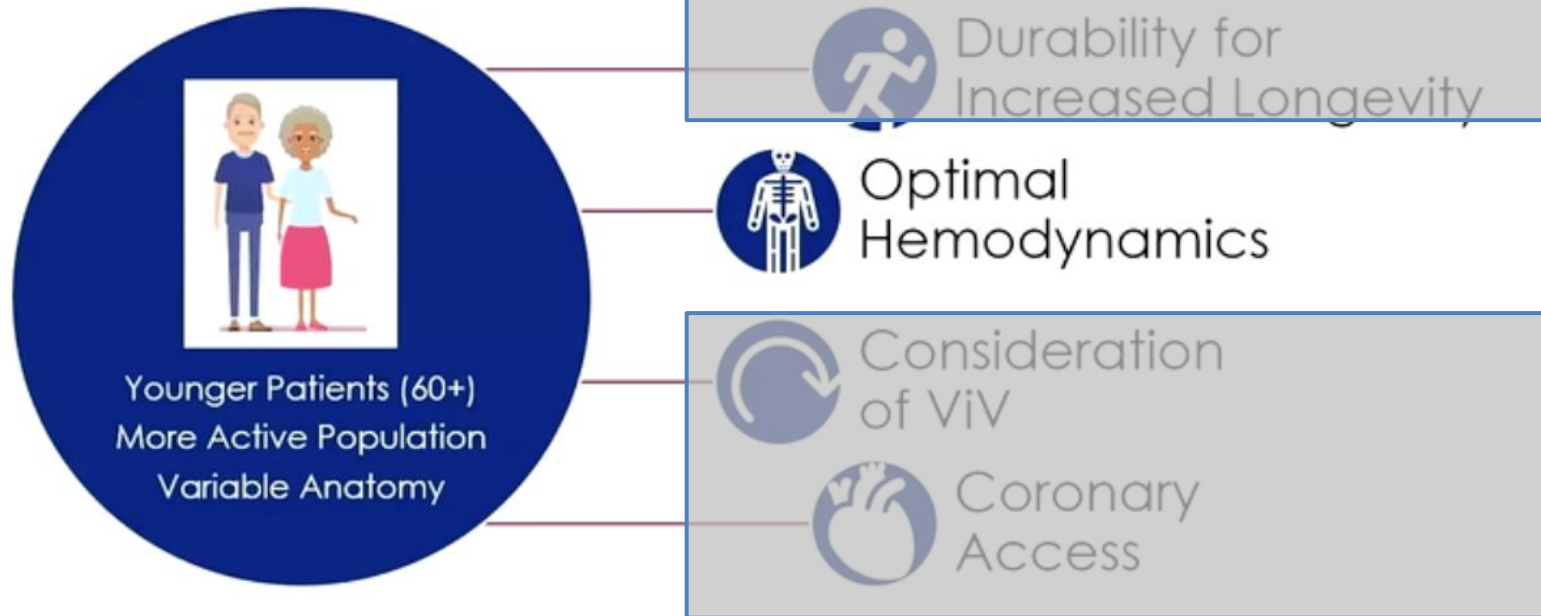
Self-expanding Transcatheter vs Surgical Aortic Valve Replacement in Intermediate-Risk Patients 5-Year Outcomes of the SURTAVI Randomized Clinical Trial



SURTAVI 5 AÑOS



Evolution of Focus: Lifetime Management



Echocardiographic assessment of transprosthetic mean gradients and paravalvular regurgitation

