Intervenciones estructurales cardiacas: ¿Cuándo y porqué?

Implante percutáneo de válvula aortica

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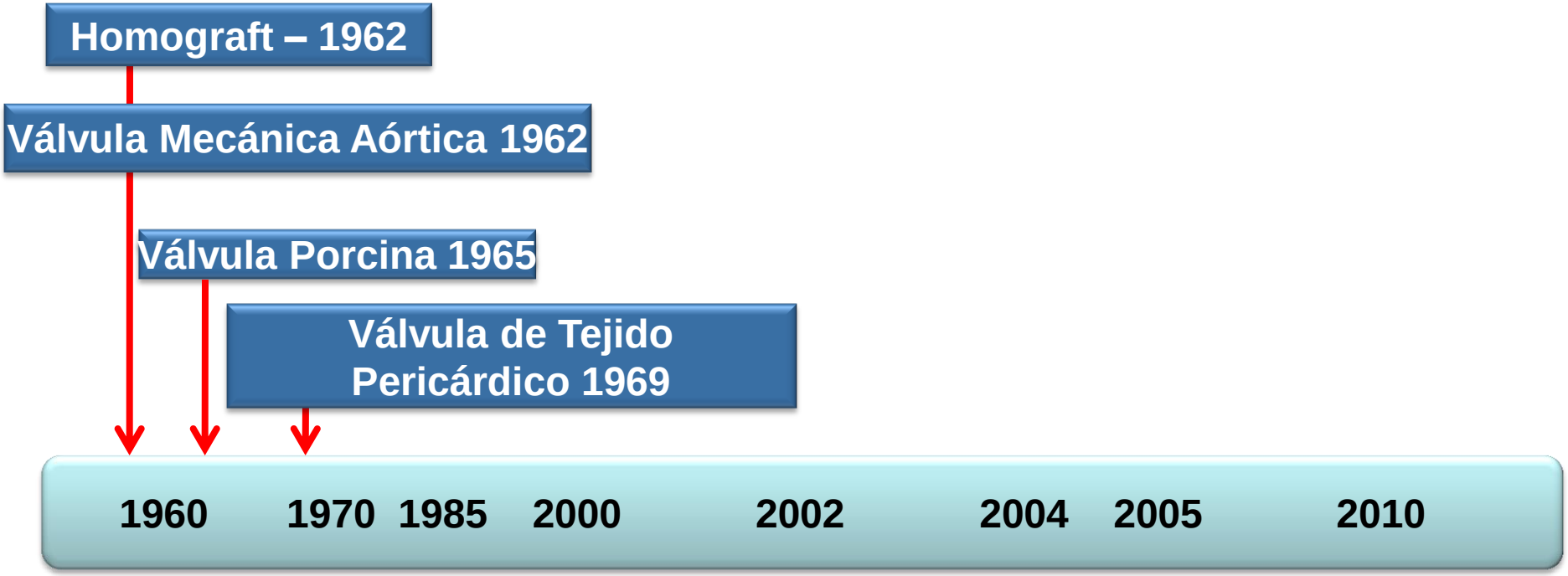
Evolución del Tratamiento de la Estenosis Aórtica



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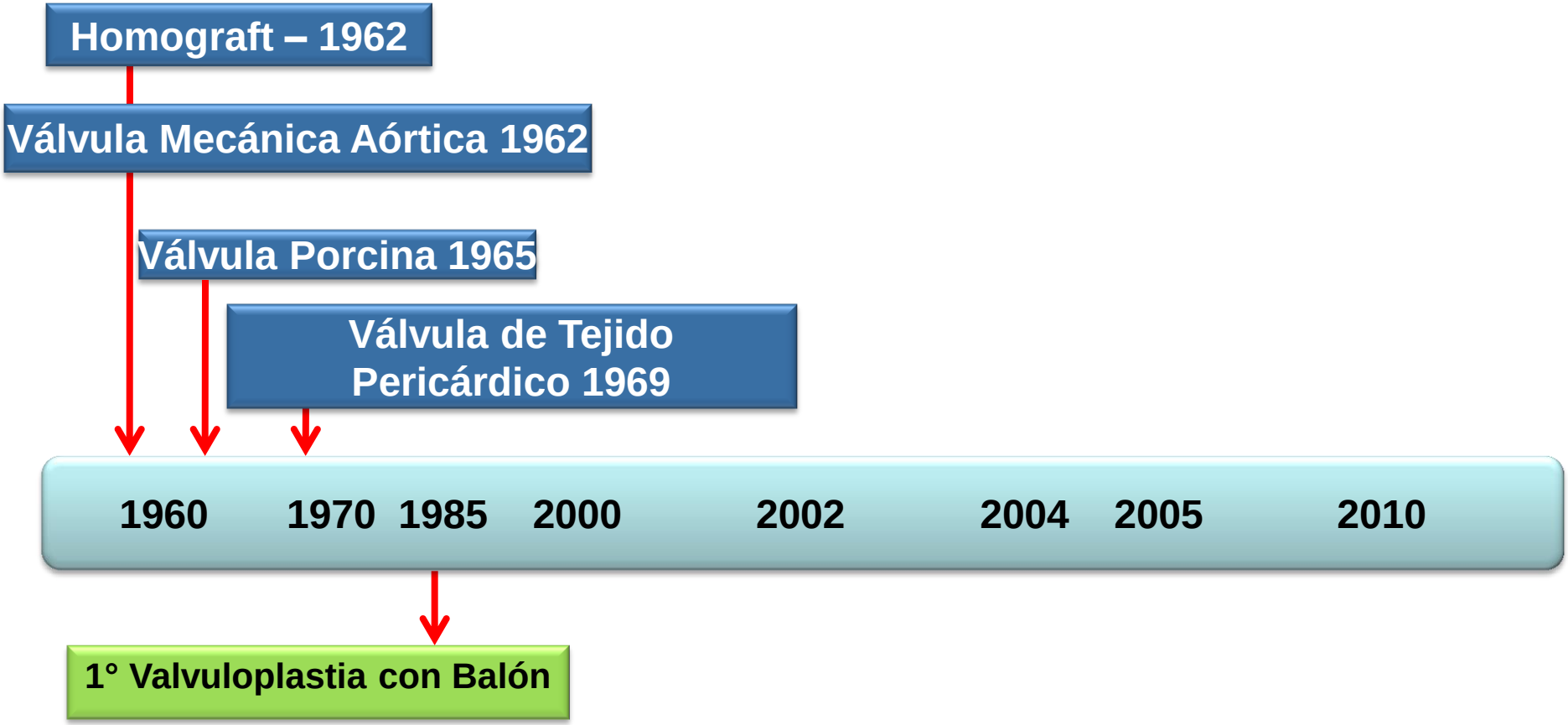

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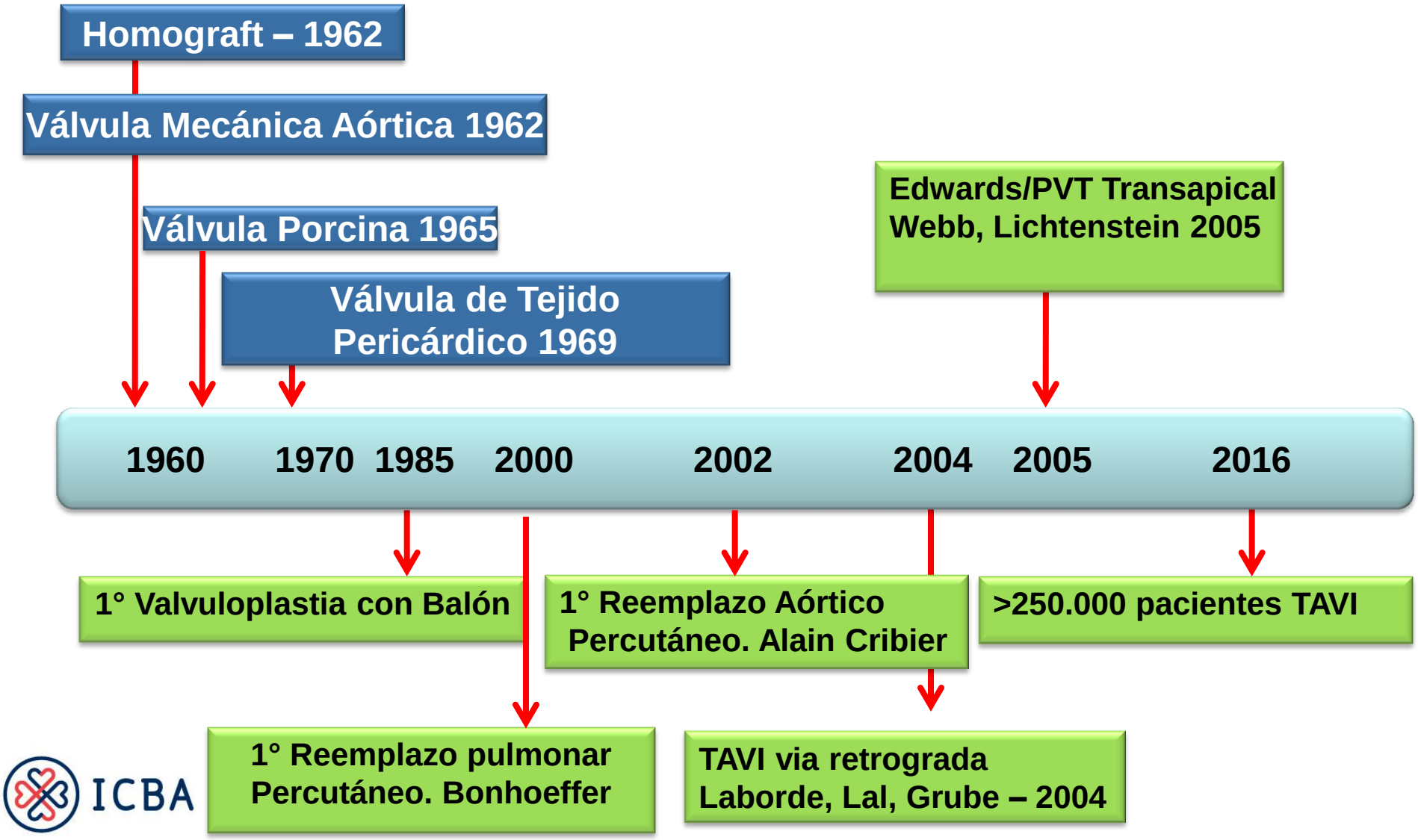
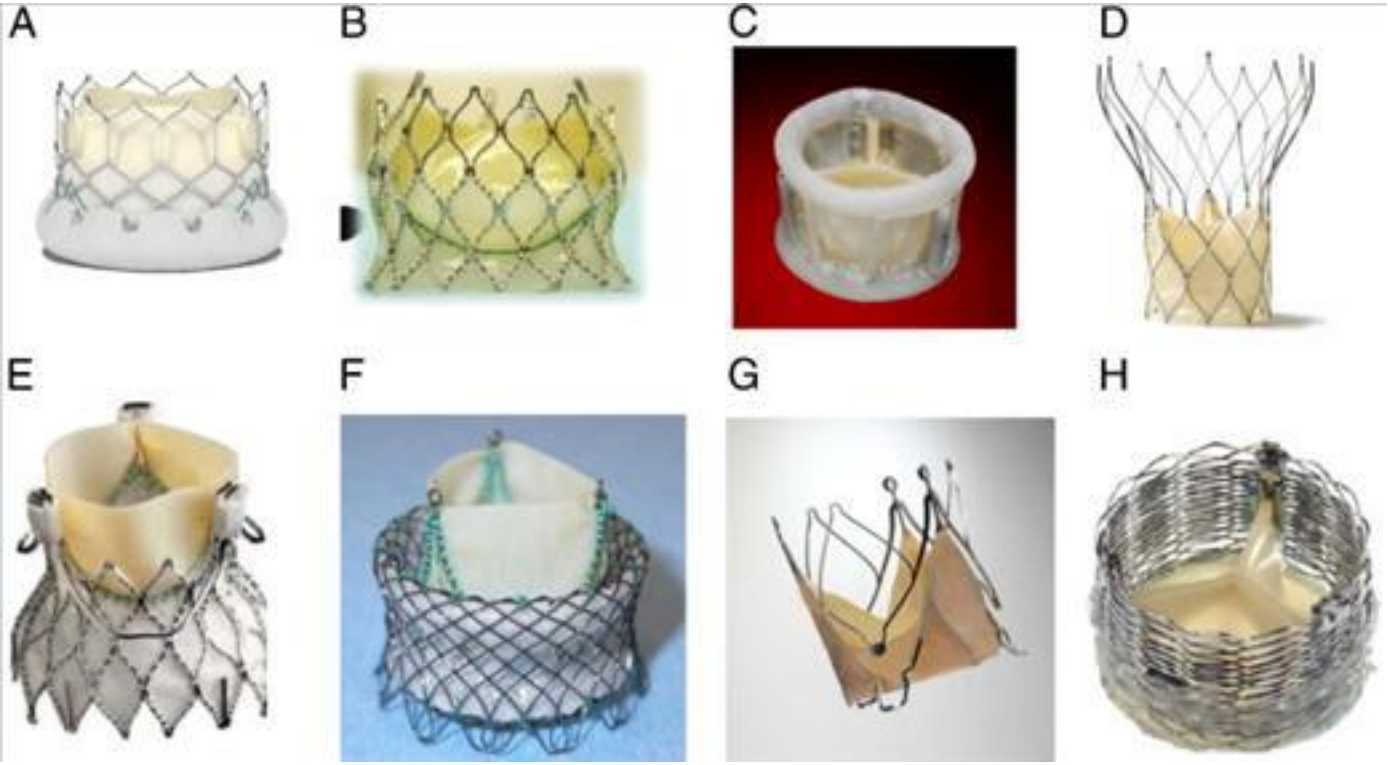
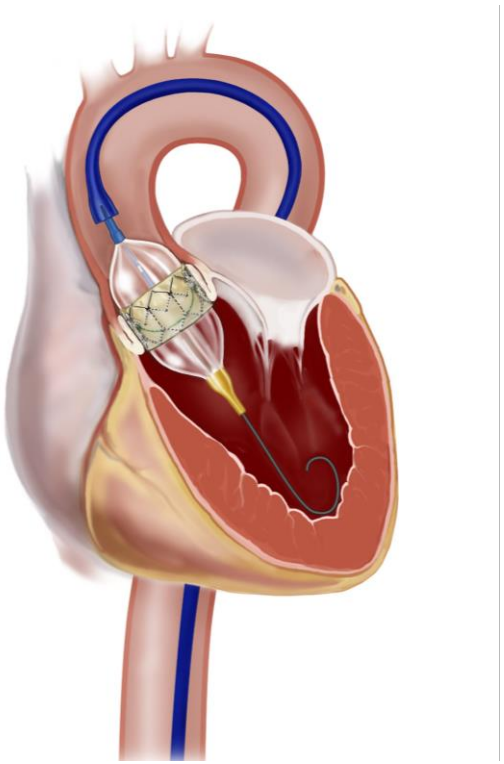
Evolución del Tratamiento de la Estenosis Aórtica



