



Implante Percutáneo de Prótesis Aórtica (TAVI)

“Cuestiones en Debate”

Hospital Álvaro Cunqueiro

Abril / 2022

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SERVIZO
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ÁREA SANITARIA DE VIGO



Área de Cardiología
Complejo Hospitalario
Universitario de Vigo

**Ningún conflicto de
interés en relación al
tema de esta
presentación**



Agenda

1 Aspectos Consolidados y No Debatidos en TAVI

2 El problema de la Epidemia de Estenosis Aórtica

3 Aspectos en debate en el tratamiento de la EAo

4 Conclusiones

Agenda

1

Aspectos Consolidados y No Debatidos en TAVI



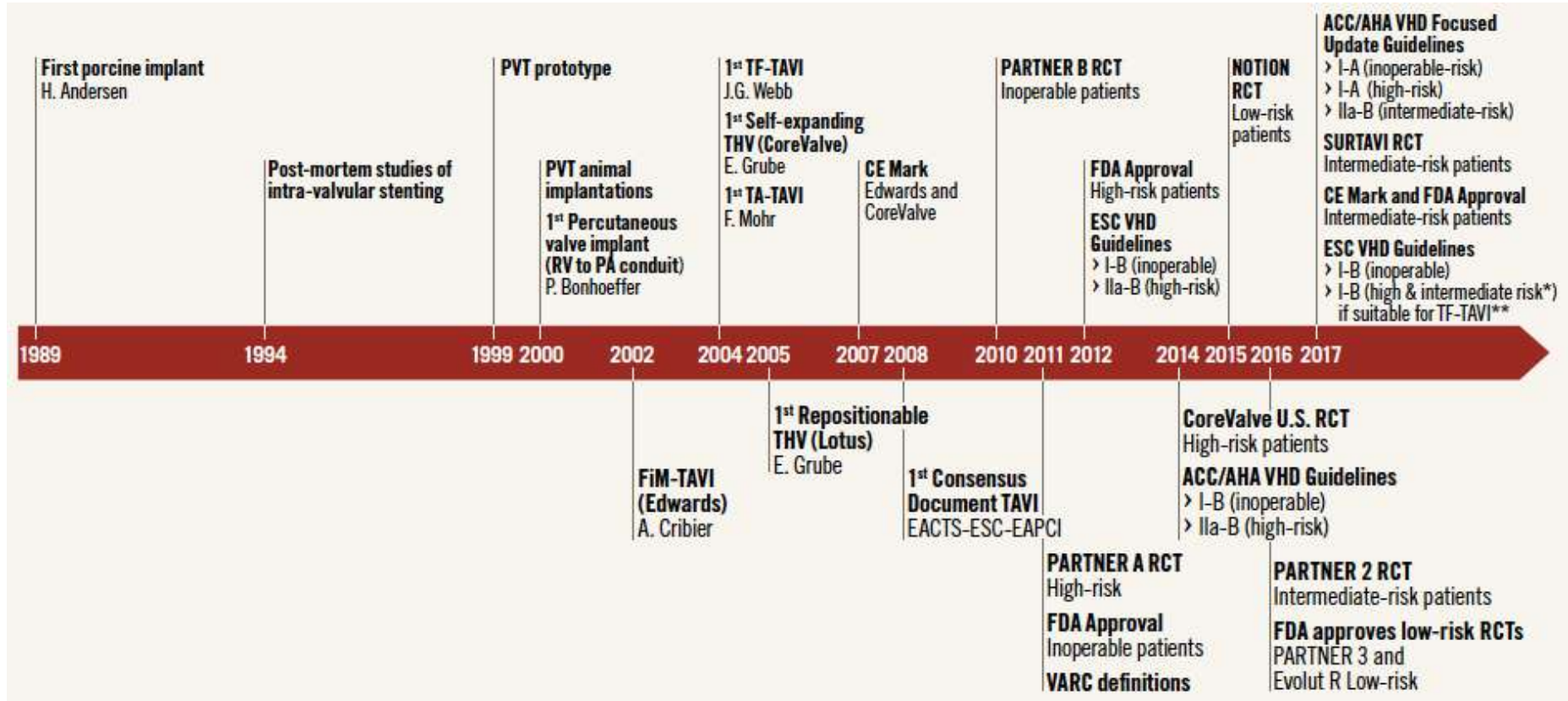
Agenda

1 Aspectos Consolidados y No Debatidos en TAVI

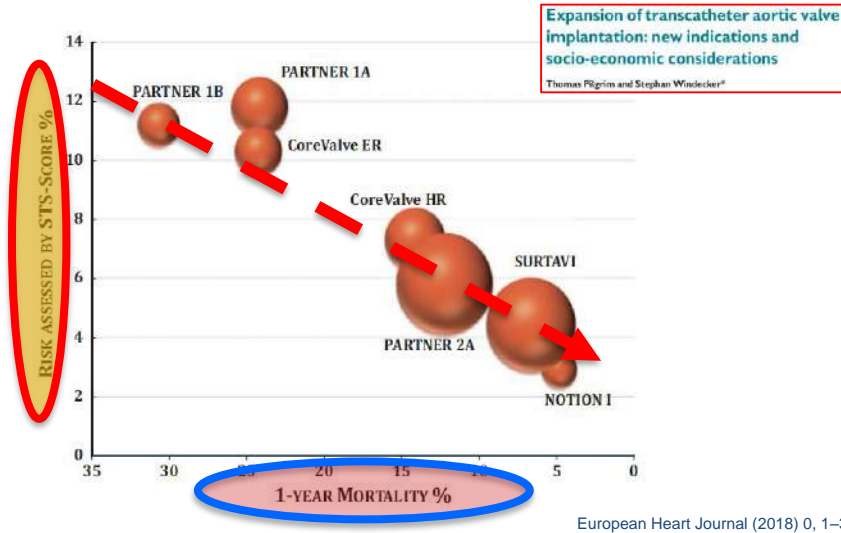
1.1 Efectividad y Seguridad del Procedimiento de TAVI



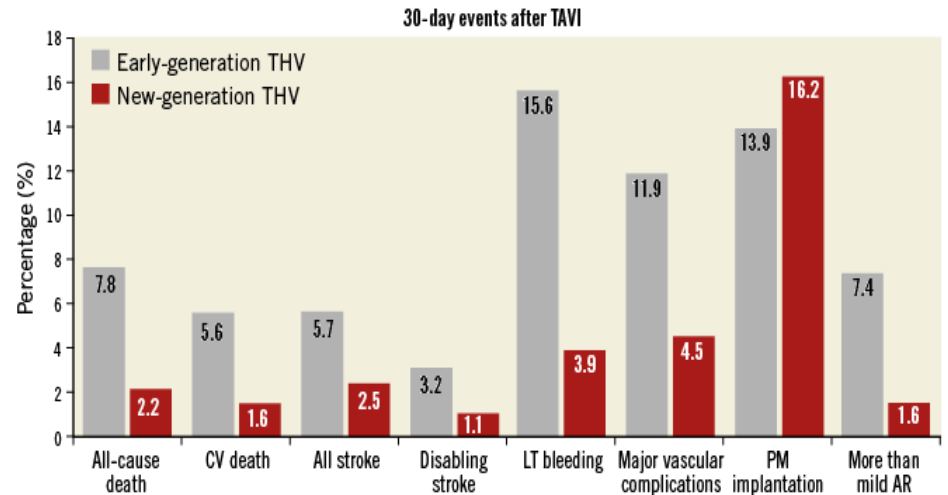
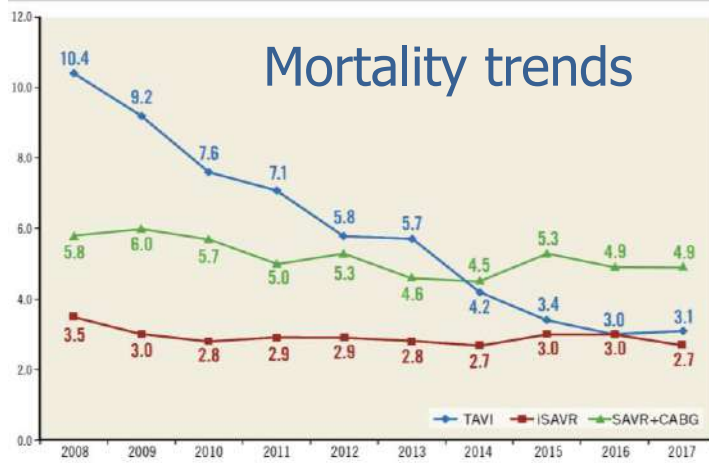
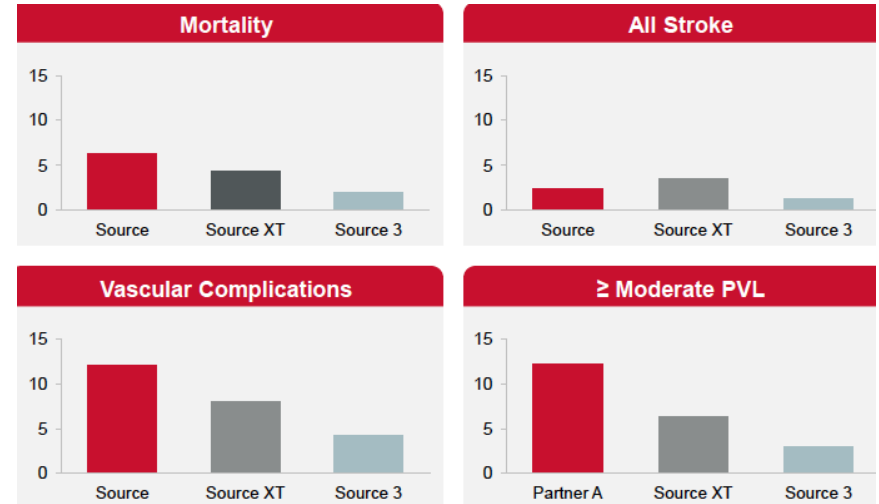
Evolución Evidencia Científica de la TAVI



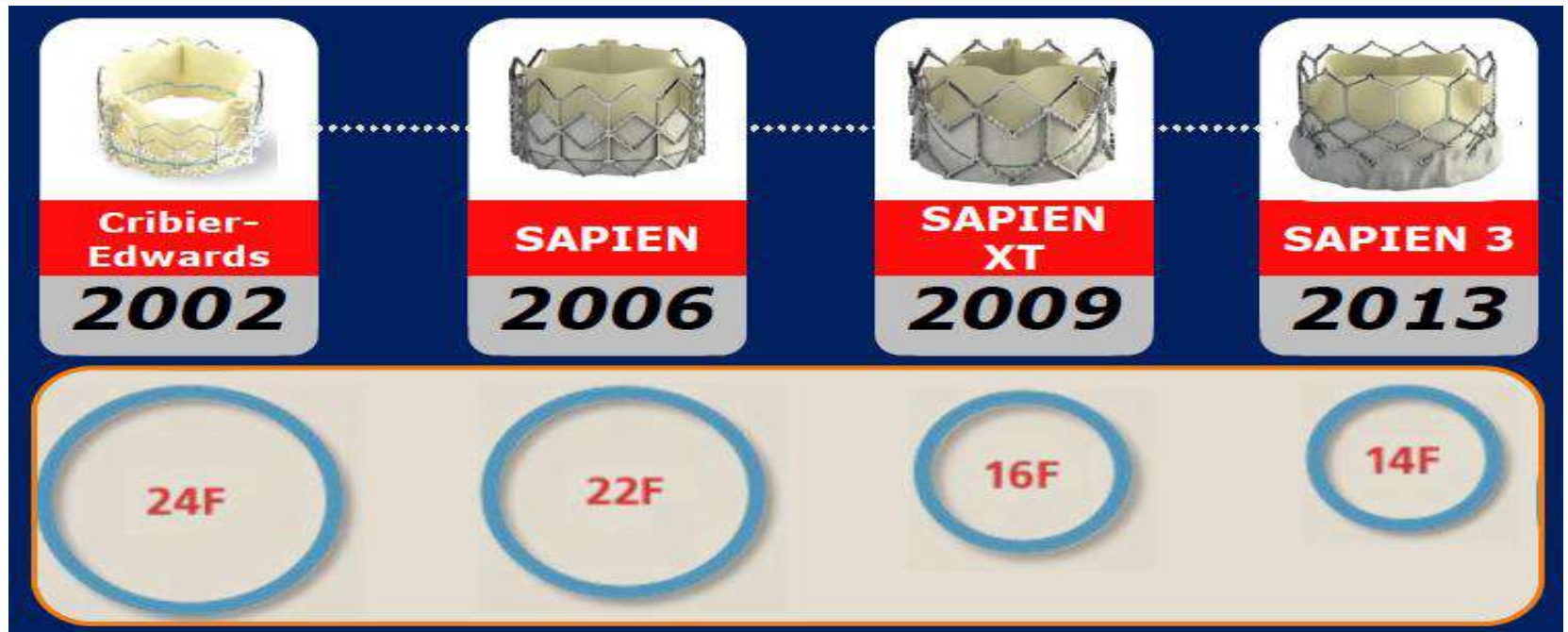
Evolución Evidencia Científica de la TAVI



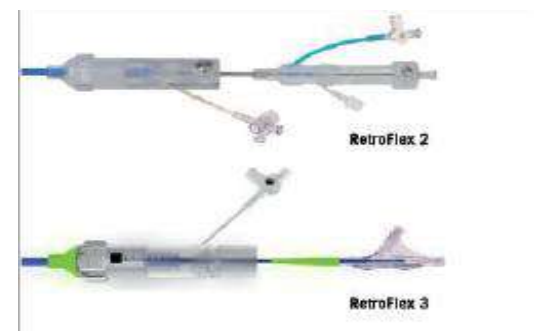
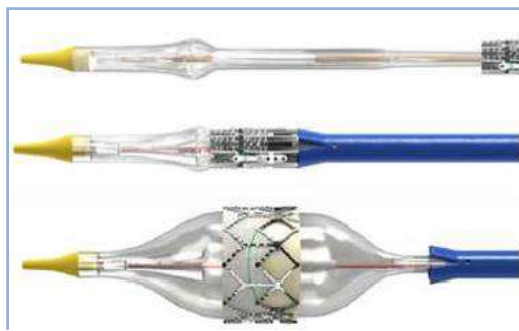
European Heart Journal (2018) 0, 1-3



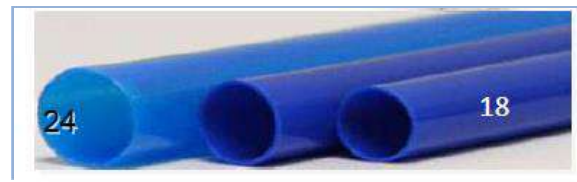
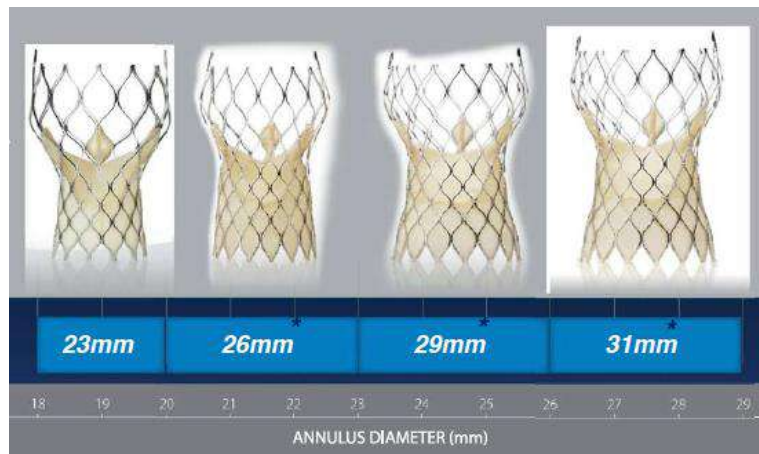
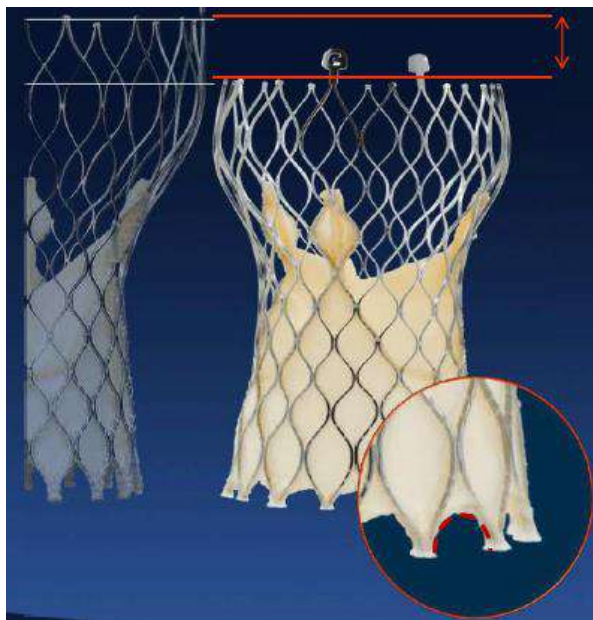
Evolución Tecnológica de la TAVI



