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Evolución y desafíos de la TAVI



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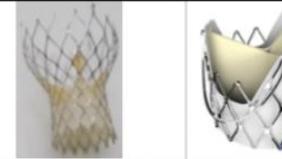
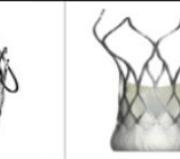
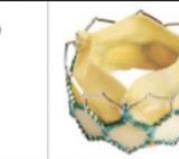
Conflictos de interes

- 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

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

August,
2017

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 trans-femoral 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

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.)

	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		+



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Figure 3 Rates of TAVR and SAVR From 2012 to 2019



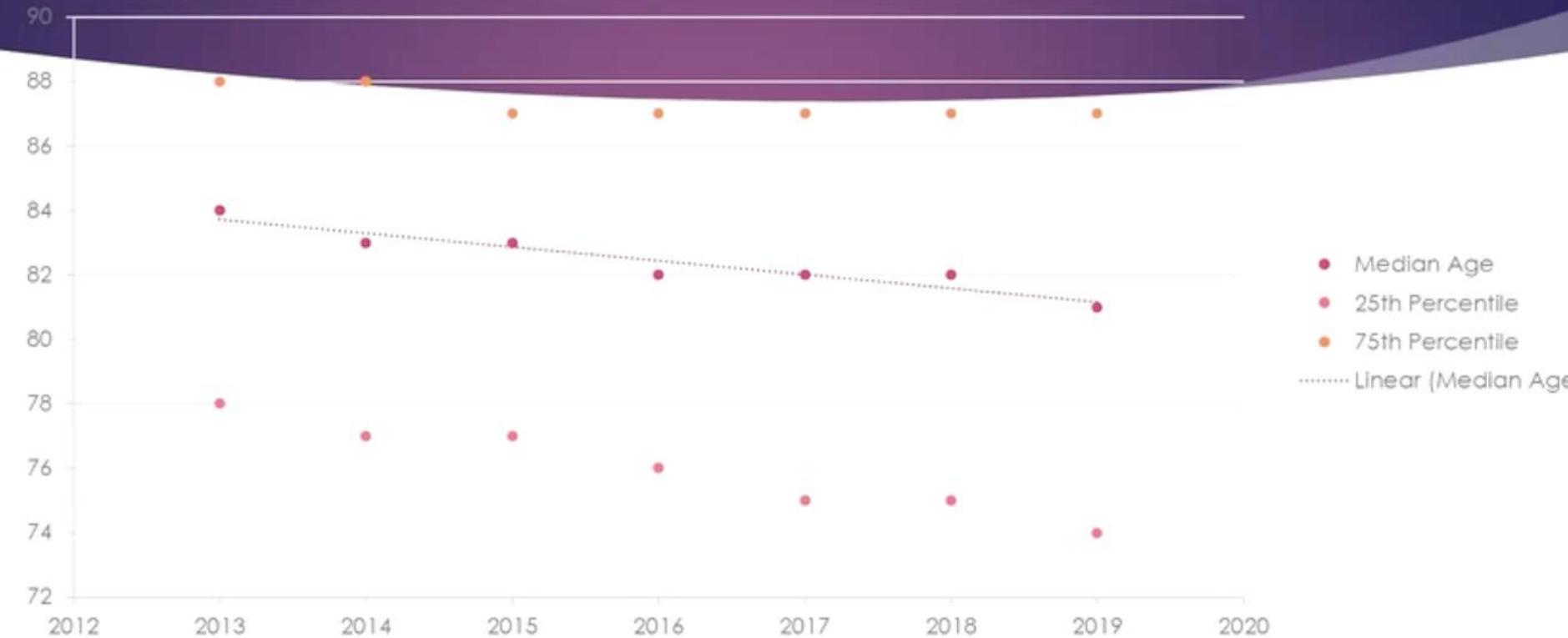


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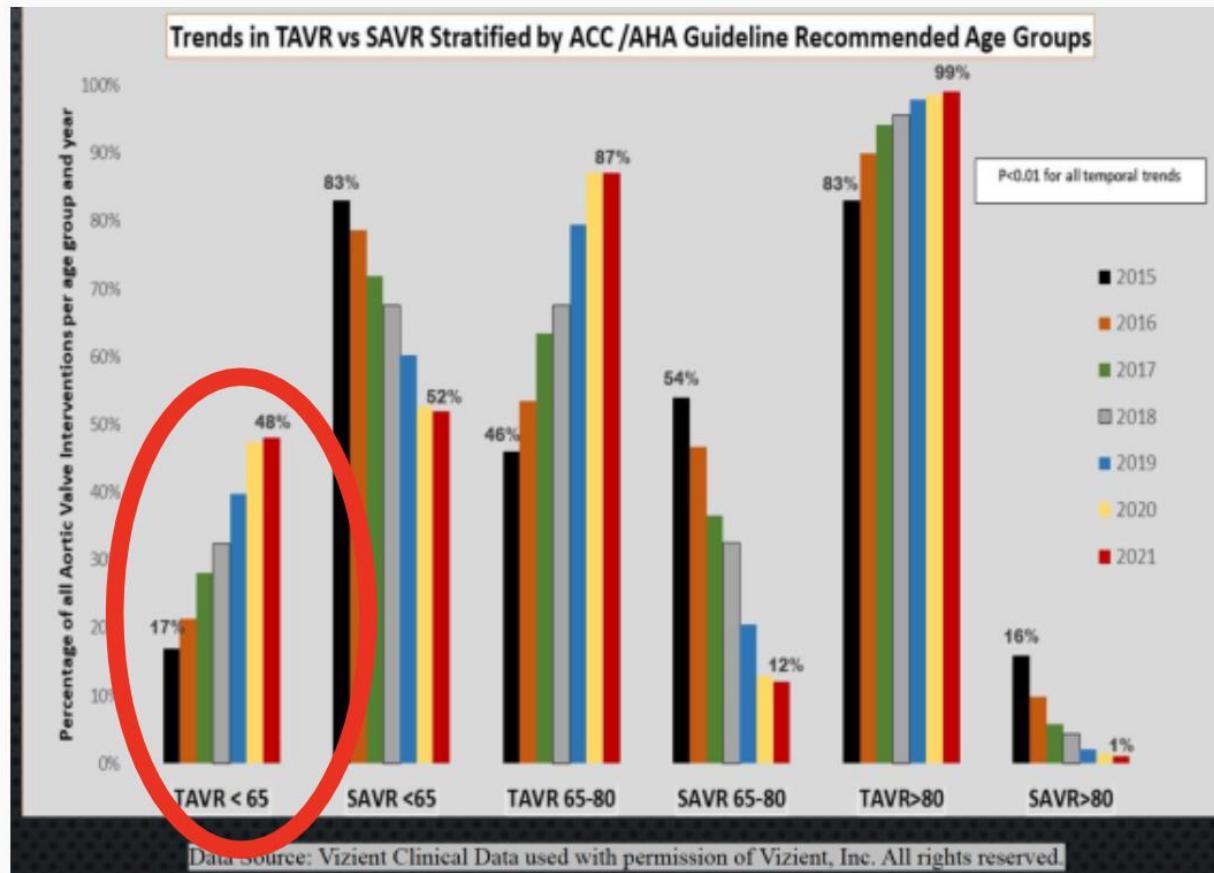
HOSPITAL
UNIVERSITARIO
CENTRAL de
ASTURIAS