TAVI





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TAVI: Cambios fisiopatológicos y durabilidad

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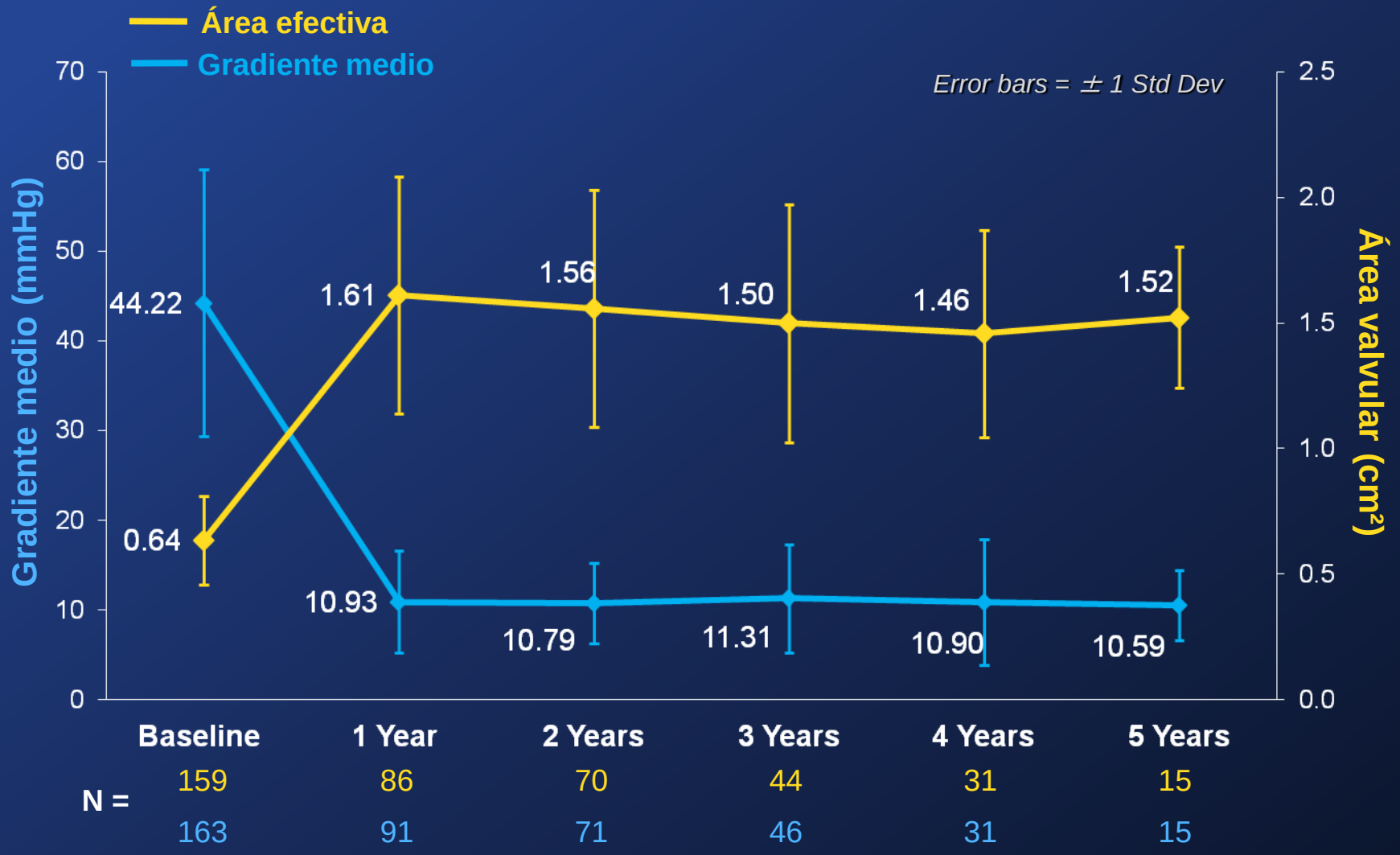
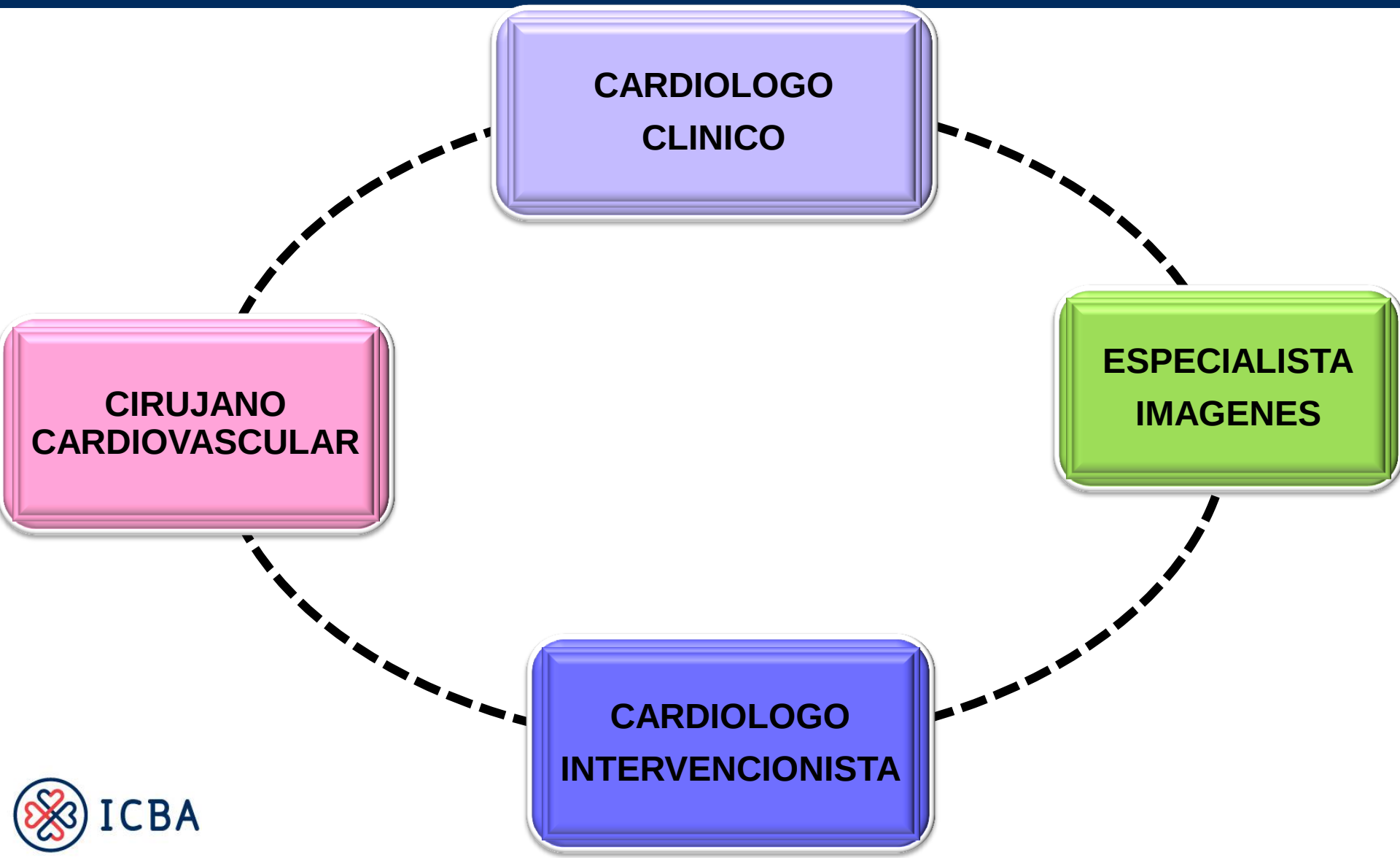
Durabilidad del Gradiente medio y área valvular



Kapadia S, Lancet. 2015 20;385(9986):2485-91

Equipo multidisciplinario
Heart Team



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EUROscore II

Important: The previous additive [1] and logistic [2] EuroSCORE models are out of date. A new model has been prepared from fresh data and is launched at the 2011 EACTS meeting in Lisbon. The model is called EuroSCORE II [3] - this online calculator has been updated to use this model. If you need to calculate the older "additive" or "logistic" EuroSCORE please visit the old calculator by clicking here.

Patient related factors			Cardiac related factors		
Age [1] (years)	0	0	NYHA	select	0
Gender	select	0	CCS class 4 angina [8]	no	0
Renal impairment [2] *See calculator below for creatinine clearance*	normal (CC >85ml/min)	0	LV function	select	0
Extracardiac arteriopathy [3]	no	0	Recent MI [9]	no	0
Poor mobility [4]	no	0	Pulmonary hypertension [10]	no	0
Previous cardiac surgery	no	0	**Operation related factors**		
Chronic lung disease [5]	no	0	Urgency [11]	elective	0
Active endocarditis [6]	no	0	Weight of the intervention [12]	isolated CABG	0
Critical preoperative state [7]	no	0	Surgery on thoracic aorta	no	0
Diabetes on insulin	no	0			
EuroSCORE II — ***Euro*SCORE II**		0			
Note: This is the 2011 EuroSCORE II	Calculate Clear				

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http://www.euroscore.org/calc.html