Tamaños disponibles: 23-26 mm 23-26-29 mm 20-23-26-29 mm



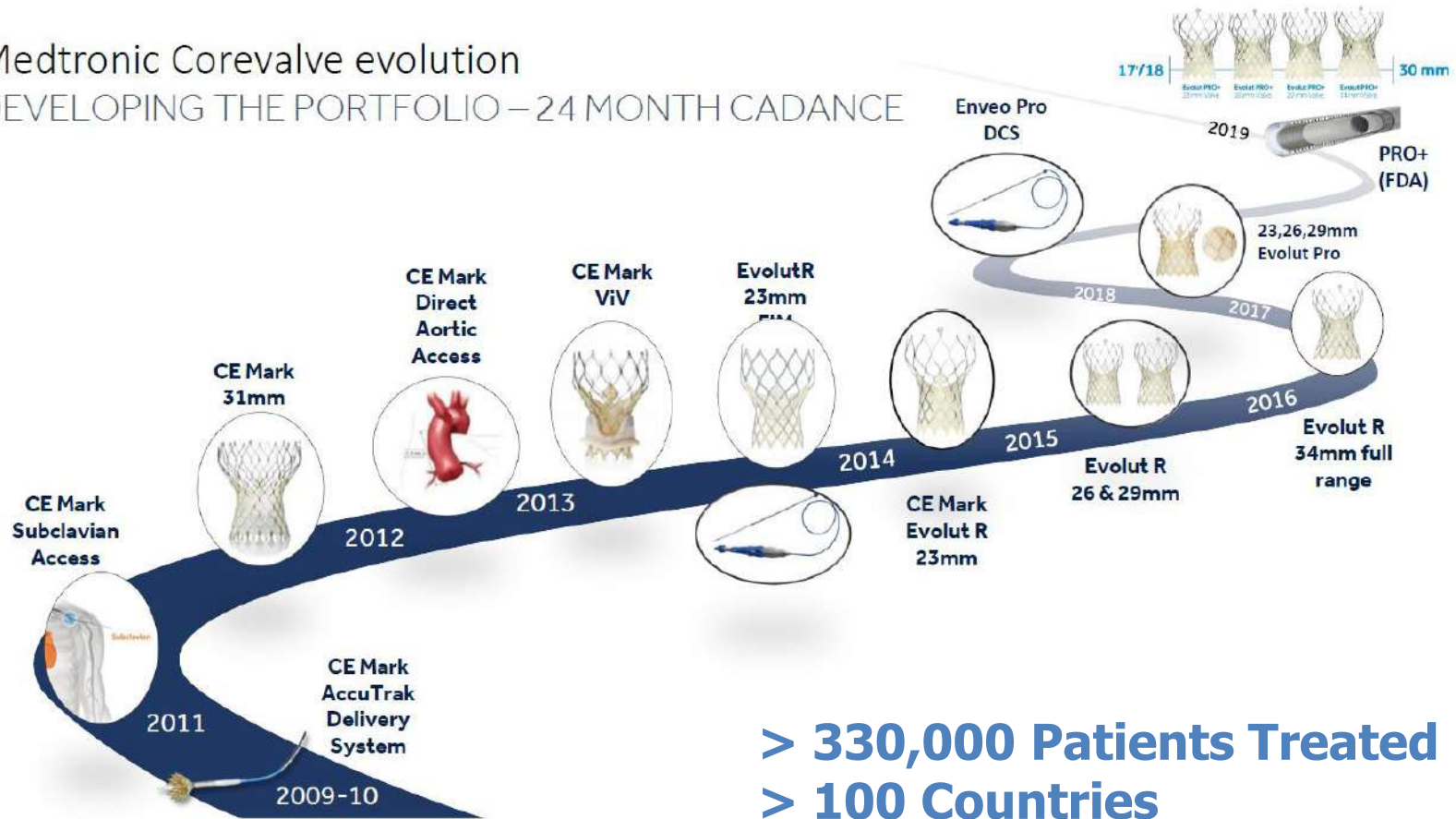
Evolución Tecnológica de la TAVI



Evolución Tecnológica de la TAVI

Medtronic Corevalve evolution

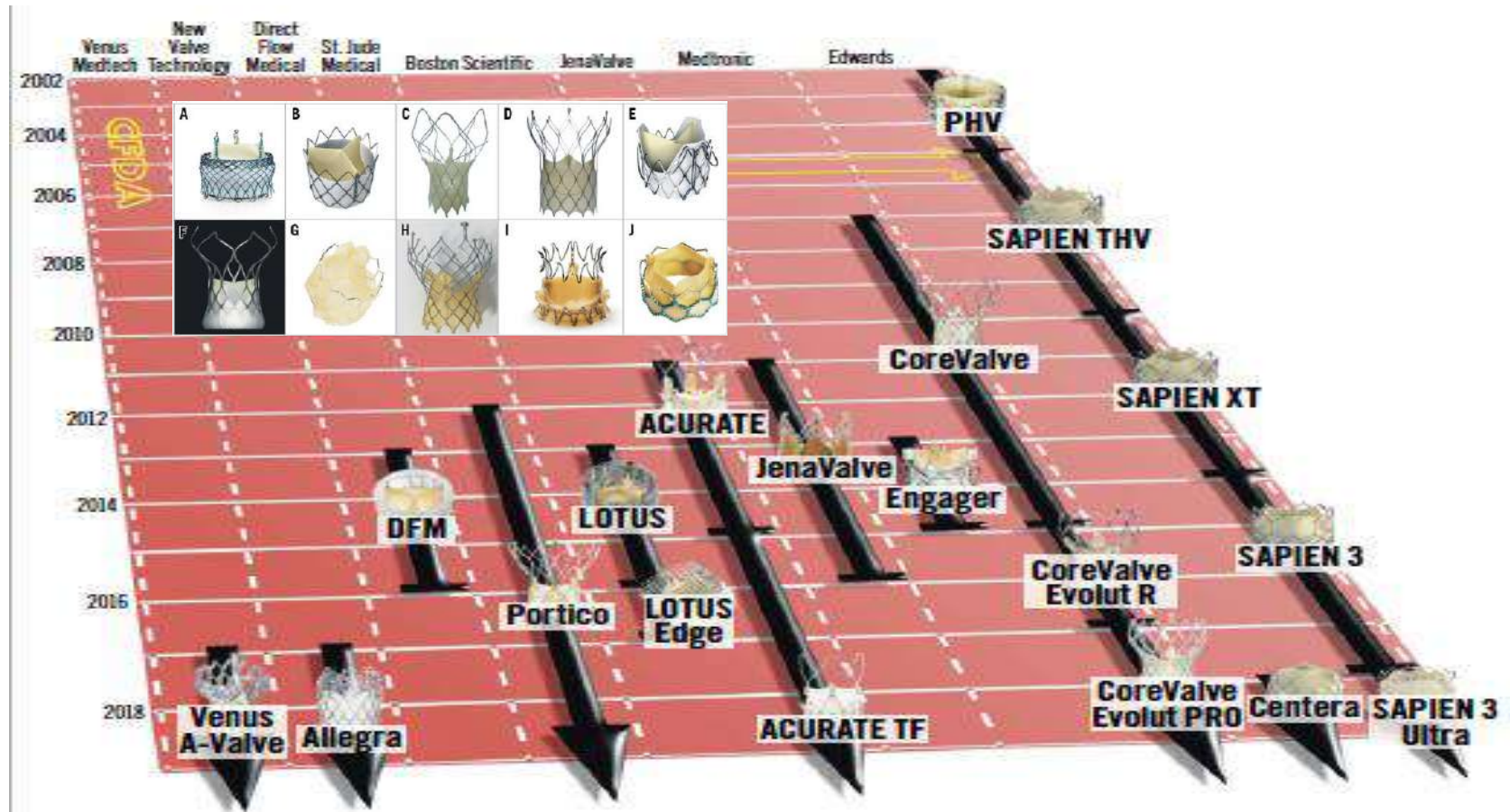
DEVELOPING THE PORTFOLIO – 24 MONTH CADANCE



- > 330,000 Patients Treated
- > 100 Countries
- > 2,000 Centers

Evolución Tecnológica de la TAVI

The evolution of device technology in transcatheter aortic valve implantation



EuroIntervention 2019;14:e1826-e1833

Agenda

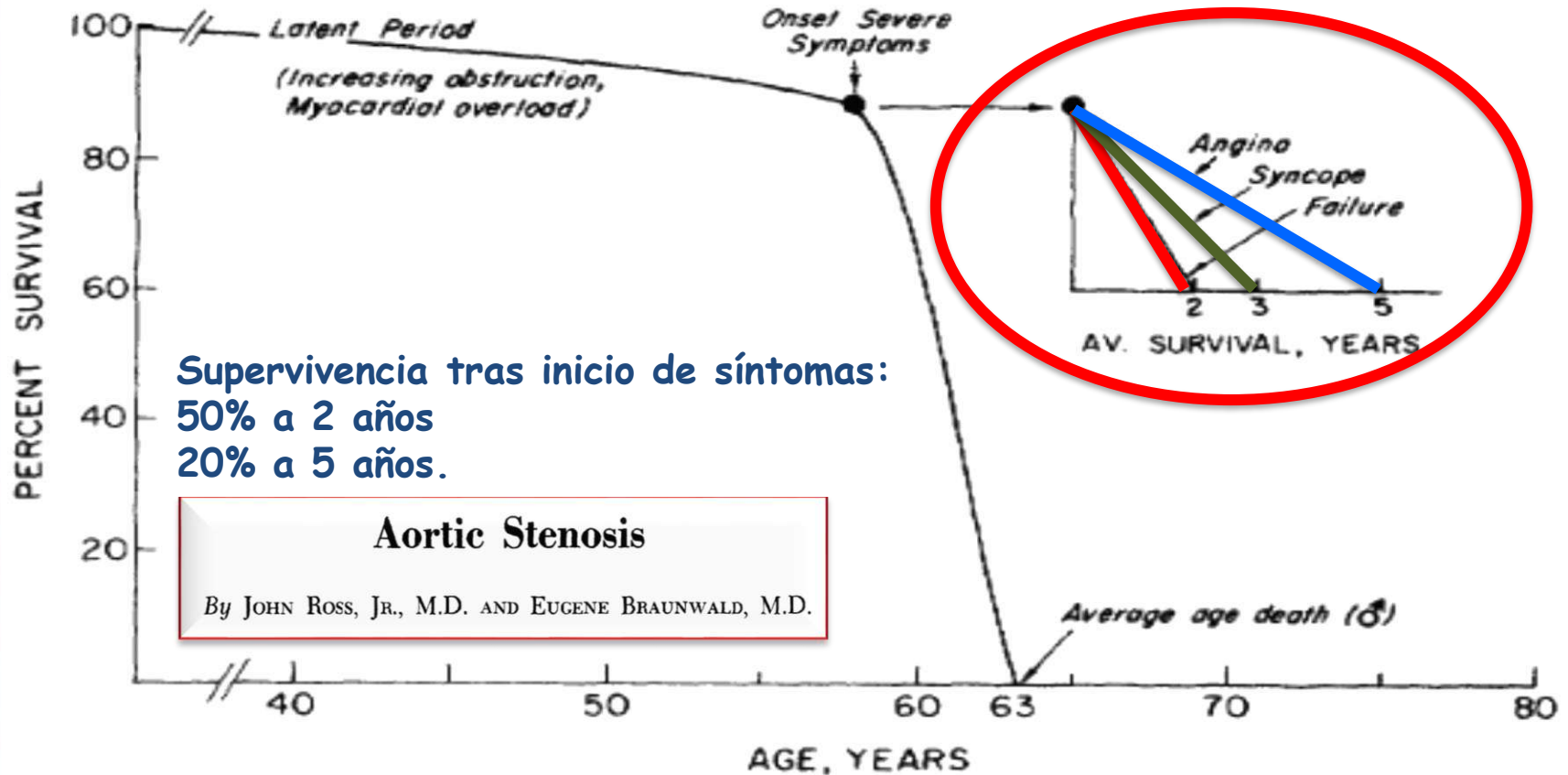
1 Aspectos Consolidados y No Debatidos en TAVI

1.2 Nuevos conceptos para la indicación terapéutica en EAo



Visión Tradicional de la Estenosis Aórtica

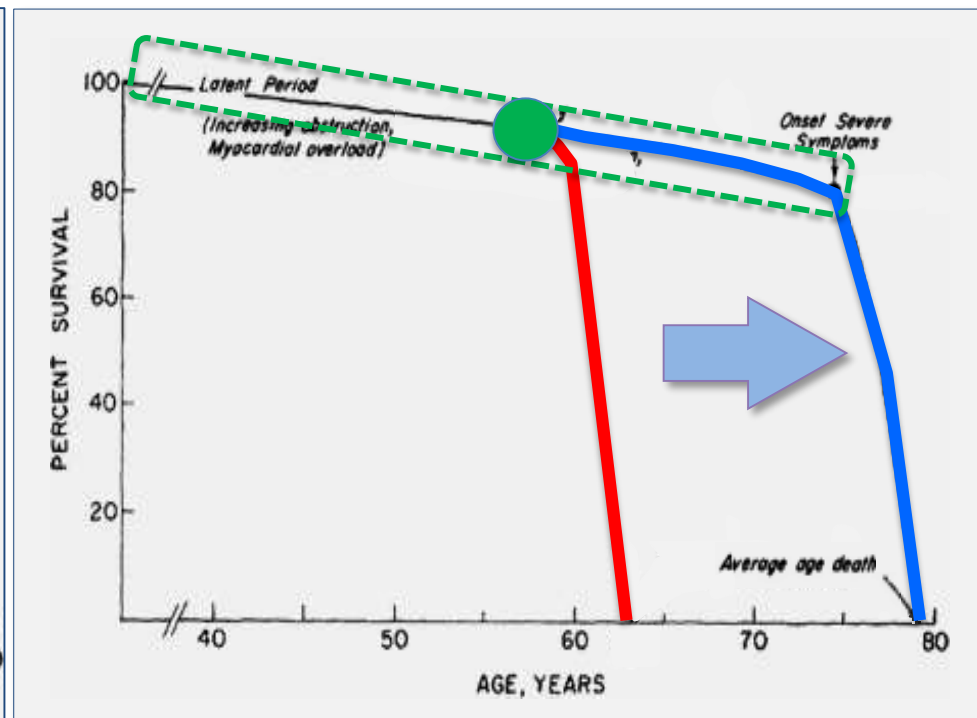
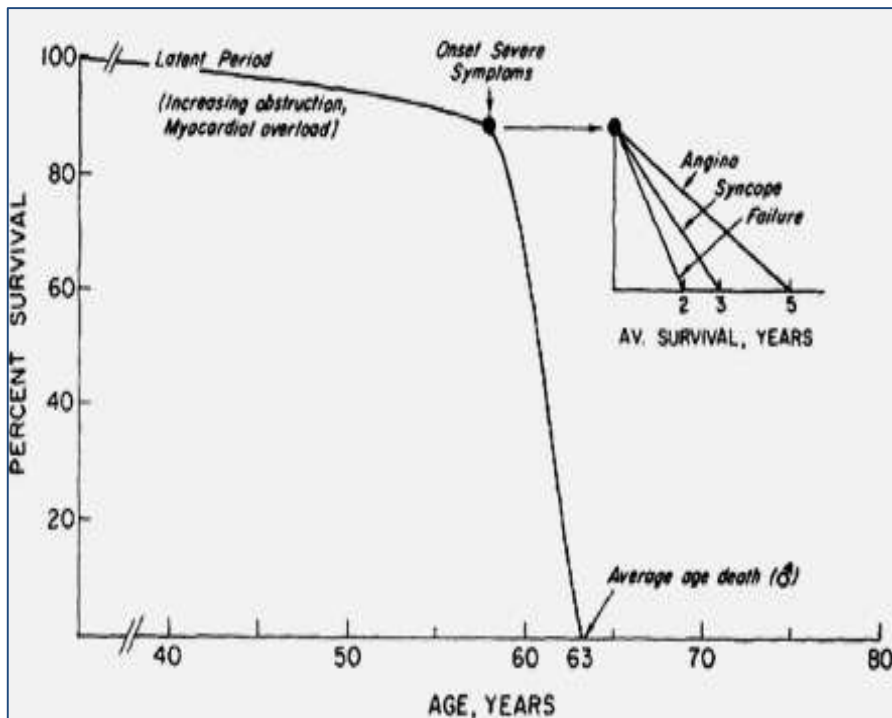
VALVULAR AORTIC STENOSIS IN ADULTS
AVERAGE COURSE
(Post Mortem Data)



Supplement V to Circulation, Vols. XXXVII and XXXVIII, July 1968

Visión Actual de la Estenosis Aórtica

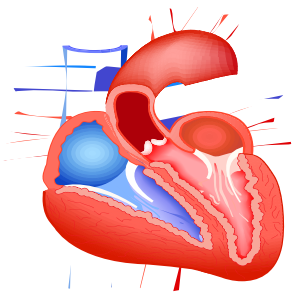
- No hay cambios estructurales irreversibles en este periodo de latencia que impacten negativamente en el pronóstico. El comienzo de los síntomas, generalmente, es fácil de identificar y ligado a la severidad de la EAo..*



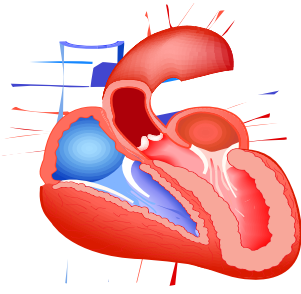
Supplement V to Circulation, Vols. XXXVII and XXXVIII, July 1968

Visión Actual de la Estenosis Aórtica

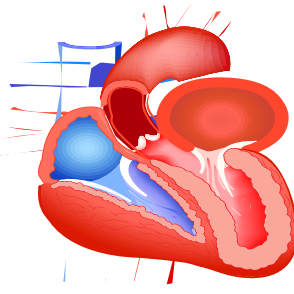
2. Podemos fácilmente clasificar el estadio de evolución de la severidad de la EAO.