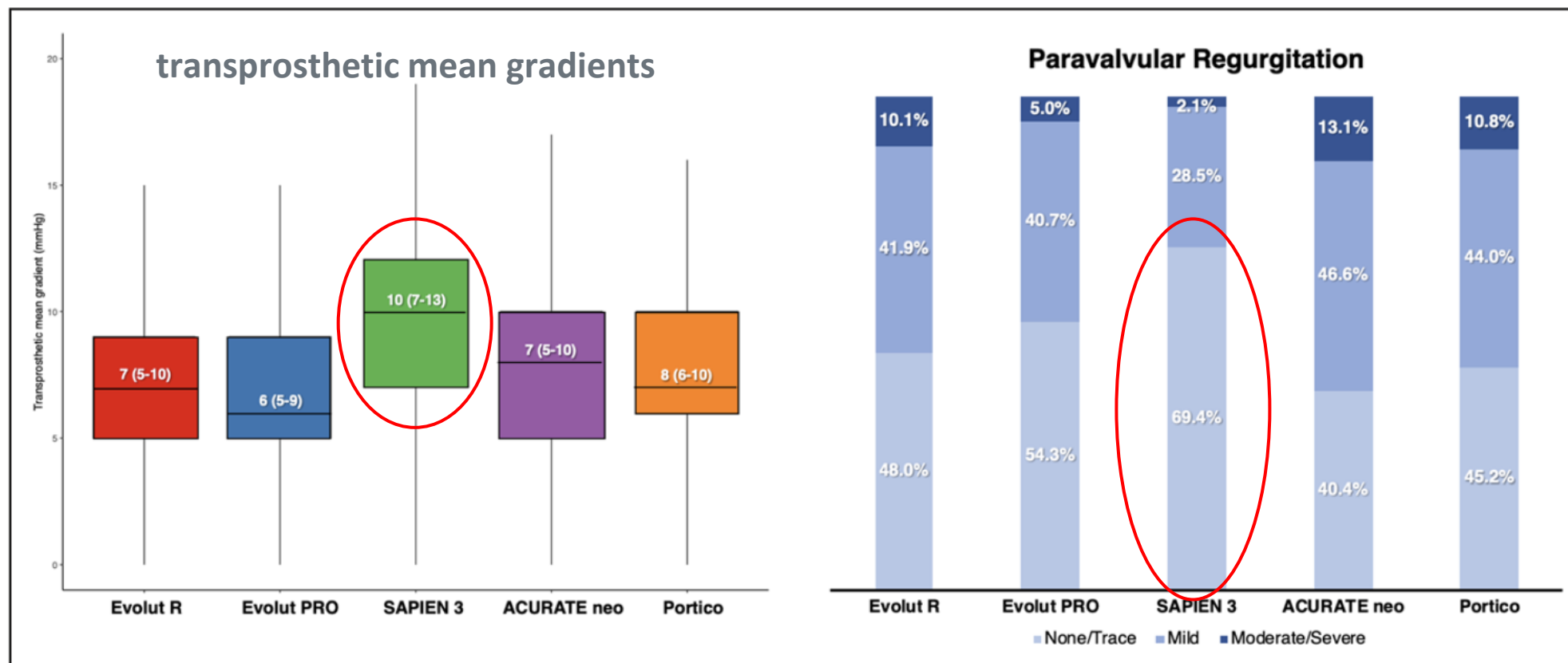


Figure 2. Adjusted echocardiographic assessment of transprosthetic mean gradients and paravalvular regurgitation after transcatheter aortic valve implantation.



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XXXIII CONGRESO MEXICANO DE CARDIOLOGÍA

V CONGRESO DE REHABILITACIÓN CARDIOVASCULAR, PREVENCIÓN Y CARDIOLOGÍA DEL DEPORTE

MUNDO IMPERIAL | ACAPULCO, GUERRERO
15 AL 18 DE MARZO 2024



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Circulation: Cardiovascular Interventions