Edad biológica ≠ Edad cronológica

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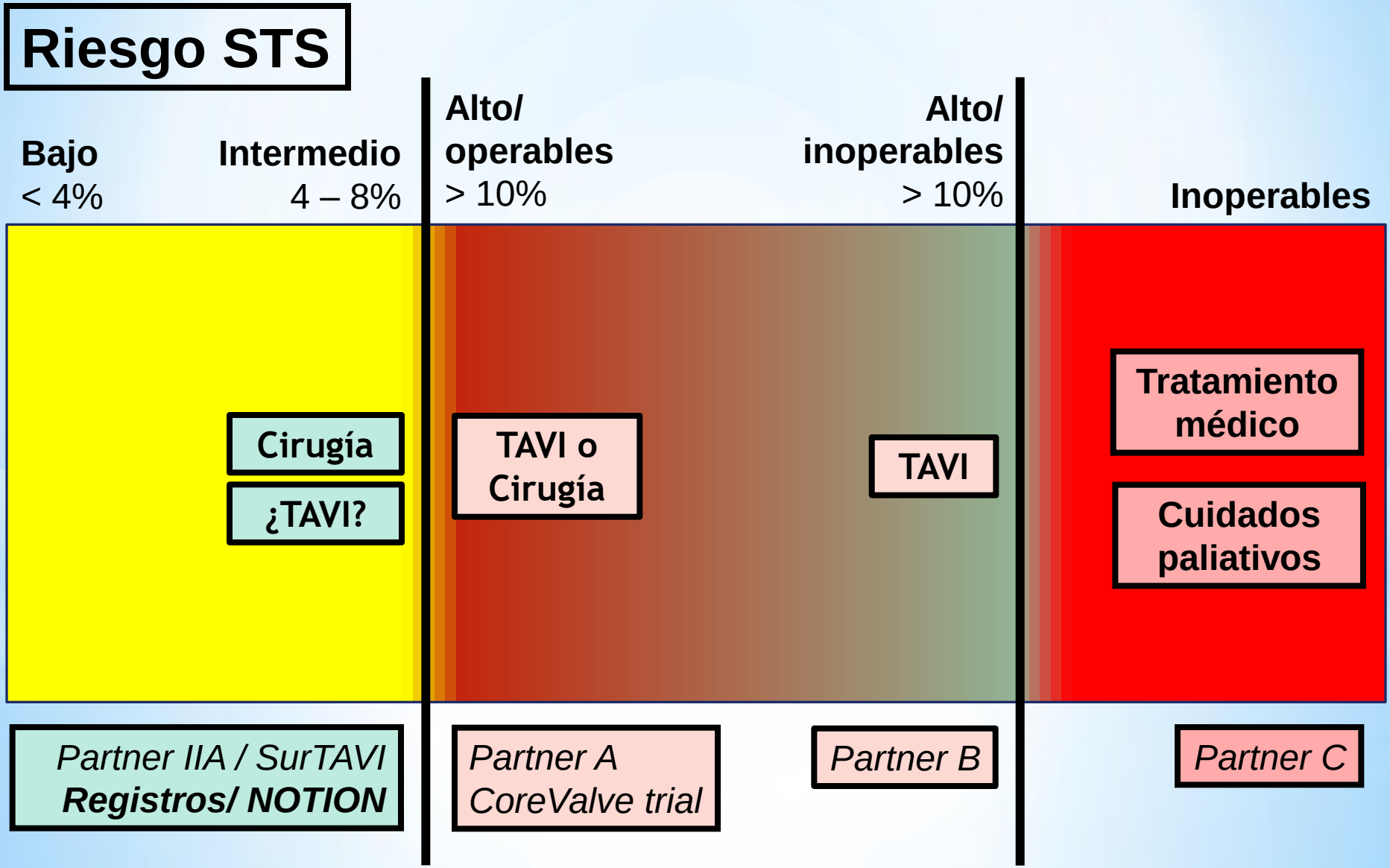
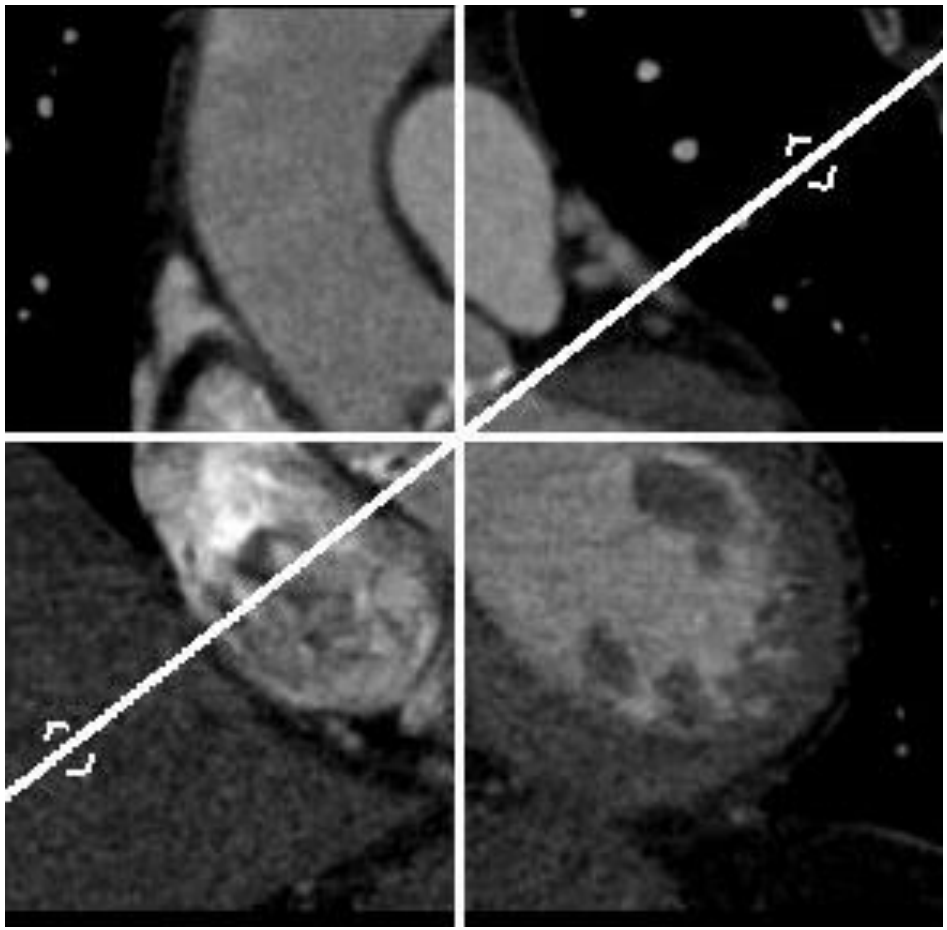
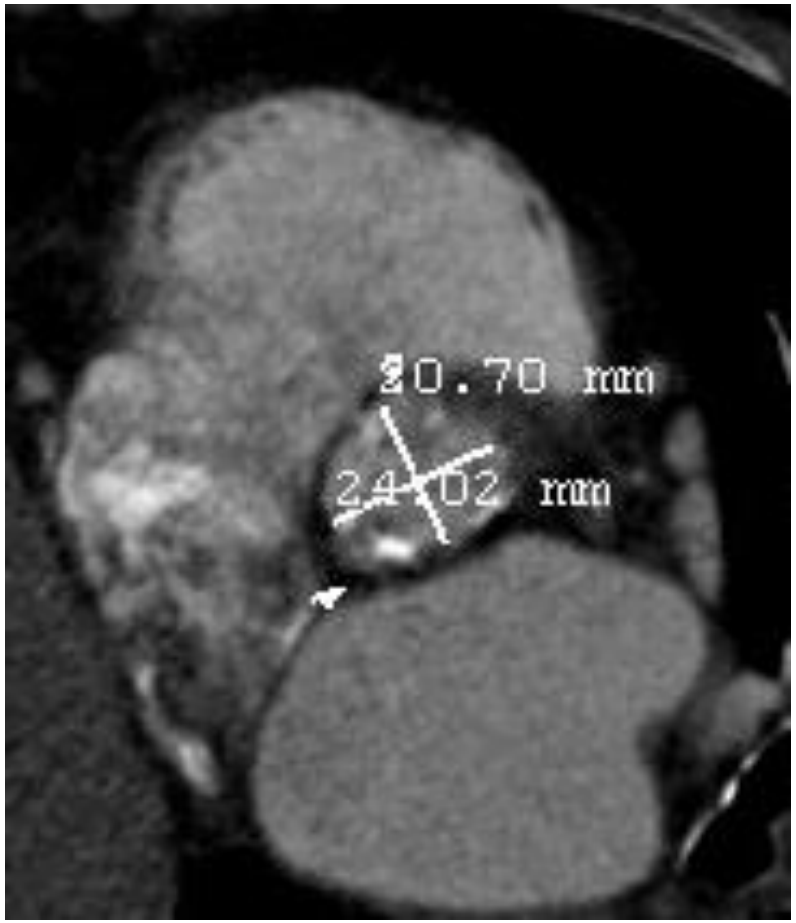
Indicaciones de la TAVI en la actualidad



Diametros anillo aortico corte axial





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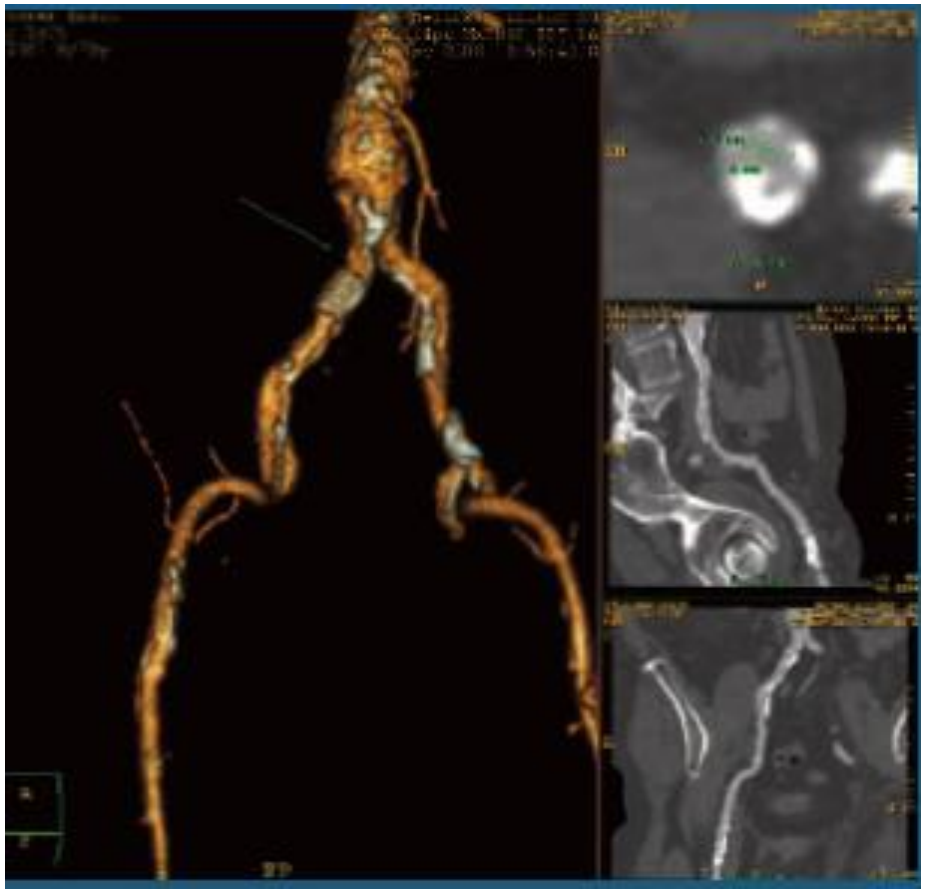
Evaluation for femoral approach



Iliac arteries: severe calcification, tortuosity, small diameter (<6-9mm according the device used), previous Ao-femoral by pass

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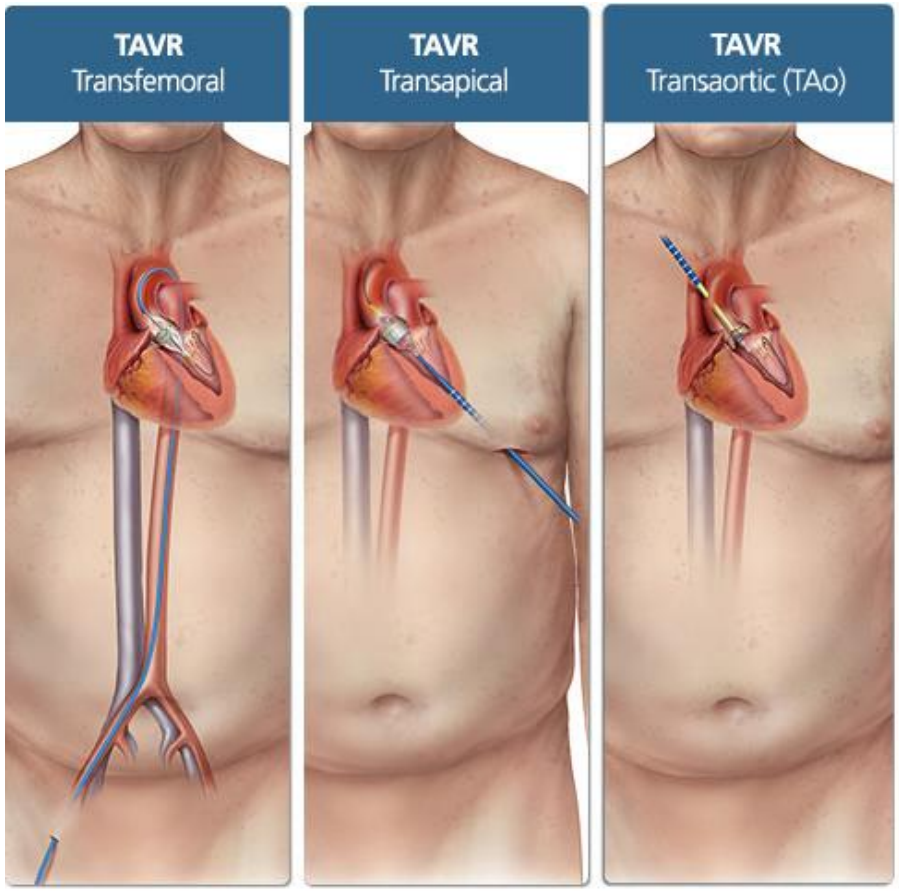
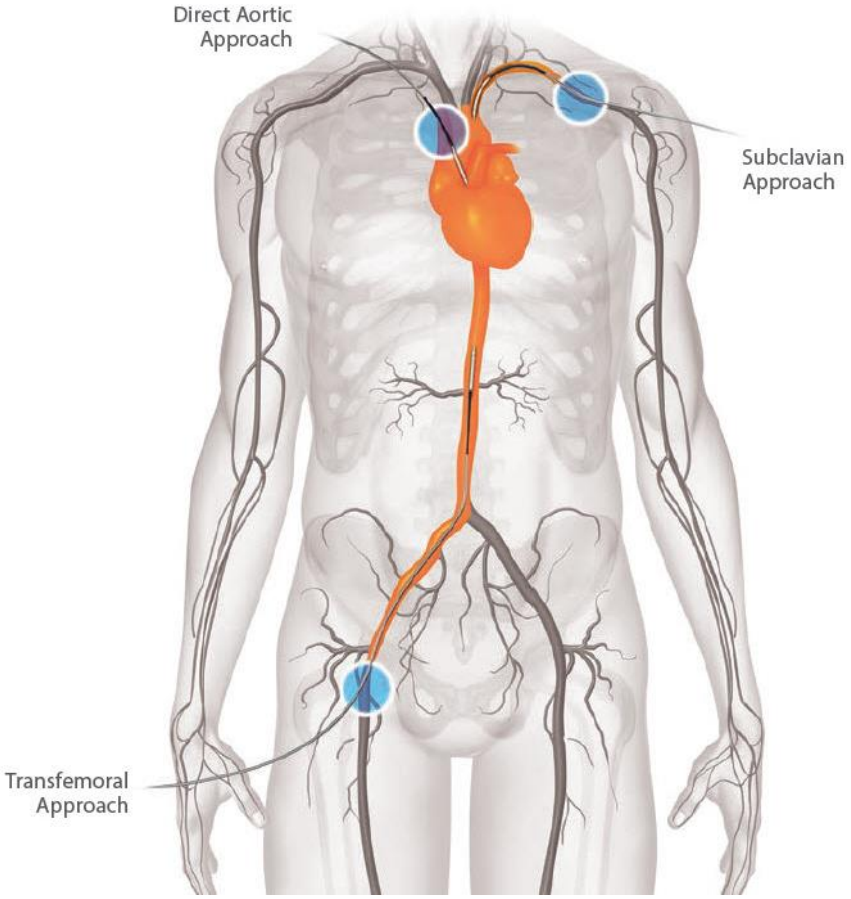
Accesos múltiples