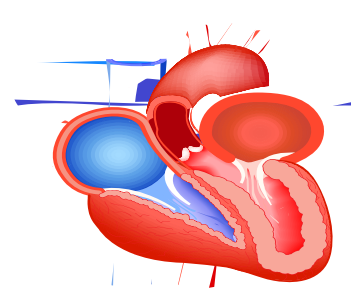
Etapa 0
Sin daño



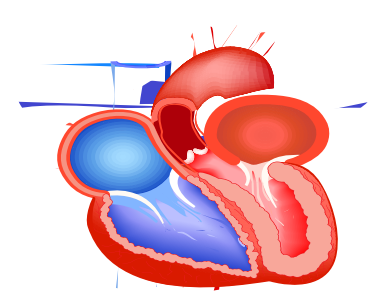
Etapa 1
Daño VI



Etapa 2
Daño AI / Mitral



Etapa 3
Daño AP /Tricus.



Etapa 4
Daño VD

Aumento Índice
Masa VI Index
>115 g/m² Hombres
>95 g/m² Mujeres

E/e' >14

FEVI <50%

Volumen Indexado
AI >34mL/m²

IM Moderada-Severa

Atrial Fibrillation

PAS ≥60mmhg

IT Moderada-Severa

Disfunción VD
Moderada-Severa

N=47
(2.8%)

N=212
(12.8%)

N=844
(50.8%)

N=413
(24.9%)

N=145
(8.7%)

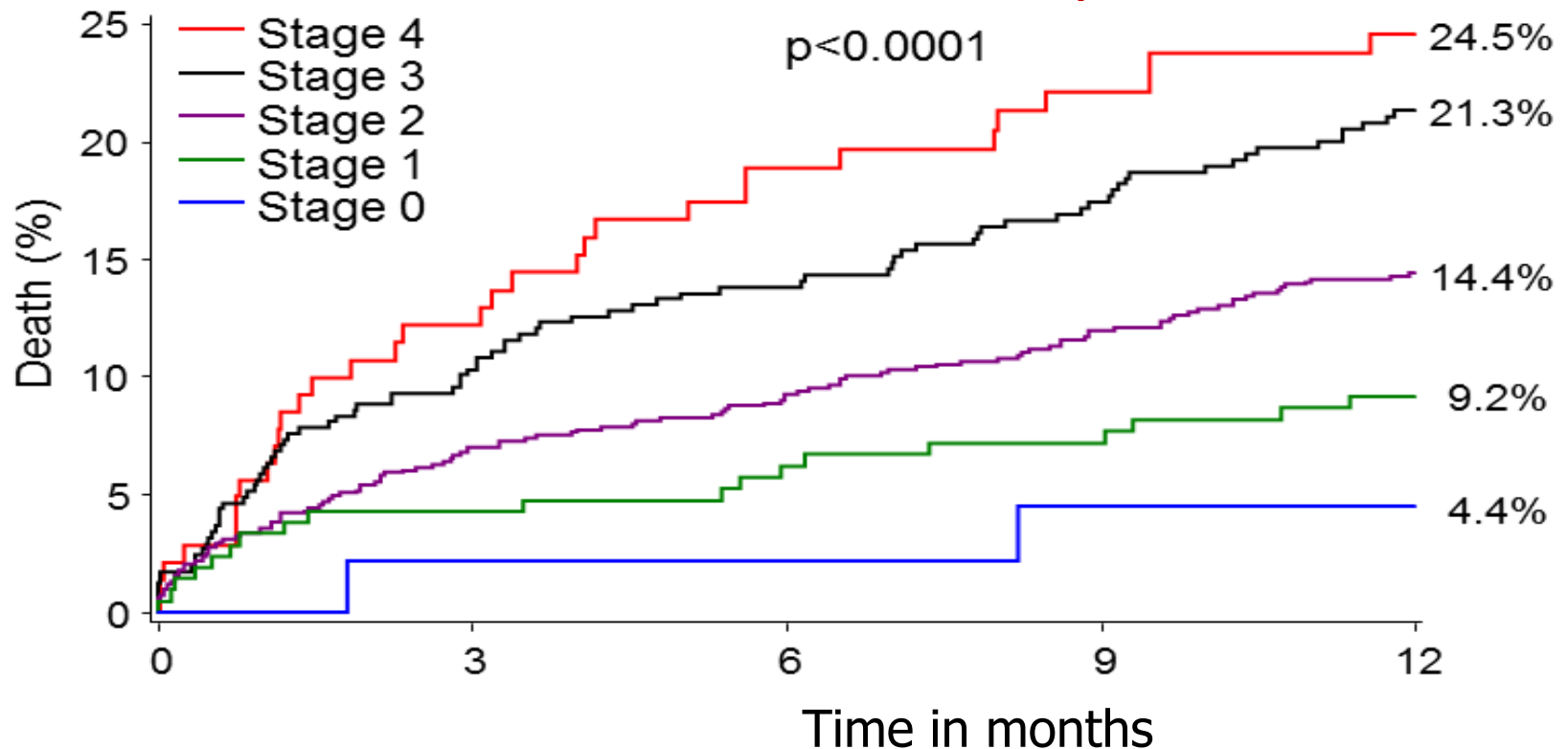
Staging Classification in Severe AS (n=1,661 pts)

Généreux et al. *Eur Heart J* 2017 Jul 21

Visión Actual de la Estenosis Aórtica

3. Podemos aumentar la supervivencia y reducir eventos adversos eligiendo el mejor estadio para el reemplazo valvular Ao.

Mortalidad a 1 año tras reemplazo VAo.



Généreux et al. *Eur Heart J* 2017 Jul 21



Agenda

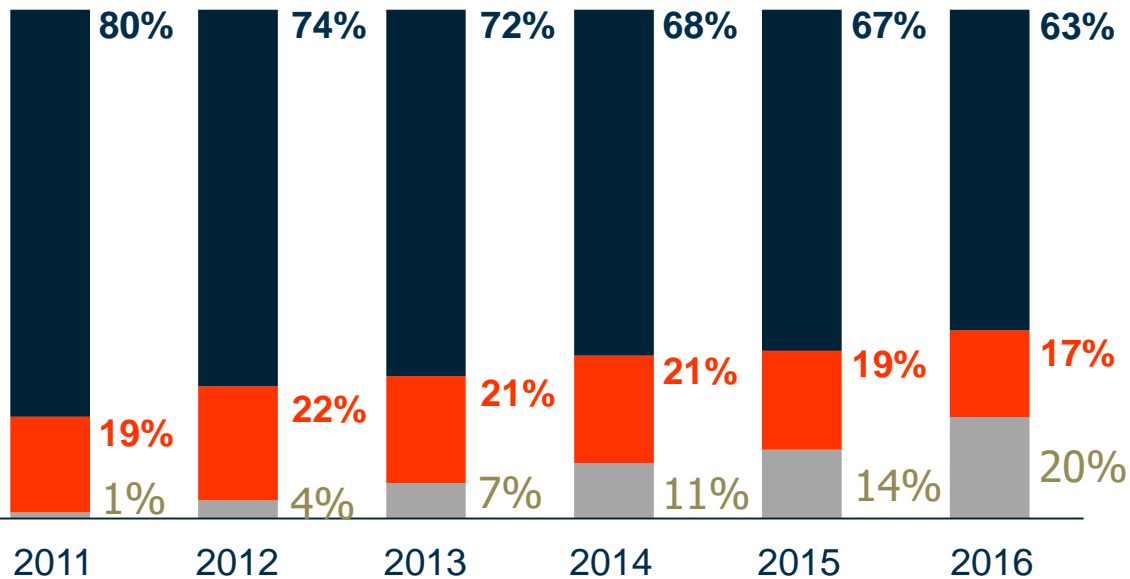
2 El problema de la Epidemia de Estenosis Aórtica



Infradiagnóstico e Infratratamiento en la EAO

OPTUM database (80 million people)

AVR treatment rate 1 year **after diagnosis** for cohort of patients with **diagnosed** severe Aortic Stenosis **ssAS** (%)



**Over
60%**

of diagnosed symptomatic severe Aortic Stenosis patients went **untreated**

■ **Untreated** ■ **TAVR** ■ **SAVR**

Treatment rates of ssAS have risen



As **TAVR** volume has grown

Matthew Brennan, J., et al. "Racial differences in the use of aortic valve replacement for treatment of symptomatic severe aortic valve stenosis in the transcatheter aortic valve replacement era." *Journal of the American Heart Association* 9.16 (2020): e015879.

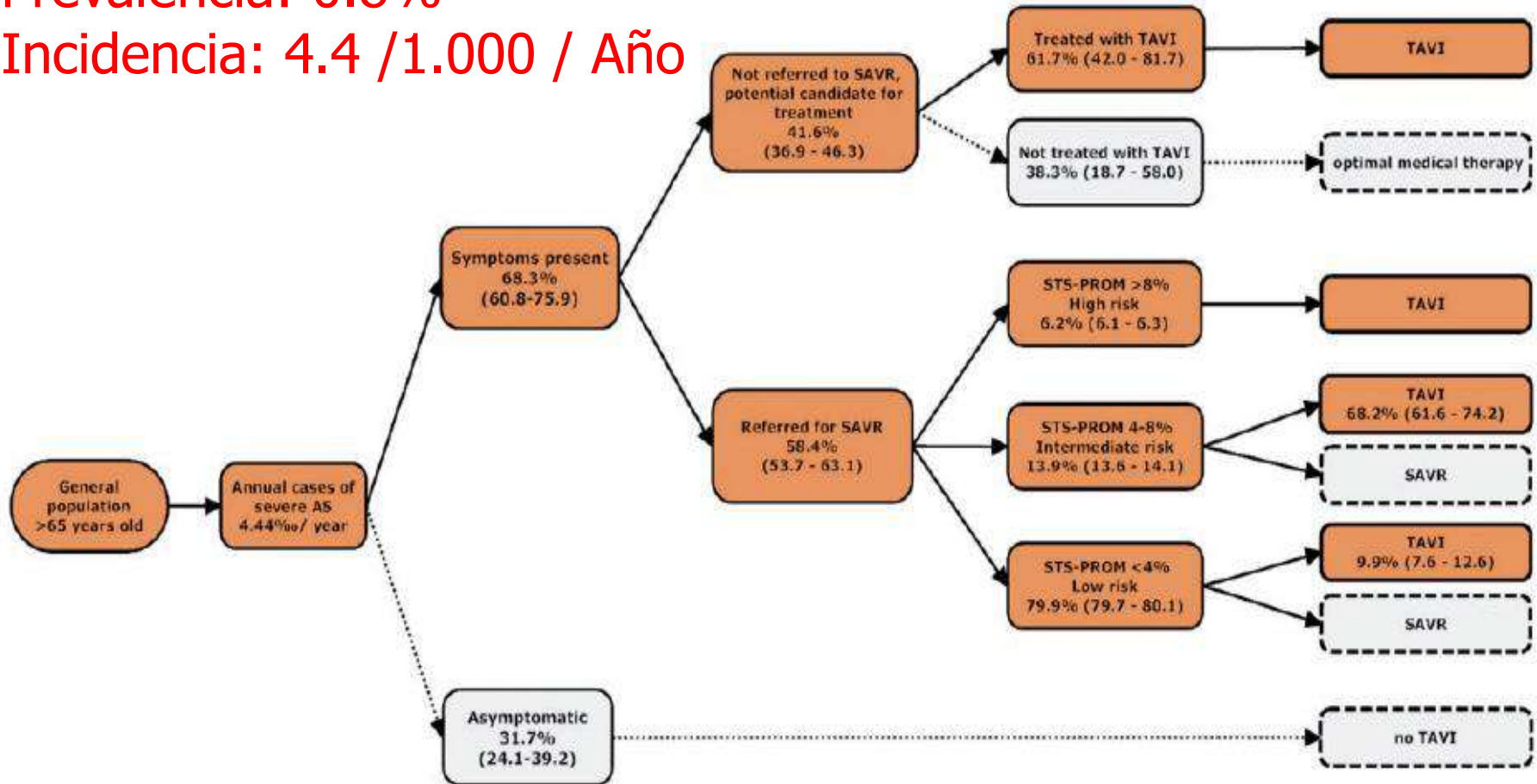
La Epidemia de E.Ao.

Annual number of candidates for transcatheter aortic valve implantation per country: current estimates and future projections

Andras P. Durko^{1*}, Ruben L. Osnabrugge¹, Nicolas M. Van Mieghem², Milan Milojevic¹, Darren Mylotte³, Vuyisile T. Nkomo⁴, and A. Pieter Kappetein¹

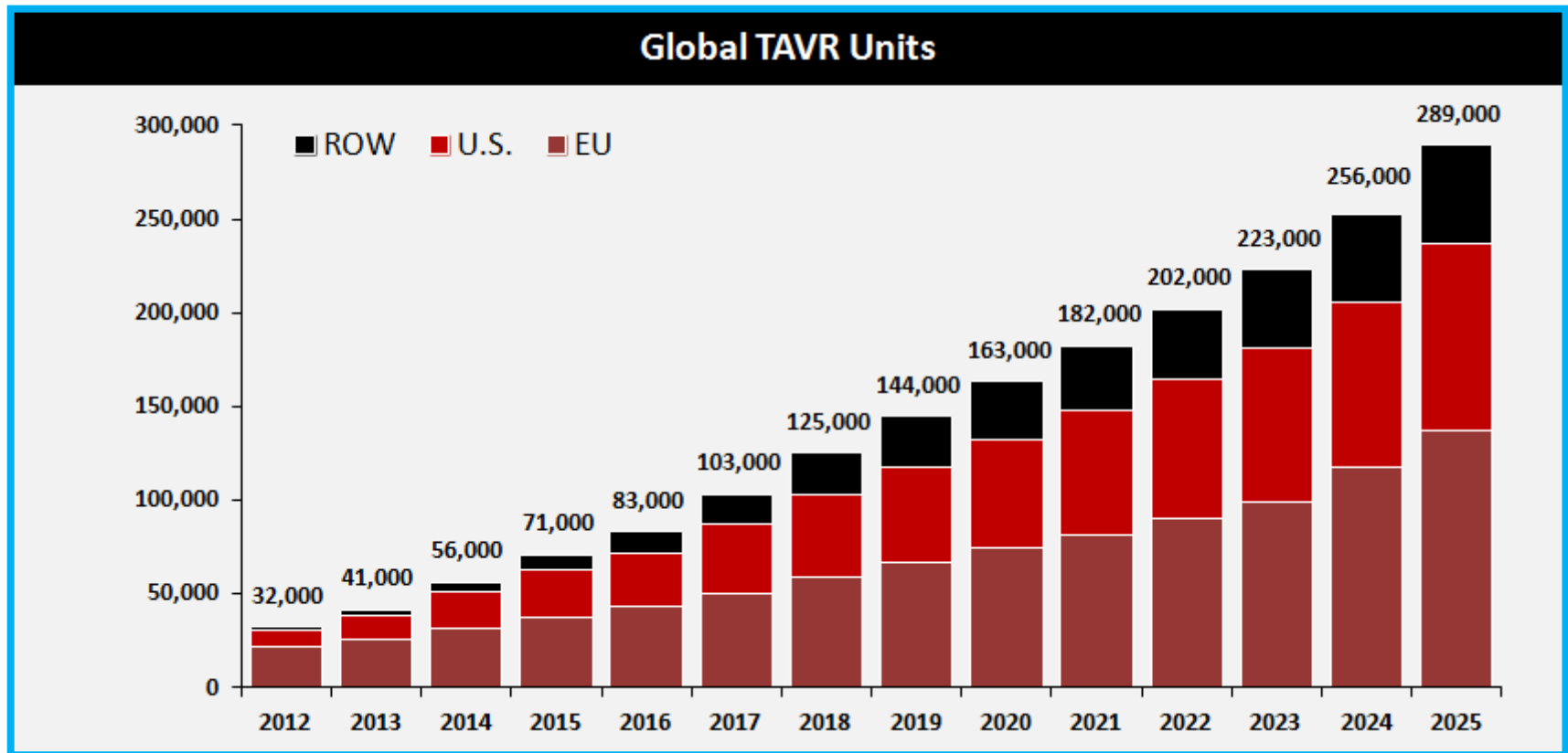
EAO en pacientes de >65 años

- Prevalencia: 0.8%
- Incidencia: 4.4 /1.000 / Año



Evolución Implantes TAVI en en Mundo

In the next 10 years, TAVR growth will increase X4!



SOURCE: Credit Suisse TAVI Comment –January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

La Epidemia de E.Ao.