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

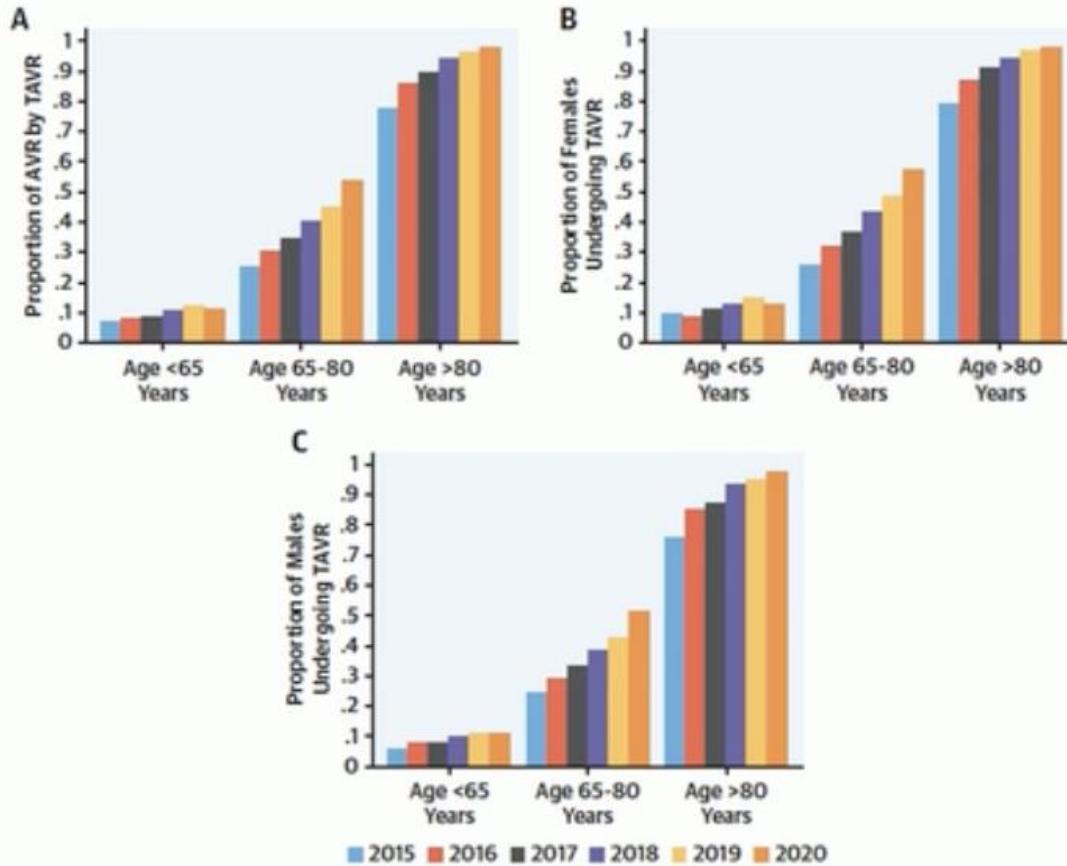


- US national database
- 279,066 patients
- Isolated AVR
- 48% of patients under 65 years had TAVI



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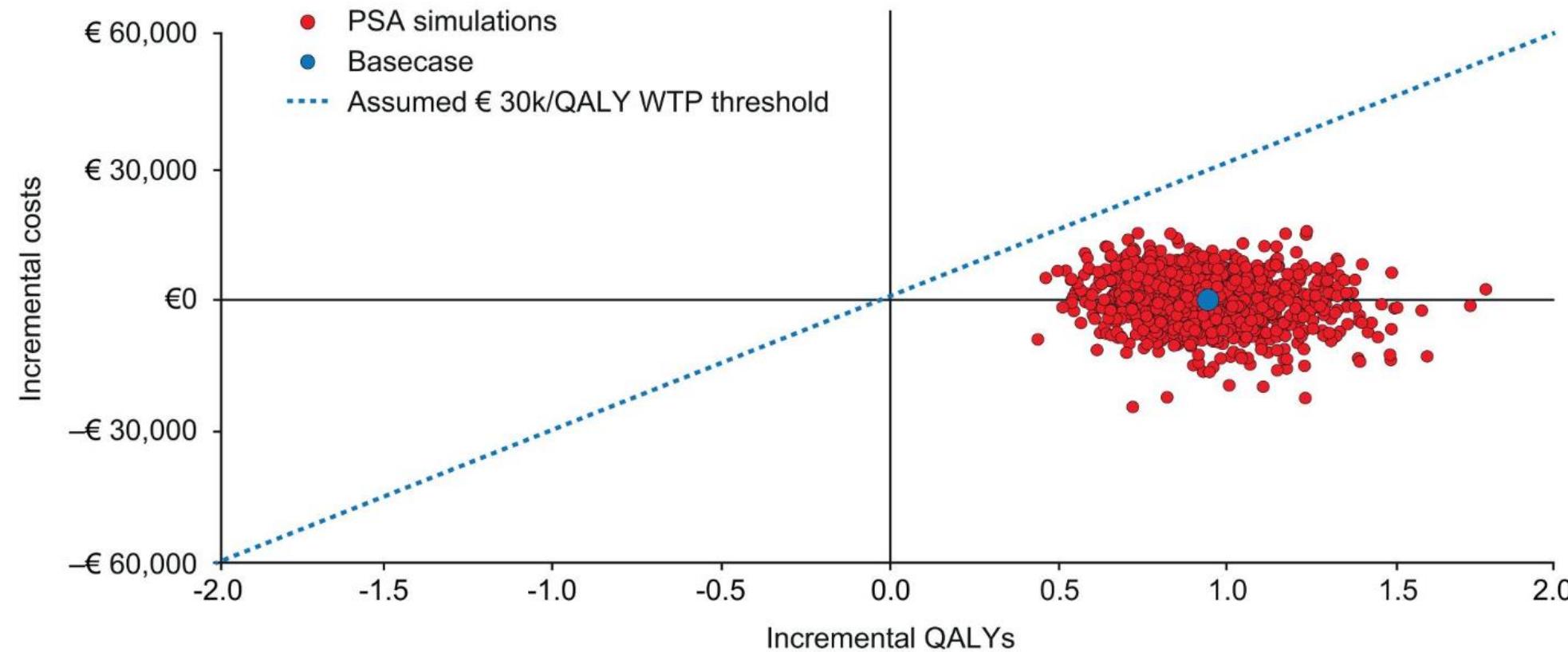
FIGURE 2 Proportion of Patients Undergoing Transcatheter Aortic Valve Replacement



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.

Graeme Prosperi-Porta et al. J Am Coll Cardiol 2023; 82:1889-1902.

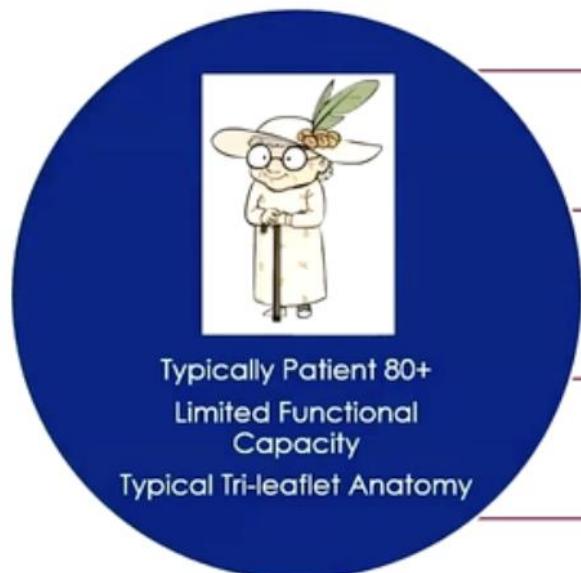
Transcatheter aortic valve implantation versus surgical aortic valve replacement in severe aortic stenosis patients at low surgical mortality risk: a cost-effectiveness analysis in Belgium





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Traditional Focus: Immediate Cure