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Impacto clínico en pacientes inoperables

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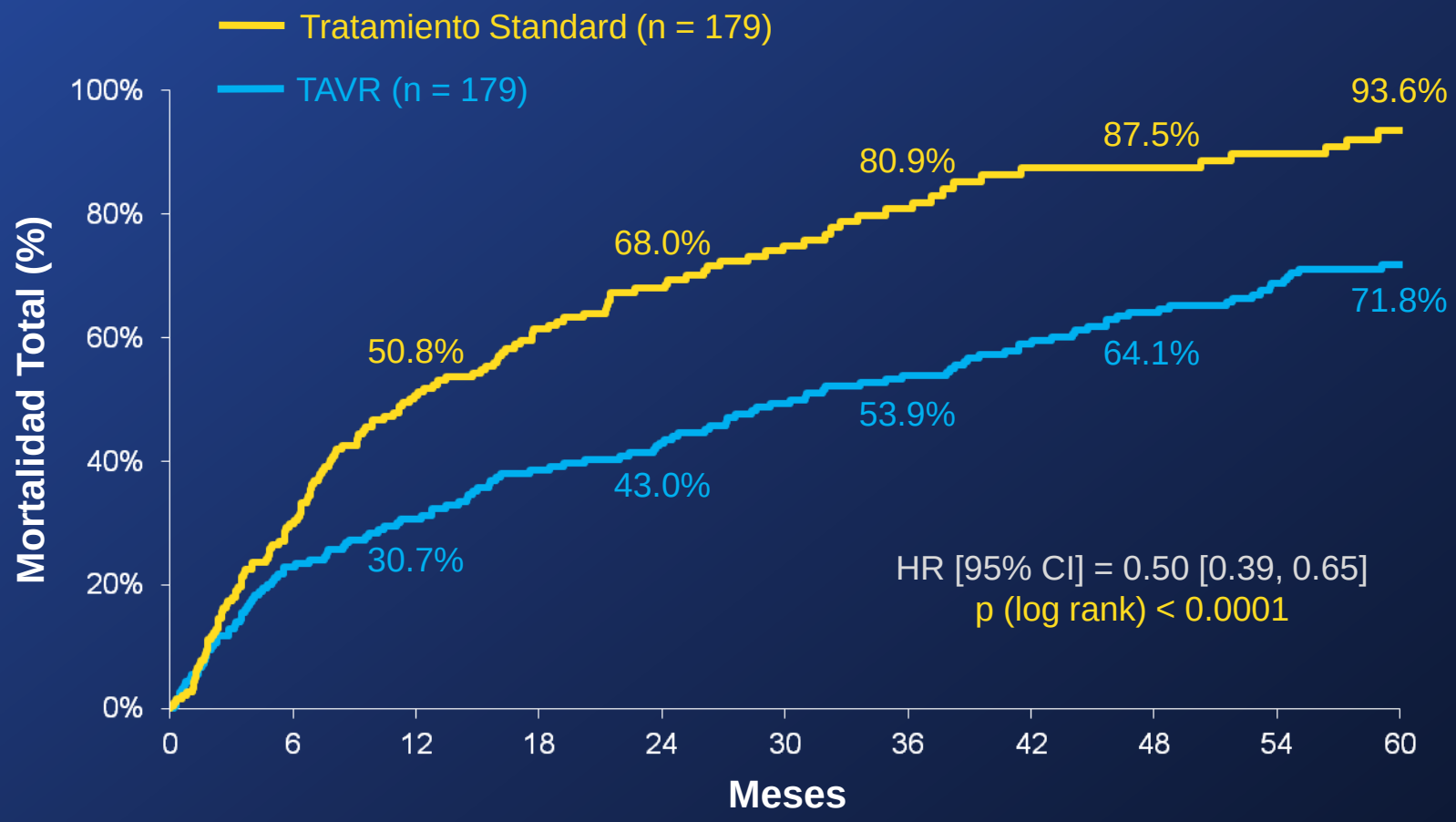
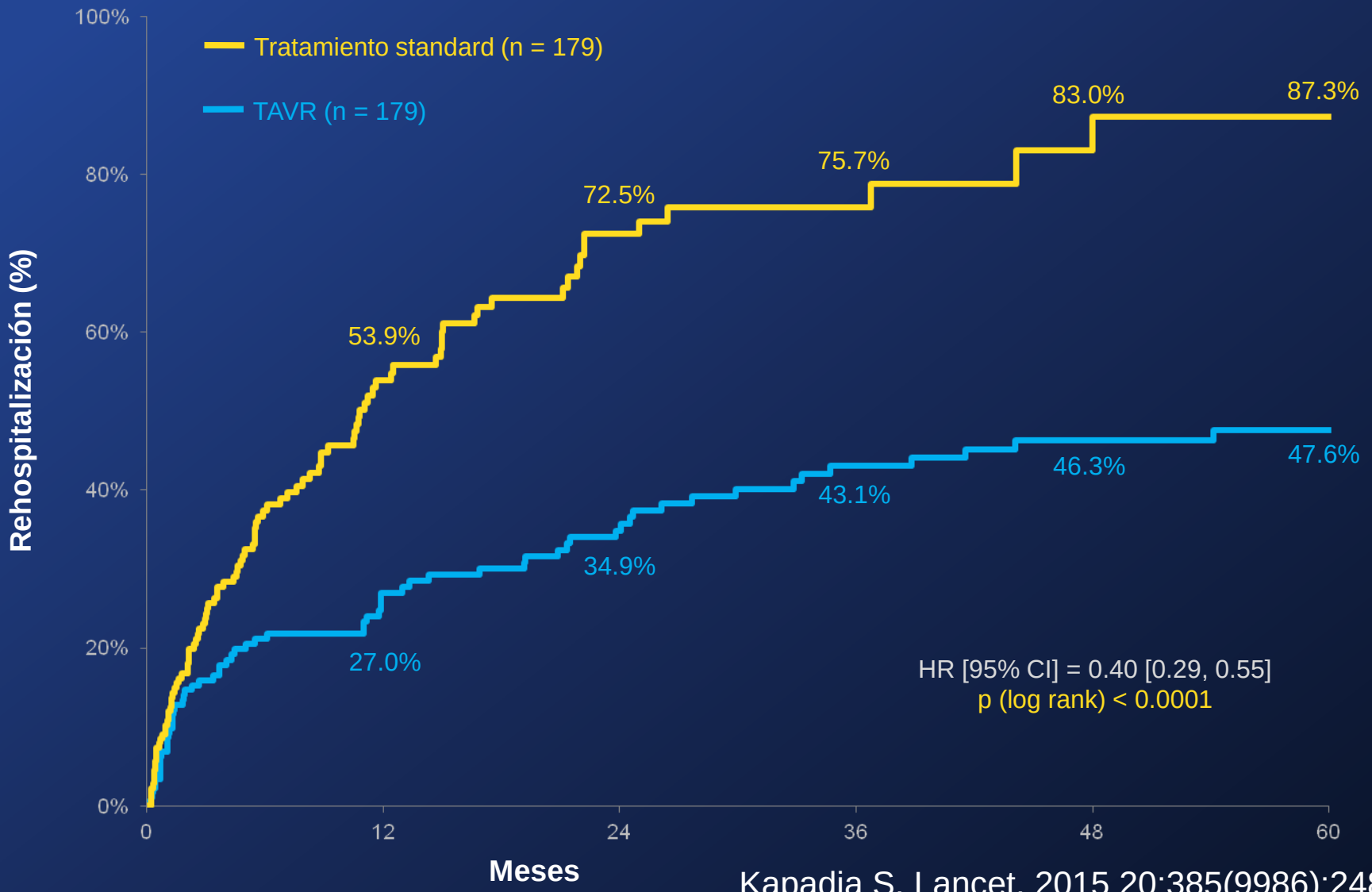
Mortalidad Total (ITT)



- *En USA la mortalidad a 5 años en una población matcheada por sexo y edad pero sin comorbilidades es del 40.5%*

Población inoperable: Rehospitalización



Kapadia S, Lancet. 2015 20;385(9986):2485-91

Impacto clínico en pacientes de alto riesgo

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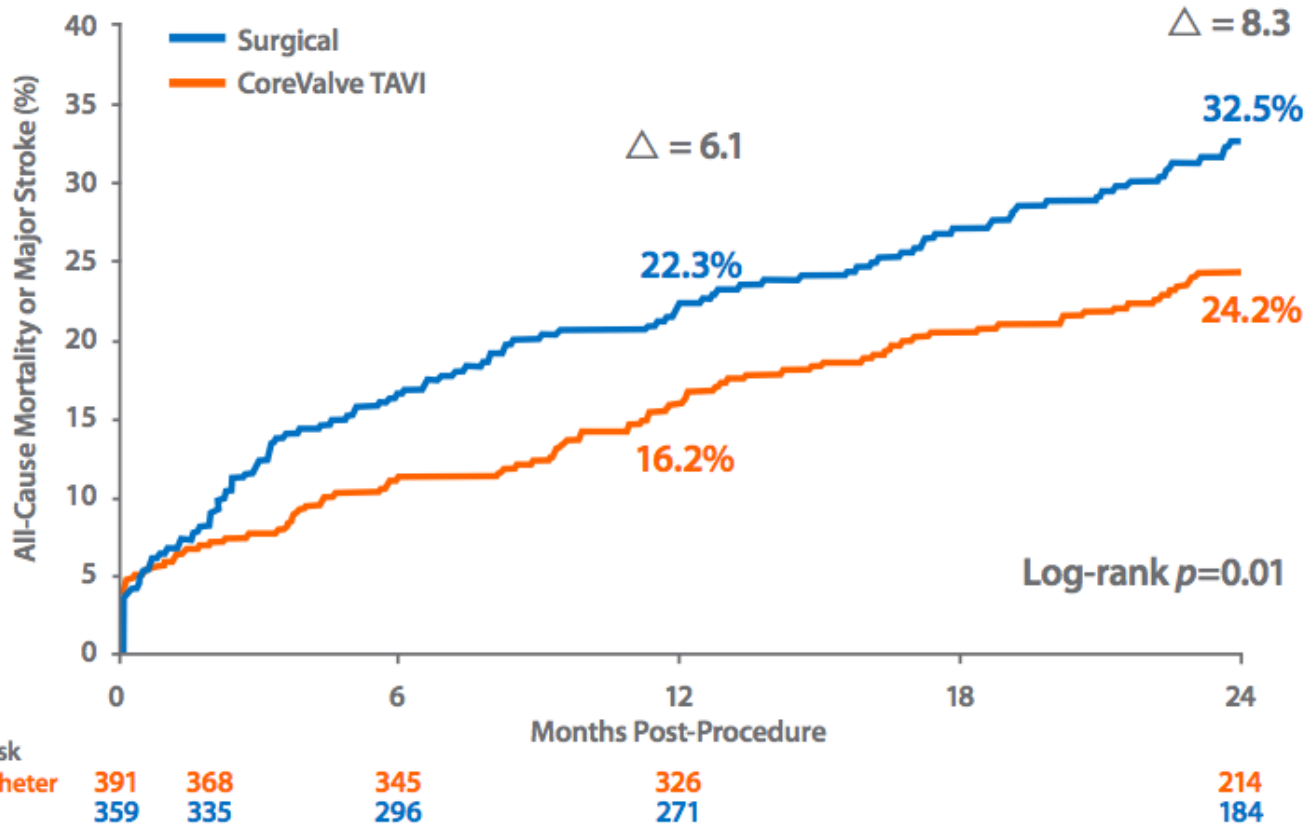
Mortalidad Total o ACV mayor a 2 años