Proyección Necesidad TAVI Área Asistencial de Vigo (aprox. 1.000.000 hab.)

	Año 2018	2022	2025
Población Total	973.945	867.801	863.909
Población de >65 años	214.512	224.607	235.830
% de >65 años / Población Total	24.5%	25.9%	27.3%
Incidencia Anual de EAo (4.4/1.000)	944	988	1.037
Sintomáticos (65%)	613	642	674
Referibles a TAVI (41%) (2018)	251	263	276
Referidos a TAVI (60%) (2022)	368	385	404
Referidos a TAVI (80%) (2025)	490	513	539

La Epidemia de E.Ao.

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¿Tenemos capacidad de asumir esta demanda?



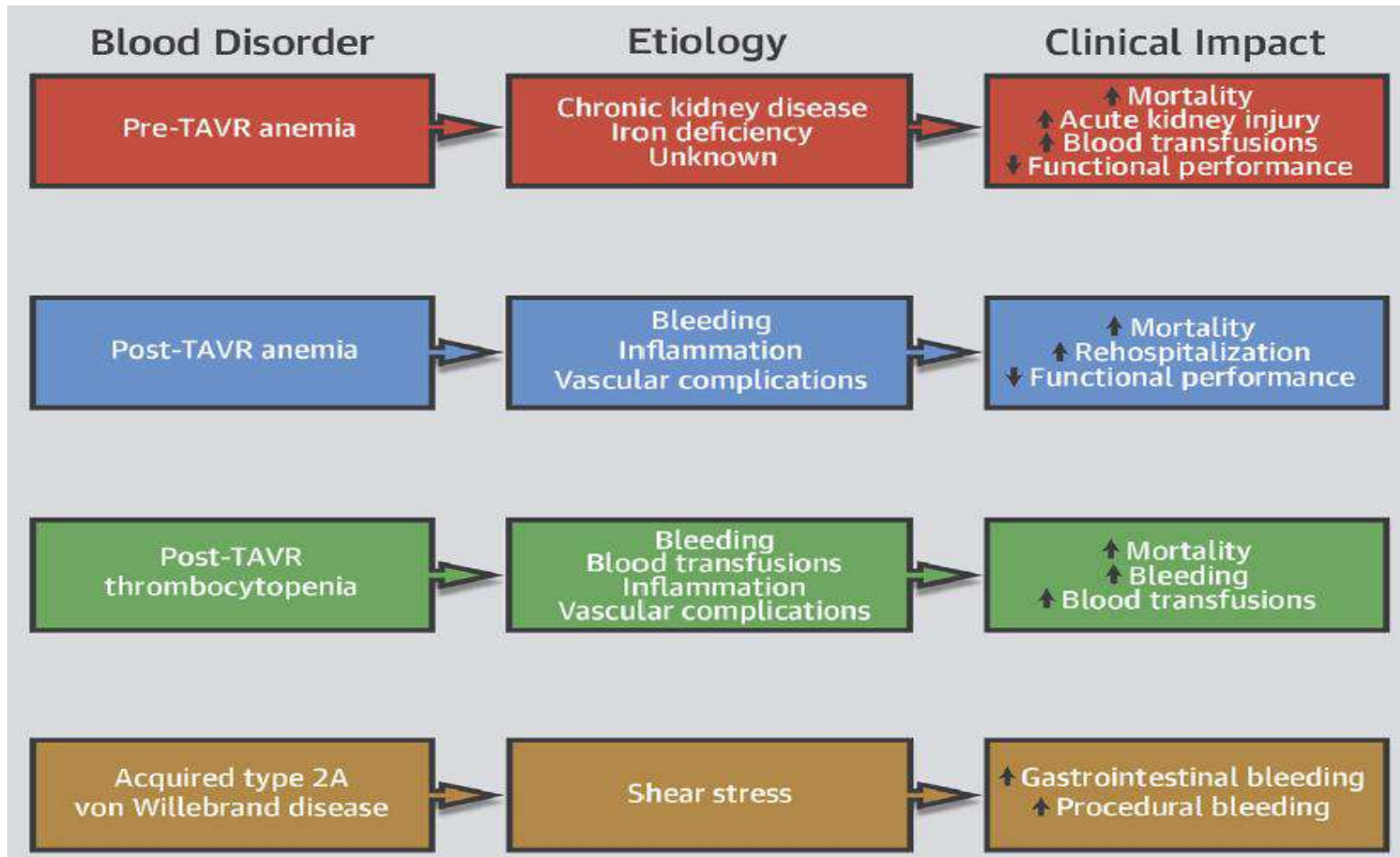
Agenda

3 Aspectos en debate en el tratamiento de la EAo

- Anemia
- ACV
- Antiagregación-Anticoagulación
- Durabilidad



1) Aspectos en Discusión en TAVI: Anemia



2) Aspectos en Discusión en TAVI: ACV

Embolic

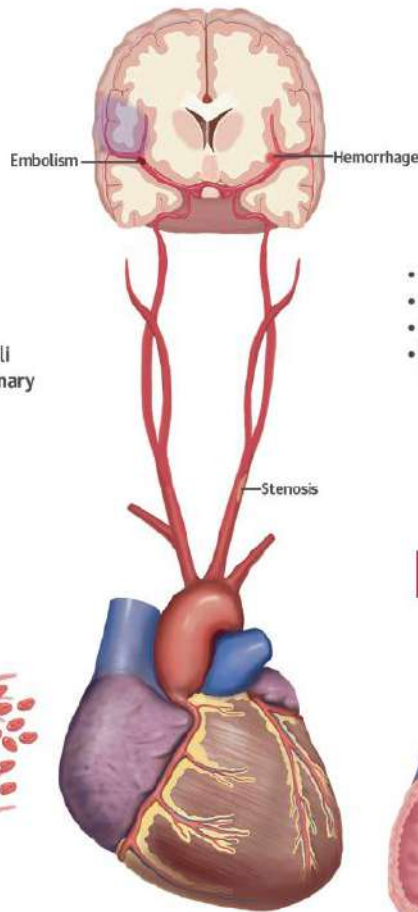


- Wire manipulation
- Cross clamp
- New-onset atrial fibrillation
- Carotid atherosclerotic emboli
- Air emboli from cardiopulmonary bypass
- Calcific debris following prosthetic aortic valve deployment

Global Ischemic



- Hemodynamic instability
- Cardiopulmonary bypass
- Distal balloon occlusion in CAS
- Vessel manipulation and isolation in CEA



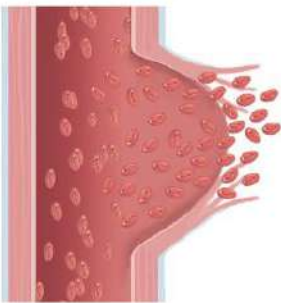
Cerebrovascular Events After Cardiovascular Procedures

Risk Factors, Recognition, and Prevention Strategies

Stroke Risk

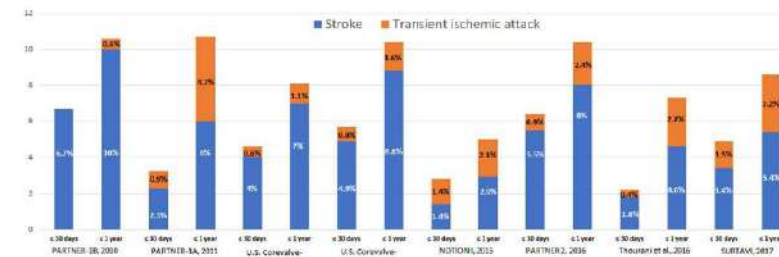
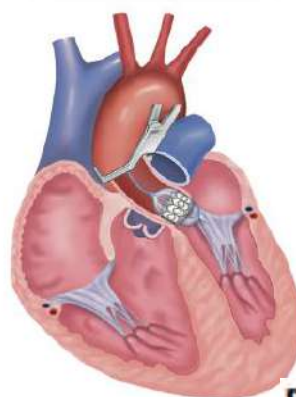
Cardiovascular Procedure	Early (<30 Days)	Late (Up to 10 yrs)
Surgery		
CABG		
On-pump	2.0 (14)	1.3 (15)
Off-pump	1.34 (14)	3.4 (15)
SAVR	1-5 (2,39)	
Mitral surgery		
Replacement	3.2 (40)	4.0 (40)
Repair	2.4 (40)	4.8 (40)
Robotic	0.0-3.0 (50)	-
CEA	2.3-8.3 (88)	1.1-19.0 (88)
Interventions		
CAS	4.1-9.1 (88)	8.3-26.7 (88)
PCI	0.37-0.44 (16-18)	0.28-1.2 (16-18)
TAVR	3.3 (81)	10.5 (89)

Hemorrhagic



- Severe hypertension
- Bleeding complications of pharmacotherapy
- Hyperperfusion syndrome

CV Procedure

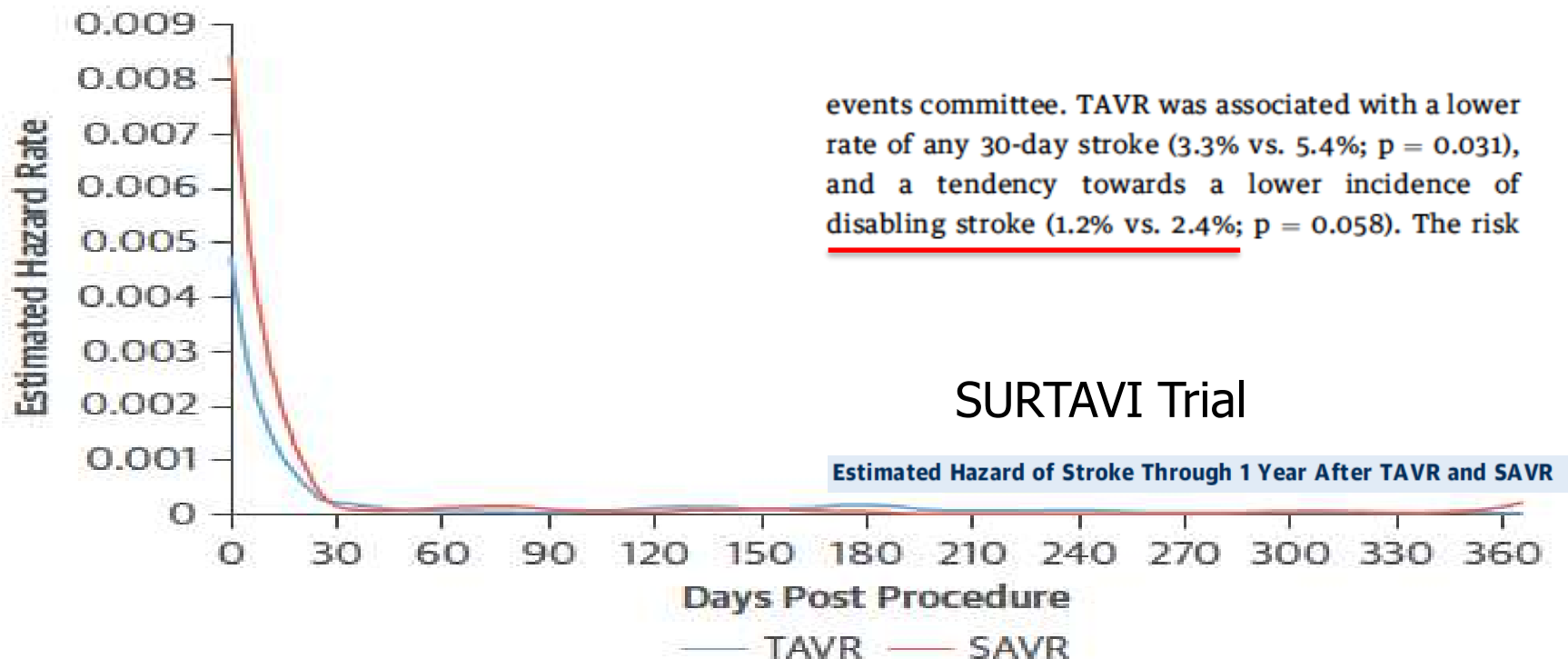


Devgun, J.K. et al J Am Coll Cardiol. 2018;71(17):1910-20.

Circ Cardiovasc Interv. 2019;12:e007411. DOI: 10.1161/CIRCINTERVENTIONS.118.007411

Aspectos en Discusión en TAVI: ACV

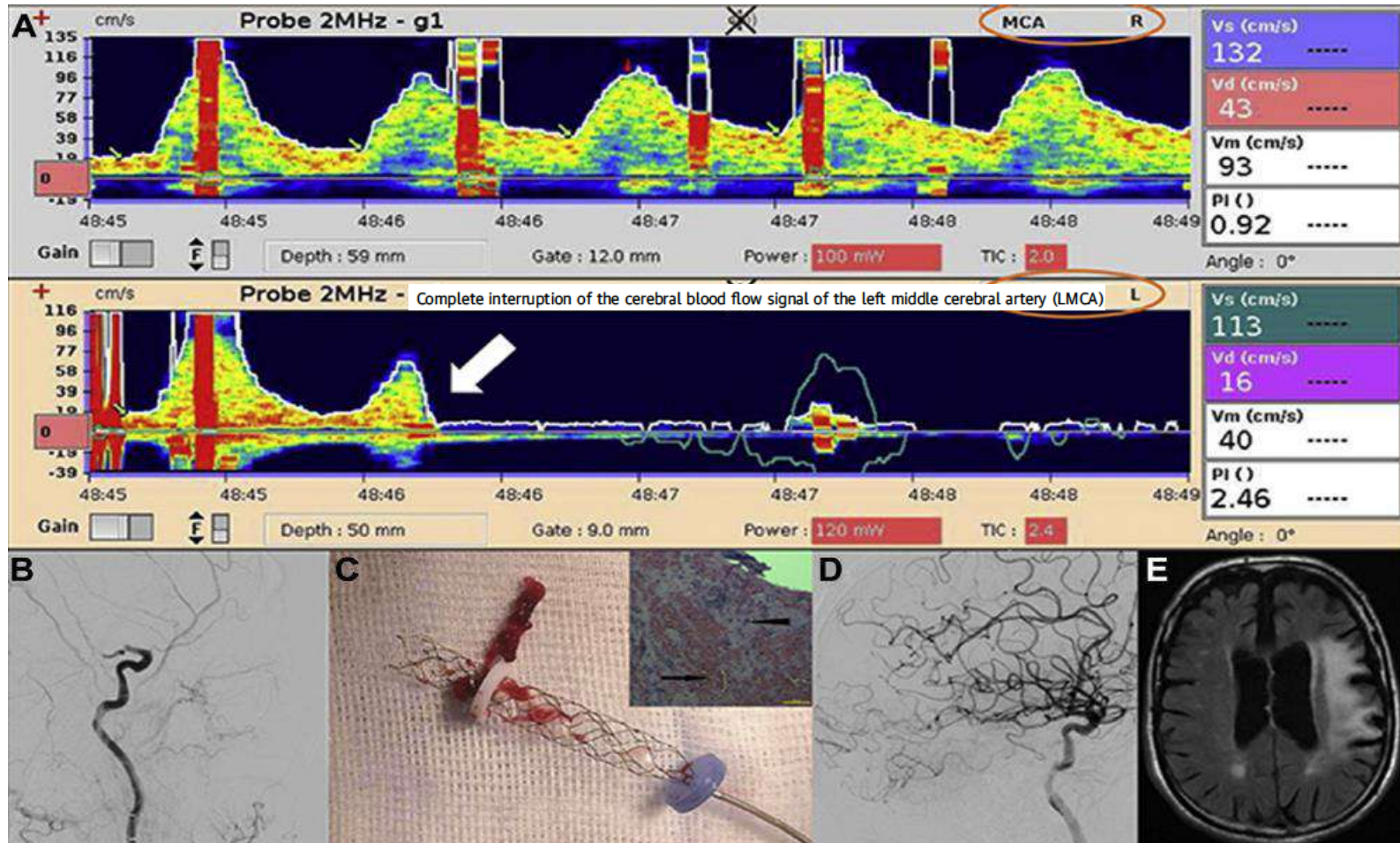
Etiología Multifactorial



Aspectos en Discusión en TAVI: ACV peri-procedimiento

Real-Time Detection of an Acute Cerebral Thrombotic Occlusion During a Transcatheter Valve Intervention

Victor Alfonso Jimenez Diaz, MD, MPH,^{1,2} Jose Antonio Raz Alonso, MD,³ Oscar Estevez Oja, BSc,⁴ Alexandre Senantes Combo, MD,⁵ Carlos Manuel Rodriguez Paz, MD,¹ Andrea Diguez Romo, MD, PhD⁶



Aspectos en Discusión en TAVI: ACV peri-procedimiento



ESC

European Society of Cardiology

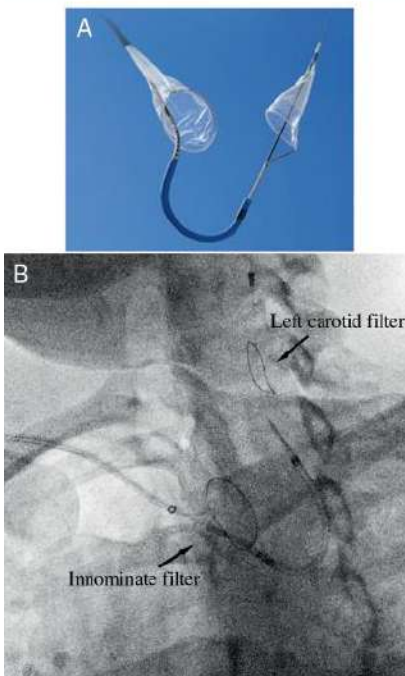
European Heart Journal (2019) 40, 1334–1339
doi:10.1093/eurheartj/ehy847