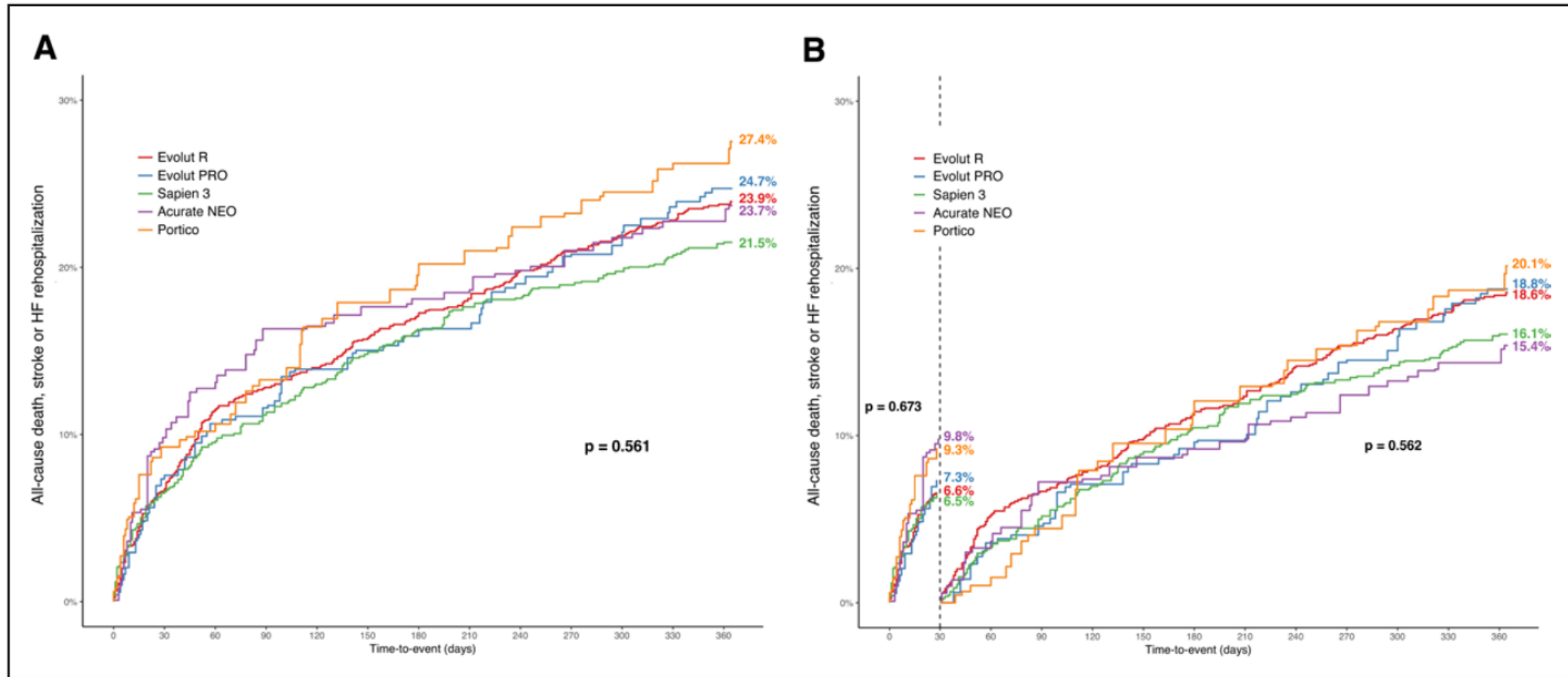
ORIGINAL ARTICLE

Real-World Multiple Comparison of Transcatheter Aortic Valves: Insights From the Multicenter OBSERVANT II Study

Giuliano Costa^{ID}, MD; Marco Barbanti^{ID}, MB; Stefano Rosato^{ID}, MSc; Fulvia Seccareccia, MSc; Giuseppe Tarantini^{ID}, MD, PhD; Massimo Fineschi, MD; Stefano Salizzoni^{ID}, MD; Roberto Valvo, MD; Corrado Tamburino, MD, PhD; Fausto Biancari^{ID}, MD; Giovanni Baglio^{ID}, MD; Gennaro Santoro, MD; Massimo Baiocchi^{ID}, MD; Paola D'Errigo, MSc; the OBSERVANT II Research Group



Ur **CONCLUSIONS:** Data from real-world practice showed low and comparable rates of complications after TAVI considering all the available devices. Patients receiving SAPIEN 3 valve had lower rates of paravalvular regurgitation and permanent pacemaker implantation, but higher transprosthetic gradients.





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Wang et al. *BMC Cardiovascular Disorders* (2023) 23:382
<https://doi.org/10.1186/s12872-023-03397-3>

BMC Cardiovascular Disorders

RESEARCH

Open Access

Comparison of outcomes of self-expanding versus balloon-expandable valves for transcatheter aortic valve replacement: a meta-analysis of randomized and propensity-matched studies



Baiqiang Wang¹, Zeyuan Mei¹, Xiao Ge¹, Yunyi Li¹, Quan Zhou¹, Xiao Meng¹ and Guipeng An^{1*}



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SAPIEN 3/Ultra



Evolut R/PRO



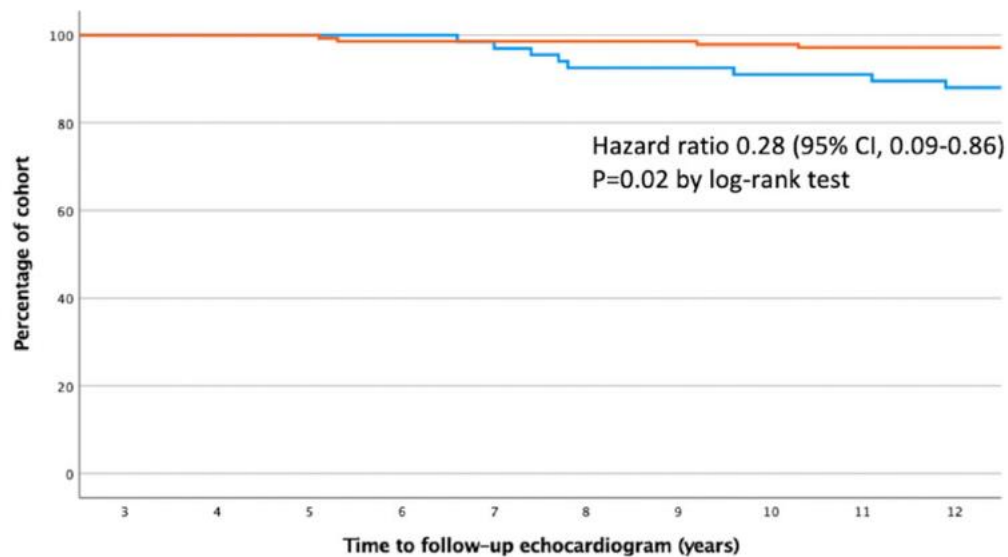
ACURATE neo

	SAPIEN	Evolut	p-value	ACURATE	p-value
30-day mortality	1.90%	2.50%	0.22	2.60%	0.19
One-year mortality	10.40%	11.80%	0.58	12.20%	0.18
Stroke	1.90%	3.30%	0.09	2.60%	2.18
PPI	11.50%	16.90%	< 0.00001	9.70%	0.001
MLTB	5.00%	3.30%	0.79	7.90%	0.13
MVC	6.70%	4.30%	0.45	7.20%	0.96
AKI	3.60%	4.40%	0.85	3.80%	0.38
MTG	Ref	-3.72	< 0.00001	-3.76	< 0.00001
CAO	0.27%	0.35%	0.87	0.39%	0.35
Mild PVL	24.50%	40.80%	< 0.00001	39.20%	0.007
Moderate to severe PVL	2.80%	5.40%	0.07	5.90%	< 0.0001
EOA	Ref	0.16	< 0.00001	0.20	< 0.00001
Severe PPM	12.40%	2.50%	< 0.00001	3.00%	< 0.00001

