

HOSPITAL ÁLVARO CUNQUEIRO



TAVI: “Valve in Valve”

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Declaración de Interés



Ningún conflicto de interés relacionado con el tema de esta presentación.

Agenda

- 1 Justificación "TAVI - Valve in Valve" (TAVI-ViV)
- 2 "TAVI-ViV": Resultados
- 3 "TAVI-ViV": Peculiaridades
- 4 Durabilidad de la "TAVI-ViV"
- 5 Mensajes Finales



1

Justificación "TAVI - Valve in Valve" (TAVI-ViV)

TAVI-ViV: Justificación

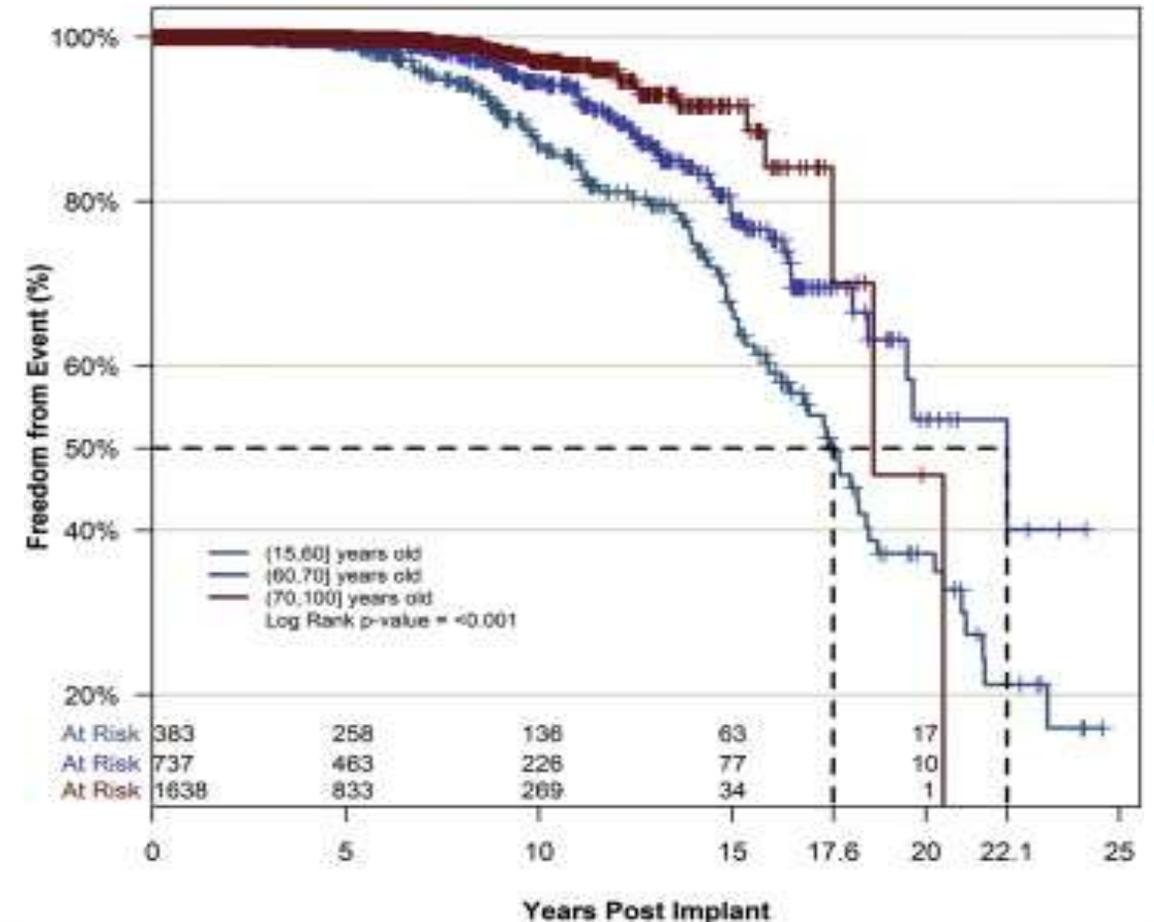
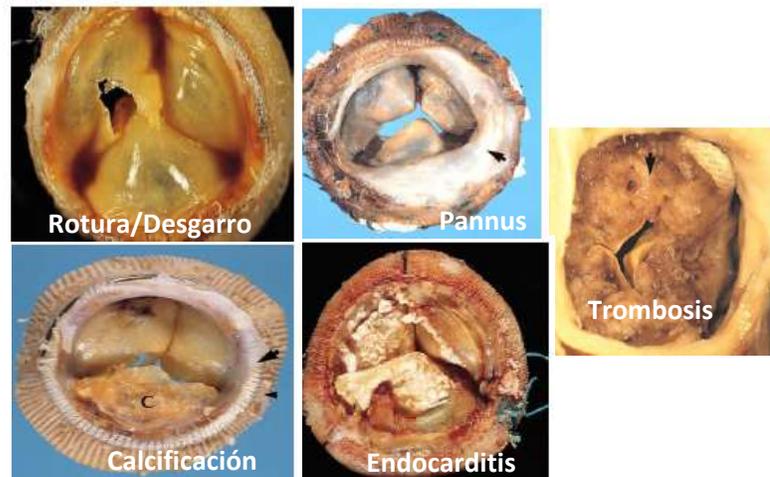


- Mejora en la durabilidad de válvulas biológicas / necesidad de reducir riesgos de sangrado -> aumento del uso de prótesis biológicas quirúrgicas.
- Mortalidad operatoria de una re-operación electiva valvular aórtica está entre el 2 - 7 %, pero es $\geq 30\%$ en pacientes de alto riesgo (*edad, cirugía previa, patología coronaria, comorbilidades*) no electivos.

TAVI-ViV: Justificación

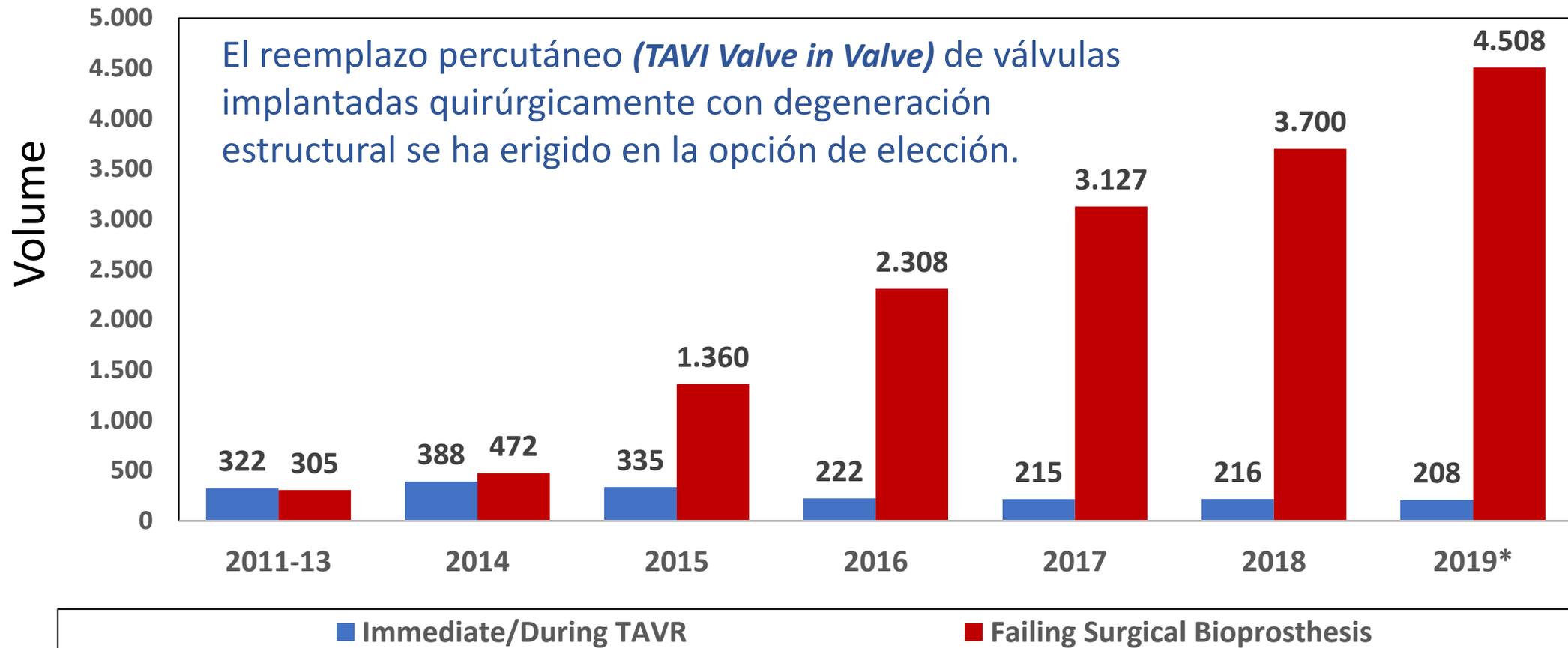
Degeneración Estructural Valvular

- El envejecimiento mas tardío -> mayor probabilidad degeneración valvular a 8-10 años -> necesidad de ser reemplazadas por nuevas prótesis.



TAVI-ViV: Justificación

Valve-in-Valve Annual Procedures STS/ACC TVT Registry



Agenda



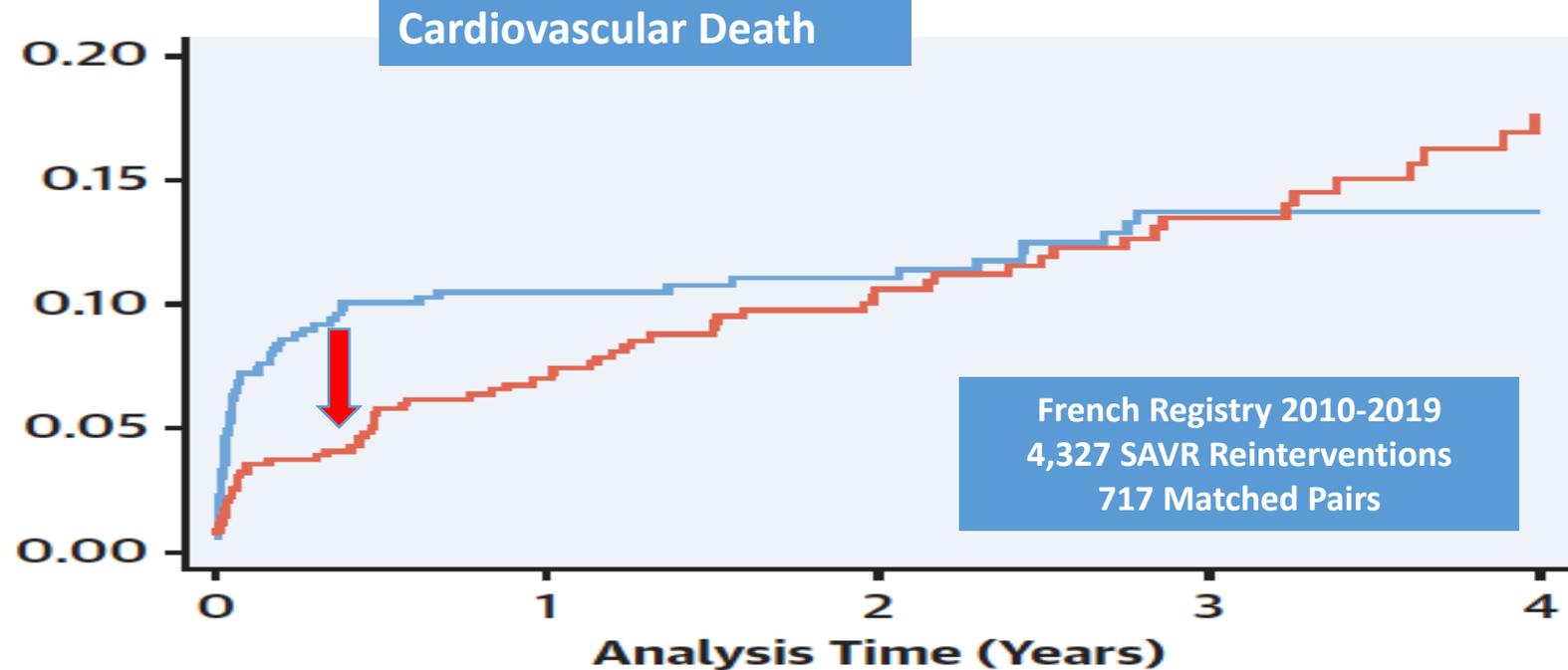
2

“TAVI-ViV”: Resultados

TAVI " Valve in Valve": Resultados

Transcatheter Valve-in-Valve Aortic Valve Replacement as an Alternative to Surgical Re-Replacement

Pierre Deharo, PhD,^{1,4} Arnaud Bisson, MD,⁵ Julien Herberich, MD,^{1,4} Thibaud Lacour, MD,^{1,4}
Christophe Saint Etienne, MD,⁶ Alizée Porto, MD,⁷ Alexis Theron, MD,⁸ Frederic Collart, MD,^{1,4}
Thierry Bourguignon, PhD,¹ Thomas Cuisset, PhD,^{1,2} Laurent Fauchier, PhD⁹