CoreValve® US PIVOTAL TRIAL | All-Cause Mortality or Major Stroke



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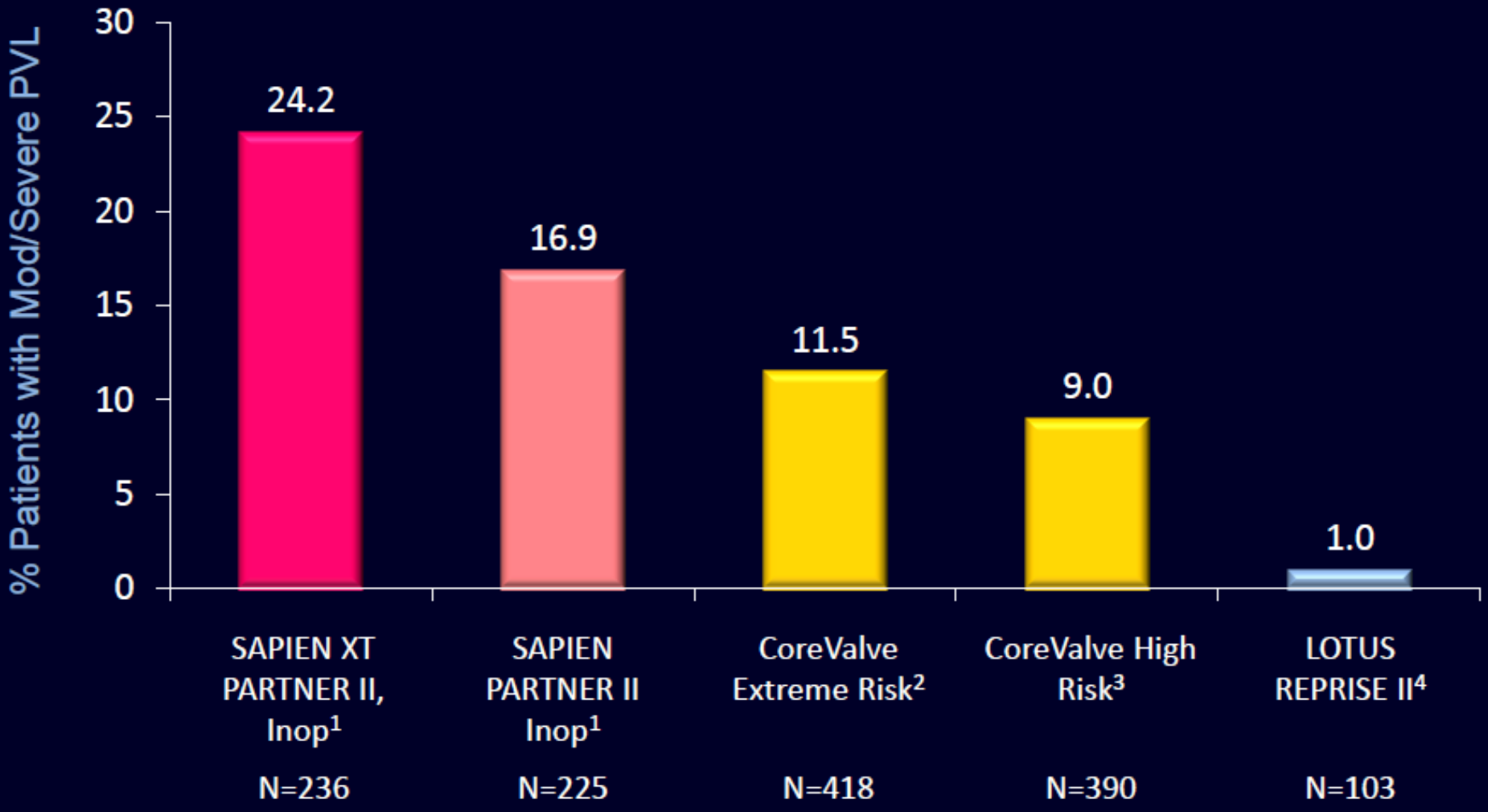
Riesgo de insuficiencia aortica

1 Month Moderate & Severe PVL

Echo Core Lab Adjudicated Clinical Trials



[1]Leon M, ACC 2013, [2]Popma J, *JACC* 2014; 63(19): 1972-81, [3]Adams D, *N Engl J Med* 2014; 370: 1790-98
[4]Meredith I et al, *JACC* 2014 (In press)

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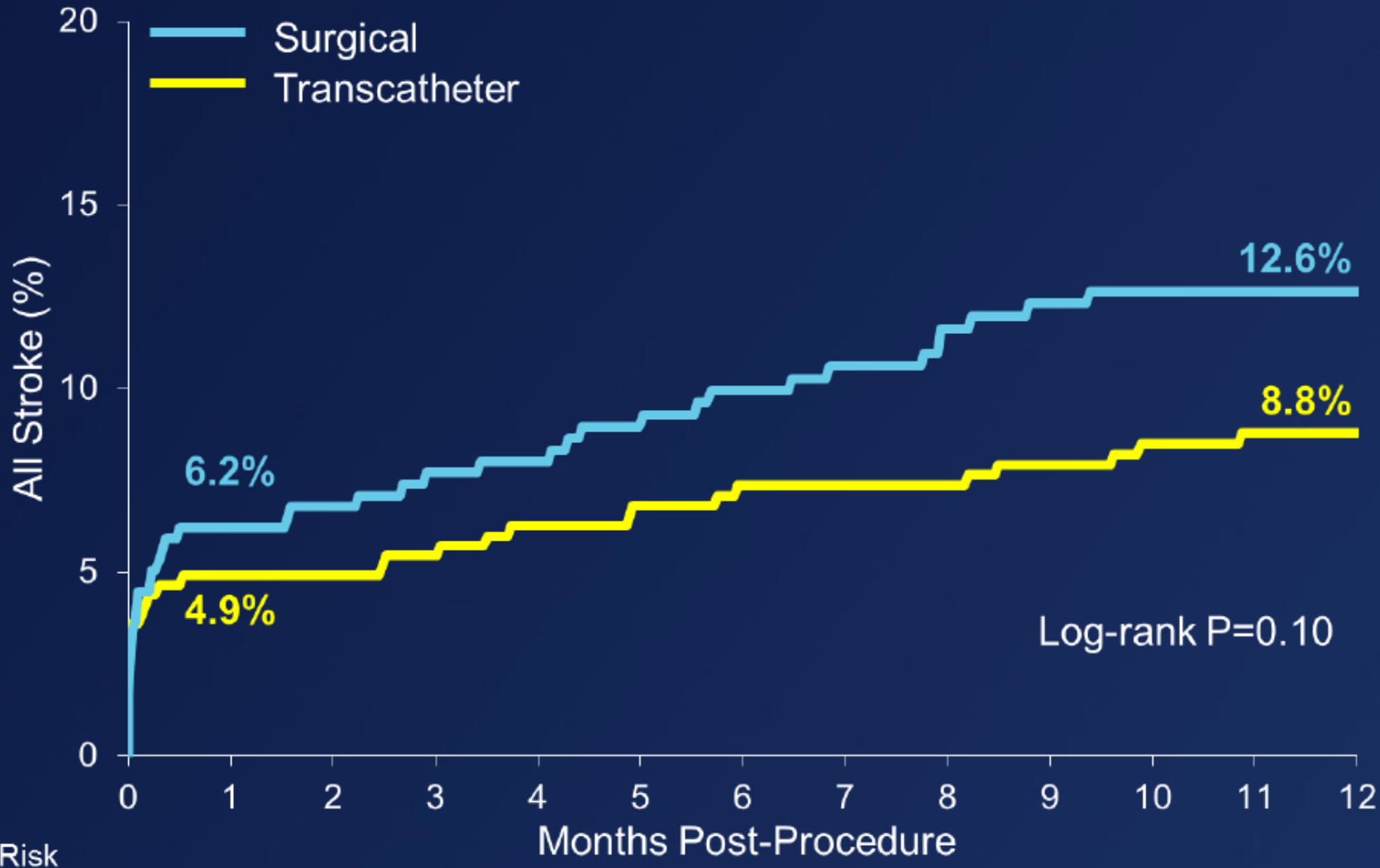
Riesgo de ACV

Stroke Total



No. at Risk

Surgical	357	322				274						249
Transcatheter	390	363				334						314

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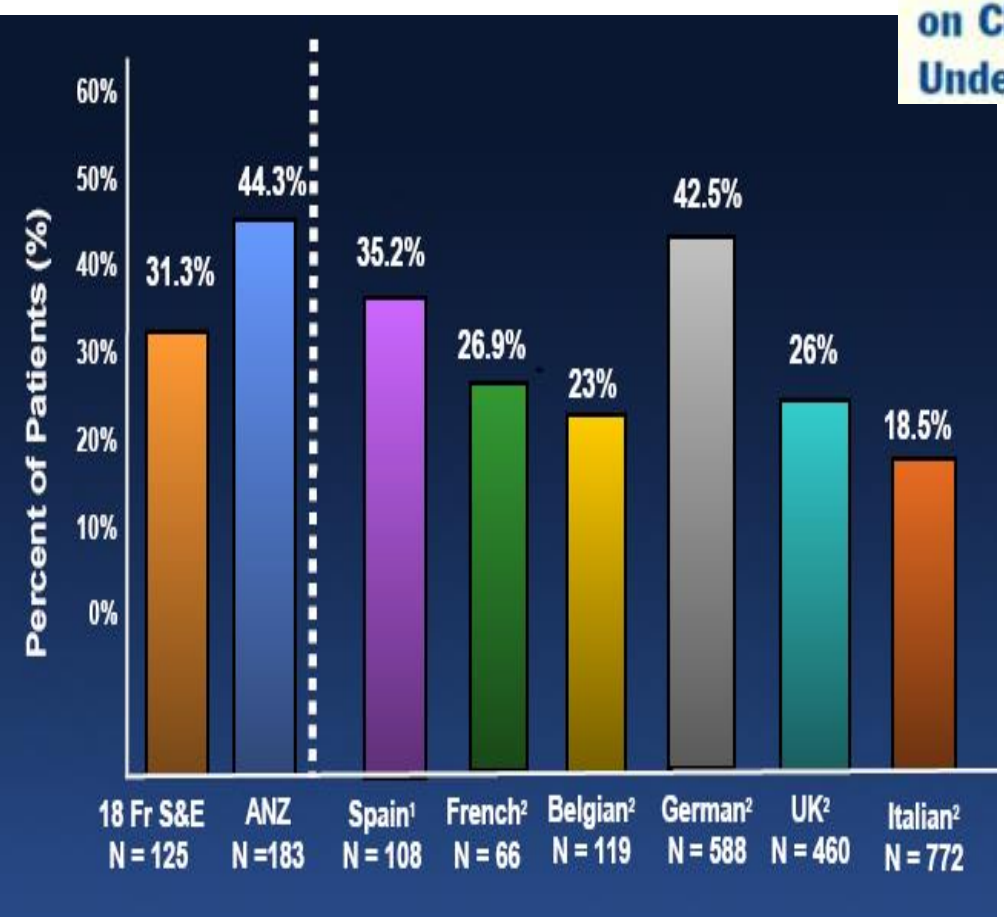
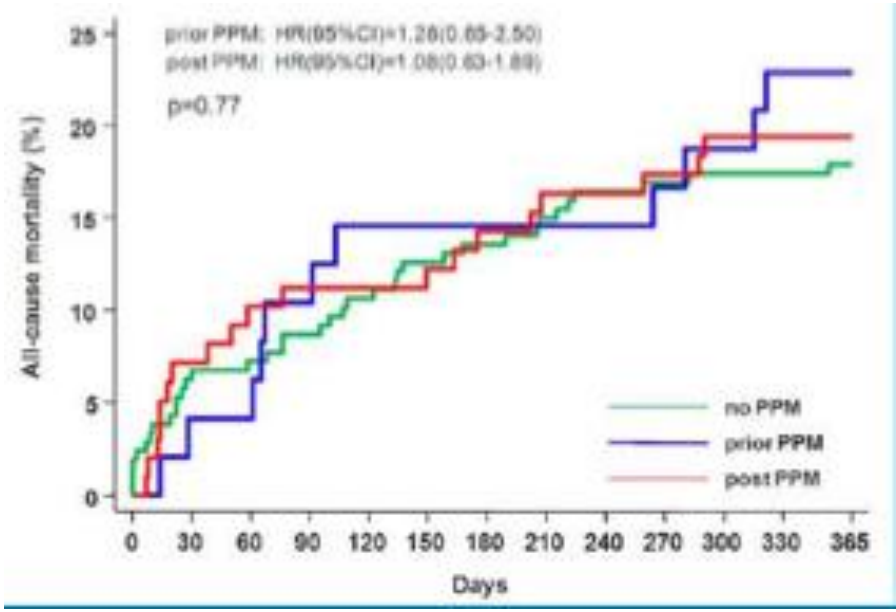
Riesgo de Marcapasos

Indicación de Marcapasos Definitivo



Impact of Permanent Pacemaker Implantation on Clinical Outcome Among Patients Undergoing Transcatheter Aortic Valve Implantation



Buellesfeld L et al; Am Coll Cardiol 2012

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¿Qué está sucediendo en el mundo?