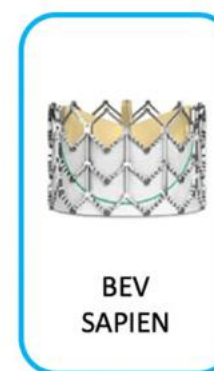
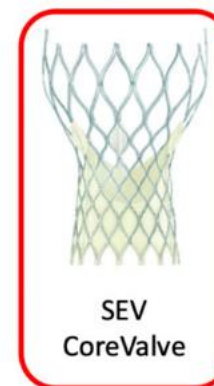
Long-term durability of self-expanding and balloon-expandable transcatheter aortic valve prostheses: UK TAVI registry

Conclusions: Hemodynamic function of transcatheter heart valves remains stable up to more than 10 years post-TAVI. Severe SVD occurred in 5.9%, and valve-related death/reintervention in 2.3%. Severe SVD was more common with BEV than SEV.

KM curves comparing balloon-expandable (SAPIEN; blue) and self-expanding (CoreValve; red) valves with respect to freedom from severe SVD over time

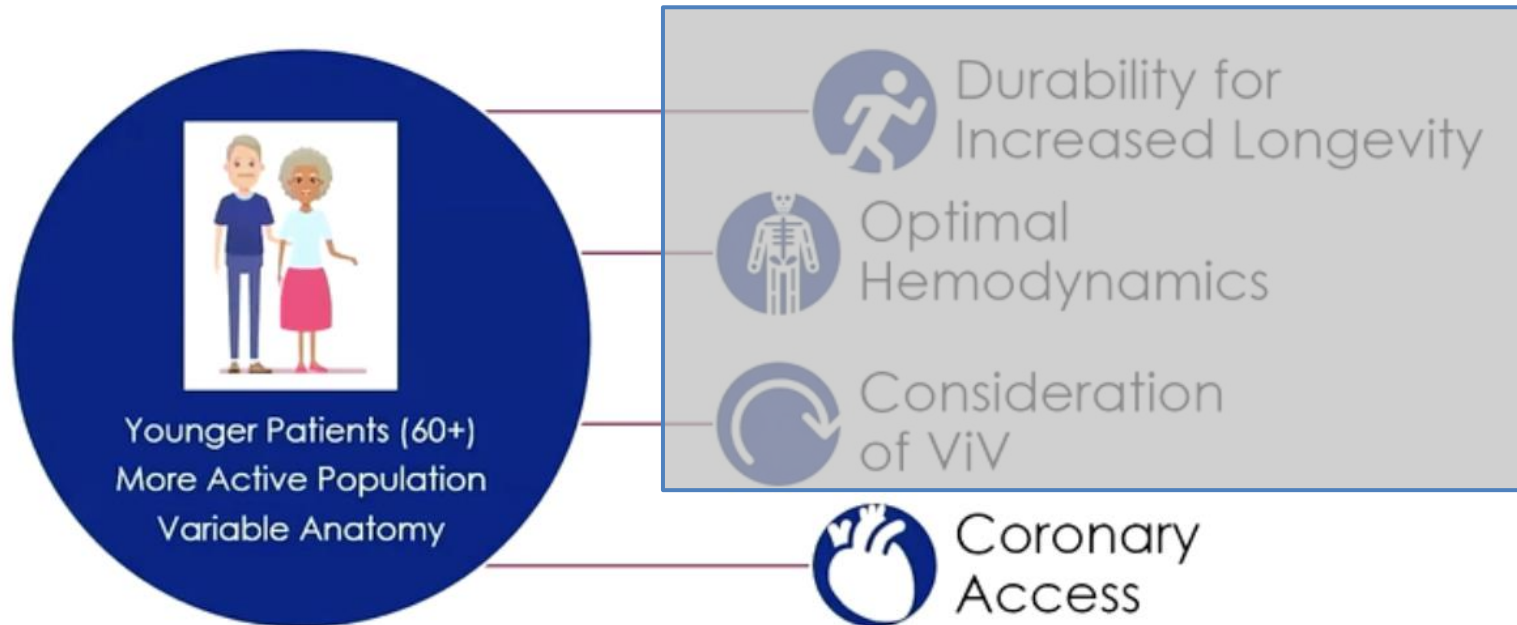


Time (years)	SEV CoreValve (n)	BEV SAPIEN (n)
3	143	67
4	143	67
5	107	54
6	107	54
7	53	31
8	53	31
9	27	16
10	27	16
11	8	2
12	8	2