Number at risk

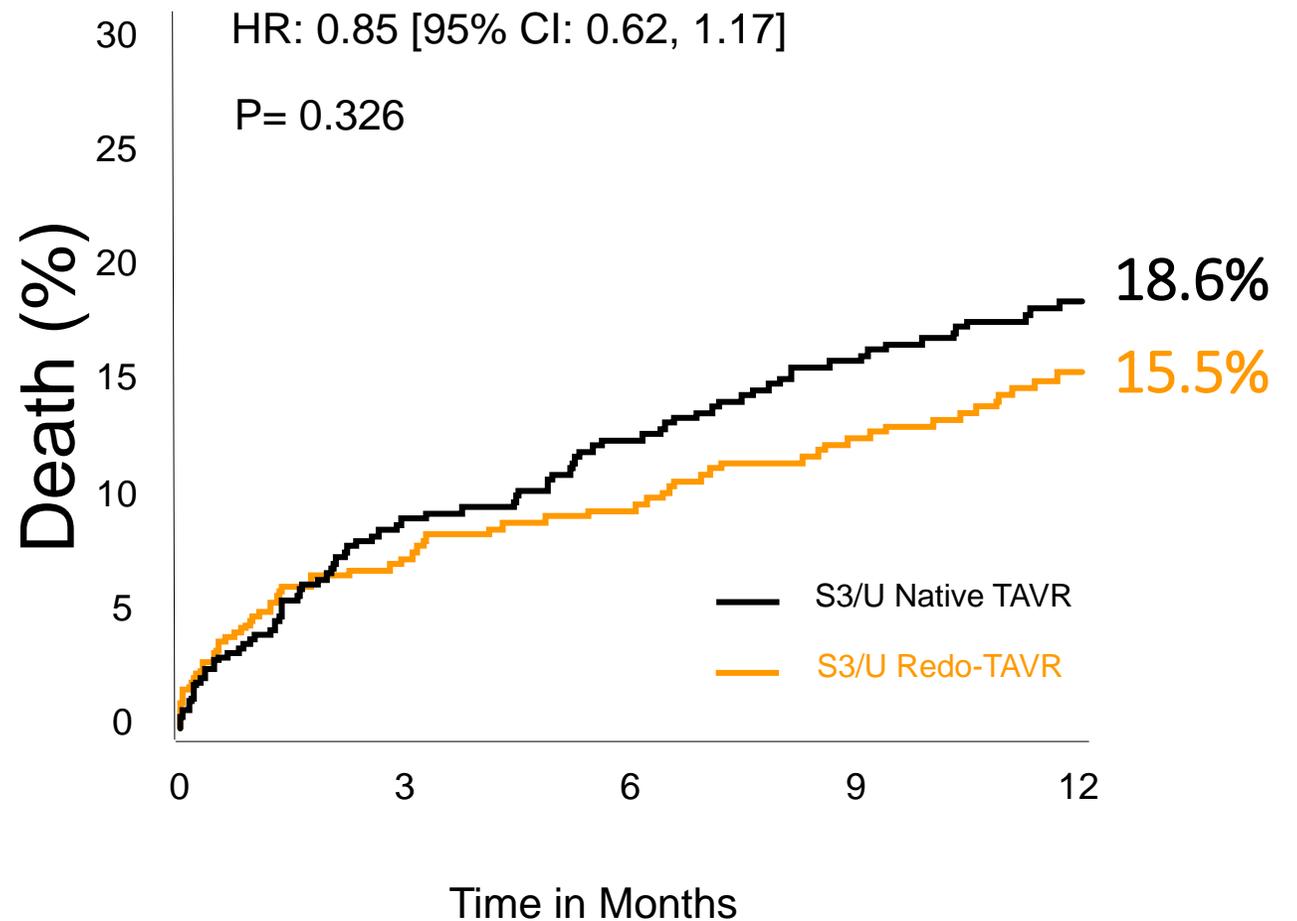
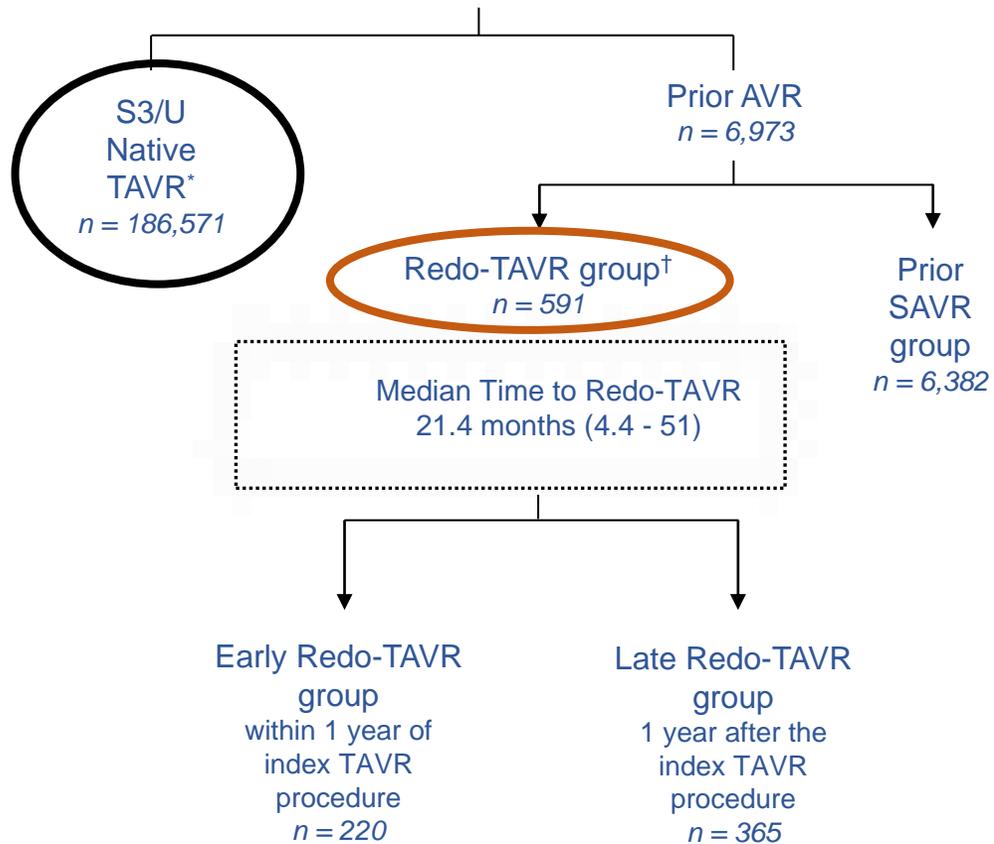
— SAVR = 717	459	404	348	307	265	223	191	165
— TAVR = 717	527	466	410	349	282	220	174	135

TAVI " Valve in Valve": Resultados



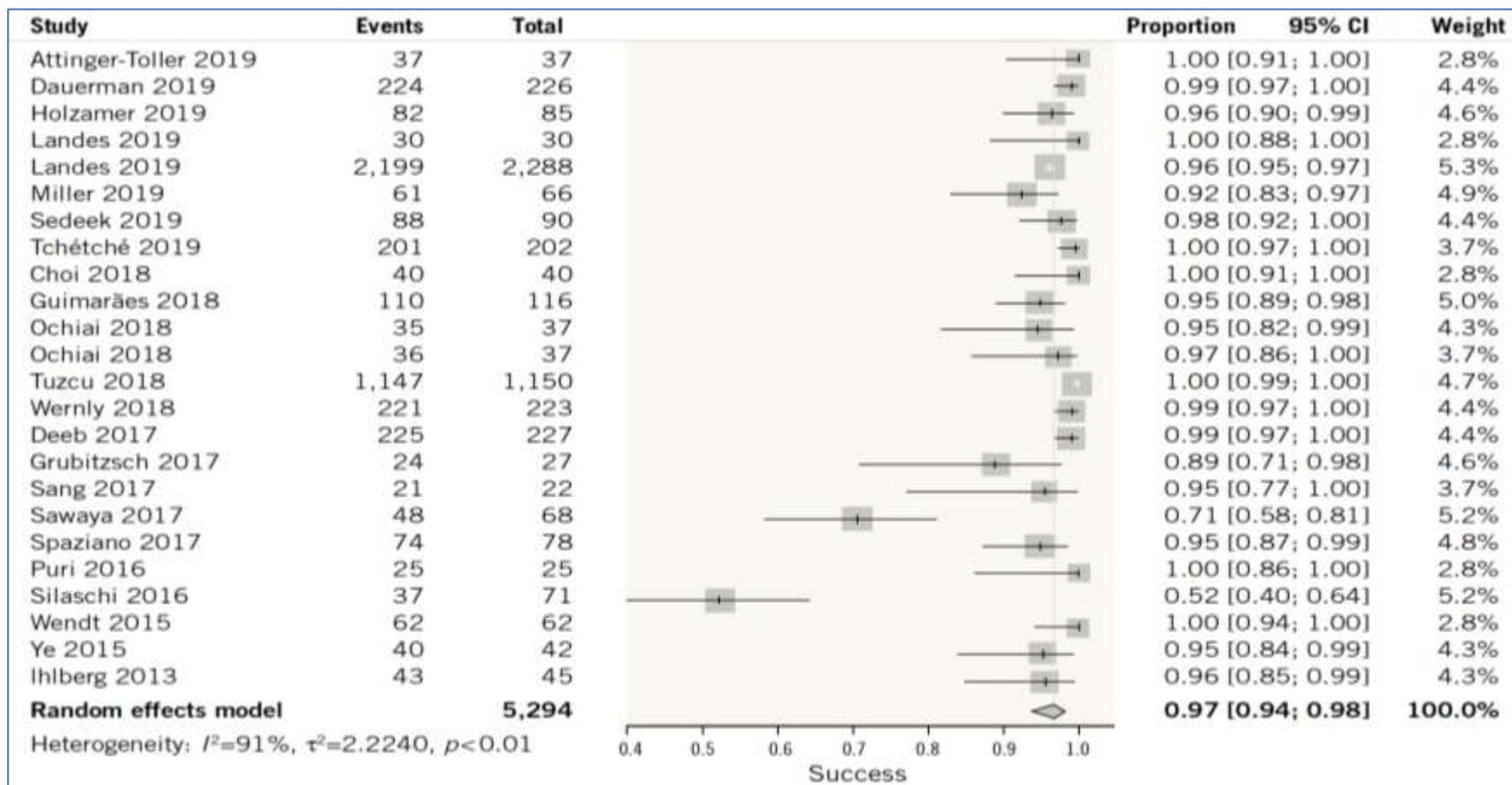
193,544 Patients with SAPIEN 3/ Ultra TAVR for Aortic Stenosis

STS/ACC TVT Registry June 2015 – December 2020



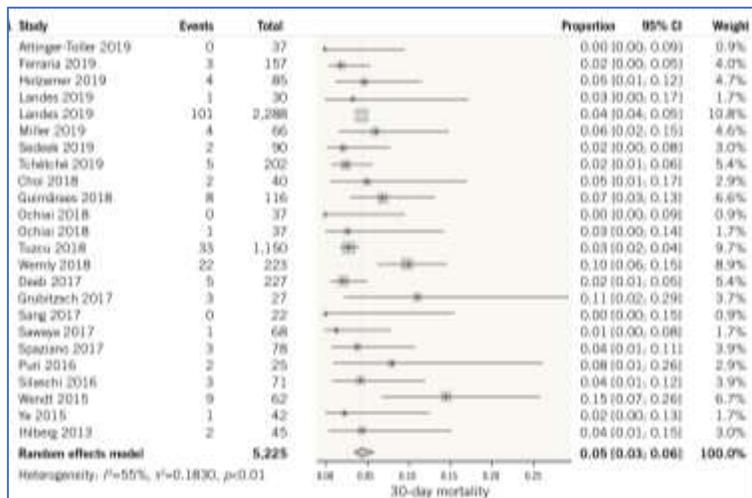
TAVI " Valve in Valve": Resultados

Éxito en el procedimiento (97%)

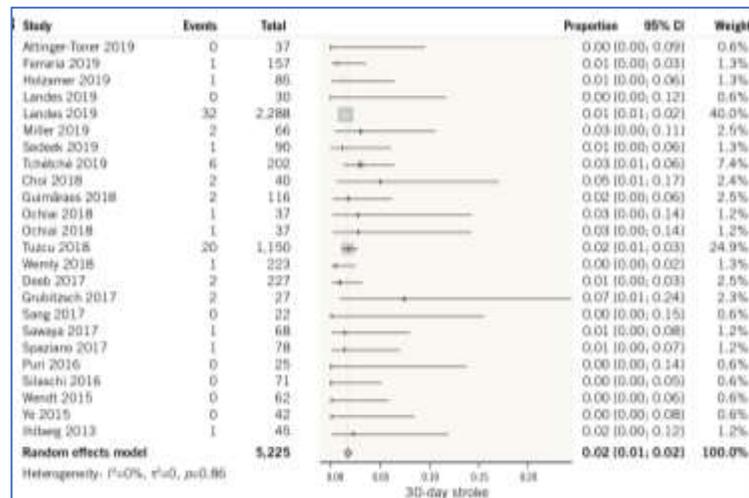


TAVI " Valve in Valve": Resultados a 30 días

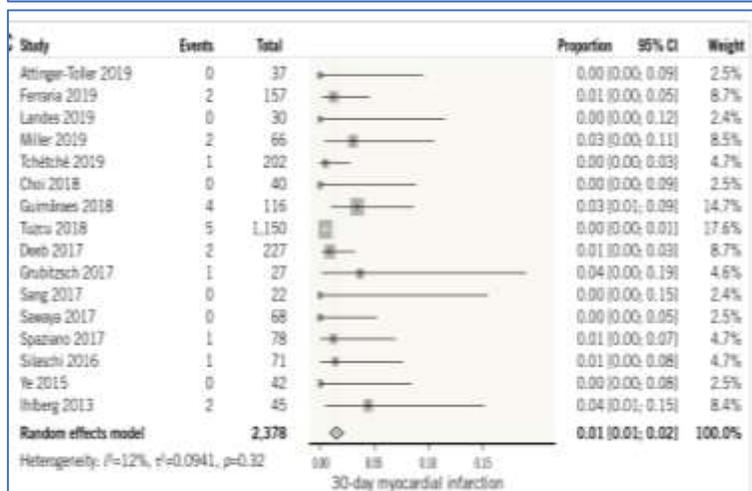
**Mortalidad
5%**



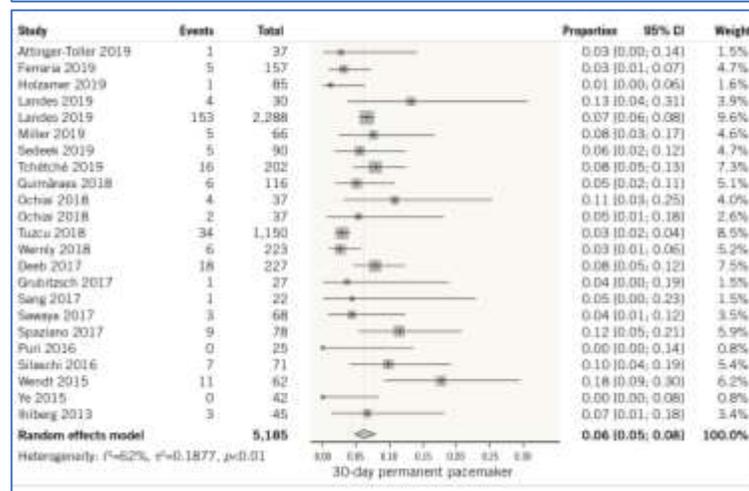
**ACV
2%**



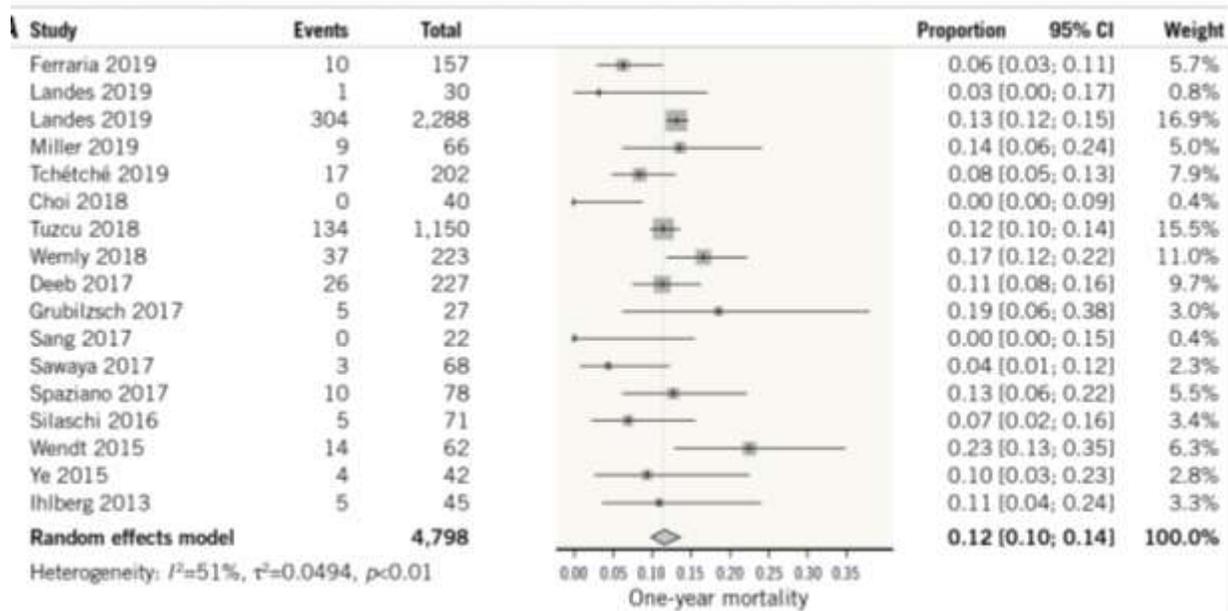
**IAM
1%**



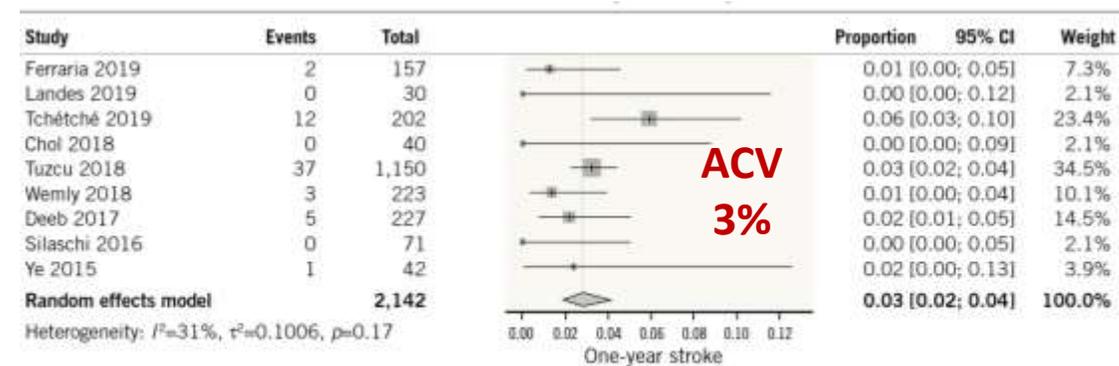
**Marcapasos
6%**



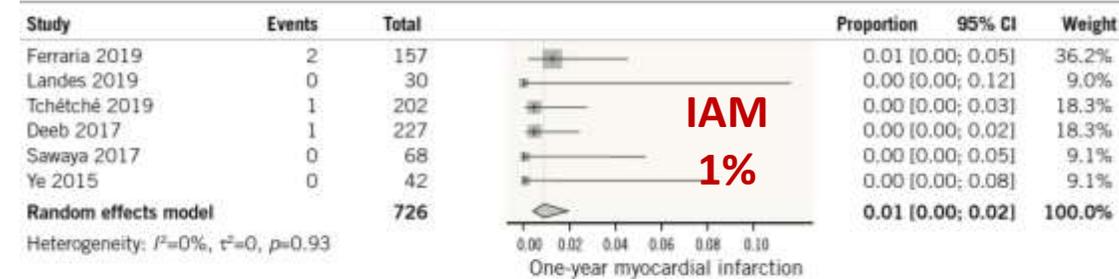
TAVI " Valve in Valve": Resultados a 1 año