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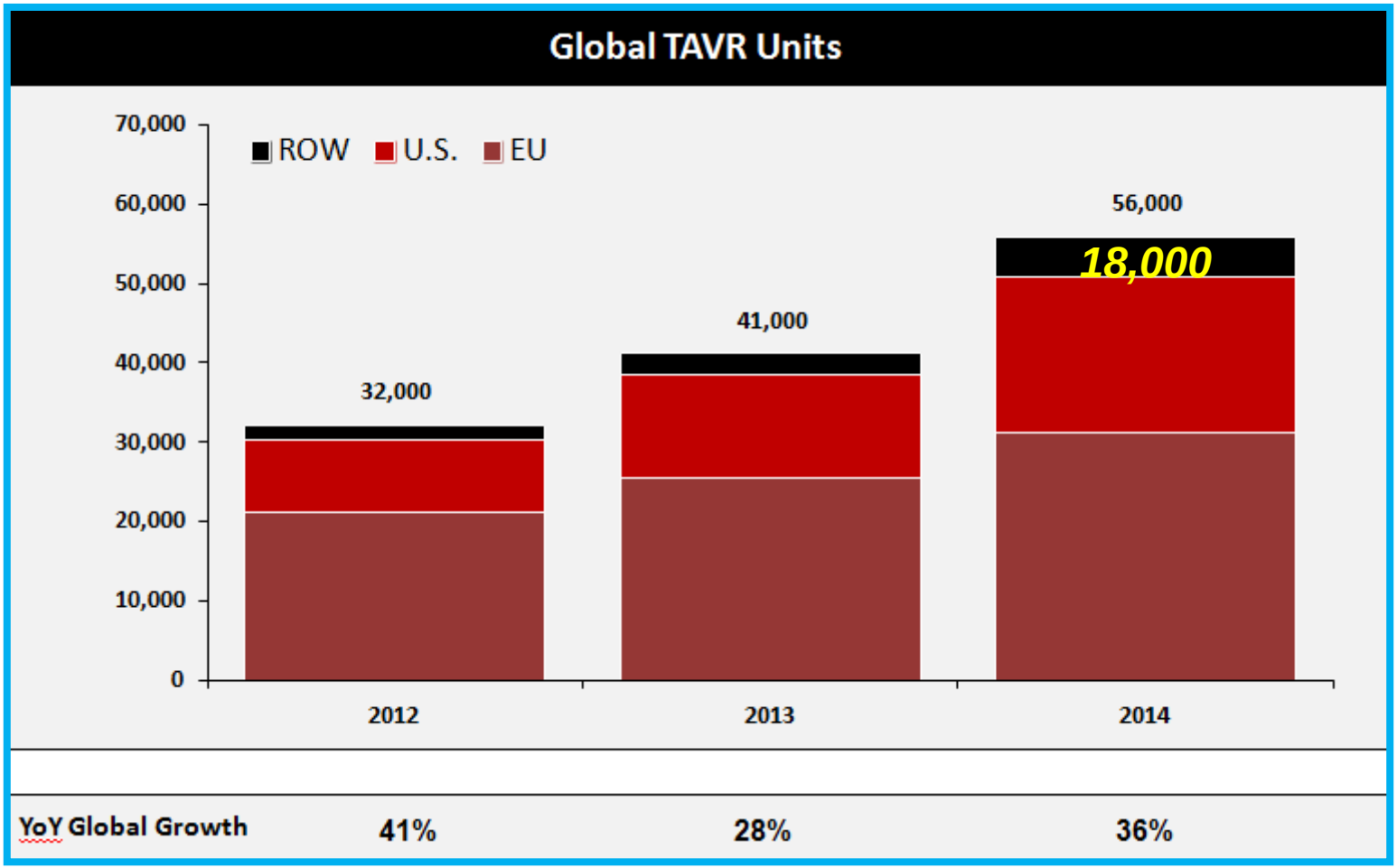
TAVI: Crecimiento global estimado



SOURCE: Credit Suisse TAVI Comment –January 8, 2015. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

Impacto clínico en pacientes de moderado a bajo riesgo

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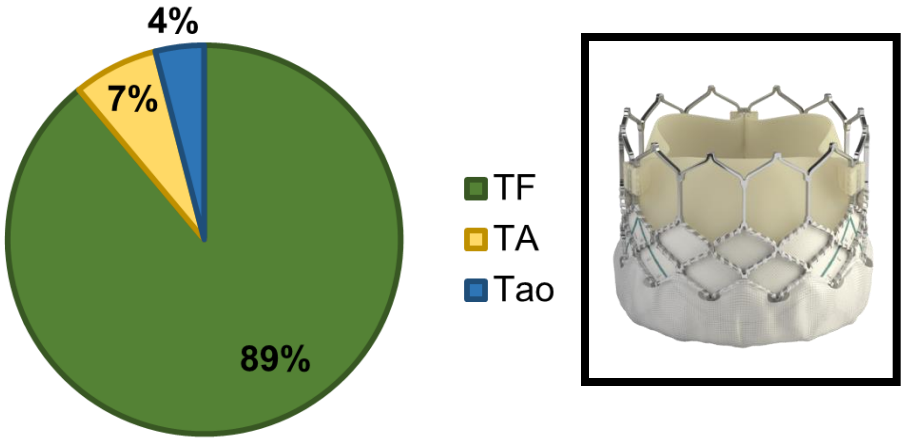
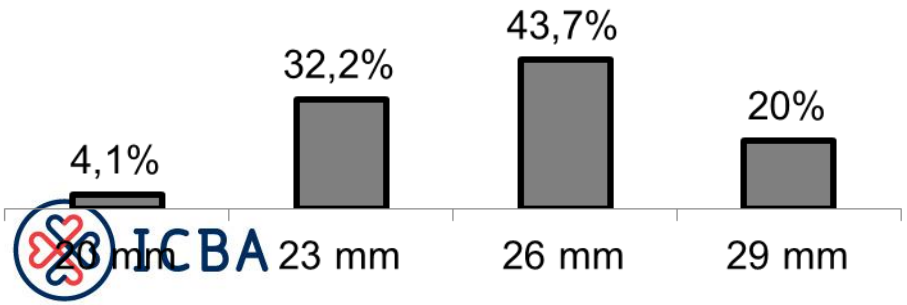
PARTNER II S3i Trial

Kodali S et al. ACC 2015, San Diego

STS promedio = **5.3%**

Edad promedio = **81.9**



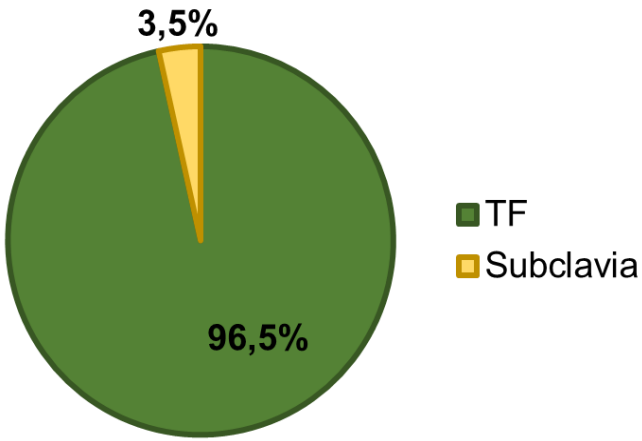


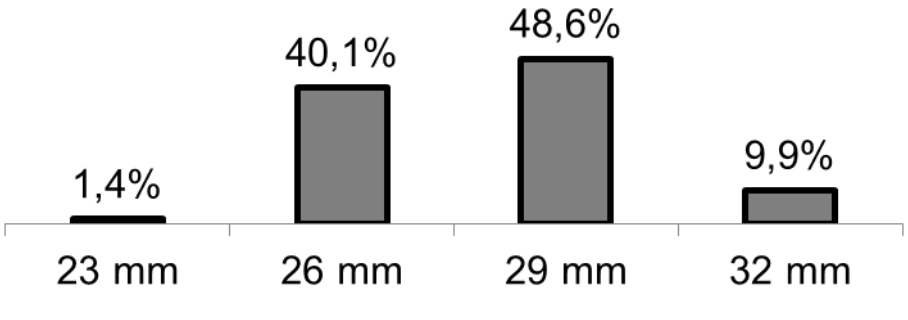
NOTION Trial

Thyregod HG et al. J Am Coll Cardiol 2015;65:2184-94.

STS promedio = **2.9%**

Edad promedio = **79.2**





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¿Qué sucede en el mundo?

Europea

Latino America

47.8

1.8

TAVR por millon habitantes

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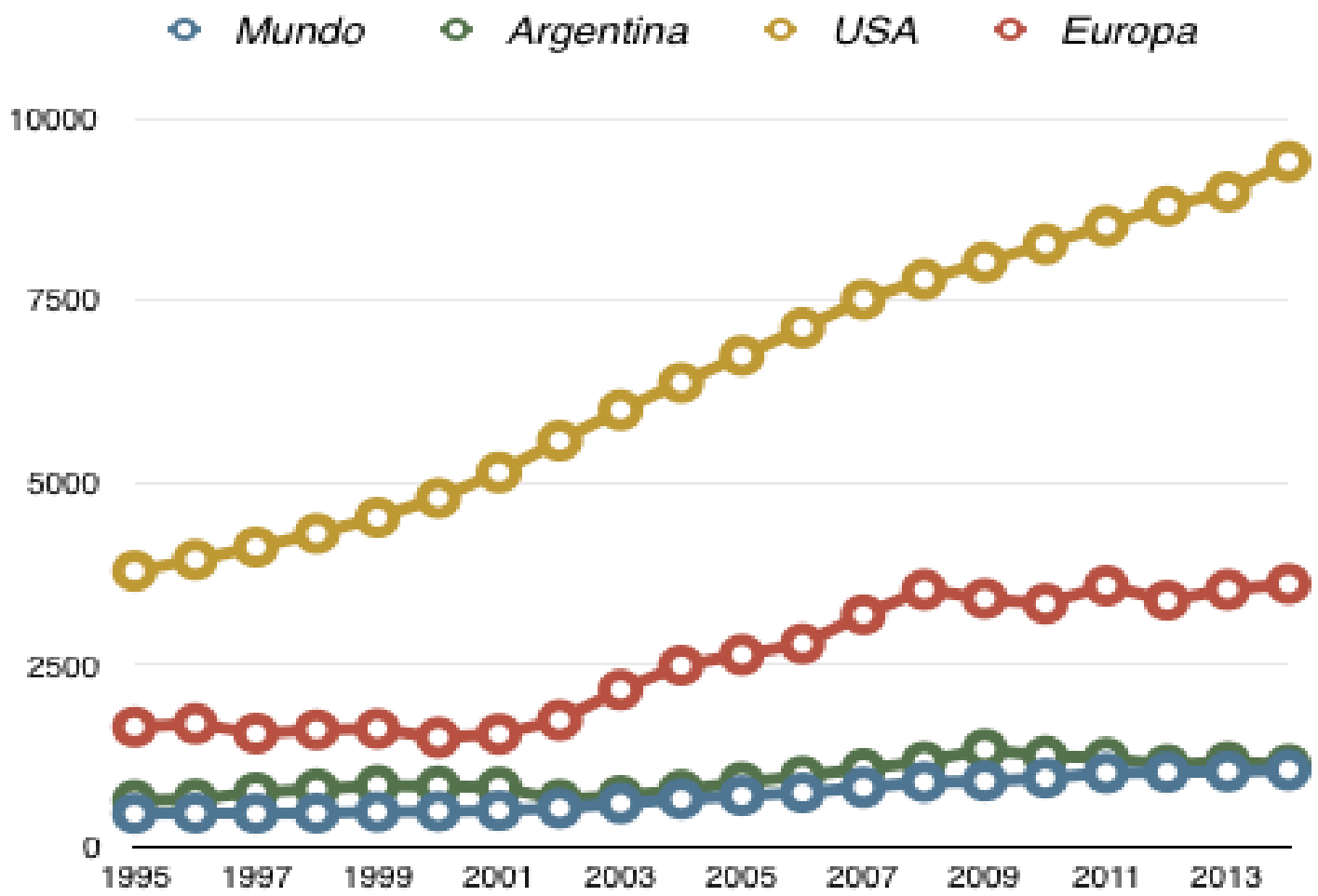
Gasto en salud (USD nómina actual)



Fuente: Banco Mundial 2015

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Muchas gracias

fcura@icba.com.ar

Tratamiento percutaneo de las enfermedades valvulares

Recomendación ACC/AHA

Table 10. Summary of Recommendations for AS: Choice of Surgical or Transcatheter Intervention

Recommendations	COR	LOE	References
Surgical AVR is recommended in patients who meet an indication for AVR (Section 3.2.3) with low or intermediate surgical risk	I	A	(74, 149)
For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care	I	C	N/A
TAVR is recommended in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12 mo	I	B	(170, 171)
TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR (Section 3.2.3) and who have high surgical risk (Section 2.5)	IIa	B	(172, 173)
Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS	IIb	C	N/A
TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS	III: No Benefit	B	(170)

AS indicates aortic stenosis; AVR, aortic valve replacement; COR, Class of Recommendation; LOE, Level of Evidence; N/A, not applicable; and TAVR, transcatheter aortic valve replacement.