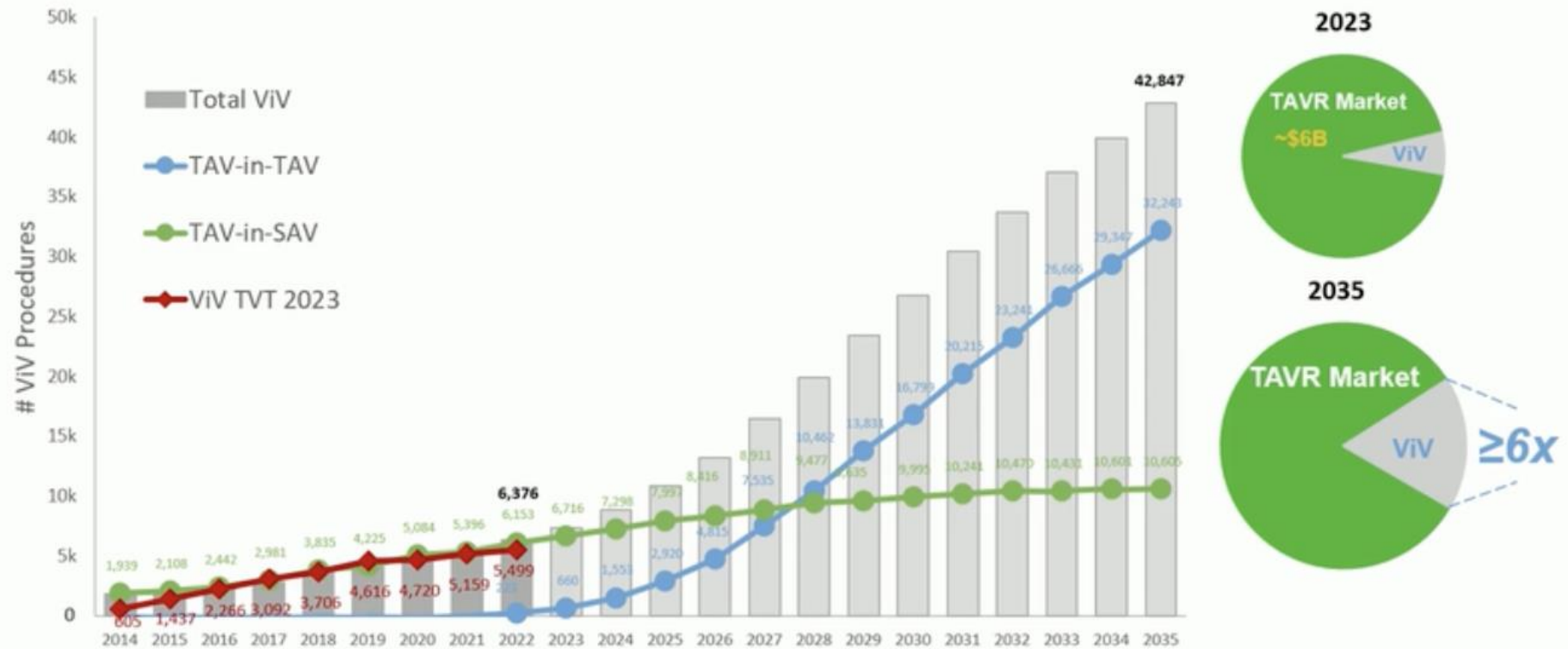


Evolution of Focus: Lifetime Management



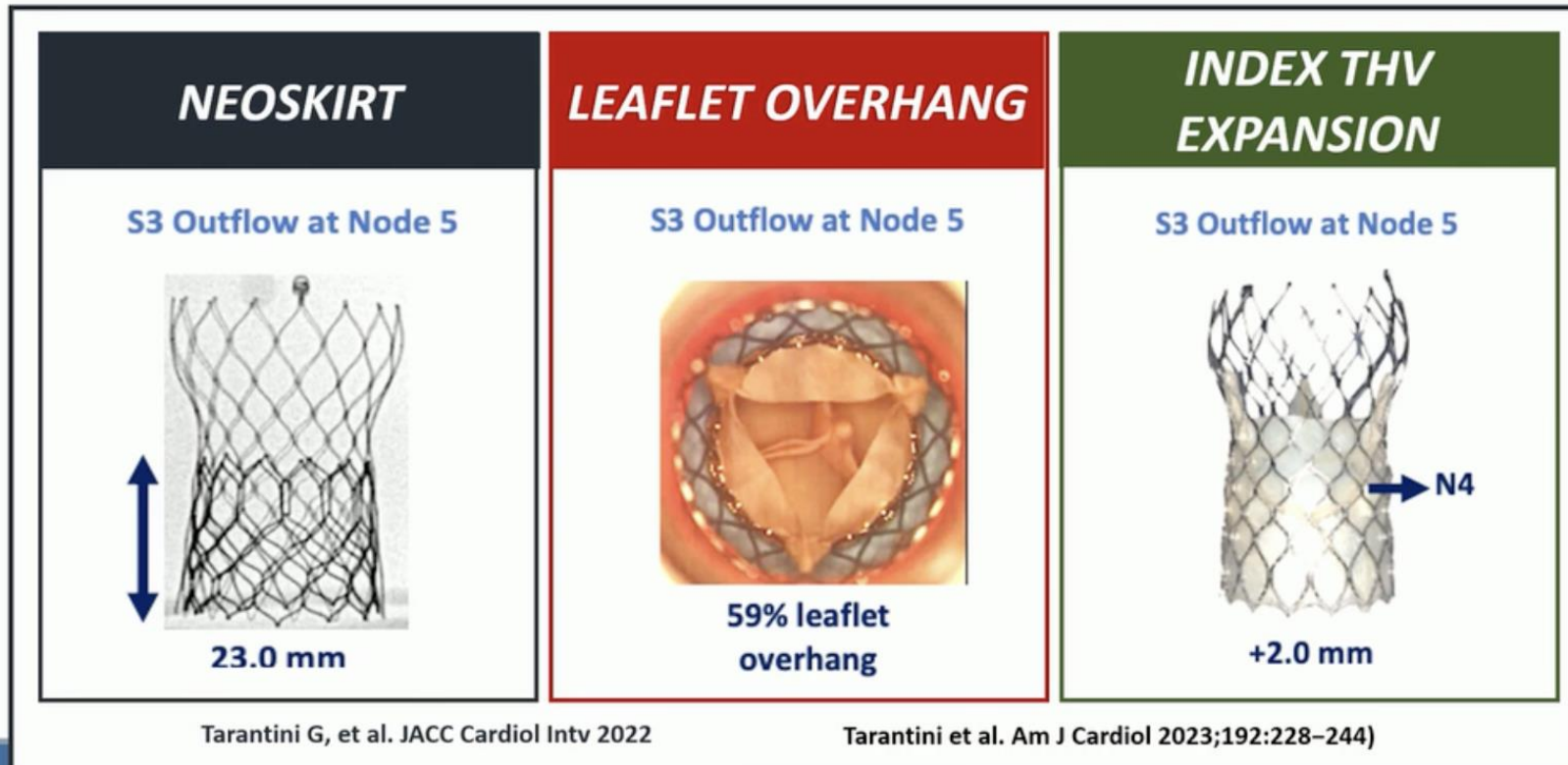