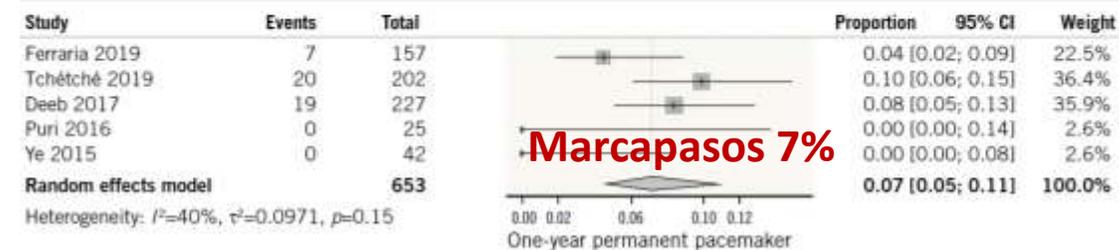
**Mortalidad
12%**



**ACV
3%**



**IAM
1%**



Marcapasos 7%

Agenda

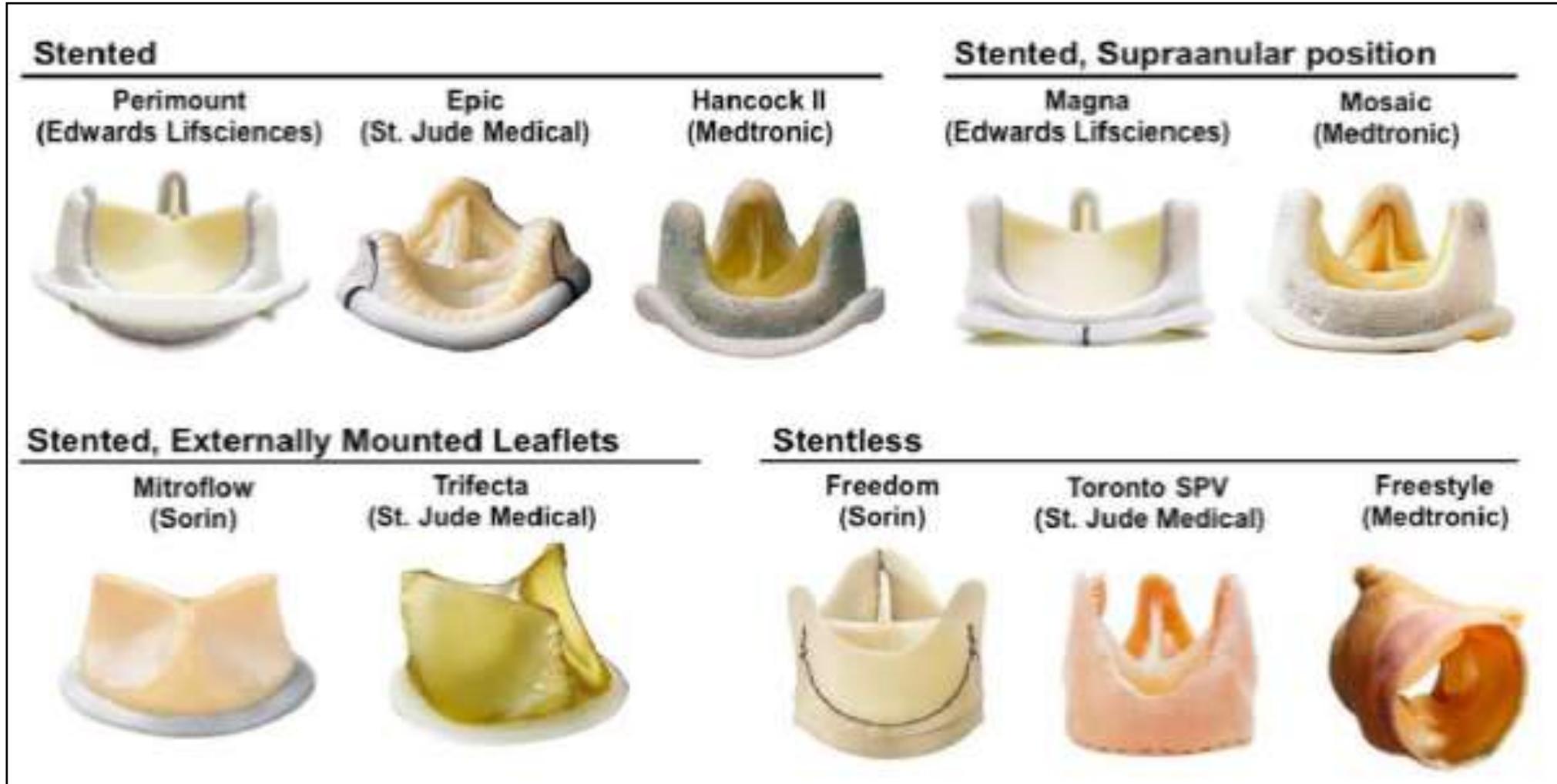


3

“TAVI-ViV”: Peculiaridades

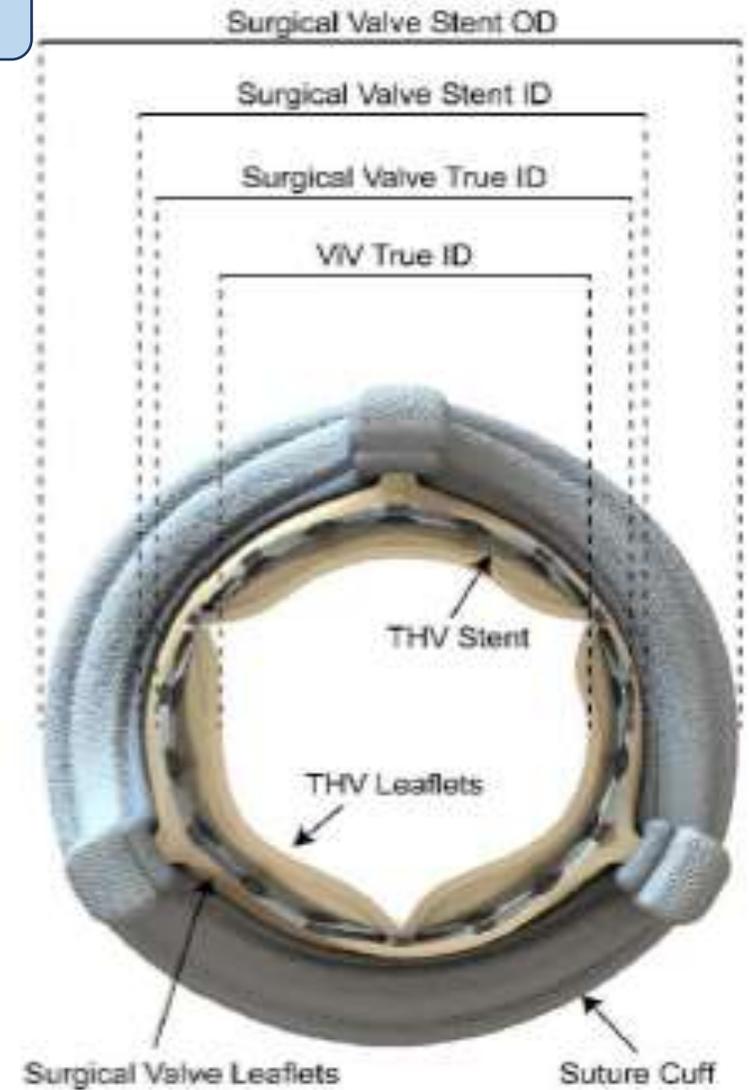
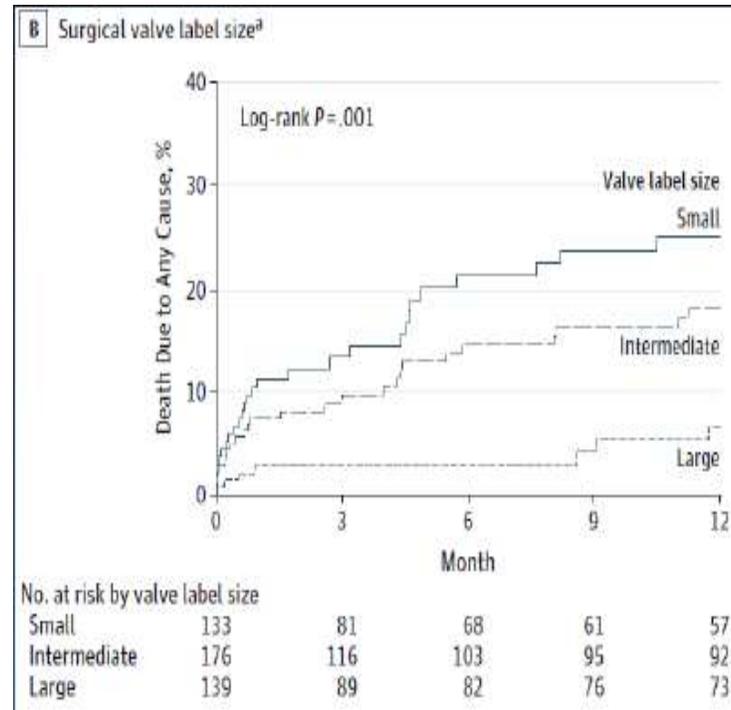
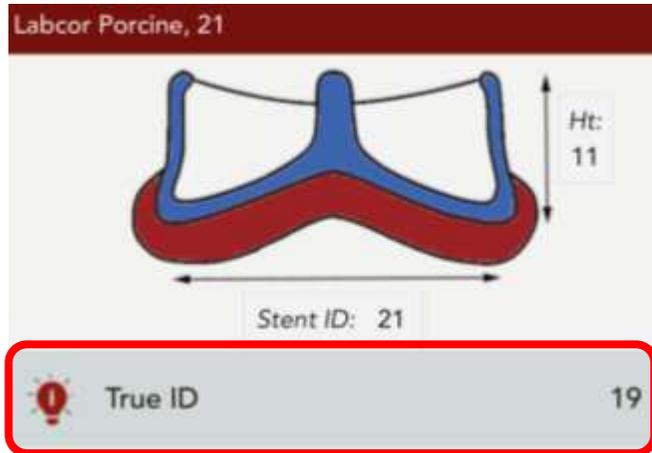
“TAVI - ViV”: Anillo y Tipo de Válvula

Tipos de válvulas biológicas quirúrgicas



"TAVI - ViV": Consideraciones sobre el anillo

1) ¿Diámetro Real del Anillo Interno?

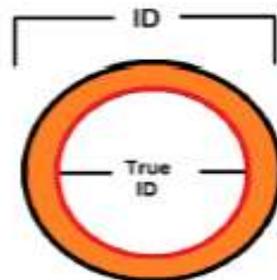


"TAVI - ViV": Consideraciones sobre el anillo

¿Diámetro Real del Anillo Interno?

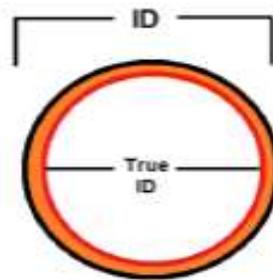
Depende del tipo de tejido valvular, y si está montado dentro o fuera del anillo de soporte

Porcine Leaflets
Mounted inside



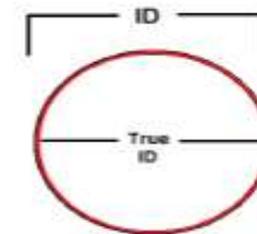
$$\text{True ID} = \text{Stent ID} - 2\text{mm}$$

Pericardial Leaflets
Mounted inside



$$\text{True ID} = \text{Stent ID} - 1\text{mm}$$

Pericardial Leaflets
Mounted outside



$$\text{Stent ID} = \text{True ID}$$

“TAVI - ViV”: Consideraciones sobre el anillo

¿Diámetro Real del Anillo Interno?

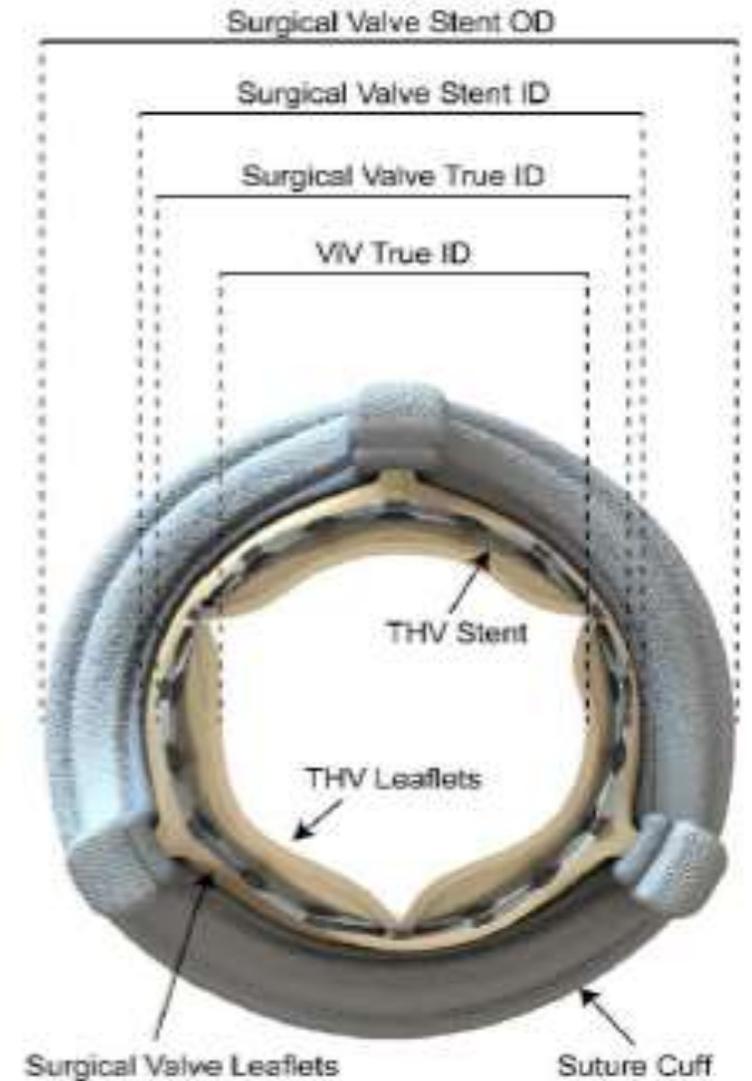
Cada fabricante y válvula es diferente a cualquier otra.