FASTTRACK CLINICAL RESEARCH

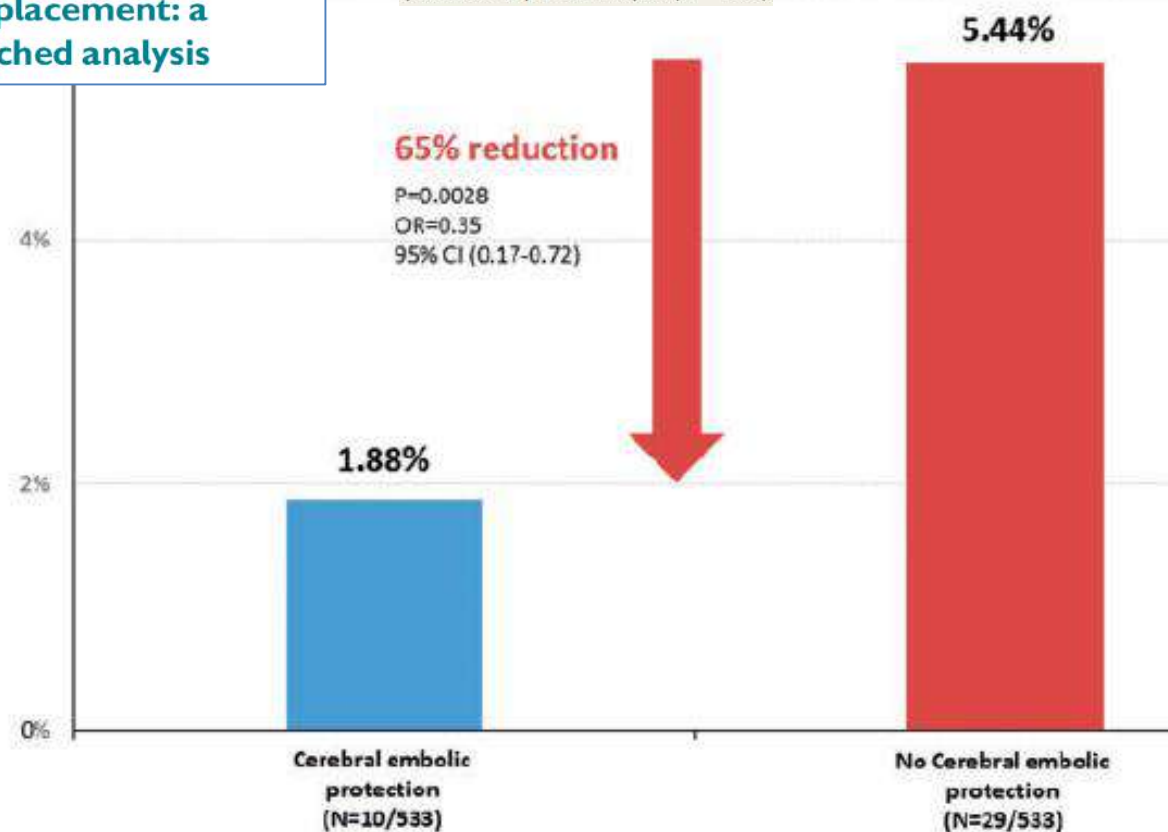
TAVI

Rate of peri-procedural stroke observed with cerebral embolic protection during transcatheter aortic valve replacement: a patient-level propensity-matched analysis

FIGURE 1 The Sentinel Cerebral Protection System



SENTINEL US IDE trial were combined with the CLEAN-TAVI and SENTINEL-Ulm study patient level pooled analysis (N = 1306).



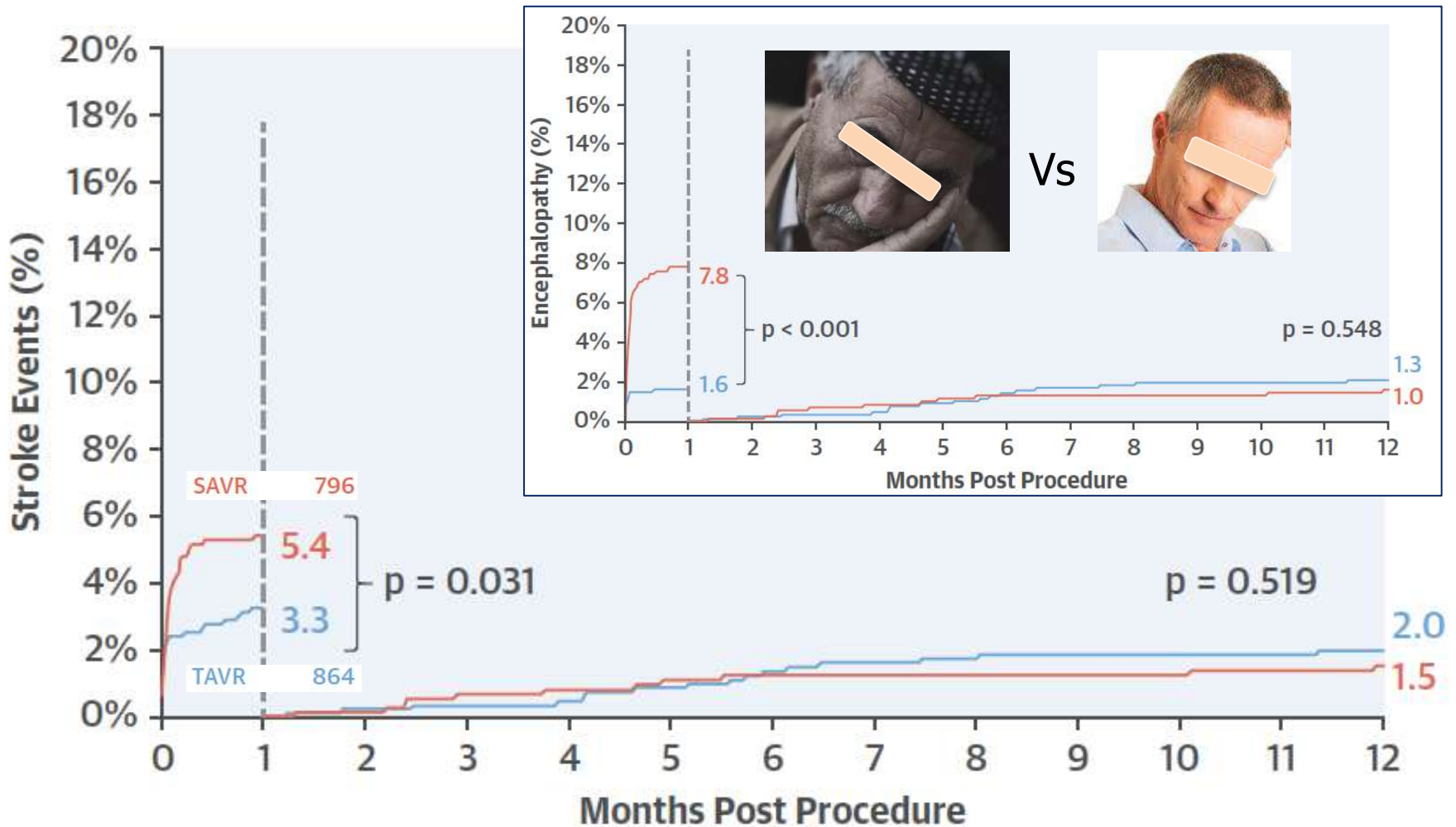
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Complejo Hospitalario Universitario de Vigo



Área de Cardiología
Complejo Hospitalario Universitario de Vigo

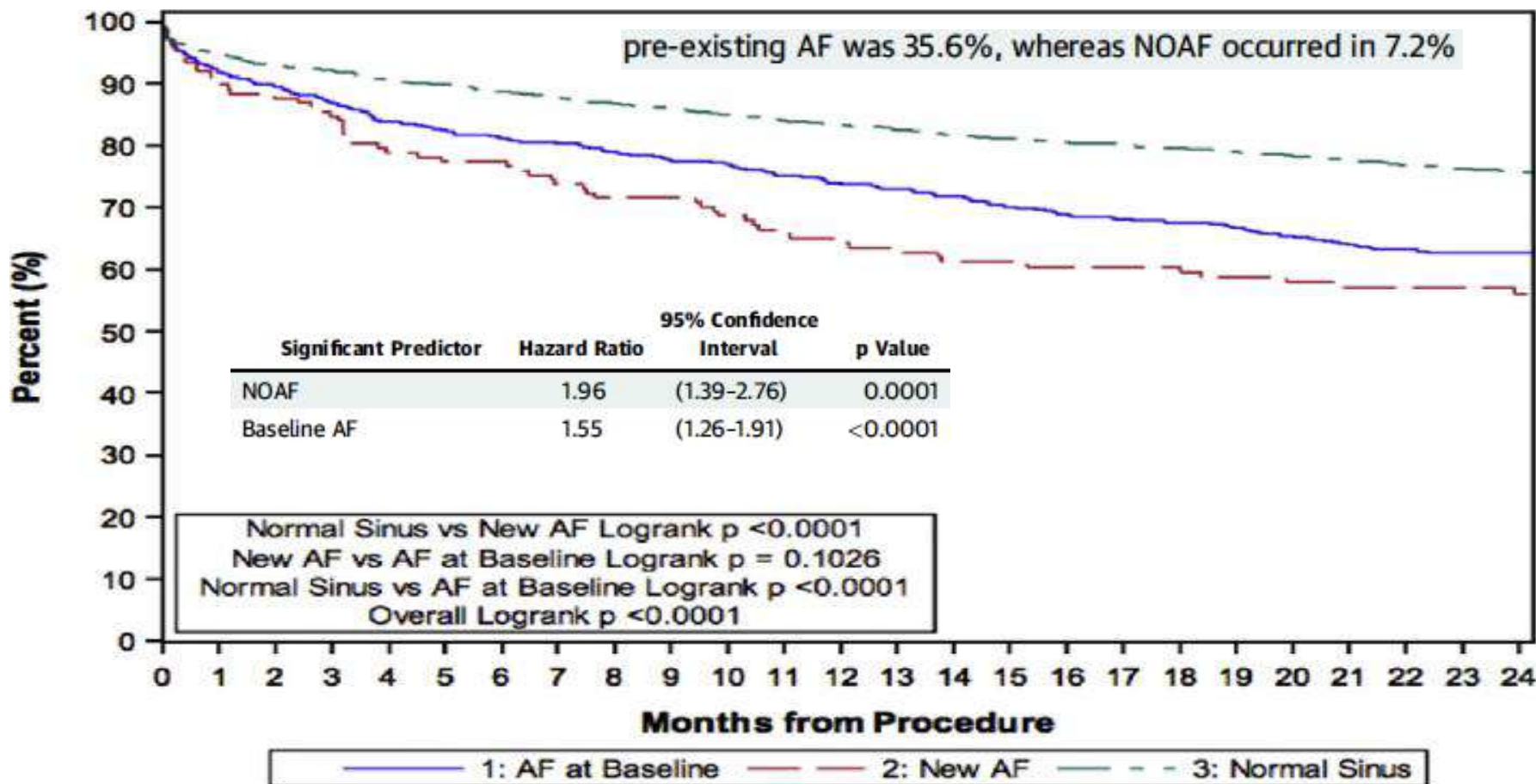
Aspectos en discusión en TAVI: ACV-Encefalopatía



Durko, A.P. et al. J Am Coll Cardiol. 2018;72(18):2109-19.

Aspectos en Discusión en TAVI: ACV-FA post-TAVI

Prevalence and Impact of Atrial Fibrillation in Patients With Severe Aortic Stenosis Undergoing Transcatheter Aortic Valve Replacement
An Analysis From the SOURCE XT Prospective Multicenter Registry

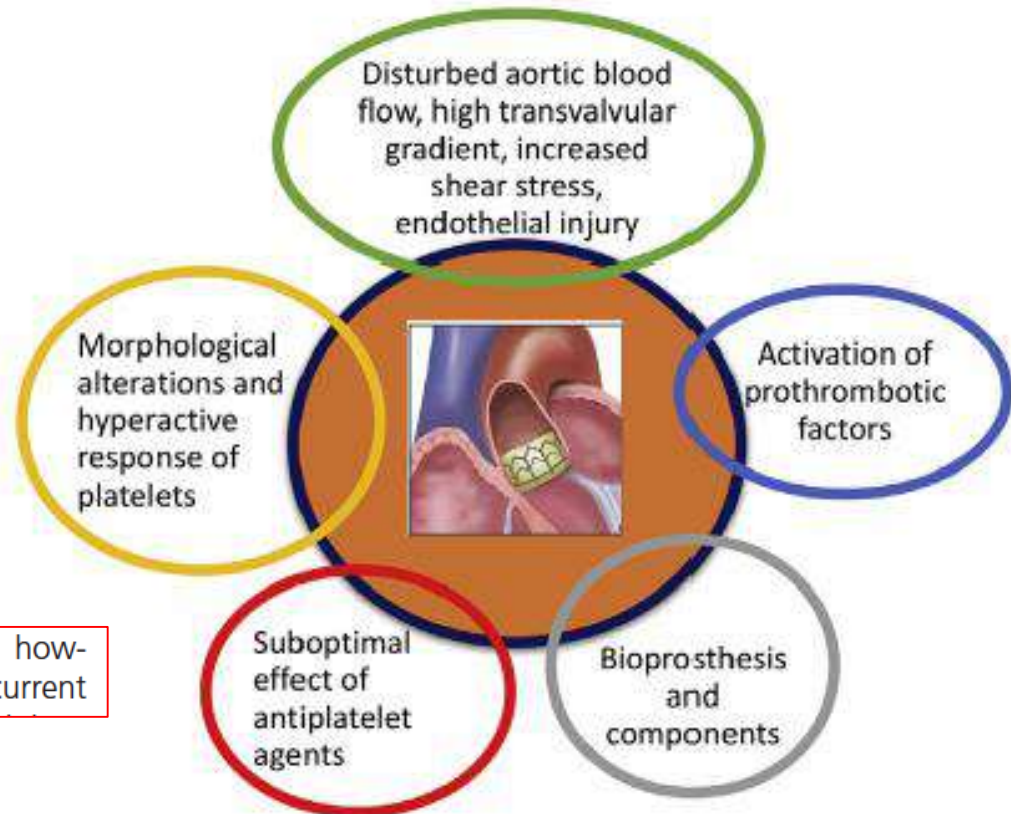


3) Aspectos en Discusión en TAVI: Tto. AA vs AC

FIGURE 5 Potential Factors Leading to Increased Platelet Activation and Prothrombotic Environment in Patients With AS Undergoing TAVR

Assessment of Platelet REACTivity After Transcatheter Aortic Valve Replacement

The REAC-TAVI Trial



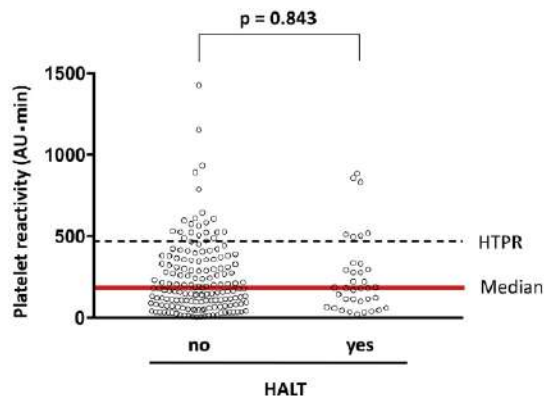
comes. The antithrombotic regimen post-TAVR, however, has mostly remained terra incognita. The current

J Am Coll Cardiol Interv 2019;12:22-32

Aspectos en Discusión en TAVI: Trombosis Valvular

The P2Y₁₂ inhibitor clopidogrel is widely used after TAVR. Current guidelines recommend a combination of ASA and clopidogrel for 3 to 6 months after TAVR on the basis of expert opinion (17,18). HALT as an

In the present study, only 14% of patients receiving clopidogrel displayed HTPR. Still, this overall effective platelet inhibition was not protective with regard to HALT. Therefore, inadequate platelet inhibition



hemodynamic deterioration. The incidence of valve hemodynamic deterioration was <2% in those prescribed OAC post-TAVR compared with 6% in those not prescribed OAC. These results suggest that an

Impact of On-Clopidogrel Platelet Reactivity on Incidence of Hypoattenuated Leaflet Thickening After Transcatheter Aortic Valve Replacement

TABLE 2 Adenosine Diphosphate-Induced Platelet Reactivity and Hypoattenuated Leaflet Thickening

	No HALT	HALT	p Value
ADPtest below median	84	16	0.58
ADPtest above median	80	20	
ADPtest ≤468 AU · min	142	29	0.43
ADPtest >468 AU · min	22	7	

Numbers of patients within respective groups. ADPtest median: cutoff 180 AU · min. The p values were calculated using chi-square tests.