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Reducción gradual de la mortalidad del TAVI

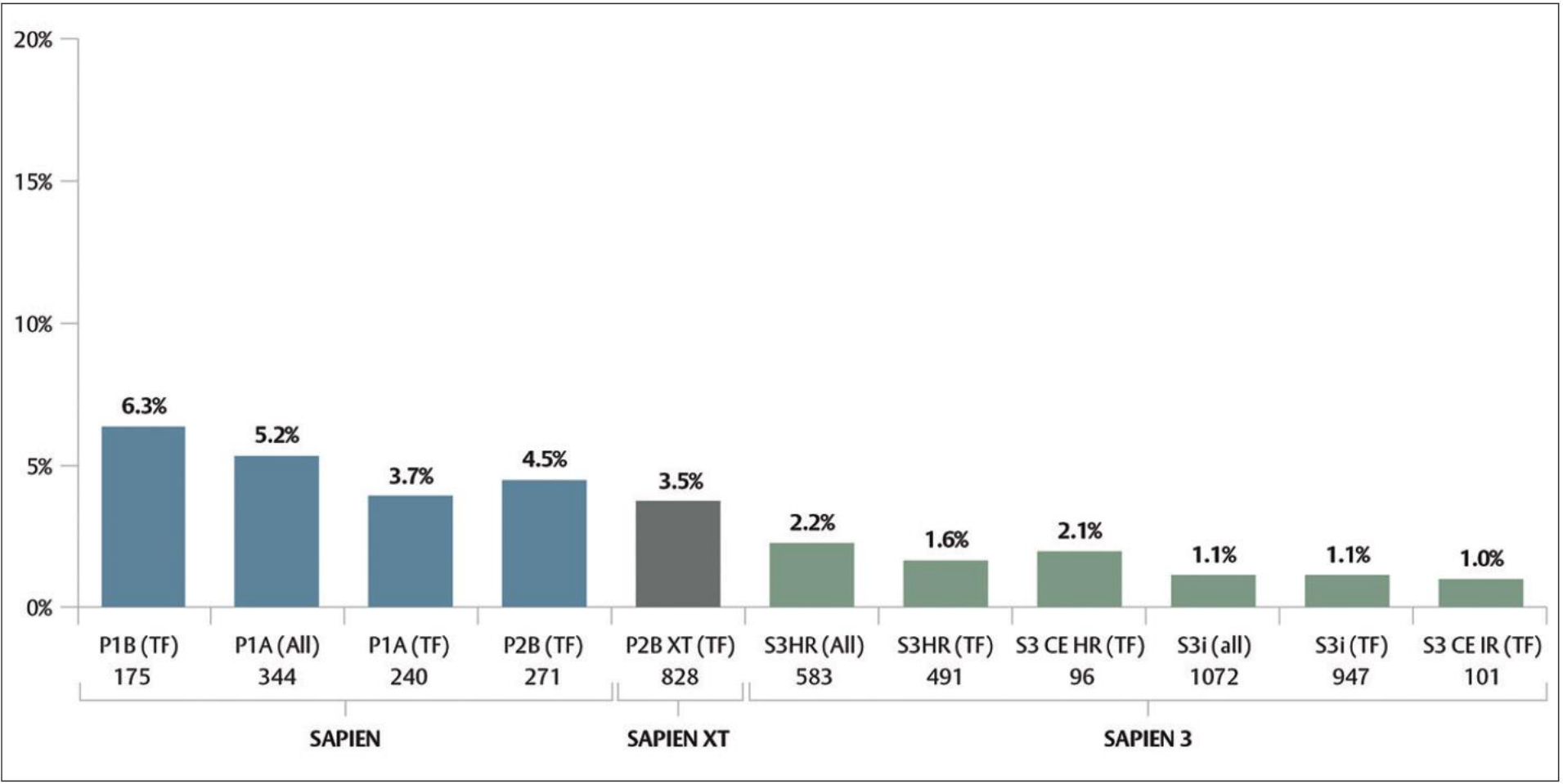
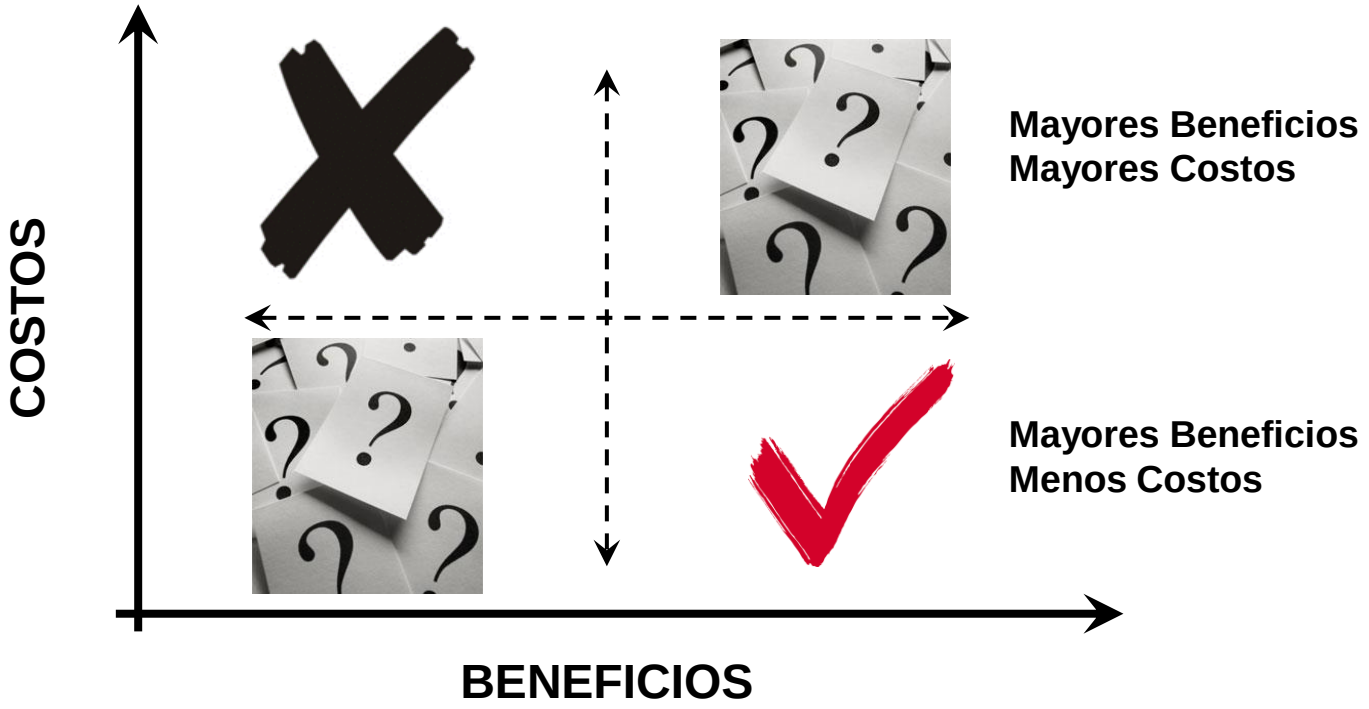


Figure 2. All-cause mortality at 30 days in the PARTNER trials. P1A, PARTNER IA; P1B, PARTNER IB; P2B, PARTNER IIB; P2B XT, PARTNER IIB XT; S3 CE HR, European CE high-risk cohort; S3 CE IR, European CE intermediate-risk cohort; S3HR, PARTNER S3 high-risk cohort; S3i, PARTNER S3 intermediate-risk cohort; TF, transfemoral.

Costo - Beneficio



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Costo-Eficacia

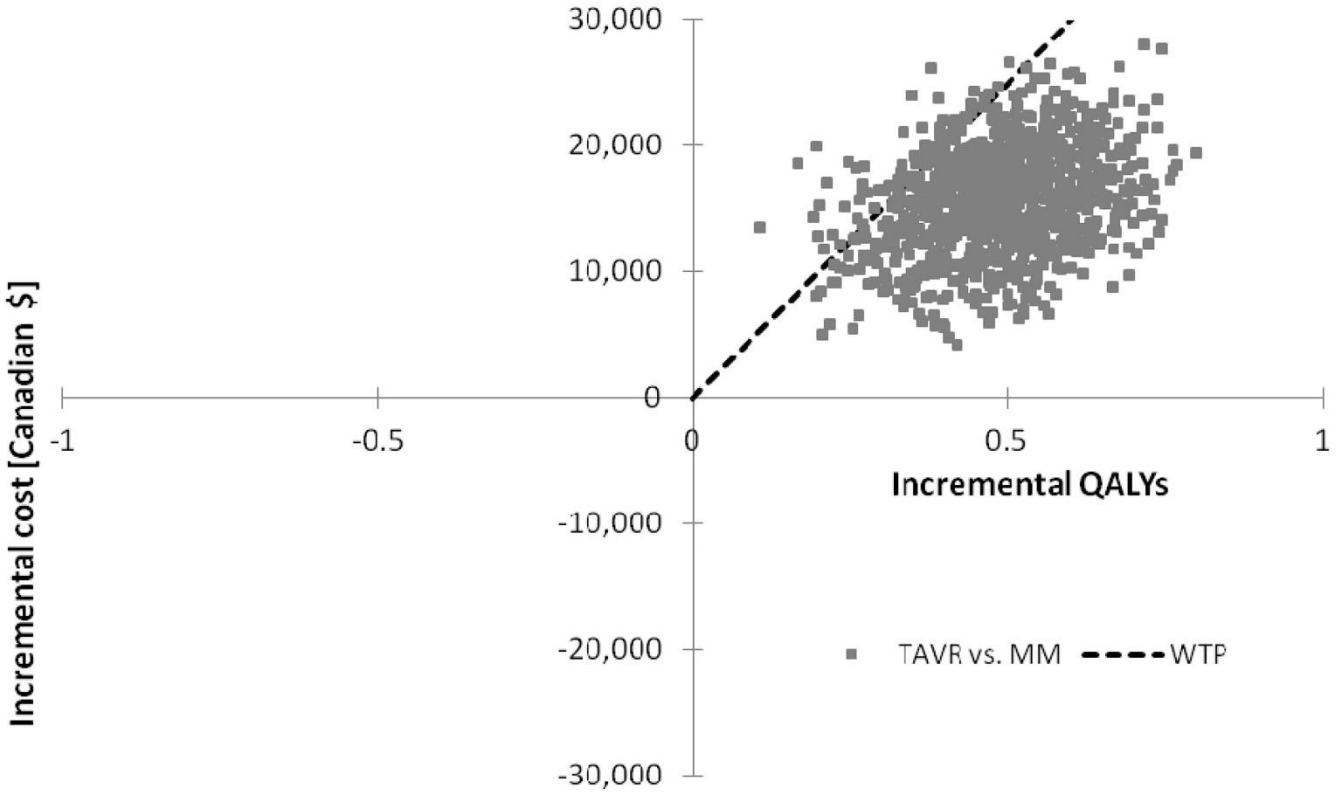
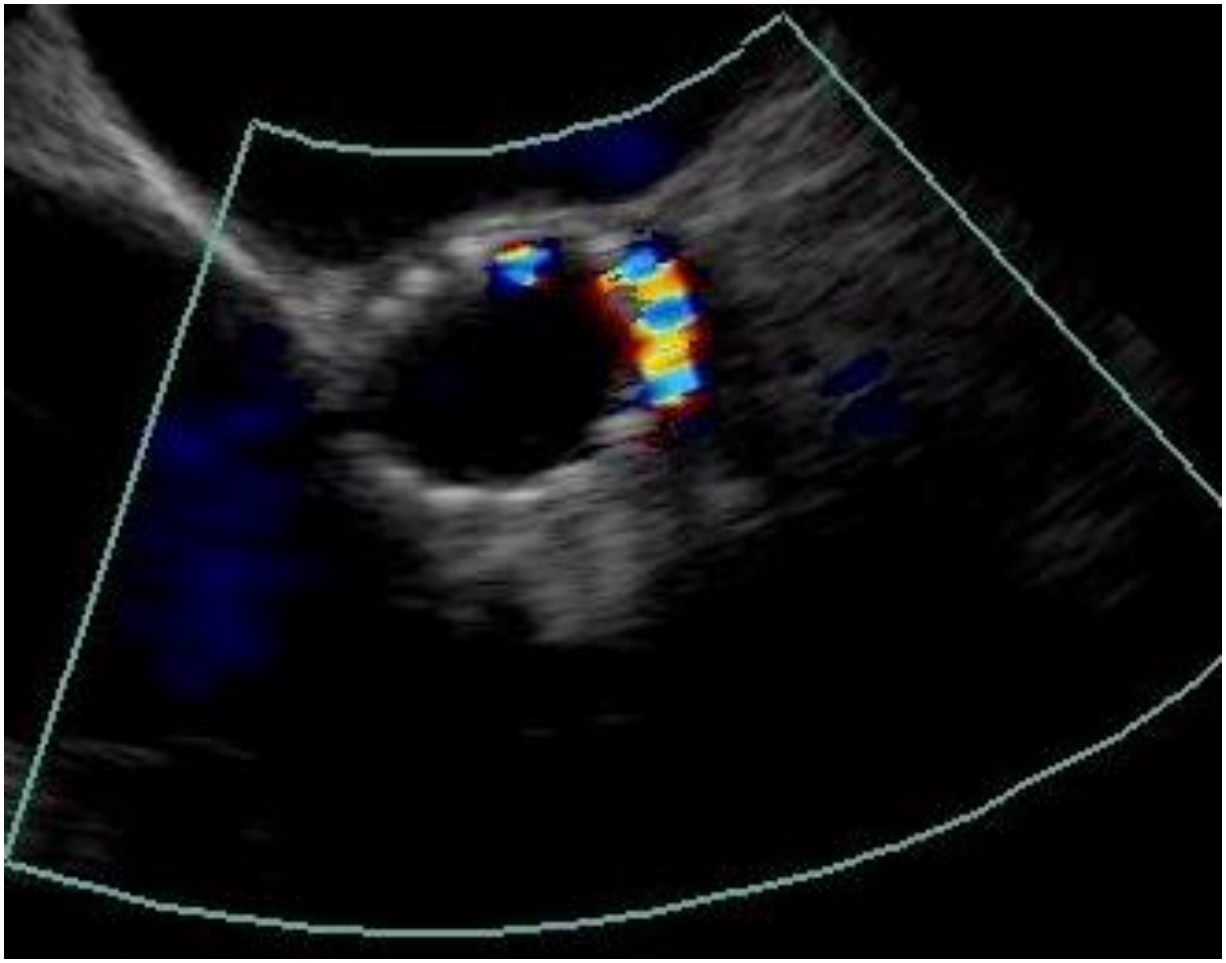


Figure 2. PSA scatter plot at 3 years. Willingness-to-pay threshold (WTP) = $50,000/QALY gained. TAVR, transcatheter aortic valve replacement; MM, medical management; QALYs, quality-adjusted life years; WTP, willingness-to-pay.