- Mortality Rate
- Stroke Risk
- Pacemaker Need
- Quality of Life



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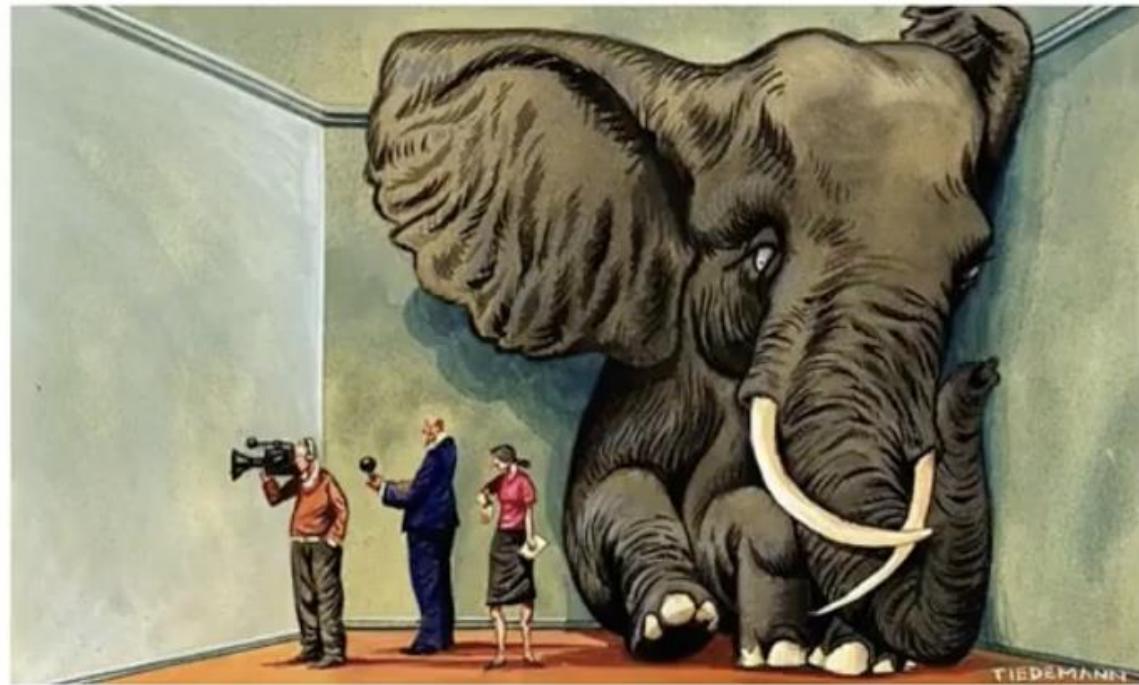
TAVI IN 2024



- 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



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- 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.



2020

2023

ESC Congress 2023
Amsterdam & Online

<p>VOL. 13,</p> <p>INTERVEN</p> <p>ulation</p> <p>HOVASCUL</p> <p>HE AMERIC</p> <p>BY ELSEVIER</p> <p>oon</p> <p>vol</p> <p>ation</p> <p>Akodad,</p> <p>L. Tang,</p> <p>MBBS, P</p> <p>Rosen, M</p> <p>Webb, MD</p> <p>ACT</p> <p>TIVES Th</p> <p>verhang,</p> <p>(LLC) tra</p> <p>ROUND</p> <p>HVs.</p> <p>DS An i</p> <p>Evolut R</p> <p>height, le</p> <p>ical con</p> <p>pectan</p> <p>expanda</p> <p>according</p> <p>valve typ</p> <p>smaller e</p> <p>(16.2% v</p> <p>($P = 0.8$)</p> <p>initial val</p> <p>residual</p> <p>(moder</p> <p>(9.1%) v</p> <p>CONCLUSI</p> <p>selected pa</p> <p>yet subsequ</p> <p>prelimin</p> <p>and more da</p> <p>© 2022 Published by Elsevier on beha</p>	<p>JACC: CARDIOPULMONARY AND VASCULAR</p> <p>© 2022 PUBLISHED BY ELSEVIER INC. ON BEHALF OF THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION</p> <p>Outcomes of Valve Implantation</p> <p>Uri Landesman, Janarthana Mohamed, Christian I. Lisa Voigt, Jules Messer, Antonio M. Nicolaïs, Marco Barf, Gidon Y. Ravid, Federico D. Vassilis C. A. Ronen Jarcho, Kolja Sievert, Sharon Braverman, Pál Maurits, Dionisia A. Nicolau, Lars L. Julia Antoniou</p> <p><i>1. San Raffaele Scientific Institute, Galvani University Hospital, Milan, Italy 2. St. Thomas' Hospital, London, United Kingdom 3. St. Thomas' Hospital, New York, NY, USA</i></p> <p><i>N. Bazzan, M. Montorfano</i></p> <p><i>This paper also includes:</i></p> <p>ABSTRACT</p> <p>BACKGROUND</p> <p>OBJECTIVE</p> <p>METHODS</p> <p>RESULTS</p> <p>CONCLUSIONS</p> <p>KEYWORDS</p> <ul style="list-style-type: none"> • coronary artery disease • coronary occlusion • TAVI <p>*Corresponding author: NY 10458, U.S.A. E-mail address: julianantoniou@nhs.uk</p>
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<p>A benefit of self-expanding stents</p> <p>Mariama Darren M. Gilbert H. John G. W.</p> <p><i>1. Centre for Cardiovascular Laboratory, Paris Sud, A Rigshospitalet, Denmark; 2. Hadassah Hospital, Jerusalem, Israel; 3. Béclère Hospital, Nanterre, France</i></p> <p><i>This paper also in</i></p>	<h2>Feasibility of reanalysis</h2> <p>Kendra J. Gilbert H. L. Lindsay M. L. G. Michael D. John K. Forrester</p> <p><i>1. Division of Cardiology, Emory University, Atlanta, GA, USA; 2. Department of Radiology, Center for Heart and Vascular Disease, Interventional Cardiology, University of Michigan, Ann Arbor, MI, USA; 3. Department of Radiology, Atlanta, GA, USA</i></p> <p>KEYWORDS</p> <ul style="list-style-type: none"> • aortic stenosis • TAVI • valve-in-valve
<p>JACC: © 2023 PUBLISHER</p> <p>NEW</p> <p>STRUCTURE</p> <p>EXPLORATION</p> <p>TRAILBLAZERS</p> <p>MICROREVIEWS</p> <p>INTERVIEW</p>	

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE
CLINICAL RESEARCH

Redo-TAVI in self-expanding Evolut valves: a CT
Redo-Transcatheter Aortic Valve Implantation Using
the SAPIEN 3/Ultra Transcatheter Heart Valves—
Expert Consensus on Procedural Planning and
Techniques

CARDIOVASCULAR INTERVENTIONS
BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER

VOL. 16, NO. 8, 2023

EuroIntervention

Check for updates

RESEARCH PAPER

STRUCTURAL

Explant vs Redo-TAVR After
Transcatheter Valve Failure

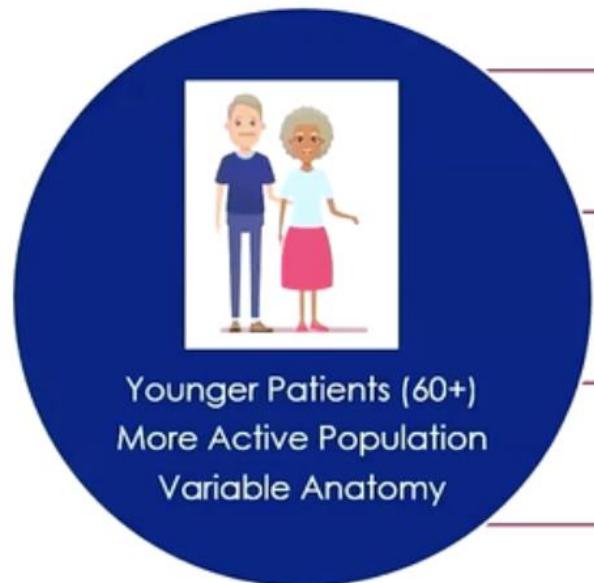
Long-Term Outcomes From the EXPLANTORREDO-TAVR
International Registry