Valve Label Size	Valve Type/Model (Manufacturer)	Sewing Ring External Diameter, mm	Stent Outer Diameter, mm	Stent Internal Diameter, mm
18	Soprano (Sorin Biomedica)	26	21	17.8
19	Magna (Edwards Lifesciences)	24	19	18
	Perimount (Edwards Lifesciences)	26	19	18
	Mosaic (Medtronic)	25	19	17.5
	Hancock Ultra (Medtronic)	24	19	17.5
	Hancock II (Medtronic)	N/A	N/A	N/A
	Mitroflow (Sorin Biomedica)	21	18.6	15.4
	Trifecta (St. Jude Medical)	24	19	N/a
	Epic/Biocor (St. Jude Medical)	N/A	N/A	N/A
	Epic Supra/Biocor Supra (St. Jude Medical)	N/A	N/A	N/A
20	Soprano (Sorin Biomedica)	28	23	19.8
21	Magna (Edwards Lifesciences)	26	21	20
	Perimount (Edwards Lifesciences)	29	21	20
	Mosaic/Hancock II (Medtronic)	27	21	18.5
	Hancock/Hancock Ultra (Medtronic)	26	21	18.5
	Mitroflow (Sorin Biomedica)	23	20.7	17.3
	Trifecta (St. Jude Medical)	26	21	N/A
	Epic/Biocor (St. Jude Medical)	N/A	21	19
	Epic Supra/Biocor Supra (St. Jude Medical)	N/A	21	21
	22	Soprano (Sorin Biomedica)	30	25
23	Magna (Edwards Lifesciences)	28	23	22
	Perimount (Edwards Lifesciences)	31	23	22
	Mosaic/Hancock II (Medtronic)	30	23	20.5
	Hancock/Hancock Ultra (Medtronic)	28	23	22
	Mitroflow (Sorin Biomedica)	26	22.7	19
	Trifecta (St. Jude Medical)	28	23	N/A
	Epic/Biocor (St. Jude Medical)	N/A	23	21
	Epic Supra/Biocor Supra (St. Jude Medical)	N/A	23	23

“TAVI - ViV”: Consideraciones sobre el anillo

¿Por qué es importante el Diámetro Real del Anillo Interno?

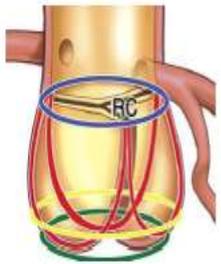
Es necesario adaptar los procedimientos a cada válvula y paciente



“TAVI - ViV”: Peculiaridades

2) ¿Cuál es la Posición del Anillo?

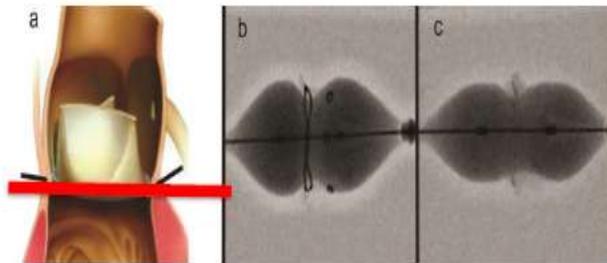
¿Donde está realmente el anillo?



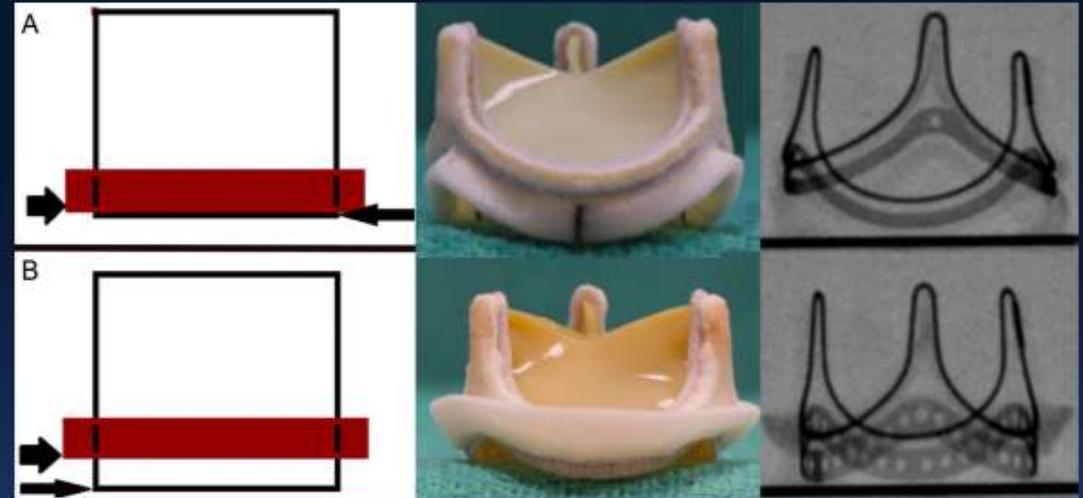
Native aortic valve



Surgical heart valve ??



Neo-Anillo
(“Nivel Menos Flexible”)



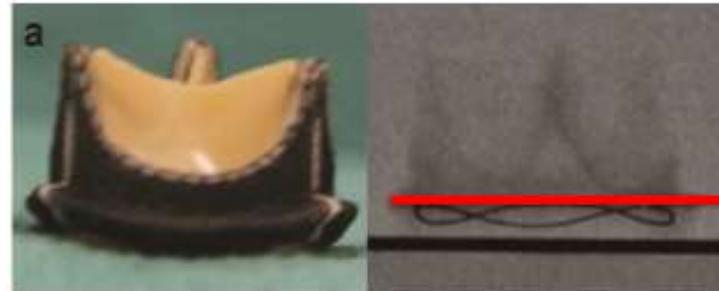
- A) Supra-Annular design = Sewing ring lowest point of valve (Magna; Edwards Lifesciences)
- B) Intra-Annular design = sewing ring is higher than the valve (Perimount; Edwards Lifesciences)

“TAVI - ViV”: Consideraciones sobre el anillo

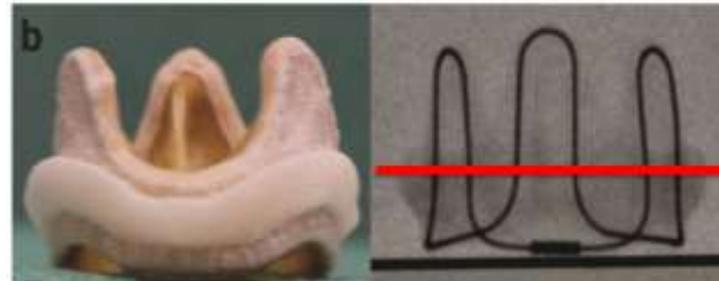
El anillo de sutura debería ser la zona de implante. Es el Neo-Anillo

Fluoroscopia

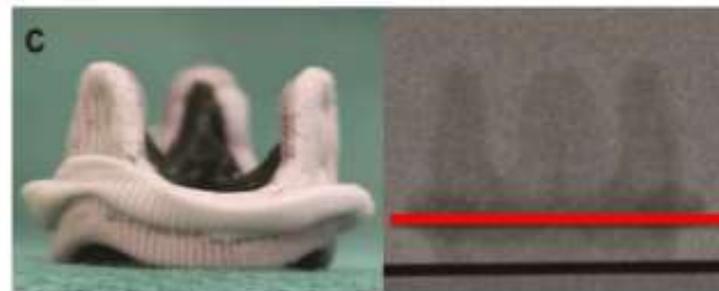
Marcador del Anillo de Sutura



Indicador del Marco del Stent



Ausencia de Marcador



“TAVI - ViV”: Consideraciones sobre el anillo

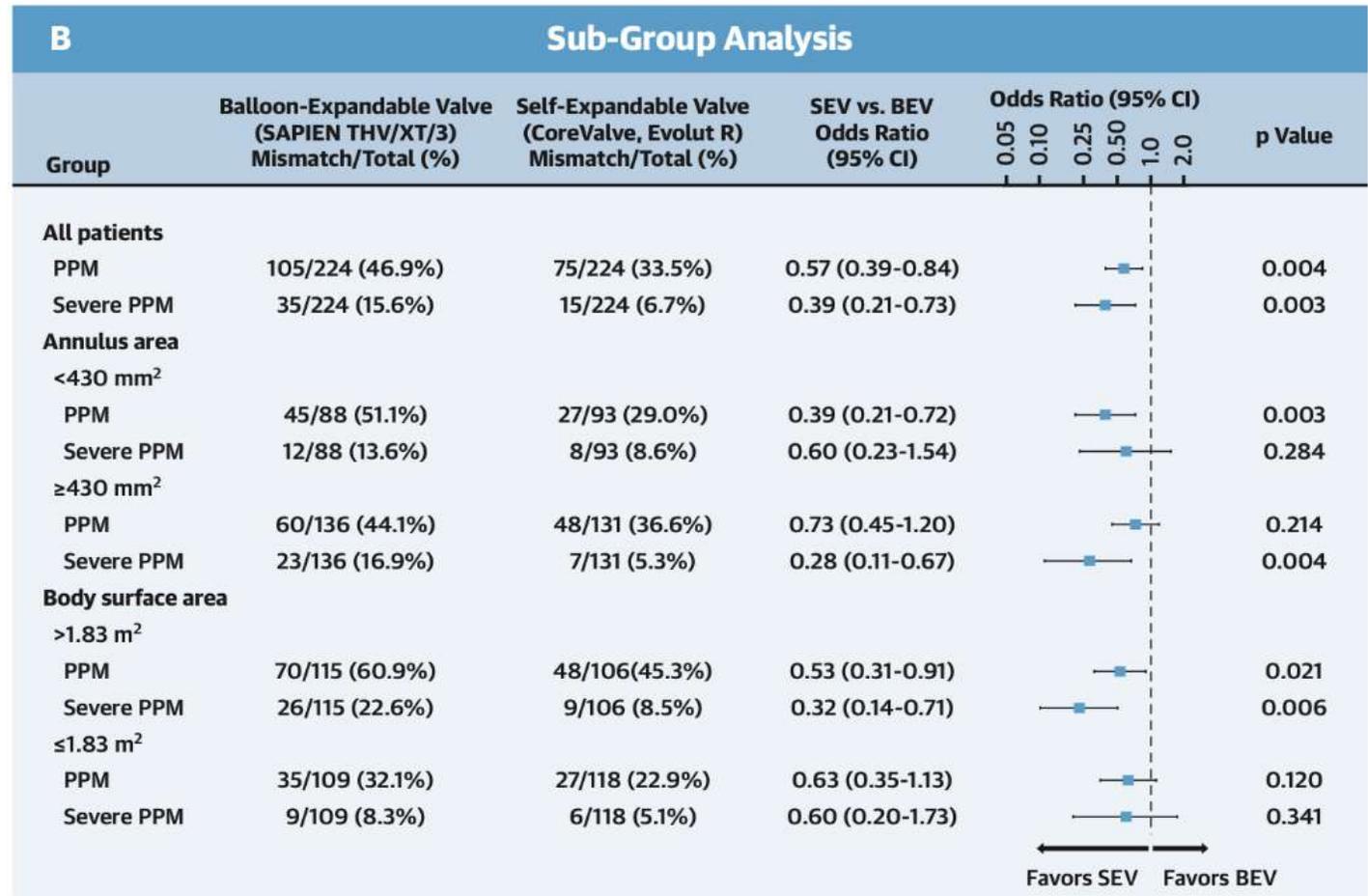
¿ Cual es el lugar apropiado para el implante?

La Válvula debe ser posicionada sobre el Neo-Anillo



"TAVI - ViV": Consideraciones sobre el anillo

Por su mejor hemodinámica, las válvulas supra-anulares autoexpandibles son especialmente recomendables en pacientes con anillo aórtico pequeño.

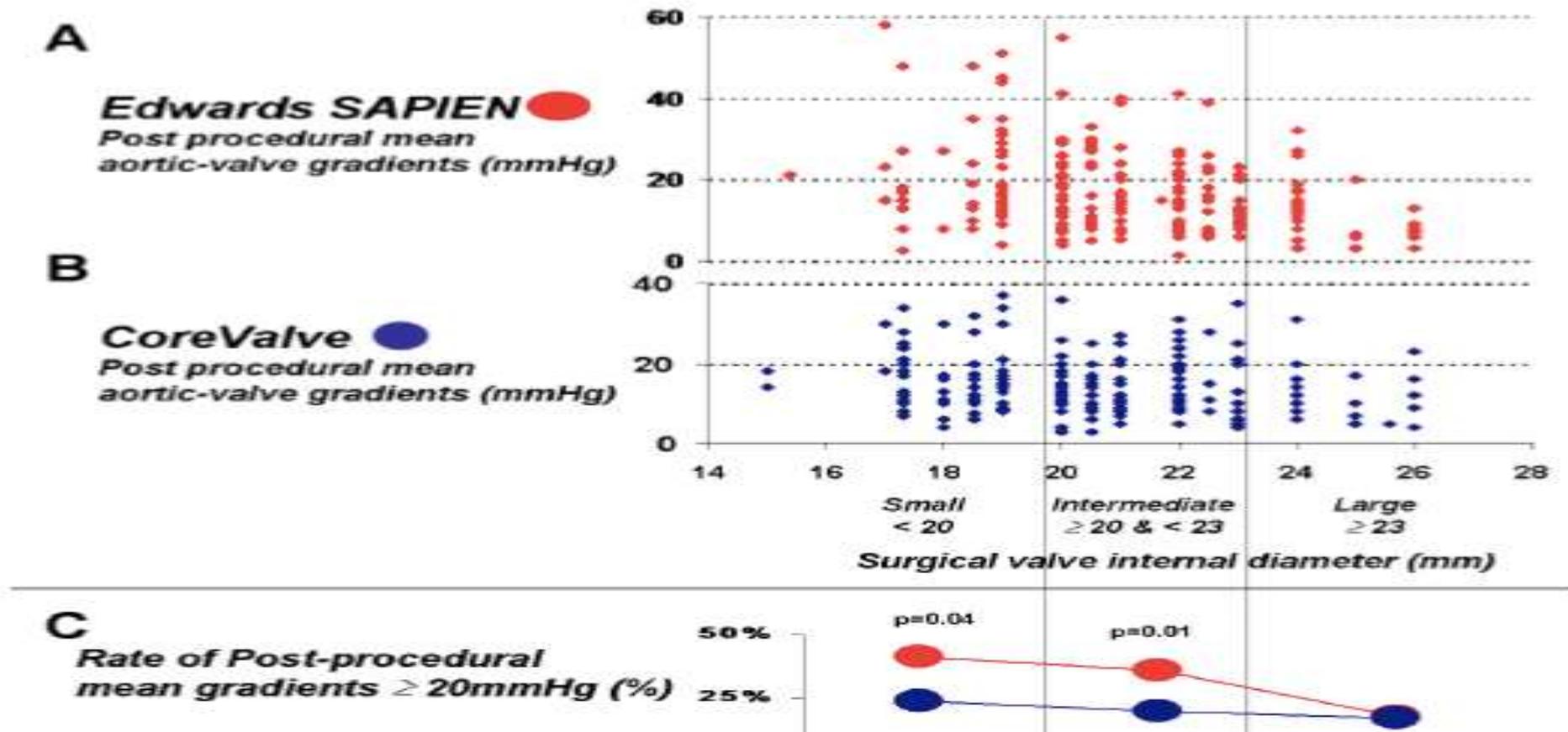


Okuno, T. et al. J Am Coll Cardiol Interv. 2019;12(21):2173-82.