US ViV Market Forecast until 2035

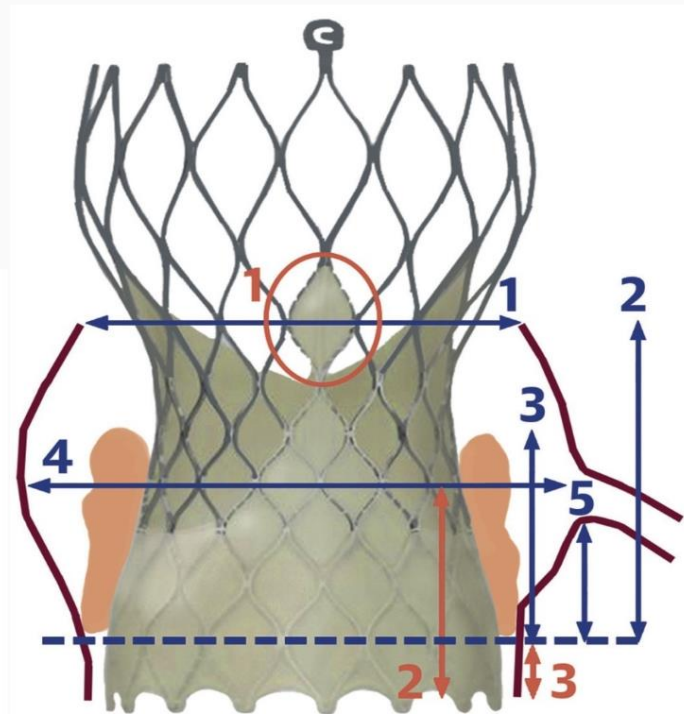
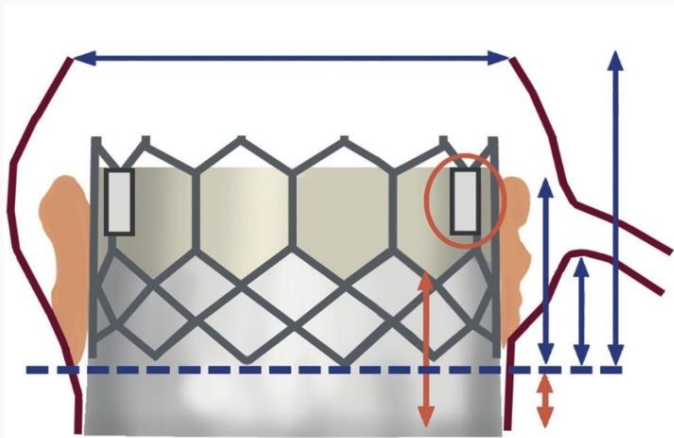




What's important in RE-Do TAVR?