Mark H.L. Tang, MD, MSc, MBA,^{a,*} Syed Zaid, MD,^{b,*} Neal S. Kleiman, MD,^b Sachin S. Goel, MD,^b Chi Fukuhara, MD,^c Mateo Marin-Cuartas, MD,^d Philipp Kiefer, MD,^d Mohamed Abdel-Wahab, MD,^d Steve Backer, MD,^e Lars Sondergaard, MD,^f Shekhar Saha, MD,^f Christian Hagl, MD,^g Michael Wyler von Ballmoos, MD, PhD, MPH,^h Oliver Bhadra, MD,^h Lenard Conradi, MD,^h Kendra J. Grubb, MD, MHA,ⁱ Shih, MD,^j J. Michael DiMaio, MD,^j Molly Szerlip, MD,^j Keti Vitanova, MD,^k Hendrik Ruge, MD,^k Unbehauen, MD,^l Jorg Kempfert, MD, PhD,^l Luigi Pirelli, MD,^m Chad A. Kliger, MD,^m Nicolas Van Mieghem, MD, PhD,ⁿ Thijmen W. Hokken, MD,ⁿ Rik Adrichem, MD,ⁿ Thomas Modine, MD, PhD, MBA,^o Corona, MD,^o Lin Wang, MD,^p George Petrossian, MD,^p Newell Robinson, MD,^p David Meier, MD,^q G. Webb, MD,^q Anson Cheung, MD,^q Basel Ramlawi, MD,^r Howard C. Herrmann, MD,^s Ash D. Desai, MD, PhD,^t Martin Andreas, MD, PhD,^t Markus Mach, MD,^t Ron Waksman, MD,^u Brian C. Schults, MD,^v Hasan Ahmad, MD,^v Joshua B. Goldberg, MD,^v Arnar Geirsson, MD,^w John K. Forrest, MD,^w Denti, MD,^x Igor Belluschi, MD,^x Walid Ben-Ali, MD, PhD,^y Anita W. Asgar, MD,^y Emanuele Taramasso, MD, PhD,^z Joshua D. Rovin, MD,^{aa} Marco Di Eusanio, MD,^{bb} Andrea Colli, MD,^{cc} Yoshi Kaneko, MD,^{dd} Tamim N. Nazif, MD,^{ee} Martin B. Leon, MD,^{ee} Vinayak N. Bapat, MBBS, MS, MClinB,^{ff} Michael J. Mack, MD,^{ff} Michael J. Reardon, MD,^{ff} Janarthanan Sathananthan, MBClinB, MPH^{ff}



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Evolution of Focus: Lifetime Management



Durability for
Increased Longevity



Optimal
Hemodynamics



Consideration
of ViV



Coronary
Access



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Lifetime Management of Aortic Disease in 2023

Bioprosthetic Valve Durability



Hemodynamic
Deterioration

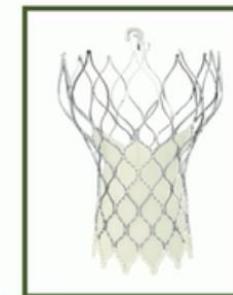
Degeneration

Failure



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Longest Follow-up of Landmark Trials of TAVR versus SAVR



10 years

5 years

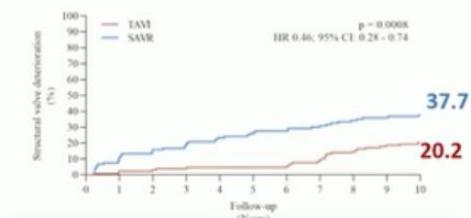
4 years

1 year

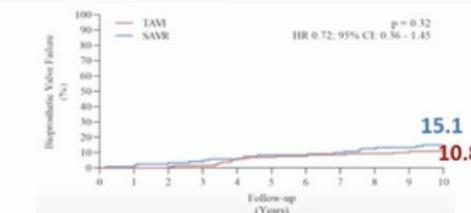
- Notion *ESC Congress 2023*
- PARTNER 1A
- Corevalve High risk
- PARTNER 2A
- SURTAVI
- PARTNER 3
- Evolut Low-Risk
- UK-TAVI (all THVs)

Notion Trial – 10y

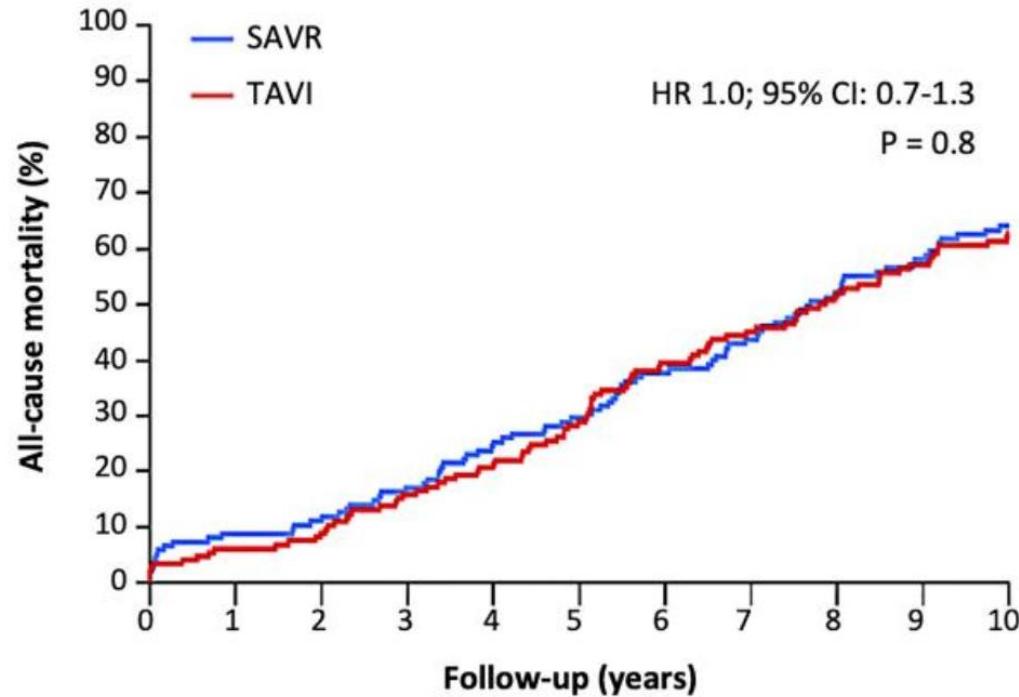
SVD - p<0.001



BVF - p= NS

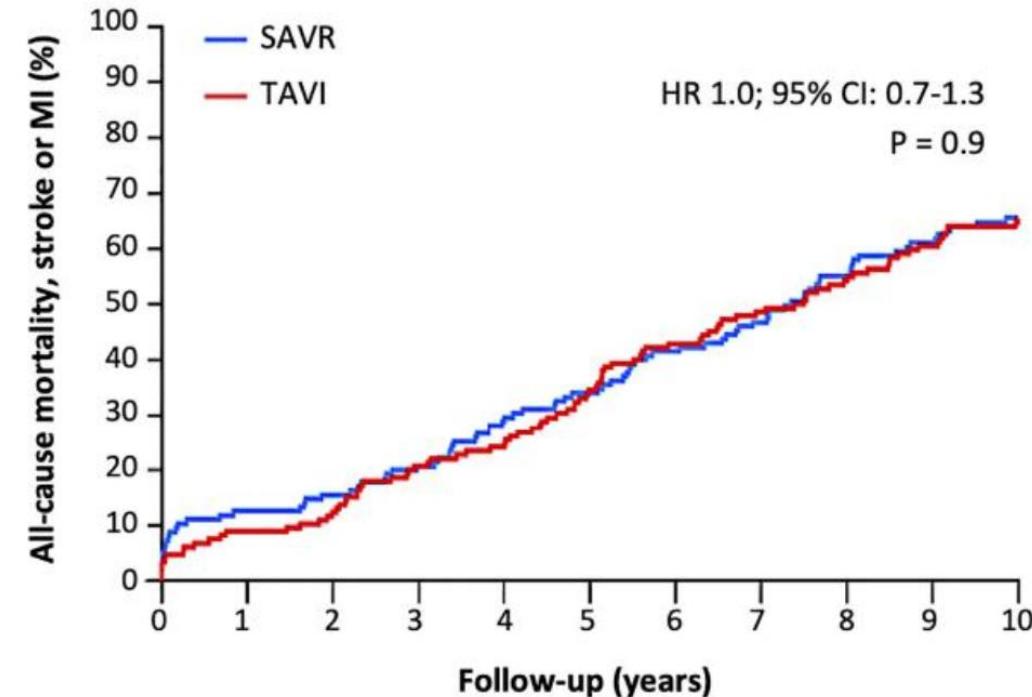


Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial



Patients at risk

Follow-up (years)	SAVR (n)	TAVI (n)
0	135	145
1	123	136
2	112	132
3	102	122
4	95	115
5	86	101
6	78	86
7	75	78
8	64	69
9	56	61
10	48	53