"TAVI - ViV": Consideraciones sobre el anillo

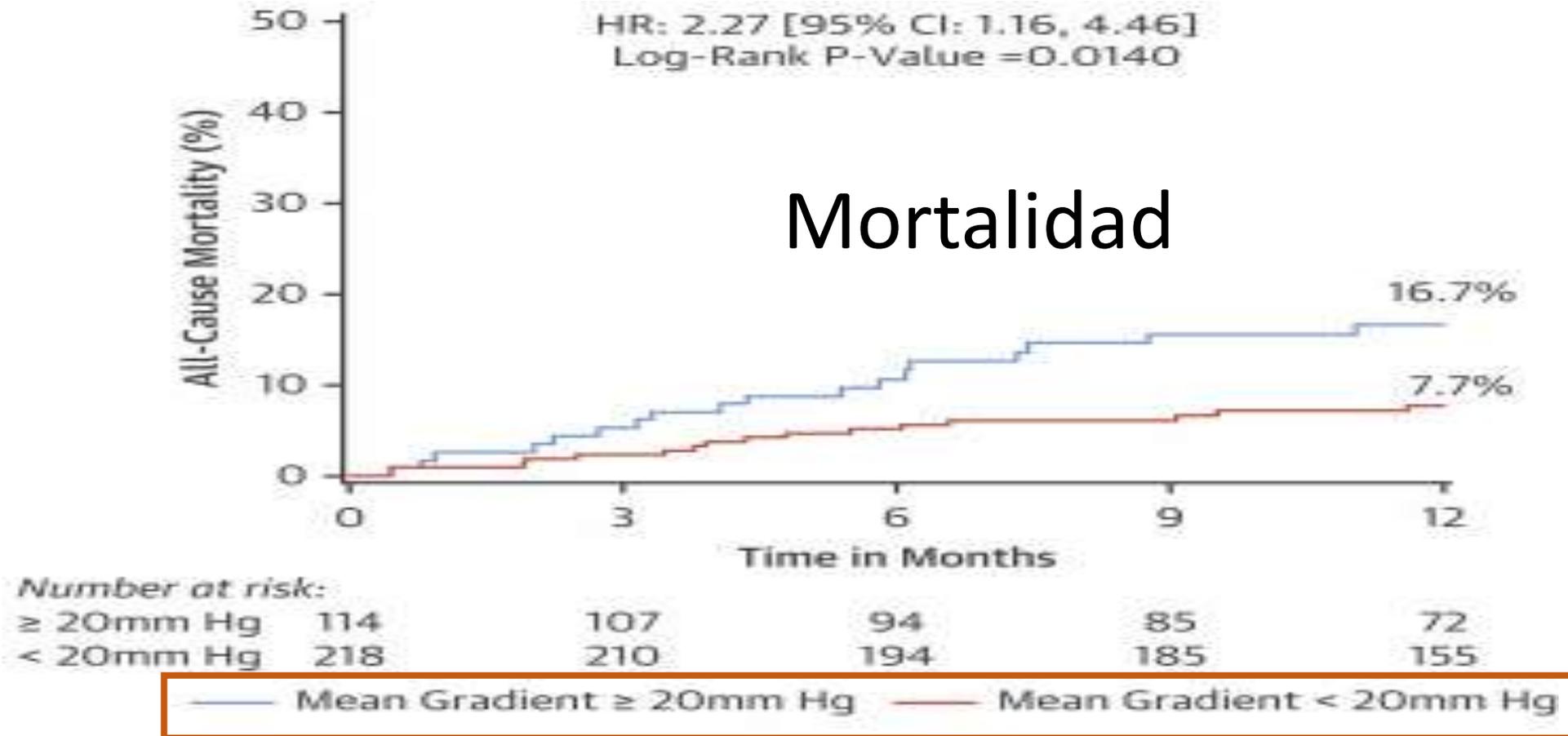
¿ TAVI Anular o Supra-anular ?

TAVI SUPRA-ANULAR CONLLEVA MENORES GRADIENTES



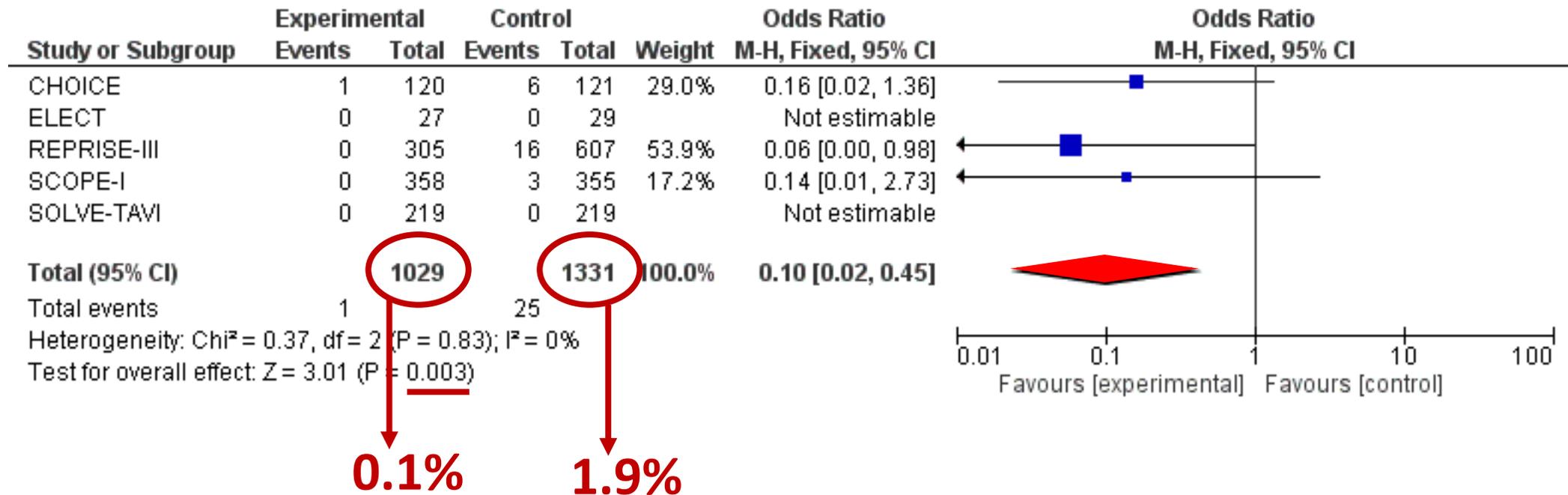
“TAVI - ViV”: Consideraciones sobre el anillo

IMPORTANCIA de los GRADIENTES POST-PROCEDIMIENTO



"TAVI - ViV": Peculiaridades

Riesgo de Trombosis

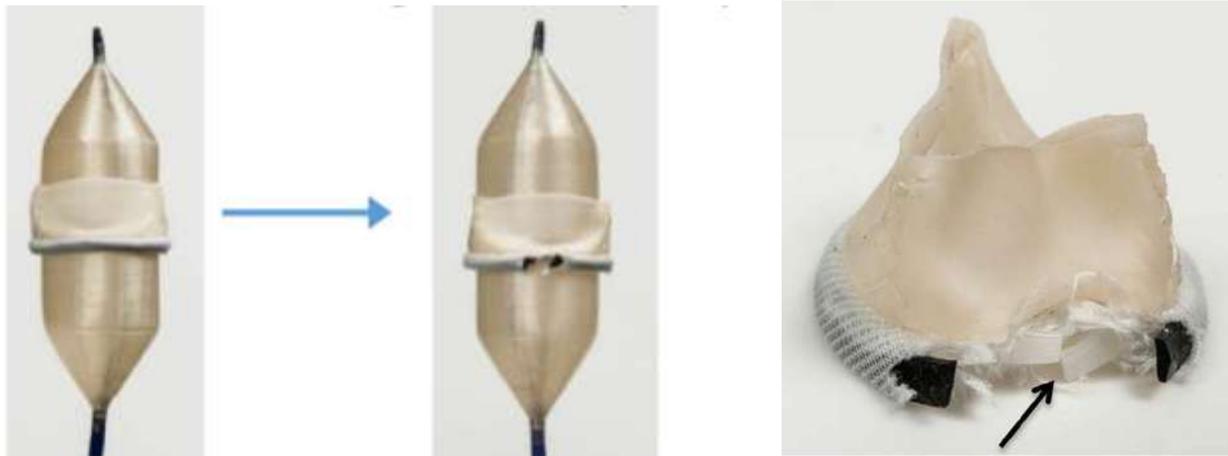


El Riesgo de Trombosis valvular es menor con válvulas supra-anales

"TAVI - ViV": Consideraciones sobre el anillo

¿Es posible Fracturar el Anillo?

No todos los tipos de anillo de válvulas protésicas quirúrgicas pueden ser fracturados



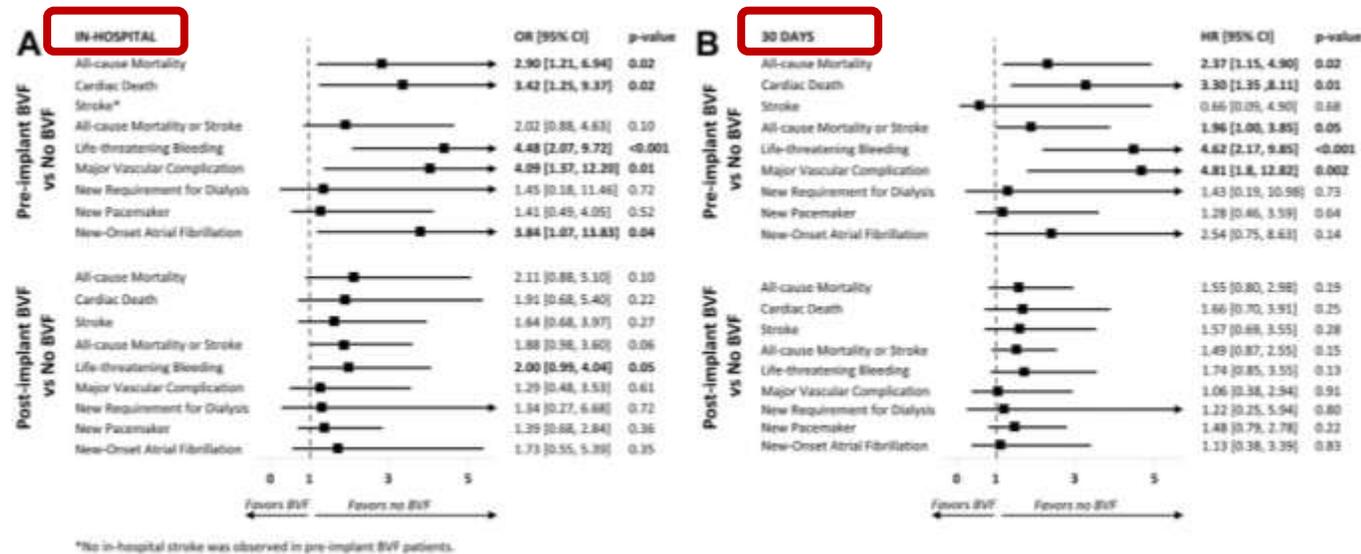
Manufacturer/ Brand	Valve Size	Bard TRU Balloon Fracture/Pressure	Bard Atlas Gold Balloon Fracture/Pressure	Appearance After Fracture
St. Jude Triecta	19 mm	NO	NO	
	21 mm	NO	NO	
St. Jude Biocor Epic	21 mm	YES / 8 ATM	YES / 8 ATM	
Medtronic Mosaic	19 mm	YES / 10 ATM	YES / 10 ATM	
	21 mm	YES / 10 ATM	YES / 10 ATM	
Medtronic Hancock II	21 mm	NO	NO	
Sorin Mitroflow	19 mm	YES / 12 ATM	YES / 12 ATM	
	21 mm	YES / 12 ATM	YES / 12 ATM	
Edwards MagnaEase	19 mm	YES / 18 ATM	YES / 18 ATM	
	21 mm	YES / 18 ATM	YES / 18 ATM	
Edwards Magna	19 mm	YES / 24 ATM	YES / 24 ATM	
	21 mm	YES / 24 ATM	YES / 24 ATM	

"TAVI - ViV": Consideraciones sobre el anillo

¿Consecuencias de Fracturar el Anillo?

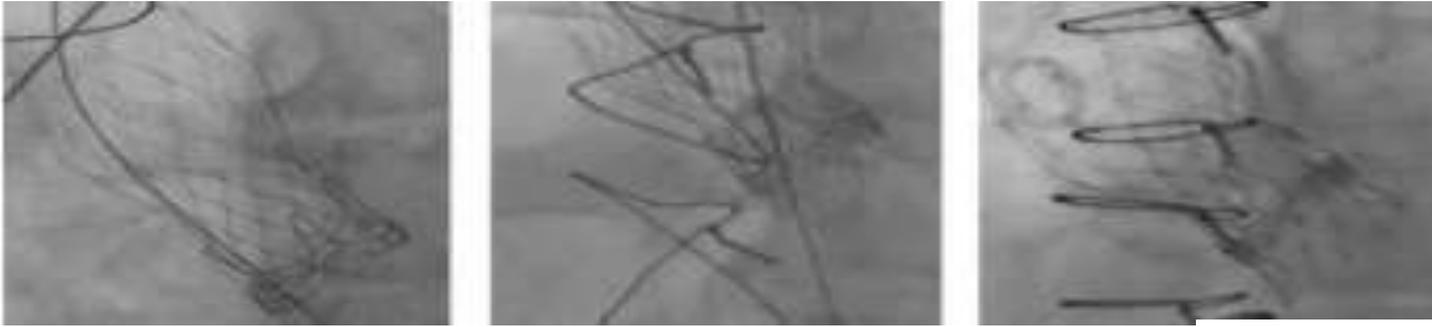
2,975 patients underwent VIV TAVR
 BVF in 619 patients (21%)
 SAPIEN 3 and SAPIEN 3 Ultra valves

	BVF, %	No BVF, %	HR (95% CI)	P Value
All-cause mortality	3.56	1.98	1.84 (1.09-3.1)	0.02
Cardiac death	2.20	1.05	2.12 (1.09-4.16)	0.03
Stroke	1.50	1.13	1.33 (0.62-2.89)	0.47
All-cause mortality or stroke	4.70	2.95	1.63 (1.04-2.55)	0.03
Life-threatening bleeding	3.43	1.51	2.35 (1.33-4.16)	<0.01