Factors impacting coronary access after TAVR



Anatomical

1. Sinotubular junction dimensions
2. Sinus height
3. Leaflet length and bulkiness
4. Sinus of Valsalva width
5. Coronary height

Device and Procedural

1. Commissural tab orientation
2. Sealing skirt height
3. Valve implant depth



Combination determines Neo Skirt and Neo skirt plane

Index TAV **Pinned** leaflets + Skirt of Second TAV



Short in Short



Tall in Tall

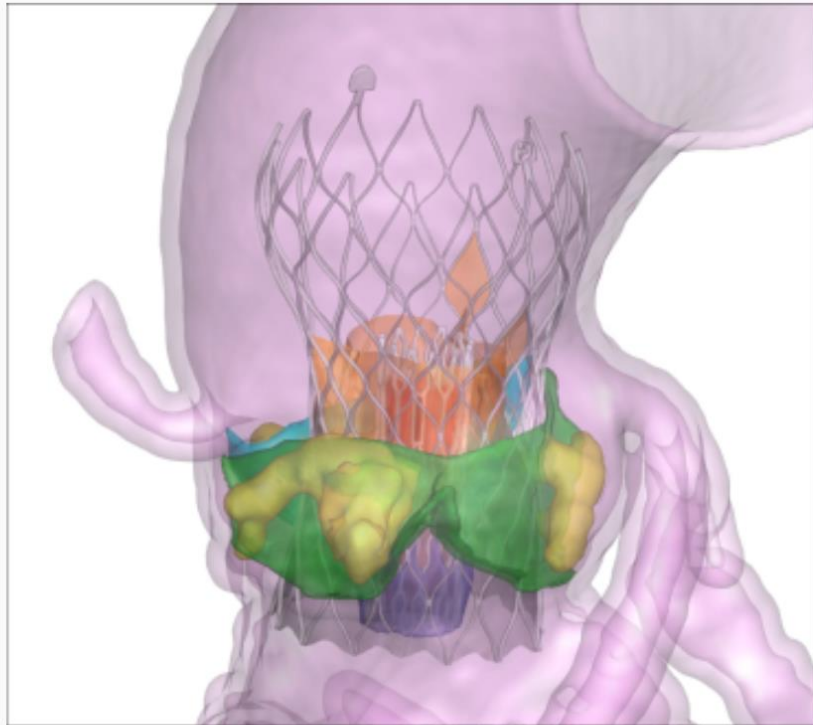


Tall in Short



Short in Tall

Planning for the 2nd procedure starts at the 1st