Patients at risk

Follow-up (years)	SAVR (n)	TAVI (n)
0	135	145
1	122	133
2	118	128
3	110	116
4	99	110
5	92	93
6	80	81
7	71	73
8	60	65
9	52	56
10	46	49

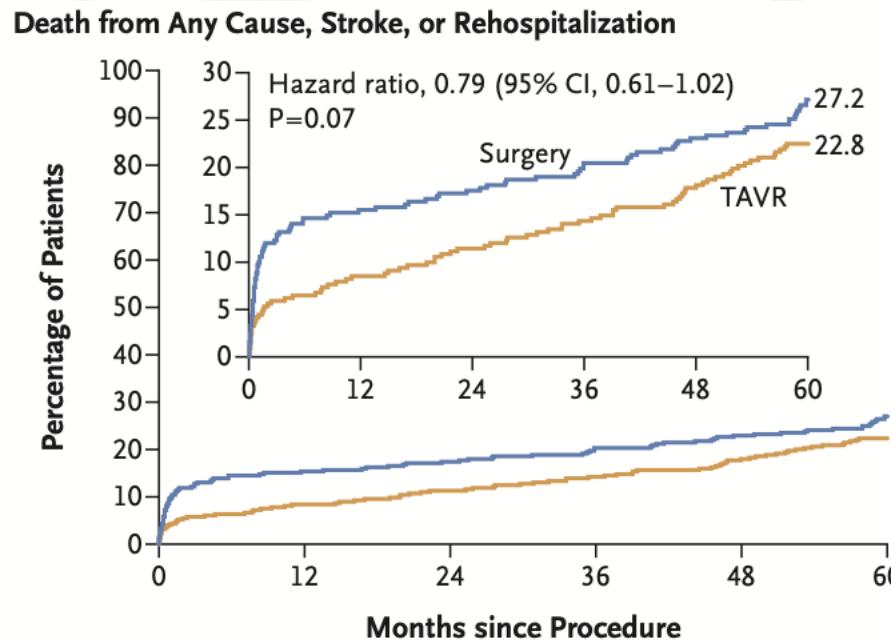
Figure 1 NOTION—clinical outcomes up to 10 years of follow-up: all-cause mortality and all-cause mortality, stroke, or myocardial infarction (MI). TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement; MI, myocardial infarction. Hazard ratio (HR); 95% confidence interval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



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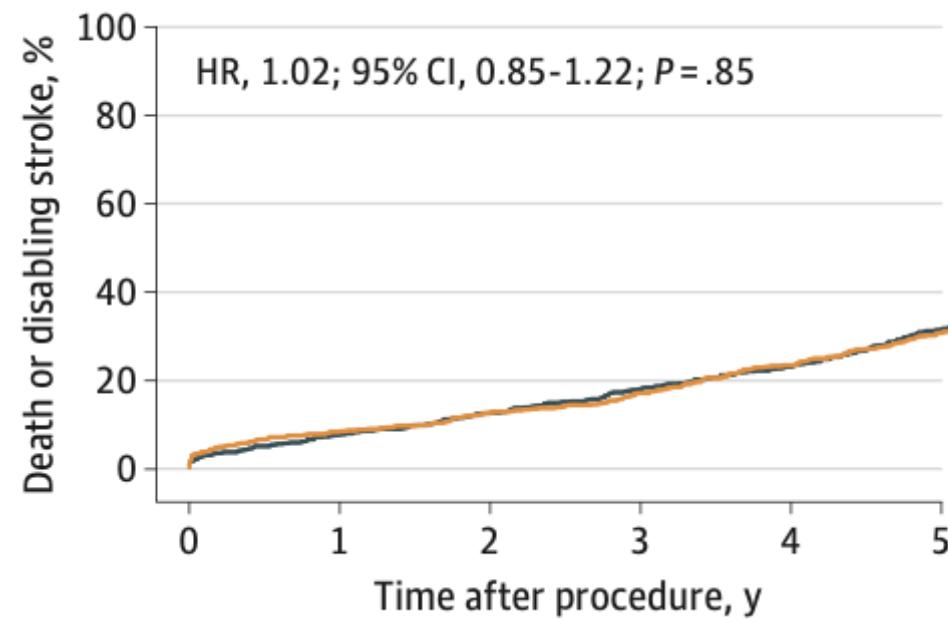
ORIGINAL ARTICLE

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



PARTNER 5 AÑOS

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

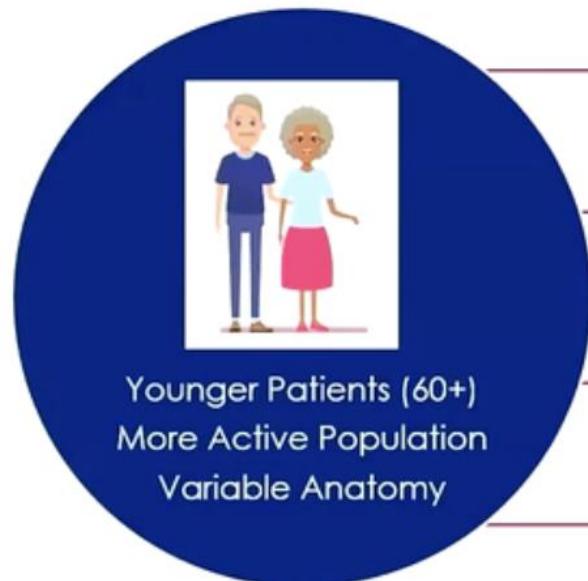


SURTAVI 5 AÑOS



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Durability for
Increased Longevity



Optimal
Hemodynamics



Consideration
of ViV



Coronary
Access

Echocardiographic assessment of transprosthetic mean gradients and paravalvular regurgitation

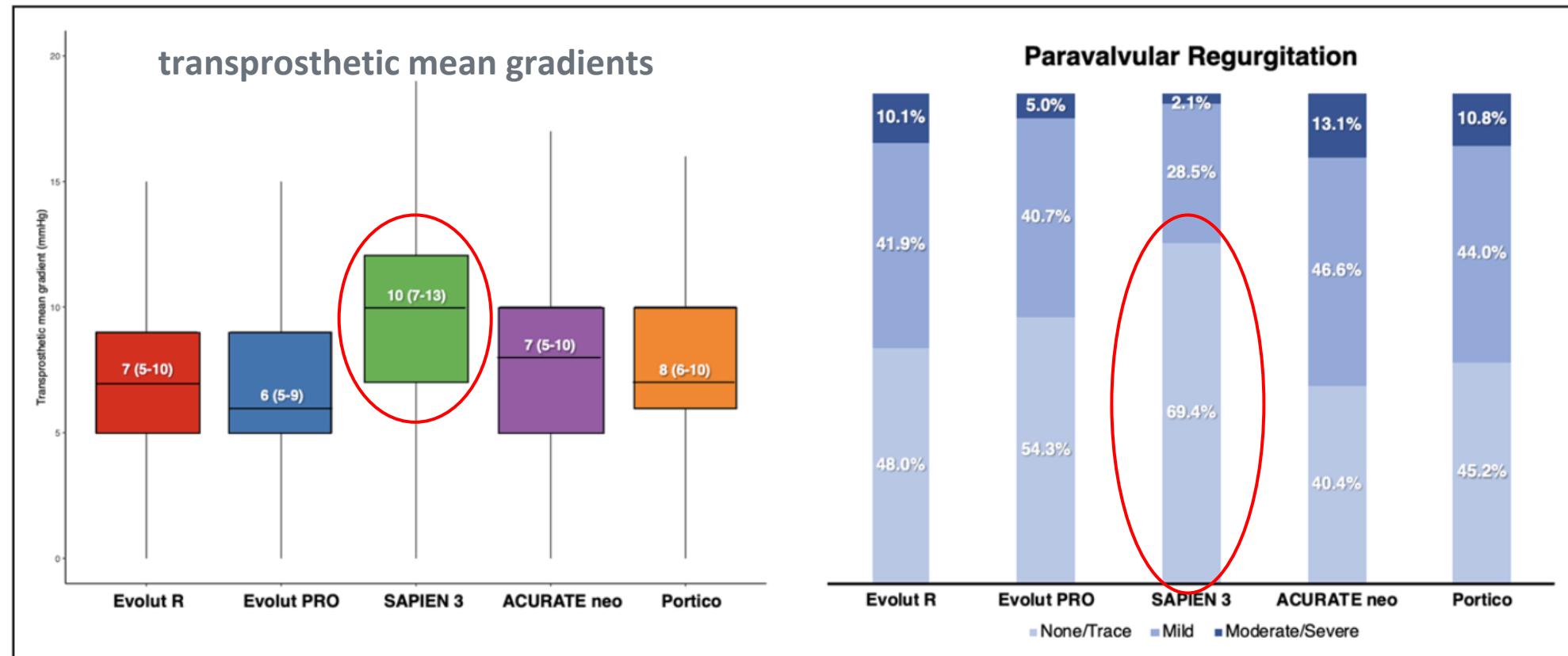


Figure 2. Adjusted echocardiographic assessment of transprosthetic mean gradients and paravalvular regurgitation after transcatheter aortic valve implantation.