MECHANISMS AND RISK FACTORS RELATED TO VALVE THROMBOSIS

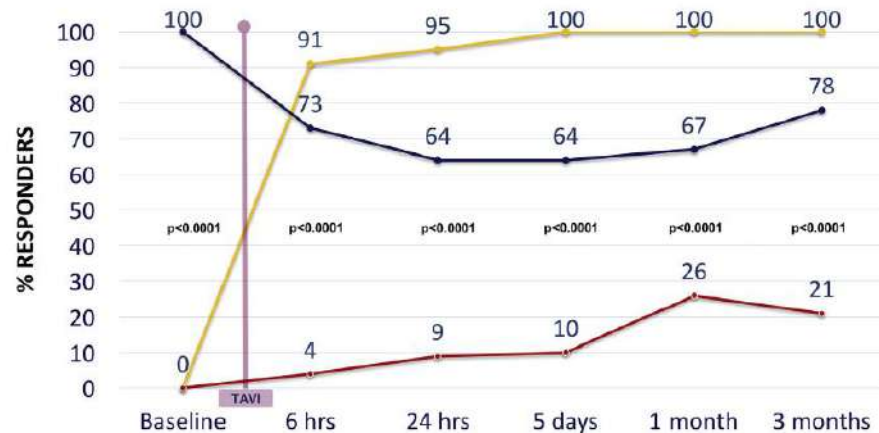
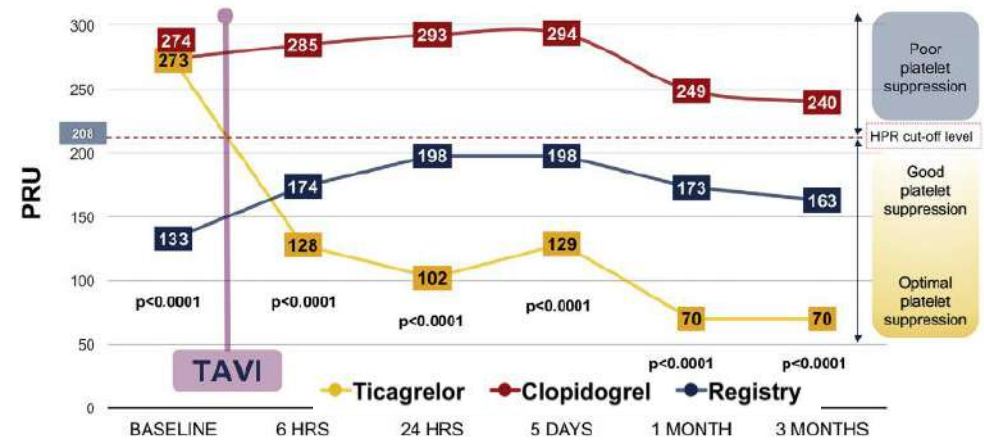
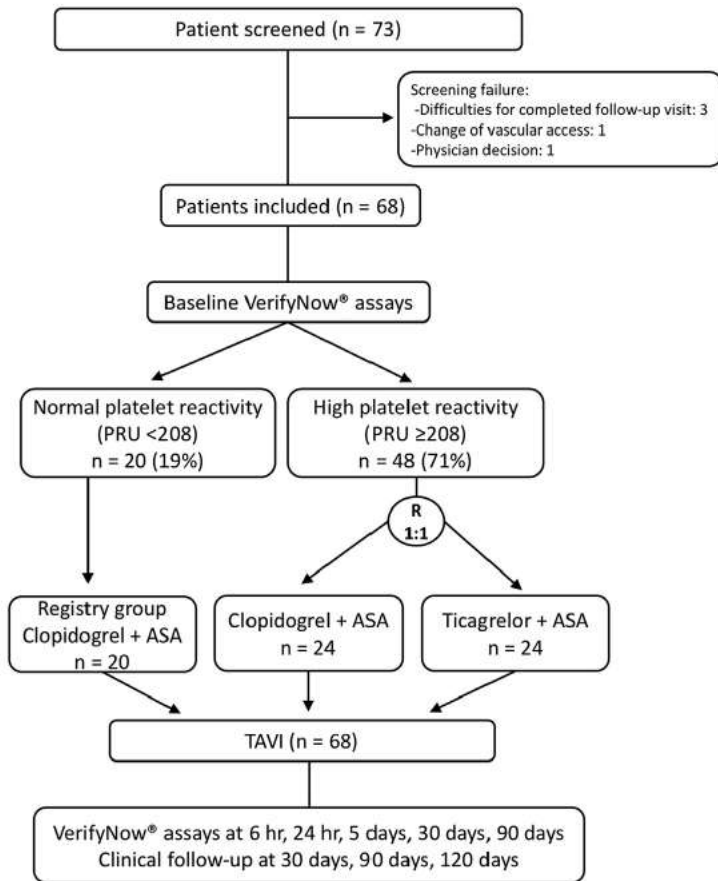
HEMOSTATIC ACTIVATION.

PERTURBATIONS IN BLOOD FLOW.

PATIENT-RELATED RISK FACTORS

Aspectos en Discusión en TAVI: Tto. Post-TAVI

Assessment of Platelet REACTivity After Transcatheter Aortic Valve Replacement The REAC-TAVI Trial



J Am Coll Cardiol Interv 2019;12:22-32

4) Aspectos en Discusión en TAVI: DURABILIDAD

5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial

Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators*

5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

Michael J Mack, Martin B Leon, Craig R Smith, D Craig Miller, Jeffrey W Moses, E Murat Tuzcu, John G Webb, Pamela S Douglas, William N Anderson, Eugene H Blackstone, Susheel K Kodali, Raj R Makkar, Gregory P Fontana, Samir Kapadia, Joseph Bavaria, Rebecca T Hahn, Vinod H Thourani, Vasilis Babaliaros, Augusto Pichard, Howard C Herrmann, David L Brown, Mathew Williams, Jodi Akin, Michael J Davidson†, Lars G Svensson, for the PARTNER 1 trial investigators*

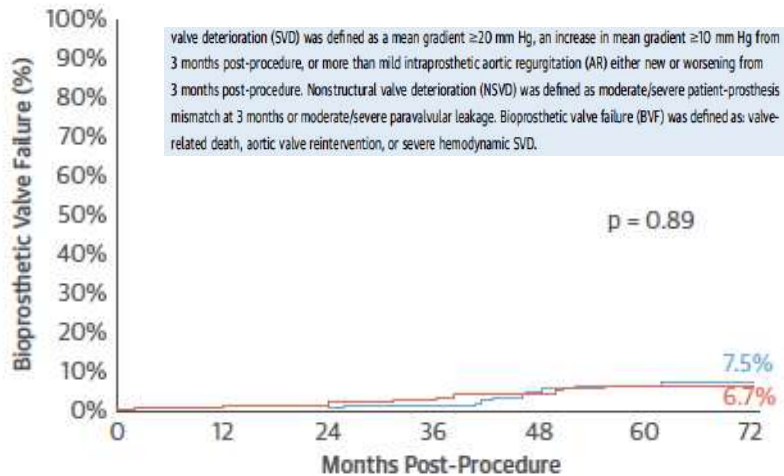
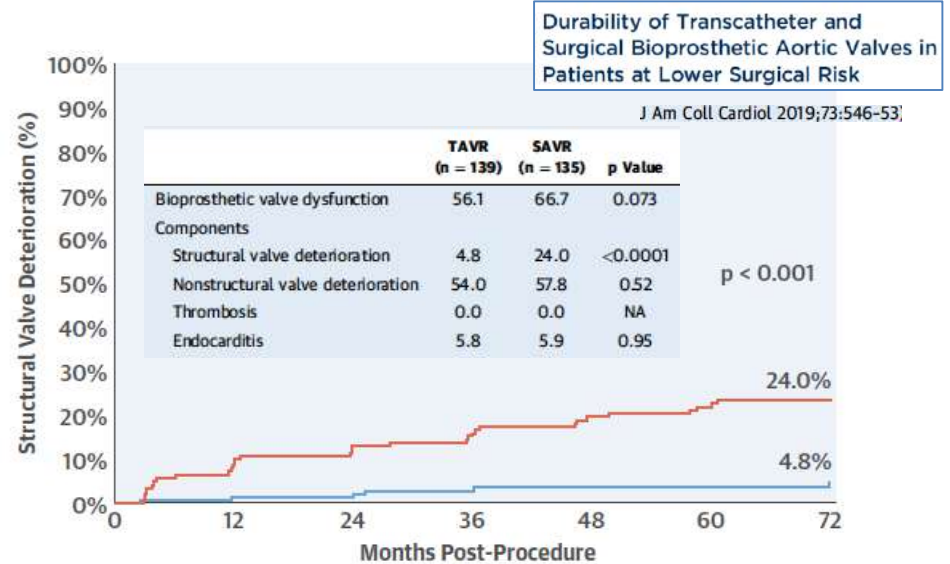
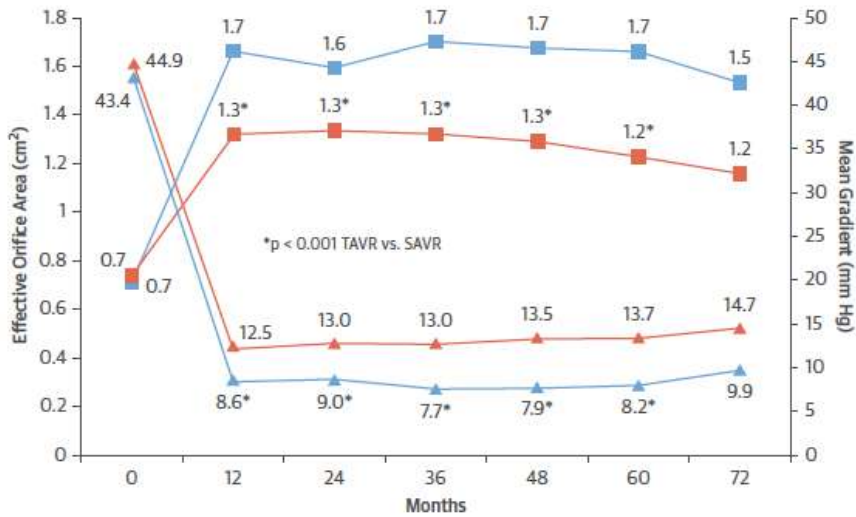
PARTNER 5-year FU in Lancet (March, 2015)

Aspectos en Discusión en TAVI: DURABILIDAD

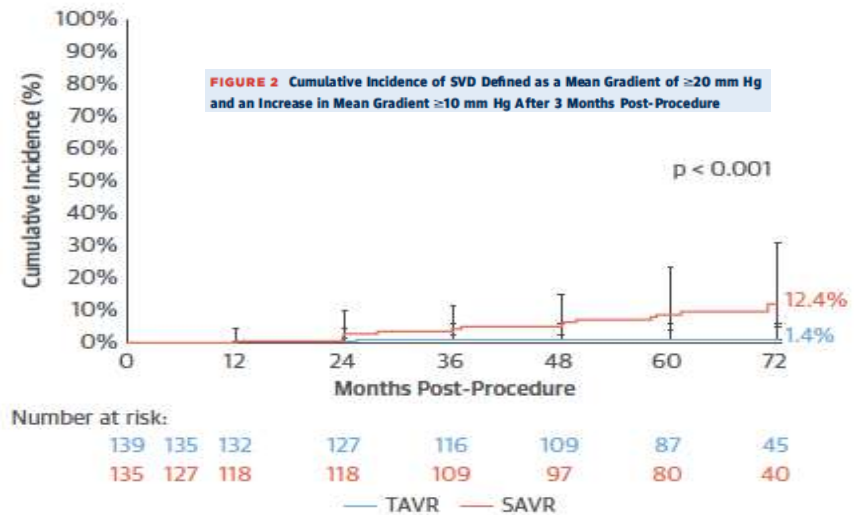


PARTNER 5-year FU in Lancet (March, 2015)

Aspectos en Discusión en TAVI: DURABILIDAD



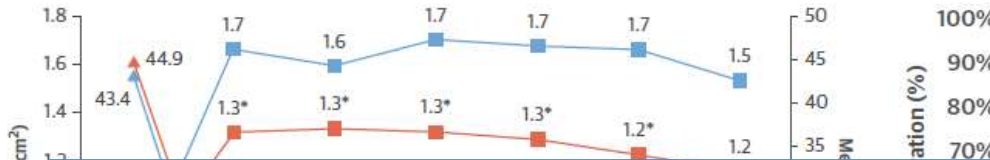
valve deterioration (SVD) was defined as a mean gradient ≥ 20 mm Hg, an increase in mean gradient ≥ 10 mm Hg from 3 months post-procedure, or more than mild intraprosthetic aortic regurgitation (AR) either new or worsening from 3 months post-procedure. Nonstructural valve deterioration (NSVD) was defined as moderate/severe patient-prosthesis mismatch at 3 months or moderate/severe paravalvular leakage. Bioprosthetic valve failure (BVF) was defined as: valve-related death, aortic valve reintervention, or severe hemodynamic SVD.



Aspectos No Resueltos en TAVI: DURABILIDAD

Durability of Transcatheter and Surgical Bioprosthetic Aortic Valves in Patients at Lower Surgical Risk

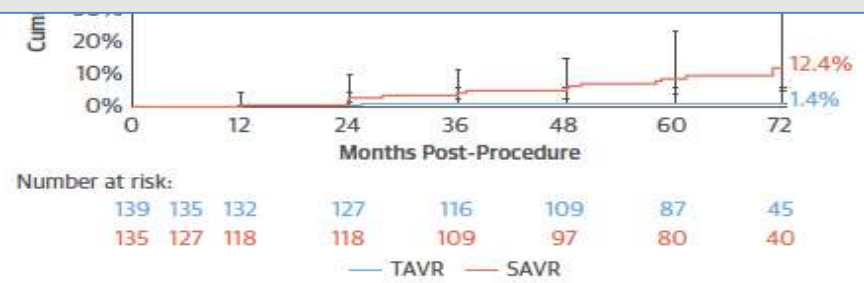
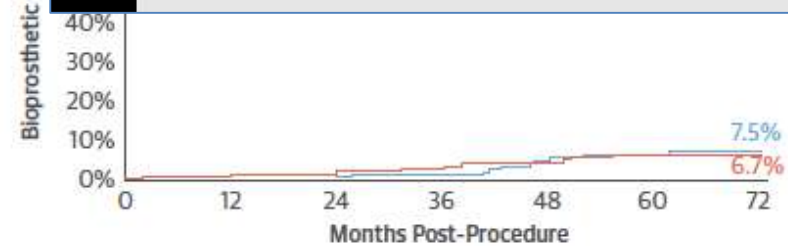
J Am Coll Cardiol 2019;73:546-53



	TAVR (n = 139)	SAVR (n = 135)	p Value
Bioprosthetic valve dysfunction	56.1	66.7	0.073

definições

- ✓ Bioprosthetic Valve Dysfunction:
 - Structural Valve Deterioration (gradiente medio >20 mmHg, incremento >10 mmHg en 3 meses, IAO intraprótesis más que leve)
 - Non-Structural Valve Deterioration (mismatch moderado/severo a los 3 meses, leak paravalvular moderado/severo).
 - Bioprosthetic Valve Thrombosis
 - Endocarditis
- ✓ Biosprosthetic Valve Failure:
 - Muerte relacionada con la válvula
 - Deterioro hemodinámico severo (Gradiente medio >40 mmHg, incremento >20 en 3 meses o IAO Severa intraprótesis)
 - Necesidad de recambio valvular



Number at risk:

Time (Months)	0	12	24	36	48	60	72
TAVR	139	135	132	127	116	109	87
SAVR	135	127	118	118	109	97	80

Aspectos en Discusión en TAVI: DURABILIDAD

Early stenosis of Medtronic Mosaic porcine valves in the aortic position

Jennifer S. Lawton, MD, Nader Moazami, MD, Michael K. Pasque, MD, Marc R. Moon, MD, and Ralph J. Damiano, Jr, MD, St Louis, Mo

The third-generation Medtronic Mosaic porcine bioprosthesis (Medtronic Inc, Minneapolis, Minn) was introduced in 1994. The valve leaflets are fixed in glutaraldehyde at zero pressure (applying equal pressure to the inflow and outflow ends of the valve); the root is dilated to a pressure of 40 mm Hg ("physiologic fixation"), the fixed tissue is treated with α -aminocaproic acid (a long-chain fatty acid that binds to the aldehyde fractions of the glutaraldehyde-preserved porcine tissue) to reduce calcification, and the tissue is

DISCUSSION

Early (2-year follow-up) results after implantation of the Medtronic Mosaic porcine valve reported appropriate valve function and no primary structural valve failure.¹ Follow-up at 6 years by Jamieson and colleagues² documented 4 cases of structural valve deterioration (2 aortic and 2 mitral) after the implantation of 657 Medtronic Mosaic porcine valves. However, no patients aged more than 60 years had aortic structural valve deterioration

Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

Douglas R. Johnston, MD, Edward G. Soltesz, MD, Nakul Vakil, MD, Jeevanantham Rajeswaran, PhD, Eric E. Roselli, MD, Joseph F. Sabik, III, MD, Nicholas G. Smedira, MD, Lars G. Svensson, MD, PhD, Bruce W. Lytle, MD, Eugene H. Blackstone, MD

Department of Thoracic and Cardiovascular Surgery, Heart and Vascular Institute, and Department of Quantitative Research Institute, Cleveland Clinic, Cleveland, Ohio

Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position

Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Carlier, MD, Alain Mirza, MD, Claudia Loardi, MD, Marc-Antoine May, MD, Rym El-Khalil, MD, Michel Marchand, MD, and Michel Aupart, MD

Department of Cardiac Surgery, Tours University Hospital, France; and Department of Biostatistics, Edwards Lifesciences, St. Paul, Switzerland

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Original Article

Early Structural Valve Deterioration of Mitroflow Aortic Bioprosthesis: Mode, Incidence and Impact on Outcome in a Large Cohort of Patients

Hancock II Bioprosthesis for Aortic Valve Replacement: The Gold Standard of Bioprosthetic Valves Durability?