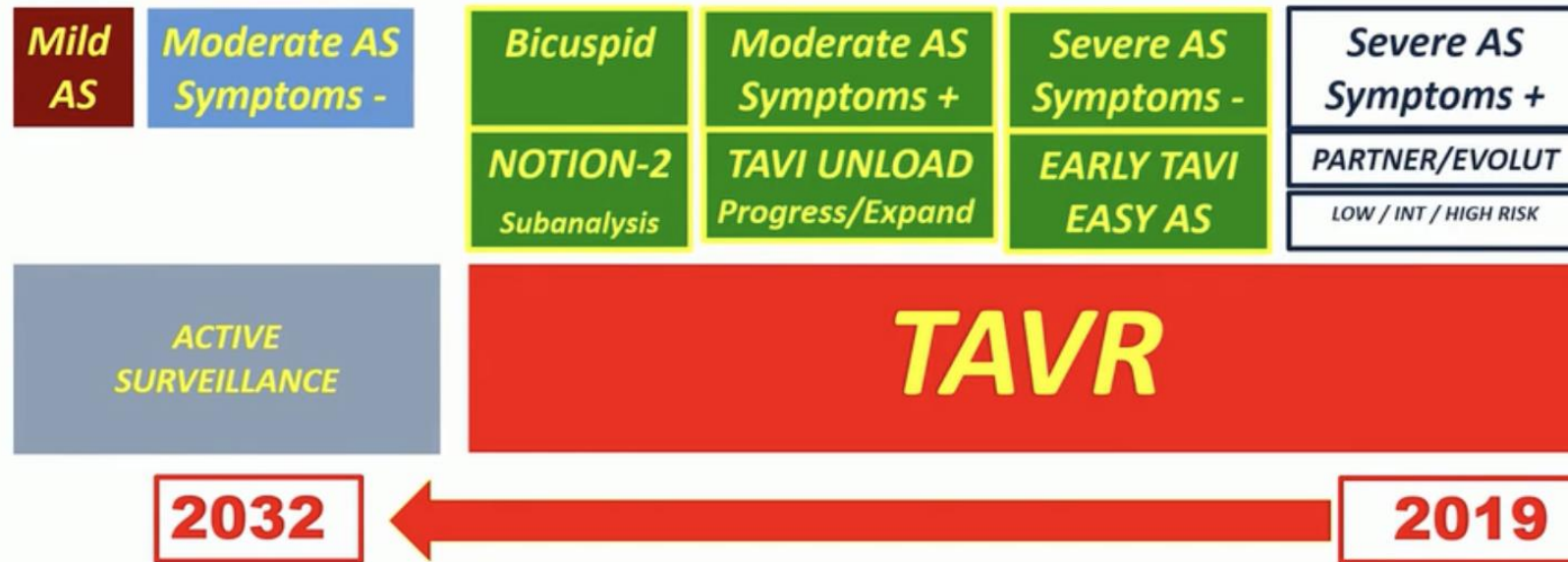
CT DASi Simulations: Sapien-in-EvoluT

- 1) Aortic root anatomy**
- 2) 1st valve choice**
- 3) Implant depth**
- 4) Implications for coronary access**
- 5) Assess repeatability**
- 6) 2nd Valve choice**



Aortic Stenosis Redefined:

Functional classification / New trigger points

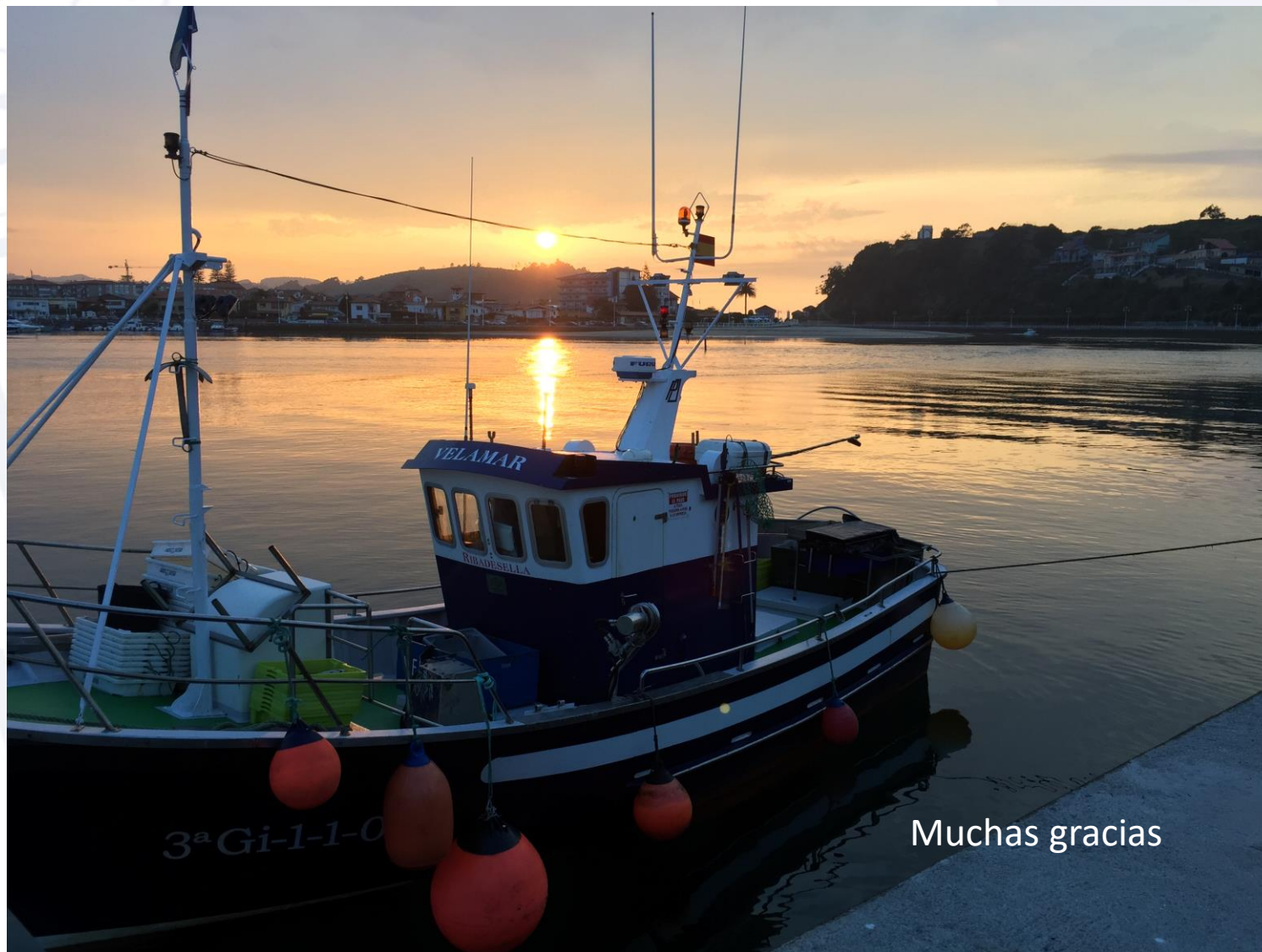




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Muchas gracias

1.INTRODUCTION



2.CURRENT INDICATIONS

3.LOW RISK DATA

4.LONG TERM DURABILITY

5.CONCLUSIONS