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Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

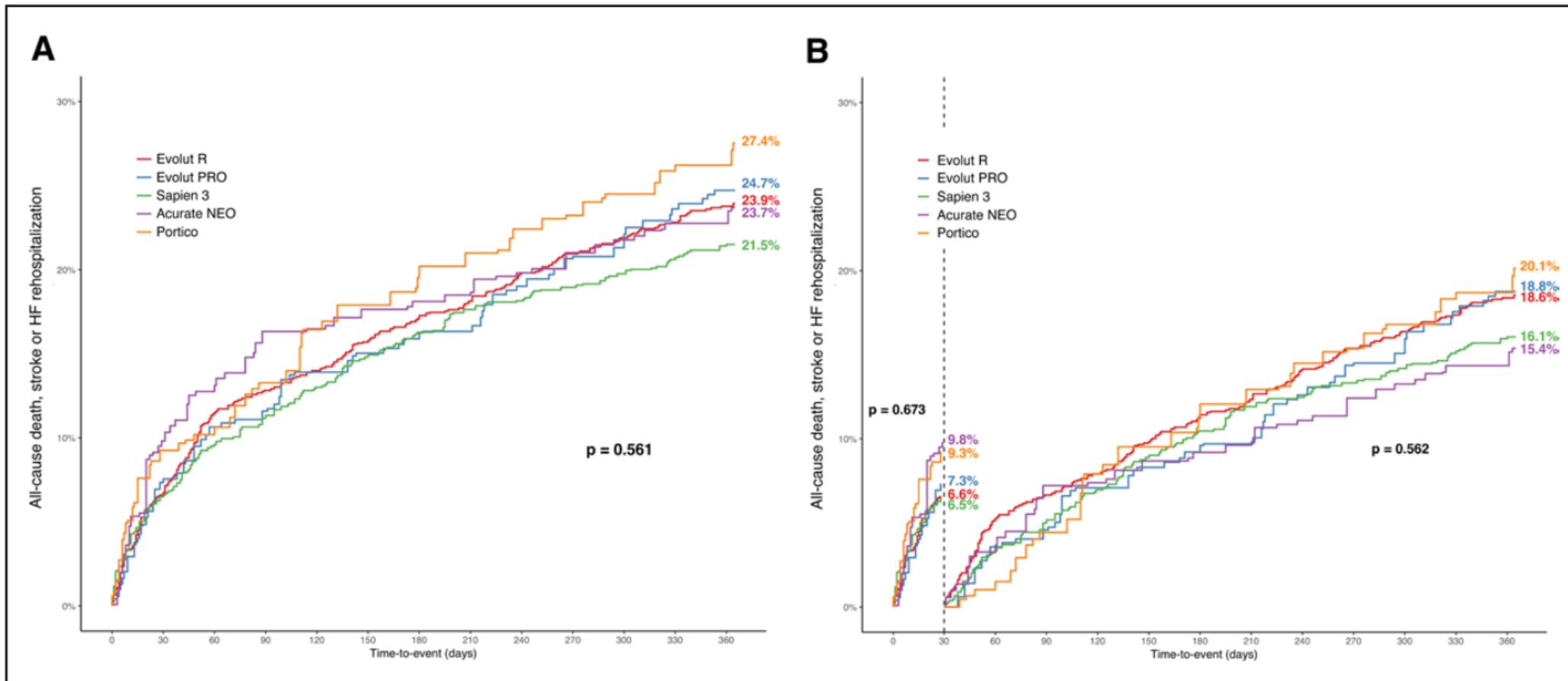
Real-World Multiple Comparison of Transcatheter Aortic Valves: Insights From the Multicenter OBSERVANT II Study

Giuliano Costa , MD; Marco Barbanti , MB; Stefano Rosato , MSc; Fulvia Seccareccia, MSc; Giuseppe Tarantini , MD, PhD; Massimo Fineschi, MD; Stefano Salizzoni , MD; Roberto Valvo, MD; Corrado Tamburino, MD, PhD; Fausto Biancari , MD; Giovanni Baglio , MD; Gennaro Santoro, MD; Massimo Baiocchi , 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



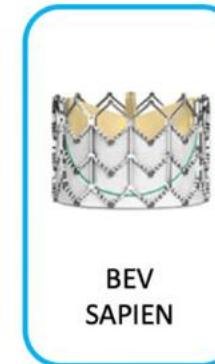
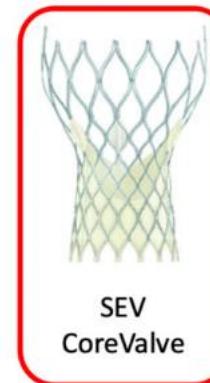
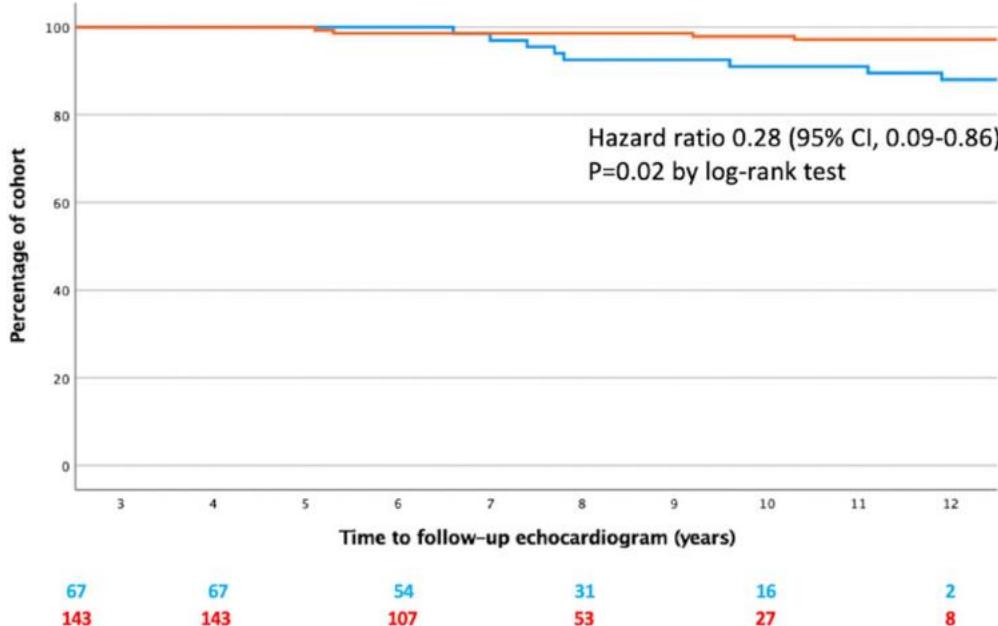
ACURATE neo

	SAPIEN	Evolut	p-valve	ACURATE	p-valve
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.