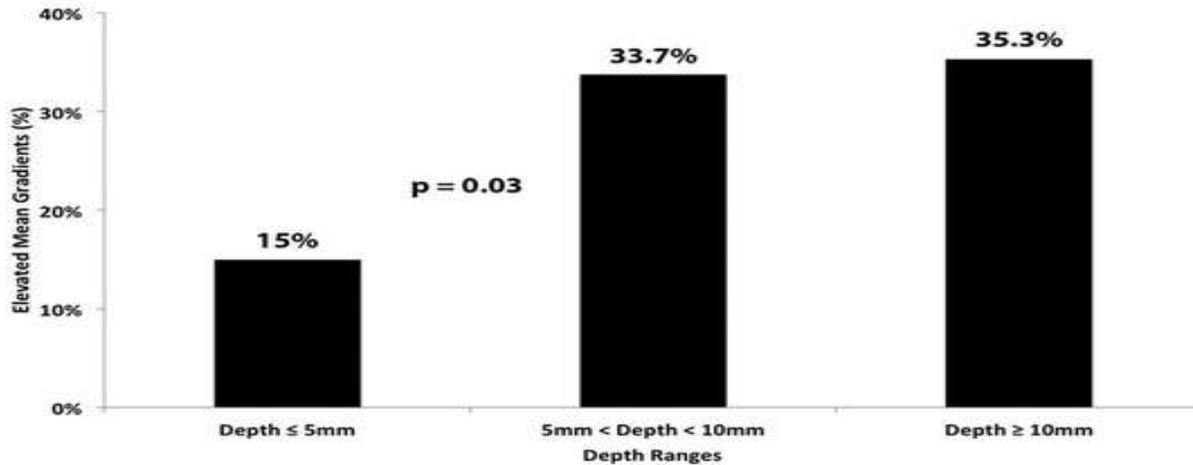
"TAVI - ViV": Peculiaridades

3) Relación Profundidad Implante/Gradiente Post/Pronóstico



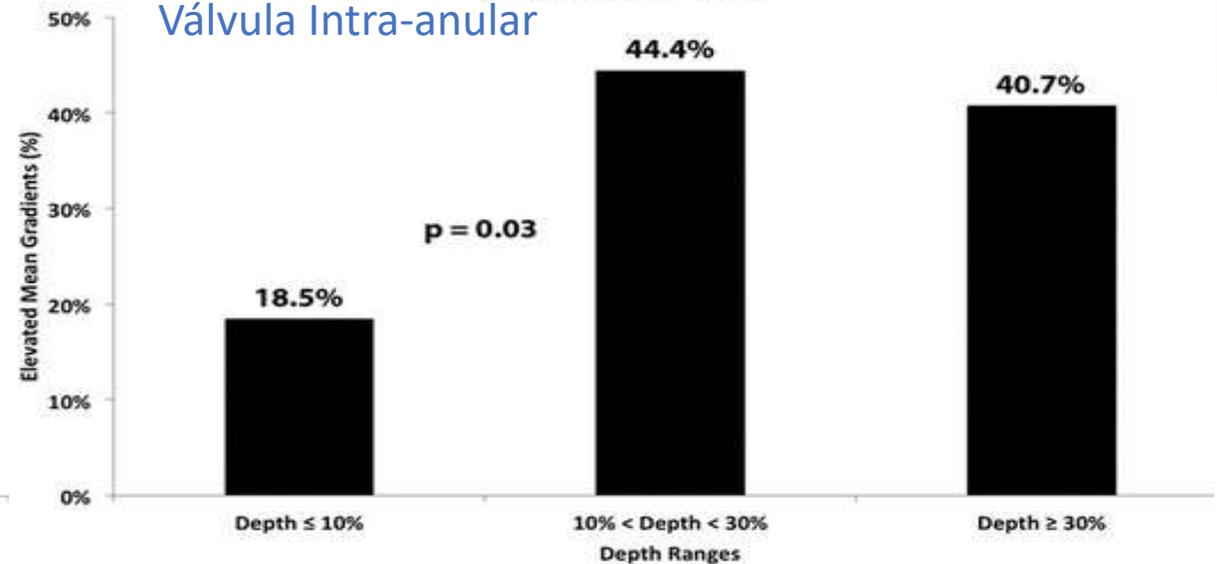
Válvula Supra-anular

CoreValve Evolut (n = 157)



Válvula Intra-anular

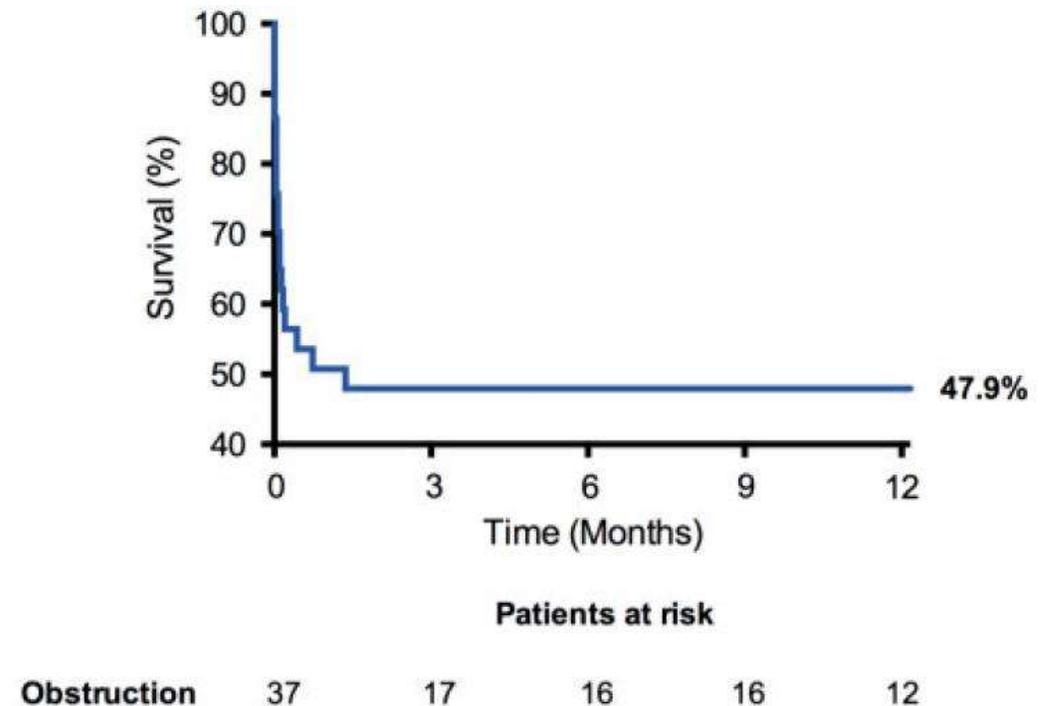
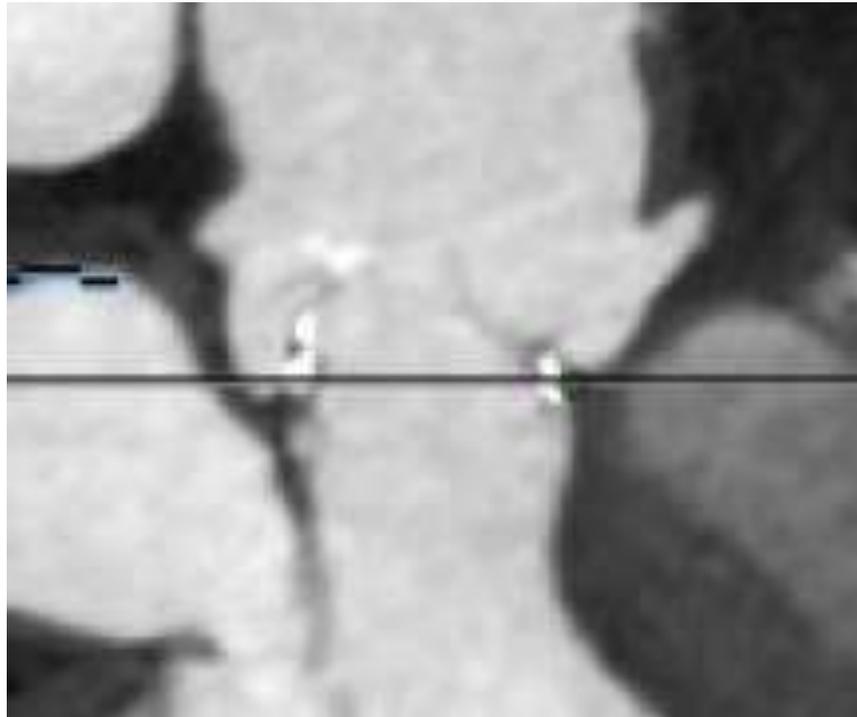
SAPIEN XT (n = 135)



“TAVI - ViV”: Riesgo de Oclusión Coronaria

4) Posición de Ostium Coronarios y Riesgo de Oclusión

Ostium Coronario Bajo = Alto Riesgo de Oclusión



“TAVI - ViV”: Riesgo de Oclusión Coronaria

Premisa: Prevenirlo y Evitarlo

Table 4 Predictors of coronary obstruction following valve-in-valve procedures

	Univariable OR (95% CI)	P-value	Multivariable model OR (95% CI)	P-value
Model for the overall population (n = 1612)				
CABG to the left system	0.36 (0.13–1.03)	0.056	0.38 (0.13–1.09)	0.07
STS-PROM	1.03 (0.99–1.06)	0.068	1.02 (0.99–1.05)	0.21
Post-dilatation	2.05 (0.92–4.56)	0.080	1.82 (0.8–4.14)	0.15
<u>Stented with external mounted leaflet or stentless bioprosthesis</u>	7.07 (3.09–16.2)	<0.001	7.67 (3.14–18.7)	<0.001



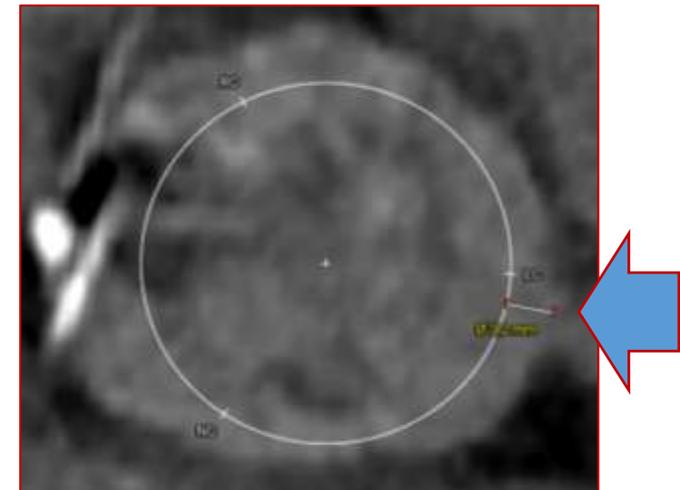
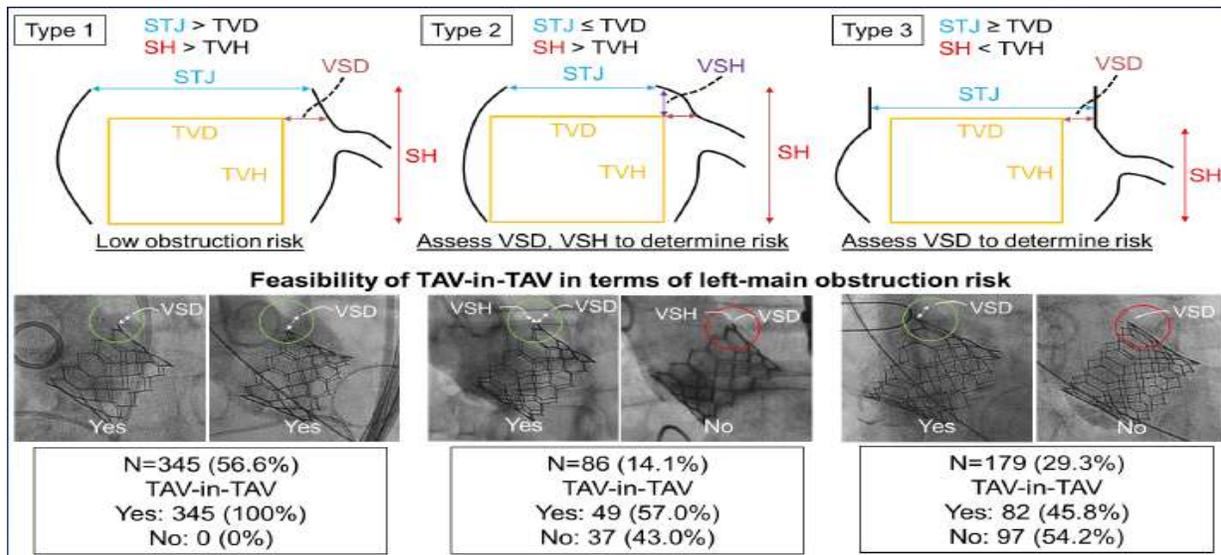
Mitroflow / Trifecta

Alto Riesgo	Stented velos exteriores	Mitroflow, Trifecta.
	Stentless	Cryolife O'Brien, Freedom, Freestyle, Toronto SPV
Bajo Riesgo	Stented velos interiores	Aspire, Biocor, Carpentier Edwards, Epic, Hancock, Labcor, Magna, Mosaic, Soprano

“TAVI - ViV”: Riesgo de Oclusión Coronaria

Table 4 Predictors of coronary obstruction following valve-in-valve procedures

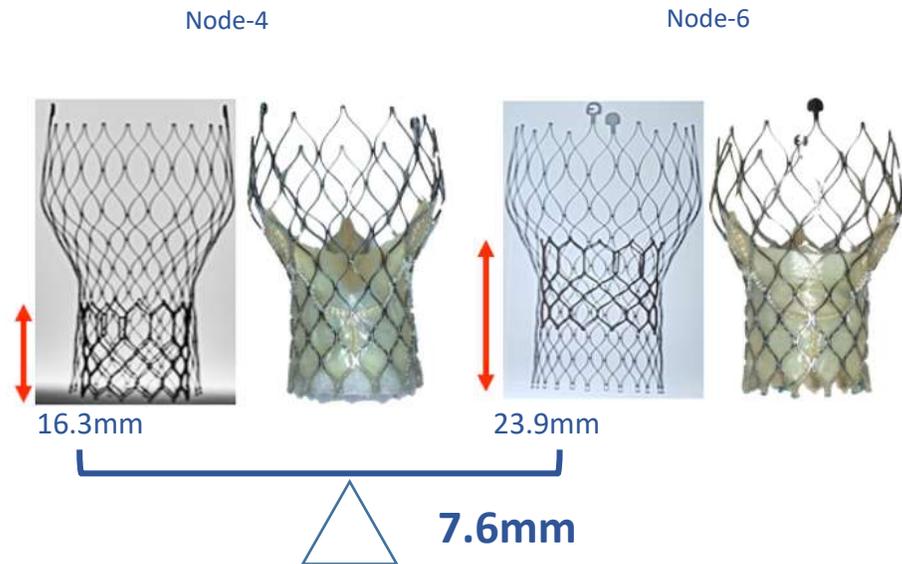
	Univariable OR (95% CI)	P-value	Multivariable model OR (95% CI)	P-value
Model for the computed tomography cohort (n = 110)				
<u>VTC^a</u>	0.18 (0.08–0.39)	<0.001	0.22 (0.09–0.51)	<0.001
<u>Sinus of Valsalva mean diameter</u>	0.70 (0.58–0.83)	<0.001	0.95 (0.72–1.25)	0.71
Stented with external mounted leaflet or stentless bioprosthesis	4.90 (1.51–15.9)	0.008	4.30 (0.85–21.7)	0.08