Tirone E. David, MD, Susan Armstrong, MS, and Manjula Maganti, MS

Division of Cardiovascular Surgery of Peter Munk Cardiac Centre, Toronto General Hospital and University of Toronto, Toronto, Ontario, Canada

Early structural valve deterioration of the Trifecta aortic valve biological prosthesis: A word of caution

Pankaj Saxena, FRACS, PhD, Kevin L. Greason, MD, and Hartzell V. Schaff, MD, Rochester, Minn

The St Jude Medical Inc (St Paul, Minn) Trifecta valve is a relatively new biological prosthesis that completed a multicenter US Food and Drug Administration Investigational Device Exemption study in 2011. During a median patient

follow-up of 0.9 years of the 1014 valve implantations in that study, 1 patient underwent explant of the valve for structural valve deterioration.¹ We report an additional case.

CLINICAL SUMMARY

A 67-year-old woman presented to us with New York Heart Association class IV dyspnea and severe Trifecta prosthetic aortic valve stenosis. She had multiple previous cardiac operations that included an aortic valve replacement plus coronary artery bypass graft surgery 18 years previously, redo coronary artery bypass graft surgery 13 years previously, and repeat aortic valve replacement with a 21-mm Trifecta valve 4 years previously.

60 to 70, and in from structural ± 4.2% in the younger than 60 70, and 99.8% ± 0.3% at 18 years). patients (74 for freedom from 9.8% ± 5.4% in 13.3% in patients der than 70. is a very dura- and is probably durability in this 2010;90:775-81) aortic Surgeons

From the Division of Cardiovascular Surgery, Mayo Clinic, Rochester, Minn. Disclosures: Authors have nothing to disclose with regard to commercial support. Received for publication April 7, 2013; revisions received July 14, 2013; accepted for publication July 19, 2013; available ahead of print Sept 16, 2013. Address for reprints: Kevin L. Greason, MD, Division of Cardiovascular Surgery, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (E-mail: greason.kevin@mayo.edu). J Thorac Cardiovasc Surg 2014;147:e10-11. 0022-5223/14/0000-0000 Copyright © 2014 by The American Association for Thoracic Surgery http://dx.doi.org/10.1016/j.jtcvs.2013.07.025

e10 The Journal of Thoracic and Cardiovascular Surgery • January 2014

Early Failures of Surgical Valves...



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Aspectos en Discusión en TAVI: DURABILIDAD

Bioprosthetic Surgical Valve Failure from VIVID Registry



Time to Failure - All VIVID Cases (n = 1304)

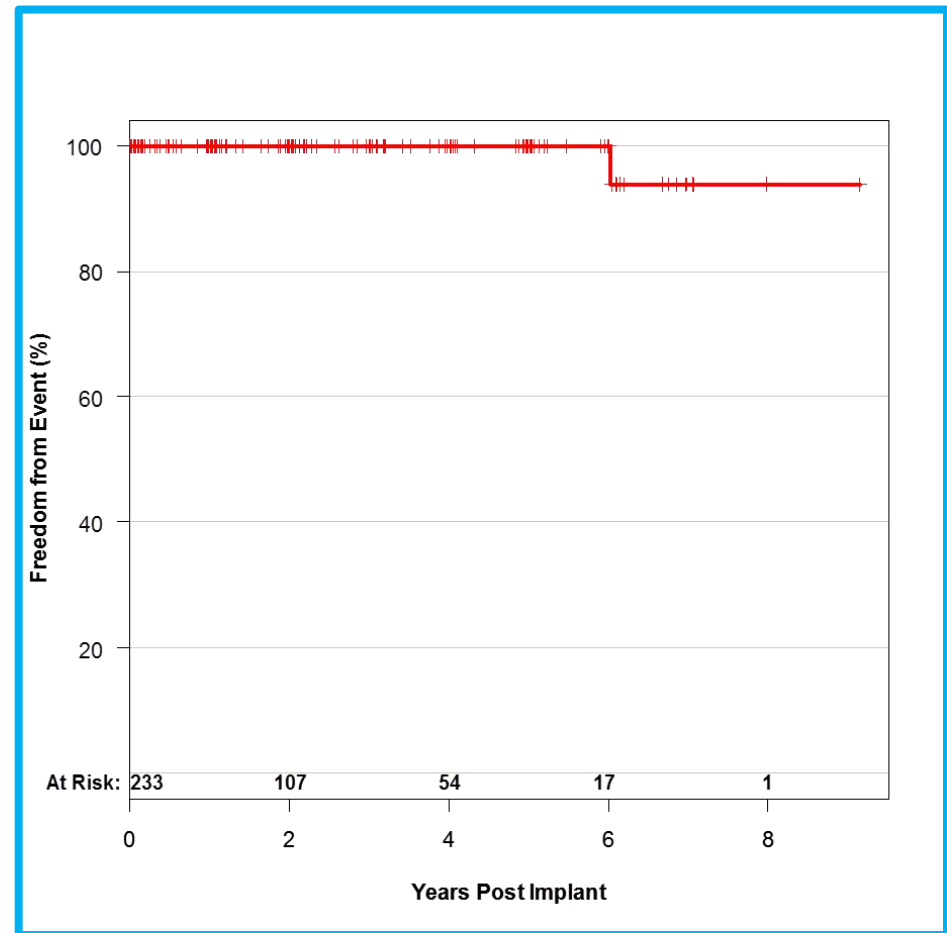


Aspectos en Discusión en TAVI: DURABILIDAD

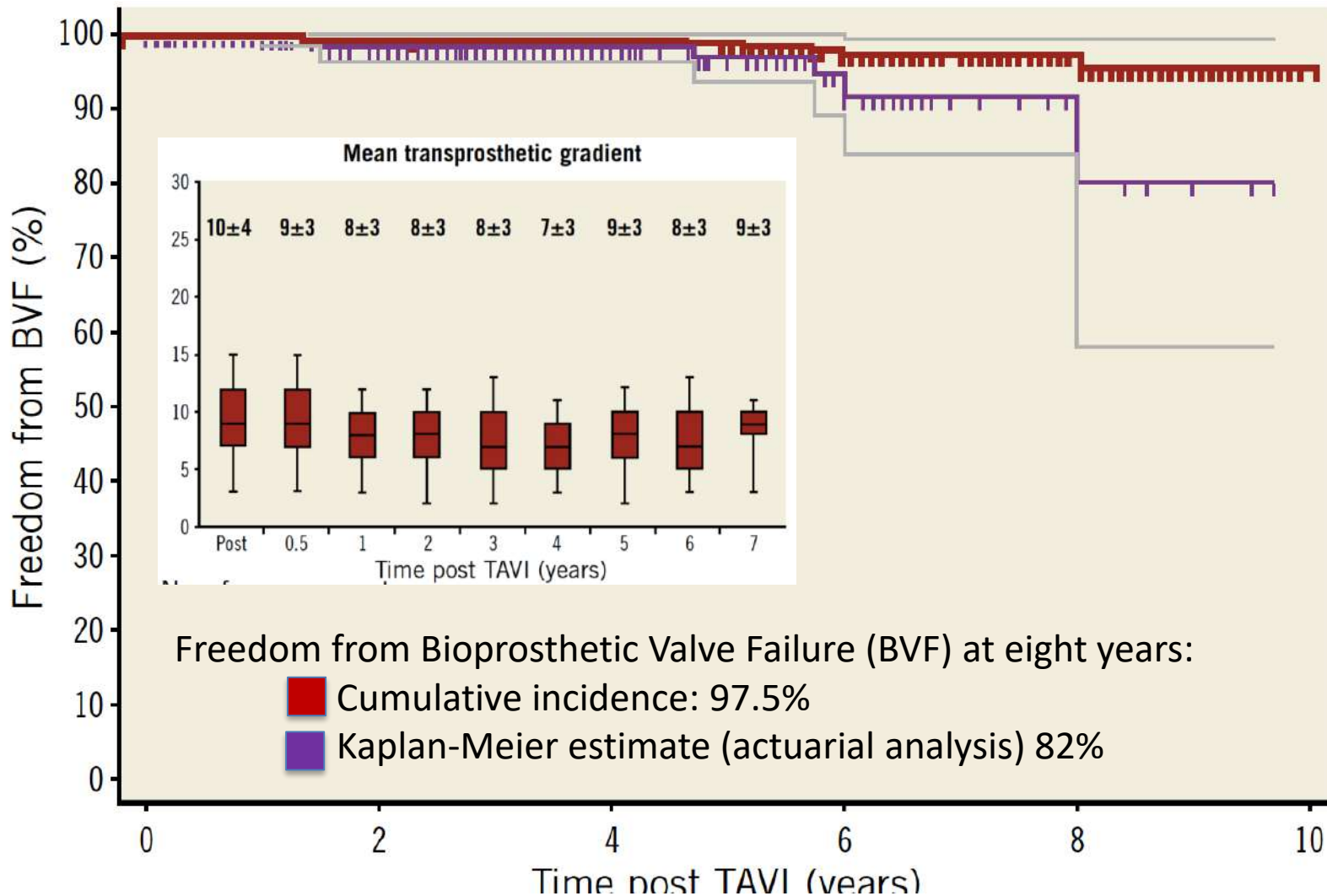
CHU Rouen. 239 pts from 2002-2011 (> 5 years FU)

Freedom from either reoperation, or if asymp, echo mean valve gradient >40 mmHg or severe AR (effective ROA > 0.3cm²)

Among survivors, none with MG >40 and only 1 pt with severe AR resulting in ViV procedure



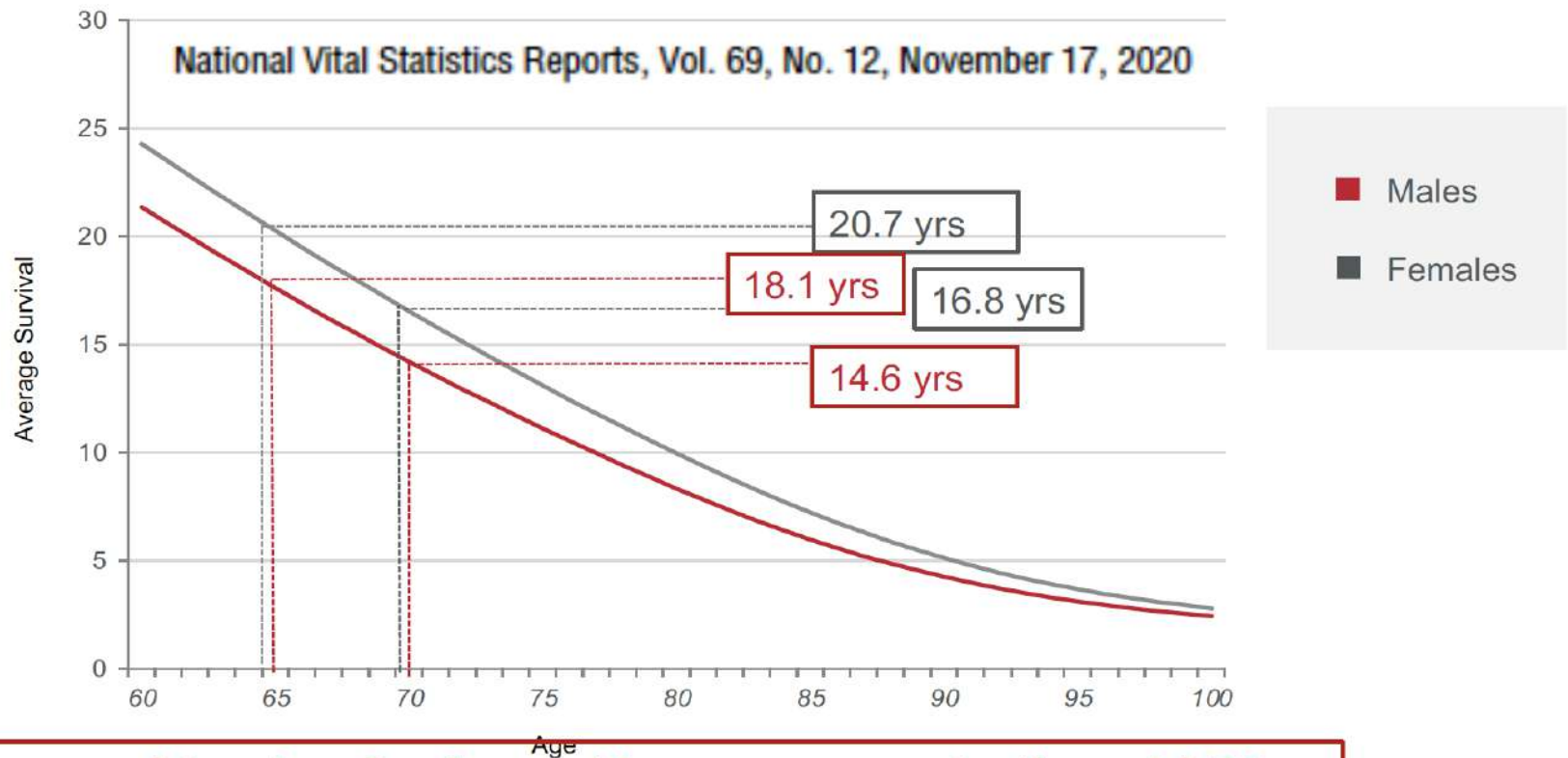
Aspectos en Discusión en TAVI: DURABILIDAD



Aspectos en Discusión en TAVI: DURABILIDAD

How durable does any procedure need to be?

Average Survival for an Individual Born in the US in 1950



You need to plan for for getting someone to the mid-80s



Agenda

4

Conclusiones



SERVIZO
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Conclusiones

- ✓ Hemos aprendido y progresado mucho, tanto en tecnología como en experiencia.
- ✓ Hoy día el procedimiento TAVI es altamente seguro, efectivo y eficiente.
- ✓ Es nuestra obligación seguir incorporando mas conocimiento que aporte mas luz sobre las cuestiones aun no clarificadas.