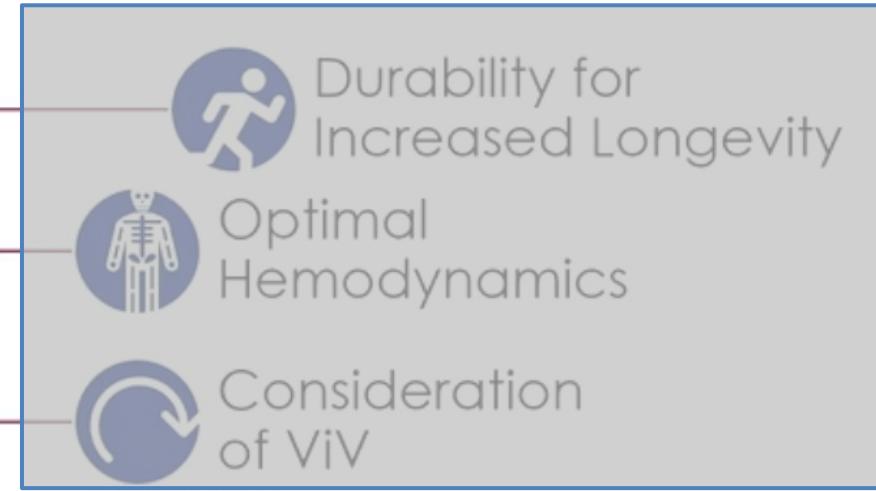
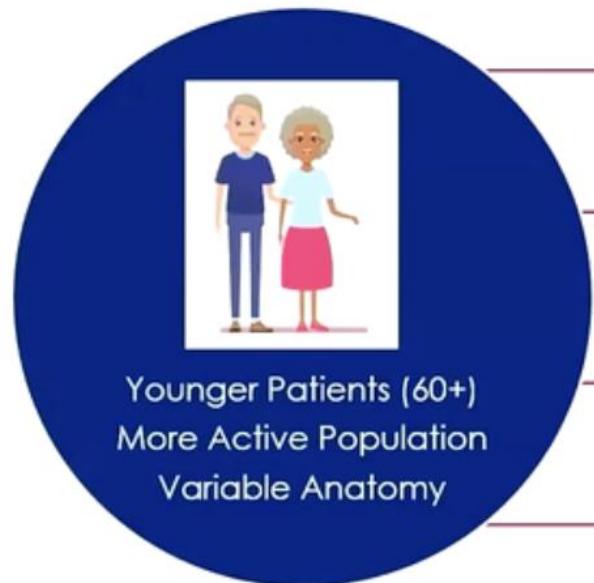
KM curves comparing balloon-expandable (SAPIEN; blue) and self-expanding (CoreValve; red) valves with respect to freedom from severe SVD over time





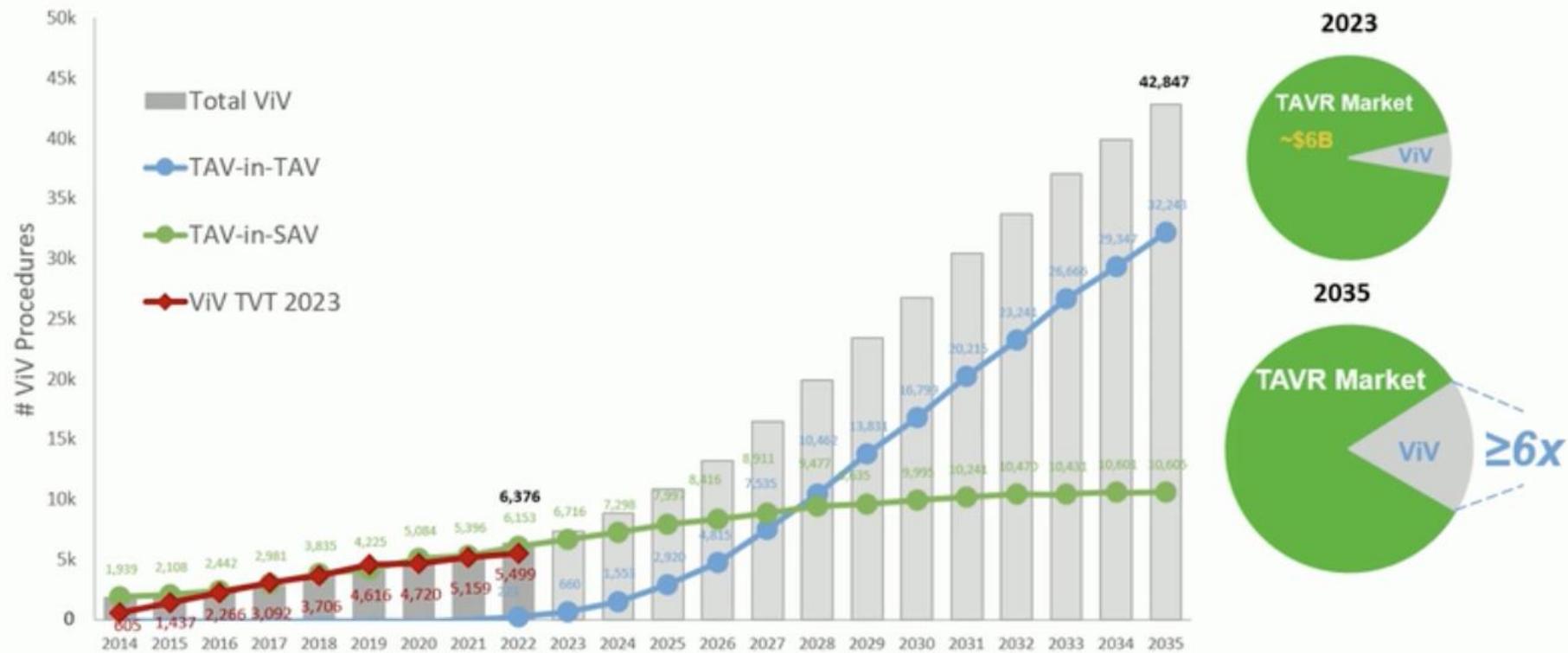
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Evolution of Focus: Lifetime Management





US ViV Market Forecast until 2035



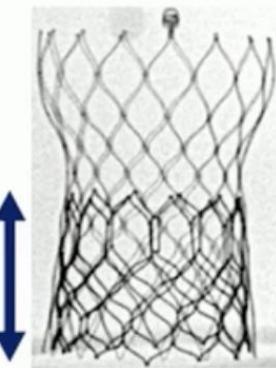


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What's important in RE-Do TAVR?

NEOSKIRT

S3 Outflow at Node 5



23.0 mm

LEAFLET OVERHANG

S3 Outflow at Node 5



59% leaflet
overhang

INDEX THV EXPANSION

S3 Outflow at Node 5



+2.0 mm

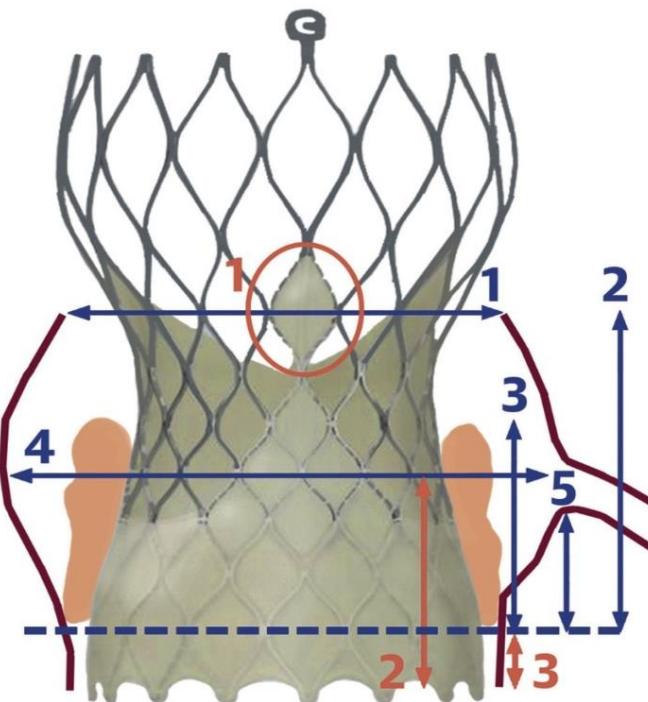
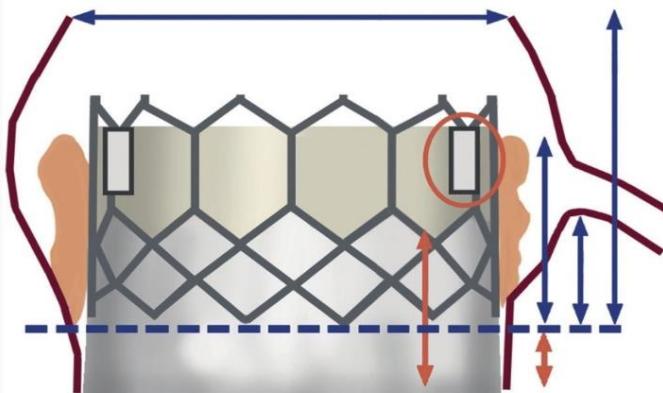
Tarantini G, et al. JACC Cardiol Intv 2022