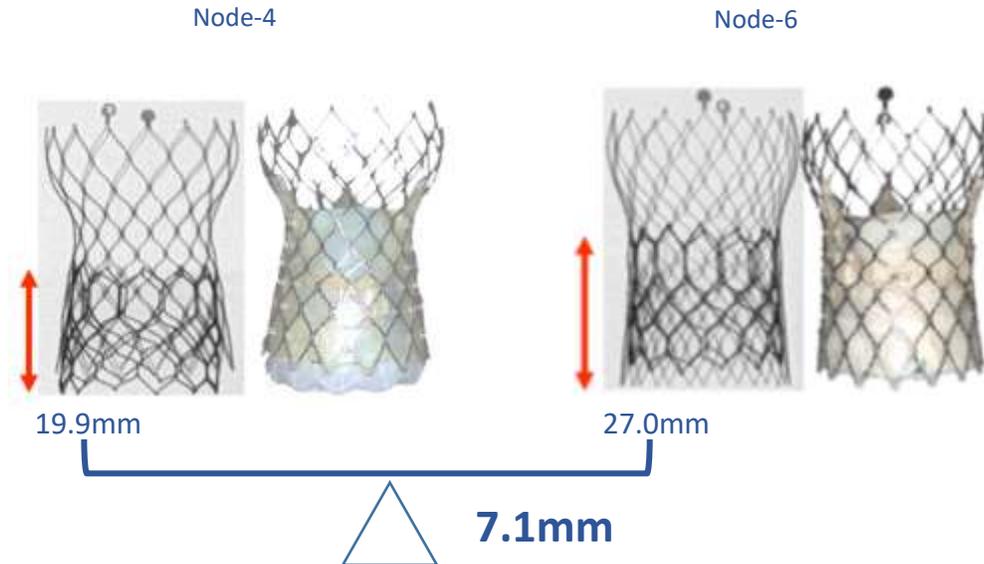
"TAVI - ViV": Riesgo de Oclusión Coronaria

Cuanta mas altura de la falda de la prótesis mayor riesgo de oclusión

20mm S3 in 23mm Evolut

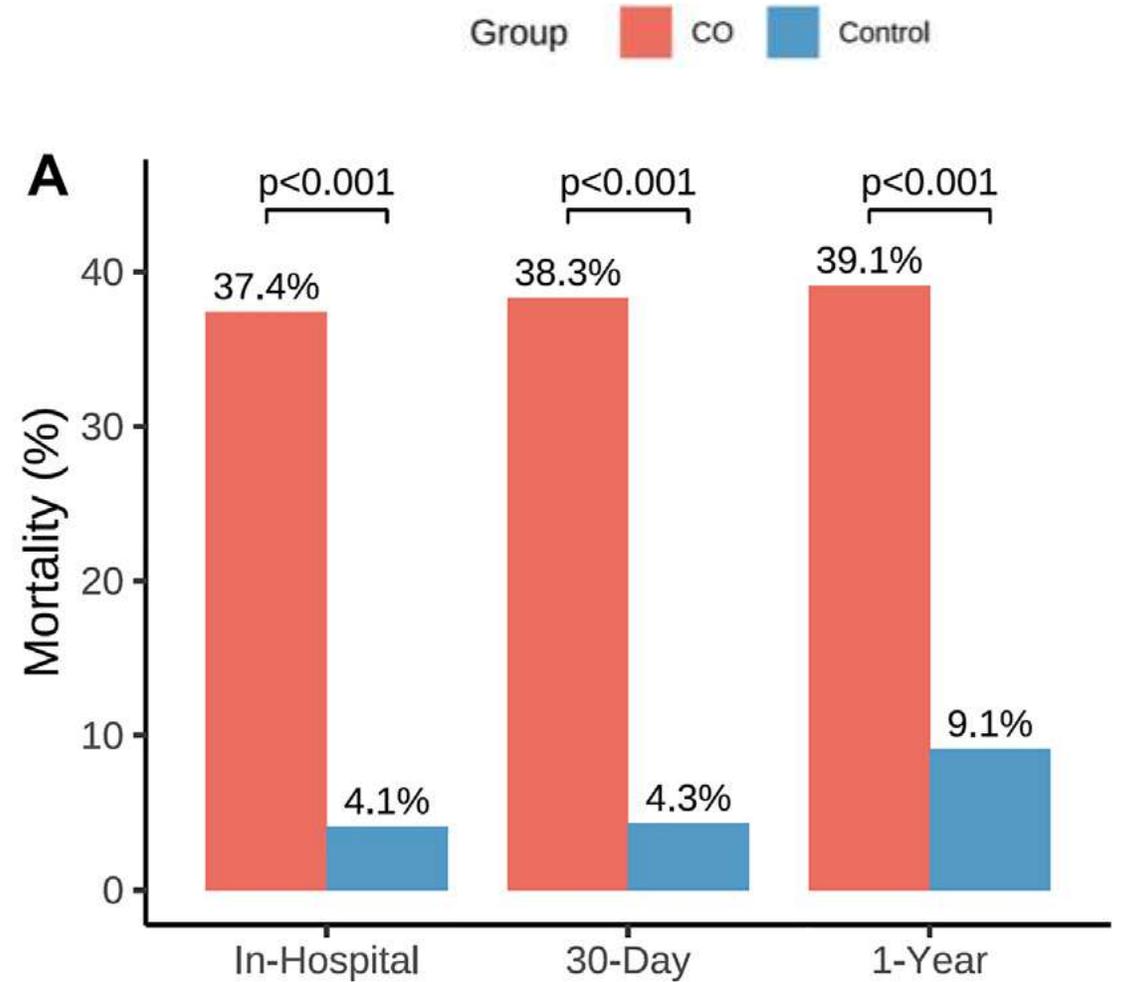
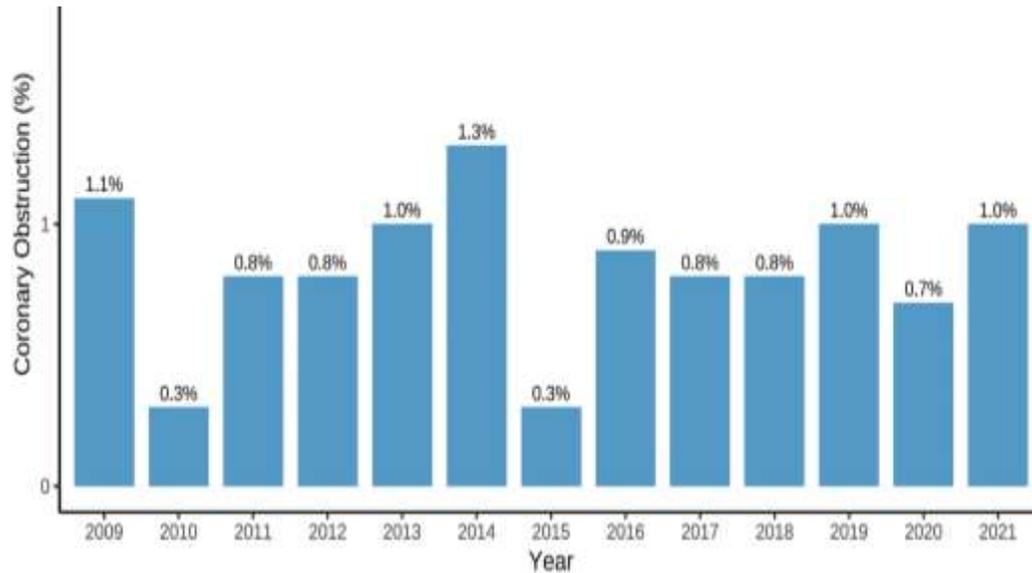
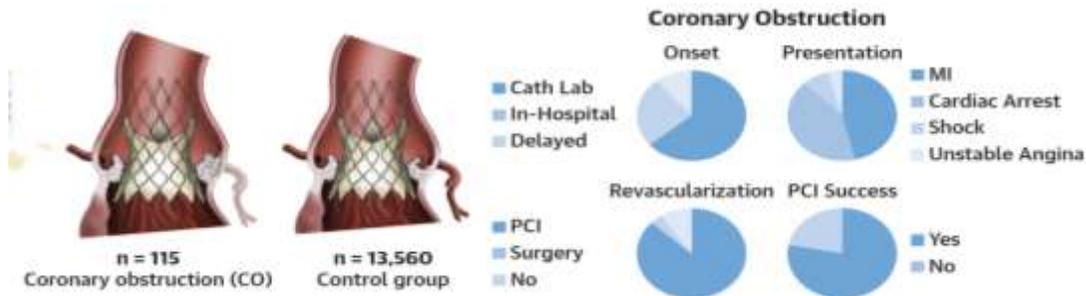


29mm S3 in 34mm Evolut



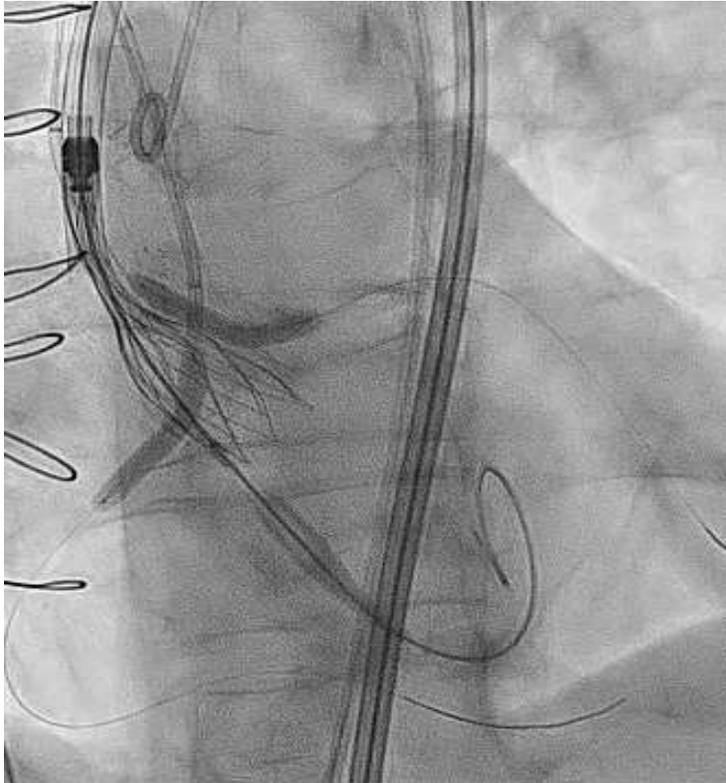
"TAVI - ViV": Peculiaridades

Riesgo de Oclusión Coronaria

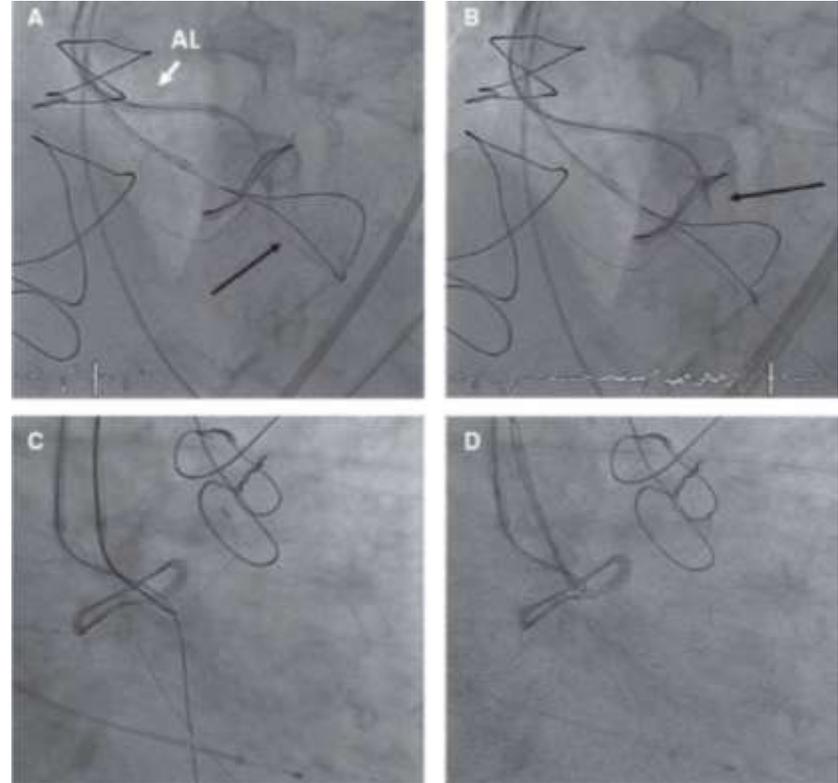


“TAVI - ViV”: Peculiaridades

Técnicas para evitar el Riesgo de Oclusión Coronaria



Protección de Coronarias (“Chimenea”)



Protección de Coronarias (“Basilica”)

Agenda



4

“TAVI-ViV”: Durabilidad y Tendencias de Uso

"TAVI - ViV": Durabilidad

Early Failures of Surgical Valves...

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 leaflets are fixed to the frame with α -aminooleic acid (a cross-linking agent to the aldehyde fractions of the porcine tissue) to reduce the risk of embolism. The valve is mounted on a Hancock II annuloplasty ring made of acetyl copolymer.

DISCUSSION

Early (2-year follow-up) results after implantation of the Medtronic Mosaic porcine valve reported appropriate

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.

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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

Thomas Sénage¹; Thierry Le Tourneau²; Yohann Foucher³; Sabine Pattier⁴; Caroline Cueff¹; Magali Michel⁴; Jean-Michel Serfaty⁴; Hubert François Carton⁴; Christian Perigaud⁴; Antoine Mugniot⁴; Ousama Al Habash⁴; Olivier Baron⁴; Jean Christian Roussel¹*

"TAVI - ViV": Durabilidad

Ten Year Follow-Up of TAVI from Vancouver

John Webb MD and Danny Dvir MD
St. Paul's Hospital, University of BC
Vancouver, Canada

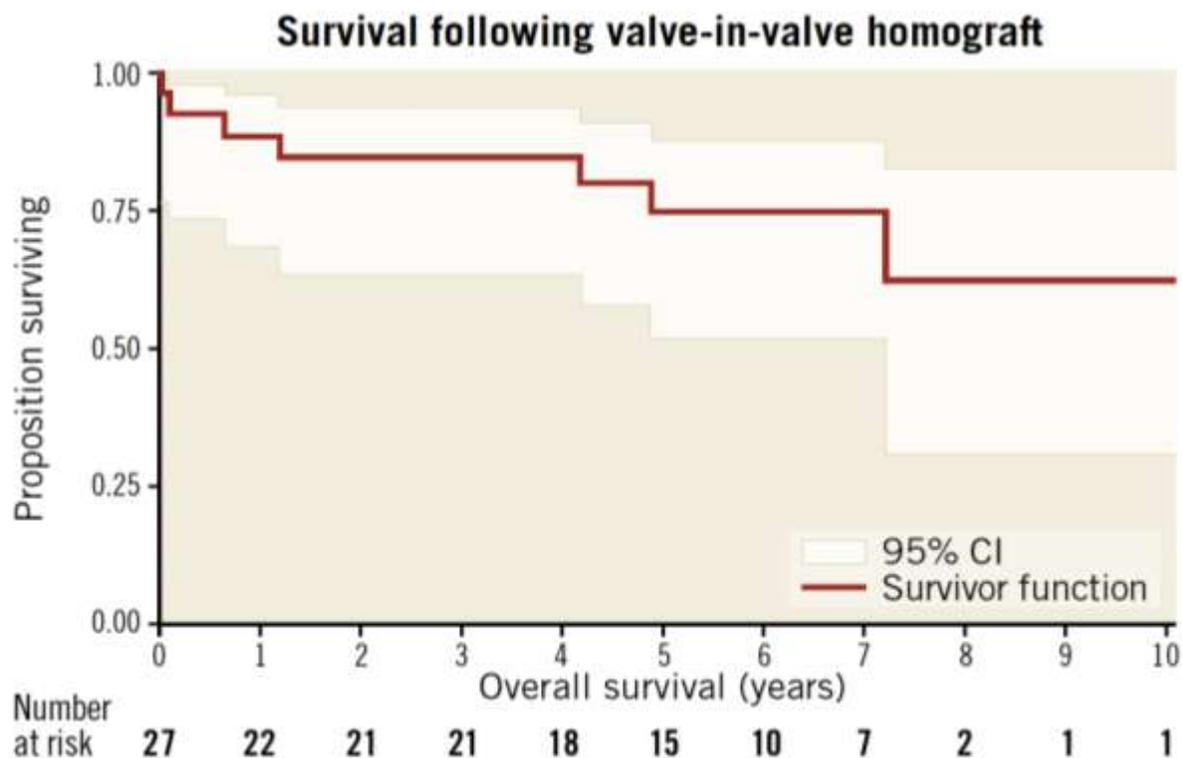
Bioprosthetic Surgical Valve Failure from VIVID Registry



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



“TAVI - ViV”: Durabilidad



Mortalidad Actuarial a:

1 año	3 años	5 años:
11.4%	15.5%	25.2%
(CI: 3.8-31.5%)	(CI: 6.1-36.2%)	(CI: 12.0-48.1%)

	30 days n=10	1 year n=11	5 years n=55	>5 years n=19
Cardiovascular death (%)	7 (70)	9 (81.8)	36 (65.5)	14 (73.7)
Procedure-related (vascular complication, bleeding, aortic or ventricular rupture)	6 (60)	-	-	-
Stroke (ischaemic and haemorrhagic)	0	5 (45.5)	1 (2)	0
Myocardial infarction	0	0	2 (3.6)	0
Sudden cardiac death, arrhythmia	0	0	2 (3.6)	1 (5.3)
Heart failure	1 (10)	1 (9.1)	9 (16.3)	3 (15.8)
Unwitnessed, unknown	0	3 (27.2)	22 (40)	10 (52.6)
Non-cardiovascular death (%)	3 (30)	2 (18.2)	19 (34.5)	5 (26.3)

Agenda



5 Mensajes Finales

Mensajes Finales

- 1) La “TAVI ViV” se ha erigido en la opción o alternativa terapéutica de elección ante la degeneración estructural de las prótesis biológicas implantadas previamente por cirugía convencional.
- 2) Su técnica de implante debe tener en consideración las peculiaridades inherentes al tipo de válvula implantada previamente, a las características anatómicas del anillo aórtico y del paciente, y al tipo de nueva válvula a implantar.
- 3) La durabilidad de estas válvulas biológicas implantadas de forma percutánea parece ser similar a la durabilidad de las implantadas quirúrgicamente.
- 4) La tendencia de uso es creciente, tanto mas a medida que la población envejece.