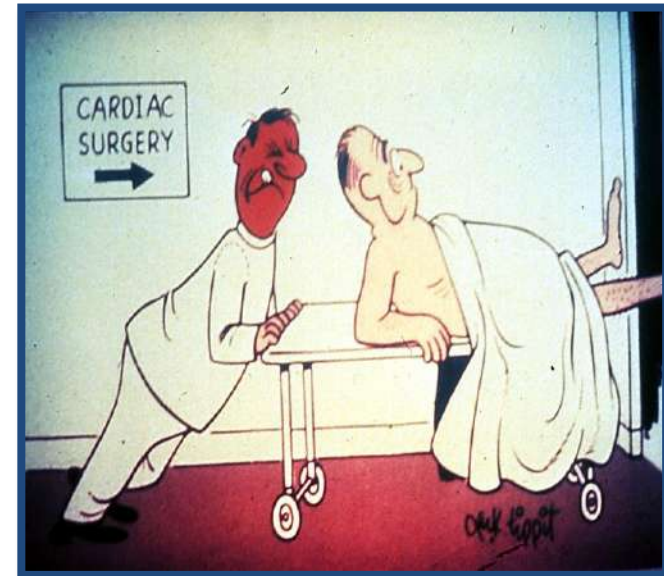
Conclusiones

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Conclusiones

- ✓ Hemos aprendido y progresado mucho, tanto en tecnología como en experiencia.
- ✓ Hoy día el procedimiento TAVI es altamente seguro, efectivo y eficiente.
- ✓ Es nuestra obligación seguir incorporando mas conocimiento que aporte mas luz sobre las cuestiones aun no clarificadas.
- ✓ Aun con ciertas incertidumbres pendientes, la TAVI se ha consolidado como el patrón oro de tratamiento de la EAo severa, tanto para los profesionales como para los pacientes



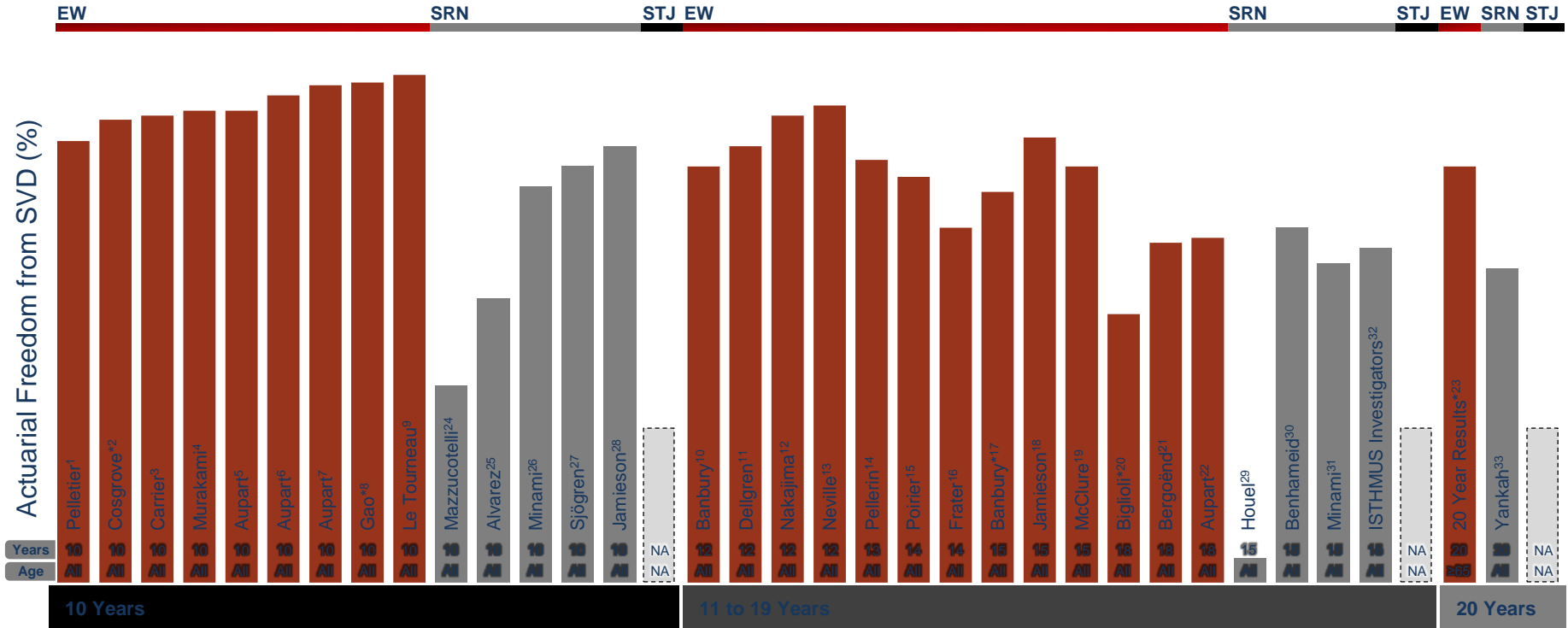
Muchas Gracias

Vigo (España)



Aspectos en Discusión en TAVI: DURABILIDAD

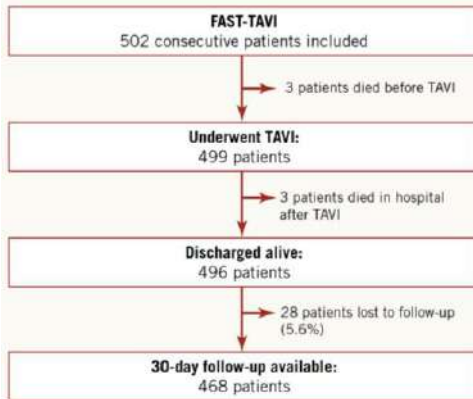
Actuarial Freedom from Structural Valve Deterioration Pericardial Aortic Bioprosthesis



* Freedom from explant / prosthesis replacement / reoperation due to SVD

Methodology: Comprehensive literature searches were conducted utilizing a combination of key words. See references section for key words, filters, and a search results summary.
Note: Patients and results are a subset of each study. See references section for total cohort size, patient mean age, and at risk population size.

Aspectos en Discusión en TAVI: ALTA PRECOZ



Reasons for not being discharged ≤ 72 hours*, **

Logistic reasons	47/135 (34.8)
Conduction disturbance	35/135 (25.9)
Bleeding	22/135 (16.3)
Mobilisation	20/135 (14.8)
Renal	14/135 (10.4)
Vascular	13/135 (9.6)
Other reasons	20/135 (27.4)

Table 2. 30-day outcomes of those discharged alive and with a 30-day follow-up available.

	Total	% with 95% CI
Primary endpoint*	61/474	12.9 (11.3-16.5)
Overall mortality	5/467	1.1 (0.2-2.0)
Stroke/TIA	8/468	1.7 (-0.6-4.0)
Stroke	4/468	0.9 (-1.7-3.5)
TIA	4/468	0.9 (-1.7-3.5)
New PPI	34/466	7.3 (5.8-8.9)
Kidney failure	2/466	0.4 (-1.4-2.2)
Major vascular complications	9/467	1.9 (0.7-3.1)
Major/life-threatening bleeding	11/467	2.4 (1.0-3.8)
Re-hospitalisation (any reason)	45/467	9.6 (7.5-11.8)
Re-hospitalisation (cardiac reason)	17/465	3.7 (1.4-6.0)

30-day outcomes	Low risk of complications & discharged ≤ 3 days
Primary endpoint*	23/328 (7.0)
Overall mortality	2/326 (0.6)
Stroke/TIA	4/326 (1.2)
Stroke	0/326 (0)
TIA	4/326 (1.2)
PPI	14/325 (4.3)
Kidney failure	0/325 (0.0)
Major vascular complications	1/325 (0.3)
Major/life-threatening bleeding	1/325 (0.3)
Re-hospitalisation (any reason)	29/327 (8.6)
Re-hospitalisation (cardiac reason)	11/326 (3.4)

Barbanti M, et al. EuroIntervention 2019;15:147-154

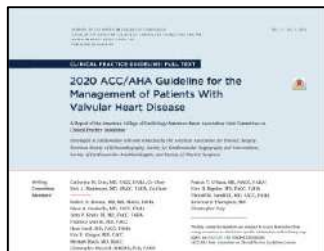
Aspectos en Discusión en TAVI: ALTA PRECOZ

CRITERIOS DE ALTA PRECOZ

- NYHA Clase \leq II,
- Sin dolor torácico atribuible a isquemia cardiaca
- Sin arritmias importantes no tratadas
- Pacientes sin complicaciones el día 0 a 1, o libre de signos o síntomas el día 3
- Sin fiebre en las últimas 24 horas y sin signos de causa infecciosa
- Movilización independiente y autocuidado posible
- Diuresis conservada (> 40 ml/hora durante las 24 horas anteriores)
- Sin lesión renal aguda no resuelta tipo 3 (según criterios VARC-2)
- Sin transfusión de glóbulos rojos (RBC) durante las 72 horas anteriores,
- Hemoglobina estable en dos muestras consecutivas (definida como una disminución de no más de 2 mg/dl)
- Sin fuga para-valvular (PVL) con insuficiencia aórtica menor que moderada
- Sin ictus/accidente isquémico transitorio (AIT)
- Sin inestabilidad hemodinámica.



Visión Actual de la Estenosis Aórtica



COR	LOE	RECOMMENDATIONS
1	A	1. In adults with severe high-gradient AS (Stage D1) and symptoms of exertional dyspnea, HF, angina, syncope, or presyncope by history or on exercise testing, AVR is indicated (74–80).
1	B-NR	2. In asymptomatic patients with severe AS and an LVEF <50% (Stage C2), AVR is indicated (81–84).
1	B-NR	3. In asymptomatic patients with severe AS (Stage C1) who are undergoing cardiac surgery for other indications, AVR is indicated (57,63,85–87).
1	B-NR	4. In symptomatic patients with low-flow, low-gradient severe AS with reduced LVEF (Stage D2), AVR is recommended (88–95).
1	B-NR	5. In symptomatic patients with low-flow, low-gradient severe AS with normal LVEF (Stage D3), AVR is recommended if AS is the most likely cause of symptoms (96–98).

5 Class 1 recommendations

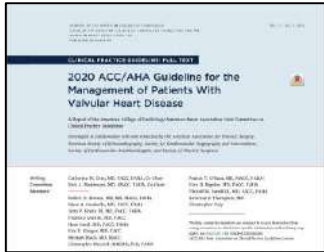
All severe AS and 3/5 with symptoms

2a	B-NR	6. In apparently asymptomatic patients with severe AS (Stage C1) and low surgical risk, AVR is reasonable when an exercise test demonstrates decreased exercise tolerance (normalized for age and sex) or a fall in systolic blood pressure of ≥ 10 mm Hg from baseline to peak exercise (61,63,64,99).
2a	B-R	7. In asymptomatic patients with very severe AS (defined as an aortic velocity of ≥ 5 m/s) and low surgical risk, AVR is reasonable (86,100–104).
2a	B-NR	8. In apparently asymptomatic patients with severe AS (Stage C1) and low surgical risk, AVR is reasonable when the serum B-type natriuretic peptide (BNP) level is >3 times normal (101,105–107).
2a	B-NR	9. In asymptomatic patients with high-gradient severe AS (Stage C1) and low surgical risk, AVR is reasonable when serial testing shows an increase in aortic velocity ≥ 0.3 m/s per year (108,109).

4 Class 2a recommendations

All severe AS and All 'apparently' asymptomatic or asymptomatic

Visión Actual de la Estenosis Aórtica



COR	LOE	RECOMMENDATIONS
1	A	1. In adults with severe high-gradient AS (Stage D1) and symptoms of exertional dyspnea, HF, syncope, or presyncope by history or on exercise testing, AVR is indicated (74–80).
1	B-NR	2. In asymptomatic patients with severe AS and an LVEF <50% (Stage C2), AVR is indicated (81–83).
1	B-NR	3. In asymptomatic patients with severe AS (Stage C1) and low surgical risk, AVR is reasonable (84–86). In asymptomatic patients with severe AS (Stage C1) and low surgical risk, AVR is reasonable if exercise testing shows an increase in aortic velocity ≥ 0.3 m/s per year (108,109).

Tanto ACC/AHA como ESC en las nuevas Guías Clínicas han elevado las recomendaciones de remplazo valvular aórtico, incluso en algunas situaciones (low-flow, low-gradient AS) y en algunos pacientes asintomáticos.

Class 2a recommendations: All severe AS and All 'apparently' asymptomatic or asymptomatic

Infradiagnóstico e Infratratamiento en la EAO

The RECOVERY Surgical AVR Trial



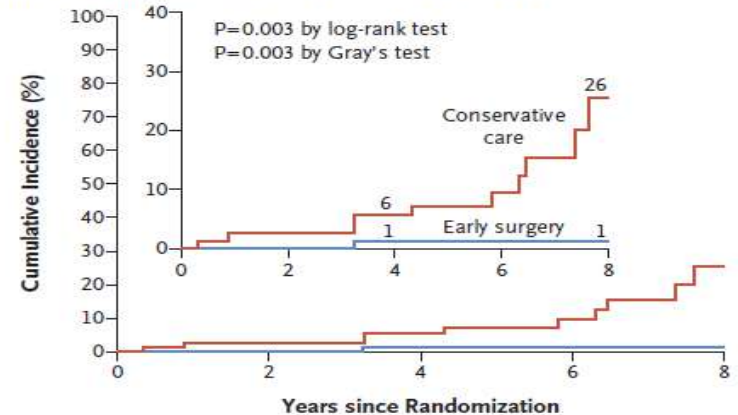
Early Surgery or Conservative Care for Asymptomatic Aortic Stenosis

Duk-Hyun Kang, M.D., Ph.D., Sung-Ji Park, M.D., Ph.D., Seung-Ah Lee, M.D., Sahmin Lee, M.D., Ph.D., Dae-Hee Kim, M.D., Ph.D., Hyung-Kwan Kim, M.D., Ph.D., Sung-Cheol Yun, Ph.D., Geu-Ru Hong, M.D., Ph.D., Jong-Min Song, M.D., Ph.D., Cheol-Hyun Chung, M.D., Ph.D., Jae-Kwan Song, M.D., Ph.D., Jae-Won Lee, M.D., Ph.D., and Seung-Woo Park, M.D., Ph.D.

- 145 asymptomatic patients w very severe AS randomized to early surgery or conservative care
- 1^{ry} endpoint (operative and FU death) was 1% vs. 15% in early surgery vs. conservative care (P=0.003)

Kang DH et al, NEJM 2020

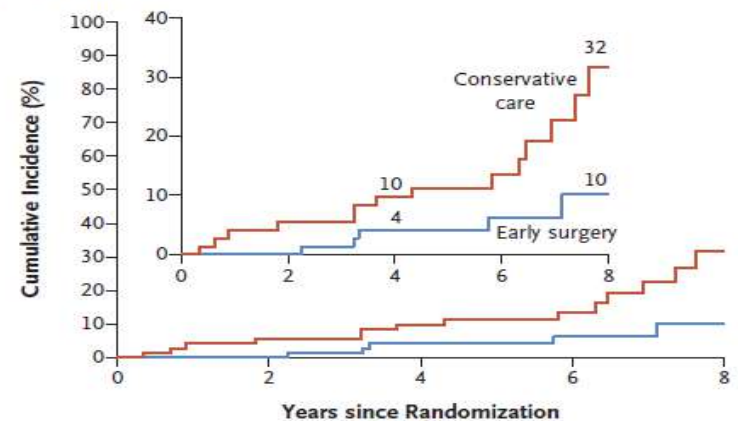
A Operative Mortality or Death from Cardiovascular Causes



No. at Risk

Conservative care	72	68	65	36	12
Early surgery	73	73	70	38	13

B Death from Any Cause



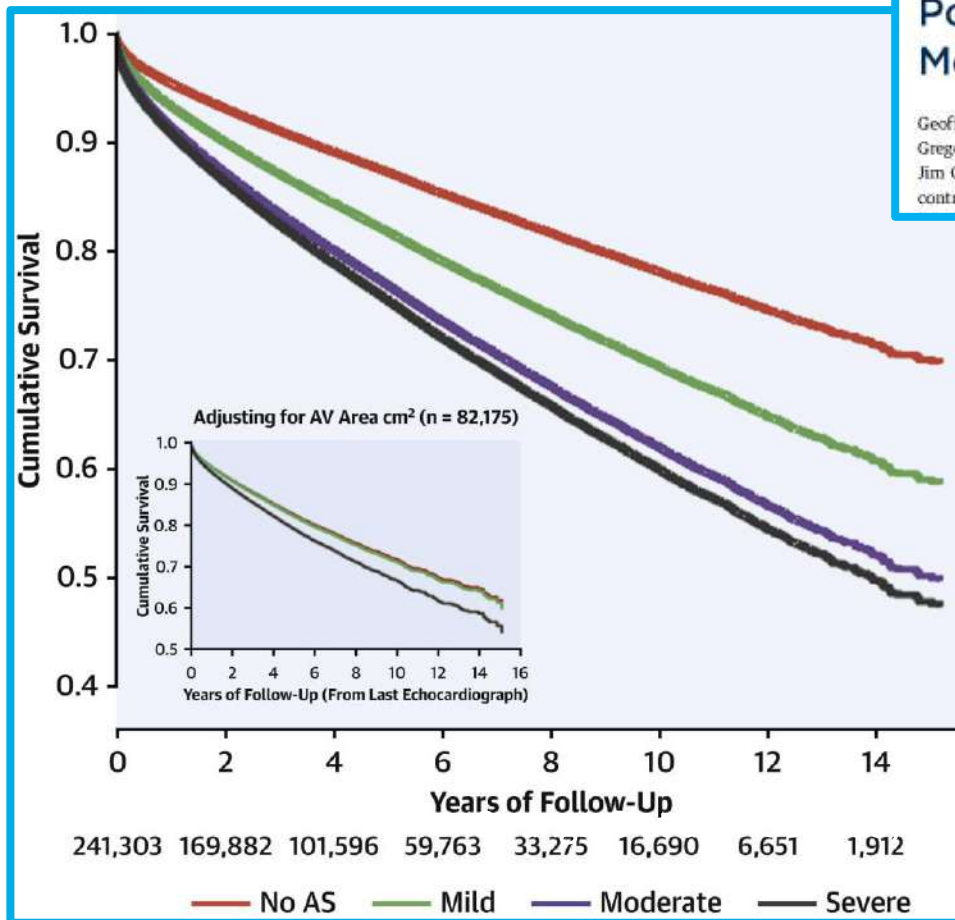
No. at Risk

Conservative care	72	68	65	36	12
Early surgery	73	73	70	38	13

Infradiagnóstico e Infratratamiento en la EAO

Natural History of Untreated Mod AS

National Echo Database



Poor Long-Term Survival in Patients With Moderate Aortic Stenosis

Geoff Strange, PhD,^a Simon Stewart, PhD,^b David Celermajer, MD, PhD,^c David Prior, MBBS, PhD,^d Gregory M. Scalia, MBBS (Hons), MMEdSc,^e Thomas Marwick, MBBS, PhD,^f Marcus Ilton, MD,^g Majo Joseph, MBBS,^h Jim Codde, PhD,ⁱ David Playford, MBBS, PhD,^g on behalf of the National Echocardiography Database of Australia contributing sites

Reasons...

- Misclassification issues?
- Echocardiography challenges
- Rapid progression to severe AS
- Already too much cardiac damage
- Intervention too late (missed opportunities) with limitations of active surveillance strategy

Strange G et al. JACC 2019; 74:1851–63