Tarantini et al. Am J Cardiol 2023;192:228–244)



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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

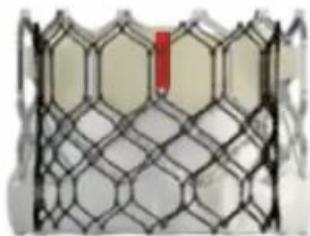
1. Commissural tab orientation
2. Sealing skirt height
3. Valve implant depth



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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



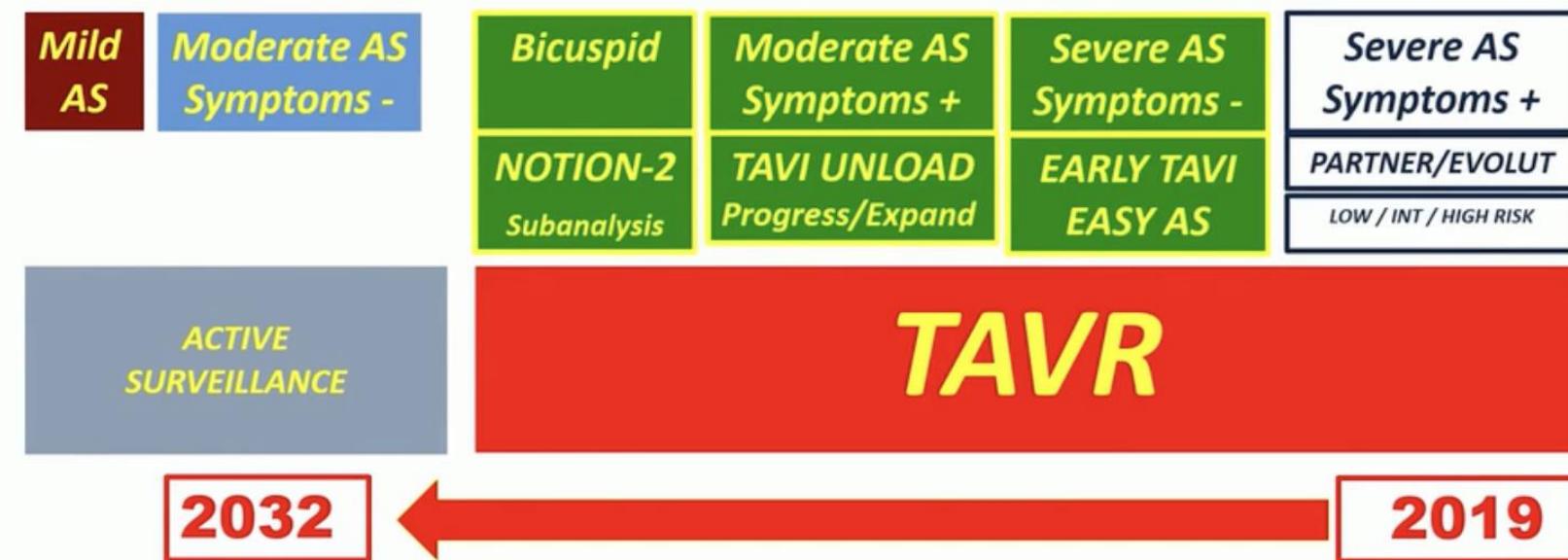
CT DASI Simulations: Sapien-in-Evolut

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



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Aortic Stenosis Redefined: *Functional classification / New trigger points*





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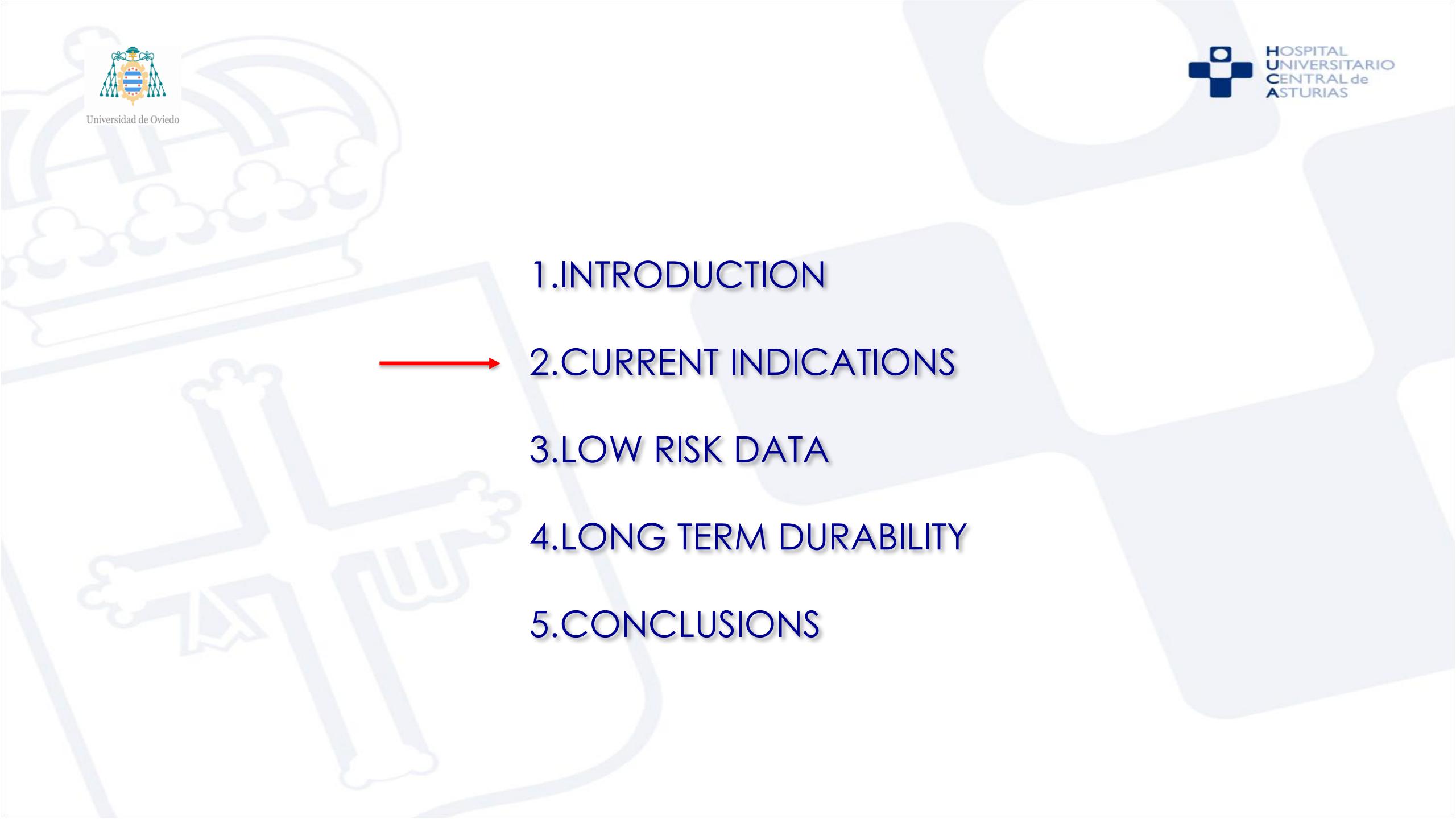
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Muchas gracias



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- 
- A faint watermark of a skull and crossbones is visible in the background of the slide.
- 1. INTRODUCTION
 - 2. CURRENT INDICATIONS
 - 3. LOW RISK DATA
 - 4. LONG TERM DURABILITY
 - 5. CONCLUSIONS
- A red arrow points from the text "2. CURRENT INDICATIONS" towards the bottom left of the slide.