¡GRACIAS!



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TAVI "Valve in Valve": Resultados

TAVI "Valve in Valve": Válvulas Convencionales Vs Sin Sutura

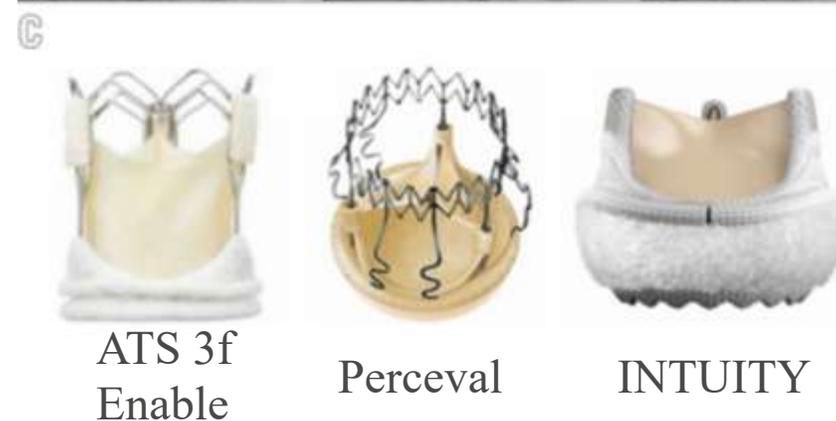
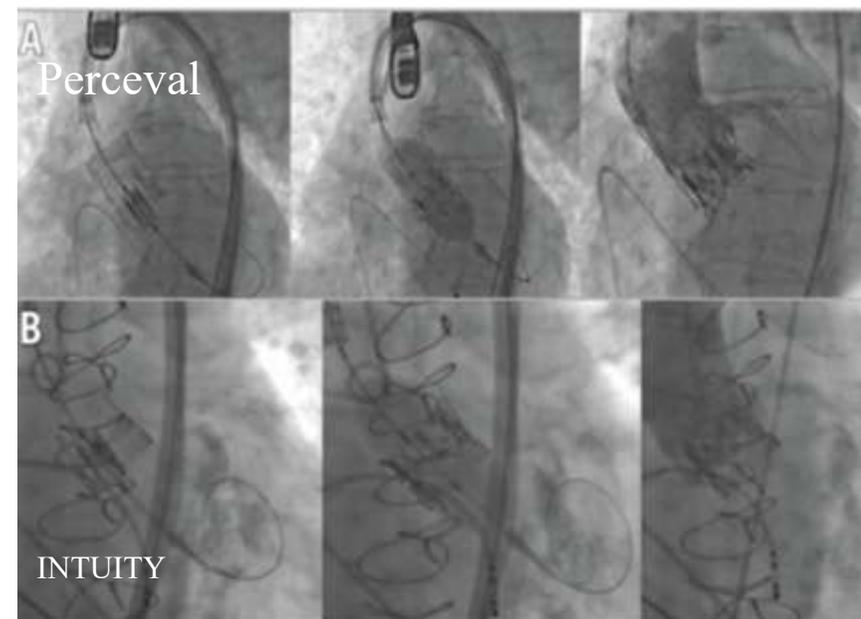
Table 2. Valve-in-valve outcome according to surgical heart valve (SHV) type.

	Rapid deployment SHV n=30	Conventional SHV n=2,288	p-value
30-day mortality	4.3%	4.4%	1
1-year mortality	9.5%	13.3%	0.94
Stroke (major)	0.0%	1.4%	1
Acute kidney injury (any)	6.7%	5.5%	0.678
Vascular complications			0.825
Major	3.3%	2.9%	
Minor	10.0%	7.2%	
Bleeding (major/life-threatening)	3.3%	4.9%	1
Valve malposition	0.0%	8.0%	0.164
Need for a second valve	3.6%	3.9%	1
Residual regurgitation			0.793
None	77.8%	66.5%	
Mild	18.5%	28.3%	
Moderate	3.7%	4.2%	
Moderate-severe	0.0%	6.0%	
Severe	0.0%	4.0%	
Aortic valve area, mm ²	1.28±0.69	1.02±0.78	0.124
Residual gradient, max (mmHg)	21.2±10.7	28.9±14.8	0.013
Residual gradient, mean (mmHg)	14.6±8.3	16.2±8.9	0.356
Need for permanent pacemaker	11.0%	6.7%	0.252
Coronary artery obstruction	0.0%	2.4%	1
Hospital stay, days	12.0±14.7	9.5±9.0	0.146

pre-matched patients' outcome.

	Rapid deployment SHV n=28	Conventional SHV n=28	p-value	Standardised difference
30-day mortality	4.5%	4.5%	1.000	0.03
Stroke (major)	0	0	1.000	0.00
Acute kidney injury (any)	0	7.1%	0.150	0.39
Vascular complications				
Major	10.7%	10.7%	1.000	0.00
Minor	0	3.6%	0.313	0.27
Bleeding (major/life-threatening)	10.7%	3.6%	0.299	-0.28
Valve malposition	3.7%	0	0.313	-0.27
Need for a second valve	3.8%	3.8%	1.000	0.01
Residual regurgitation				
None	68.0%	76.0%	0.529	0.20
Mild	28.0%	20.0%	0.508	-0.30
Moderate	0	4.0%	0.312	0.28
Moderate-severe	0	0	1.000	0.00
Severe	0	0	1.000	0.00
Aortic valve area, mm ²	0.91±0.61	1.28±0.70	0.228	0.40
Residual gradient, max (mmHg)	31.5±18.0	20.9±10.9	0.061	-0.71*
Residual gradient, mean (mmHg)	17.2±8.8	14.7±8.6	0.306	-0.26
Need for permanent pacemaker	4.0%	12.0%	0.297	0.28
Coronary artery obstruction	0	0	1.000	-0.27
Hospital stay, days	8.7±8.7	12.6±15.1	0.275	0.32

* – standardised difference is larger than might occur simply by chance. AKI: acute kidney injury; SHV: surgical heart valve

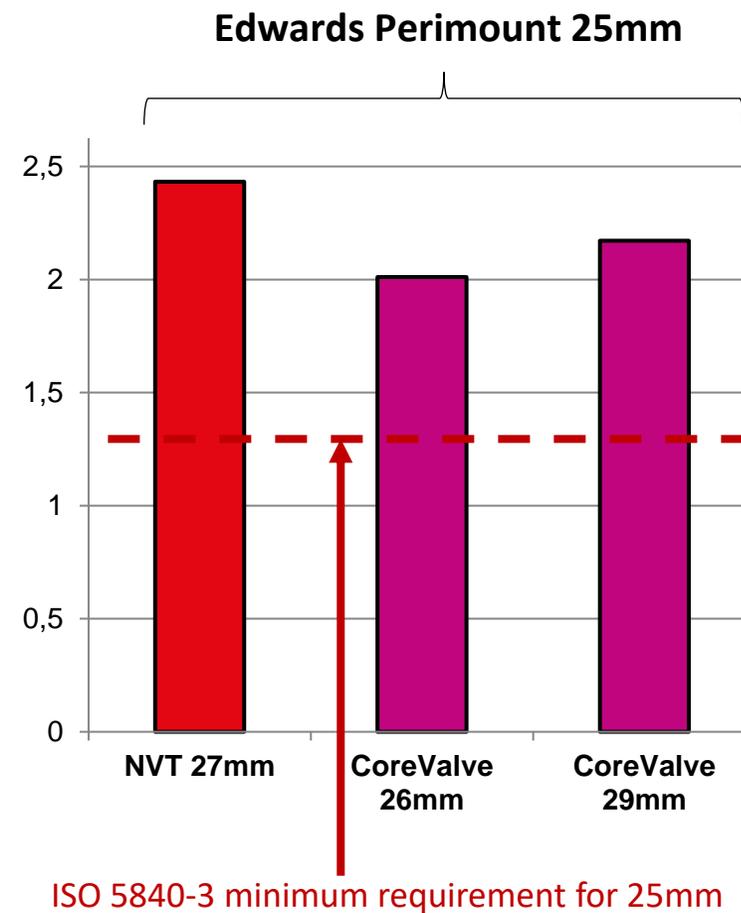
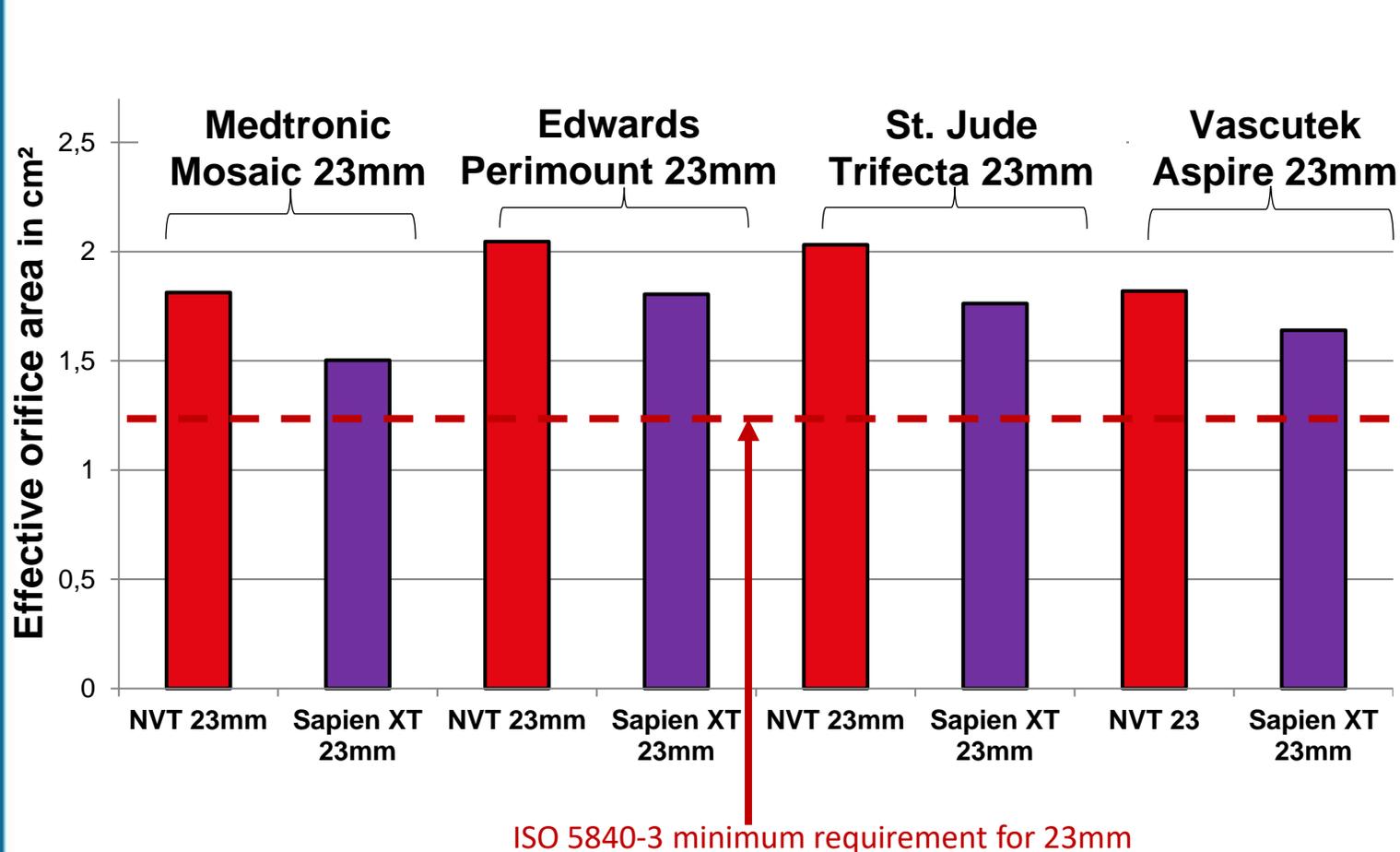


LIMITACIONES de los Procedimientos TAVI “VALVE-IN-VALVE”

- Mayores gradientes transvalvulares vs TAVI para estenosis aórtica nativa.
- Desajuste frecuente de la prótesis.
- Impacto en la mortalidad a largo plazo.
- Mayor frecuencia de PVL en comparación con rehacer SAVR.
- Mayor riesgo de oclusión coronaria vs TAVI para estenosis aórtica nativa.
- Especialmente en válvulas montadas externamente con stent.
- El riesgo de trombosis valvular vs TAVI para la estenosis aórtica nativa.

"TAVI - ViV": Peculiaridades

Valve-in-valve: Area Efectiva del Orificio Interno



TAVI "Valve in Valve": Resultados

	VIVID Aortic	PARTNER 2	CoreValve US	VIVA	TVT
N	2,318	365	227	202	1,150
Age (years)	78	79	77	80	79
STS (mean)	8.8%	9.1%	9.0%	6.6%	6.9%
CoreValve	39.1%	0%	100%	9.4%	19%
Evolut	14.2%	0%	0%	90.6%	42%
SAPIEN XT	26.9%	100%	0%	0%	25%
SAPIEN 3	13.9%	0%	0%	0%	14%
Outcomes at 30 days					
Mortality	4.4%	2.7%	2.2%	2.5%	2.9%
Stroke	1.4%**	2.7%	0.9%	3.0%	1.7%
Coronary obstruction	2.3%	0.8%	0.9%	2.0%	0.6%
Annular rupture	0%	0%	0%	0%	0%
PVL >=moderate	5.2%	3.2%	3.5%	2.0%	3.3%
Conversion to open surgery	0.7%	0.6%	0.5%	0.5%	0.2%
New pacemaker	6.7%	1.9%	8.1%	7.0%	3.0%
Mean gradient (median)	16.2	17.7	17.0	12.2	16.0
Valve area (cm2)	1.2	1.1	1.4	1.5	1.3

“TAVI - ViV”: Durabilidad