Published in: Rebecca L. Hancock-Howard; Christopher M. Feindel; Josep Rodes-Cabau; John G. Webb; Ann K. Thompson; Kurt Banz; *Journal of Medical Economics* **2013,** 16, 566-574.
DOI: 10.3111/13696998.2013.770747

Insuficiencia Aórtica
Intervención guiada con ETE



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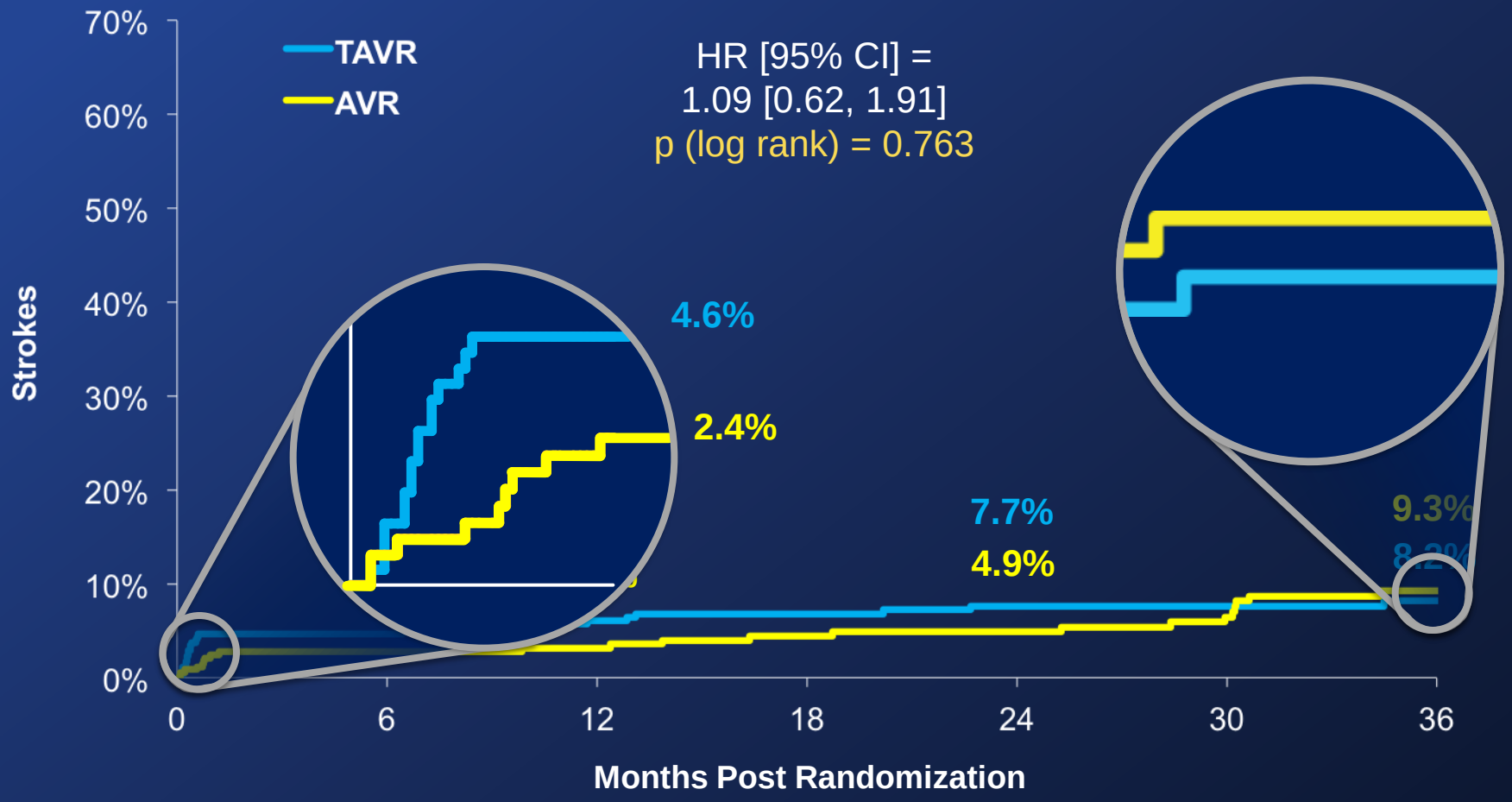
Strokes (ITT)



No. at Risk

TAVR	348	287	250	228	211	176	139
AVR	351	246	230	217	197	169	139

Efectos del implante de la valvula con el sistema de conducción

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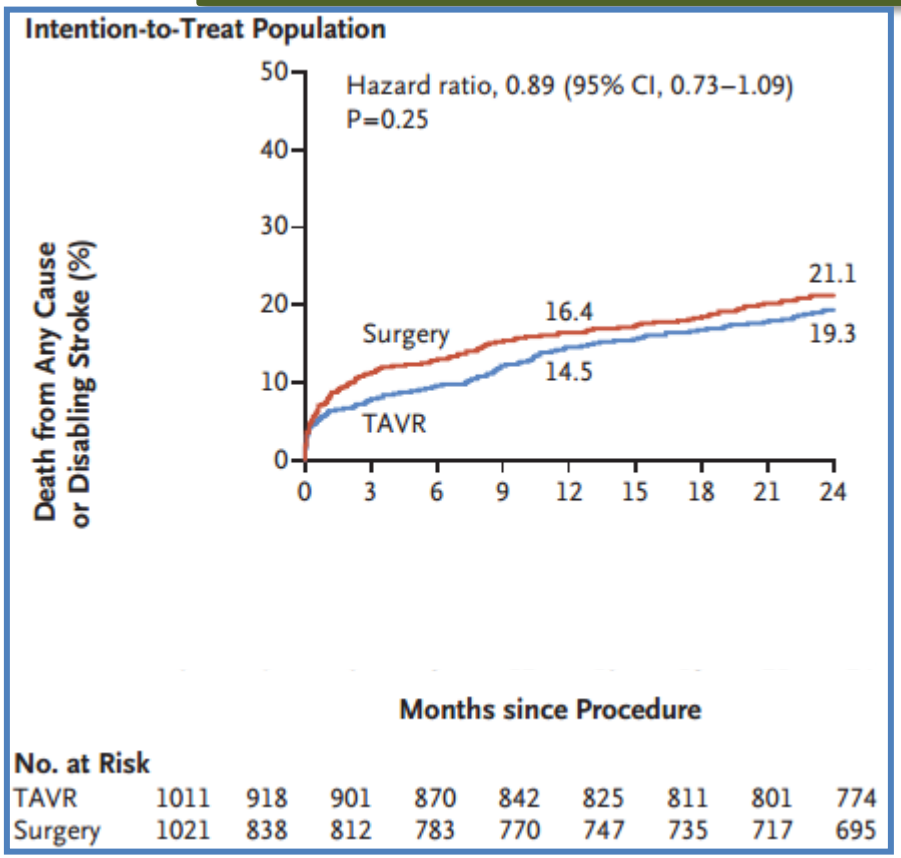
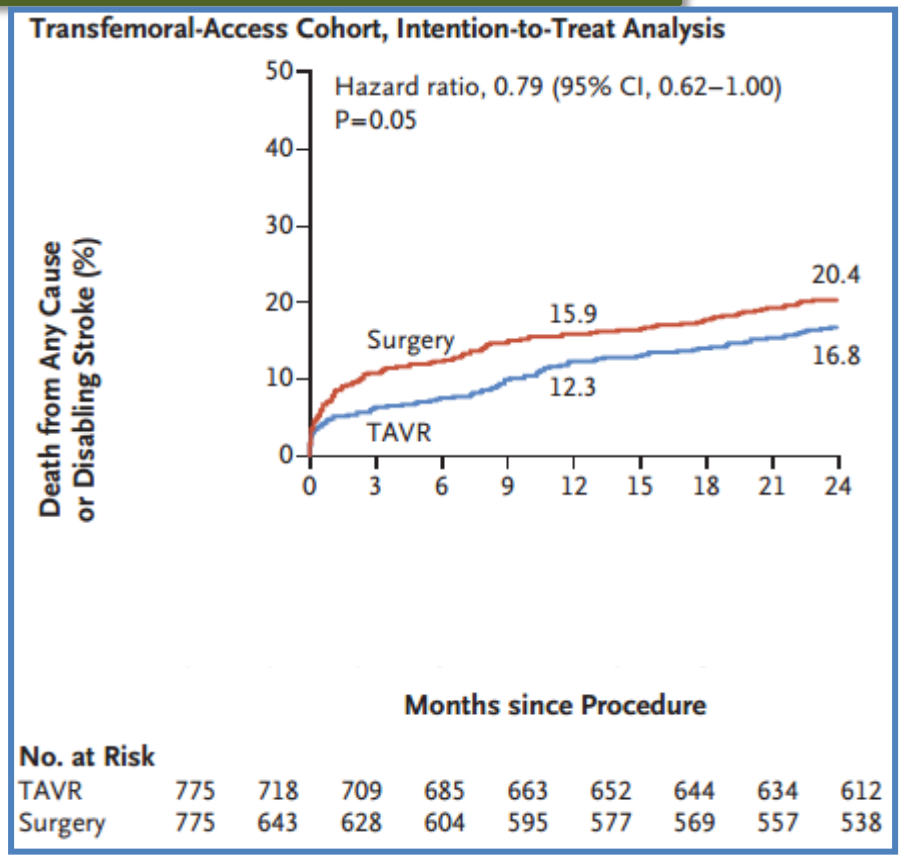
PARTNER 2 Trial

Endpoint primario: Muerte por cualquier causa + ACV severo





RR: *0,92 (IC95% 0,77 – 1,09)*
p-no inferioridad: 0,001

Leon MB et al. N Engl J Med 2016;374:1609-20.

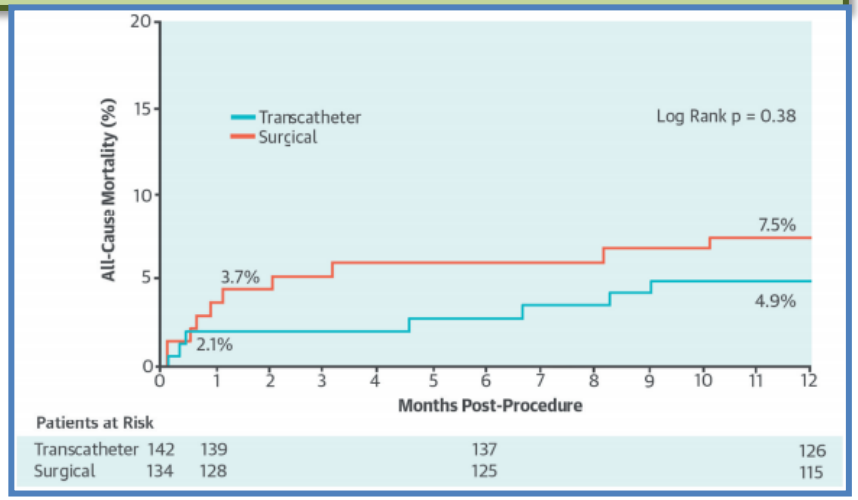
NOTION Trial

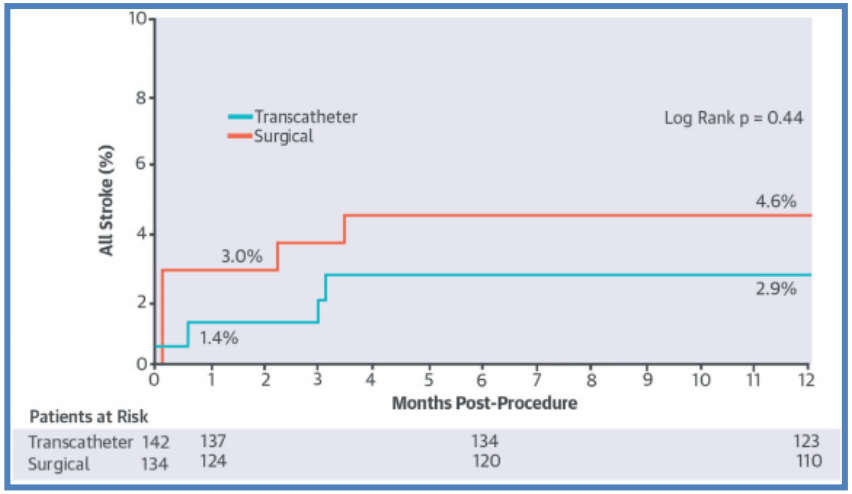
Endpoint primario: Muerte por cualquier causa + ACV severo + IAM

TAVI
13,1%

Cirugía
16,3%

p= 0,43





Thyregod HGH et al. J Am Coll Cardiol 2015;65:2184-94.

PARTNER 2 Trial

End Point	At 30 Days			At 1 Year			At 2 Years		
	TAVR (N=1011)	Surgery (N=1021)	P Value	TAVR (N=1011)	Surgery (N=1021)	P Value	TAVR (N=1011)	Surgery (N=1021)	P Value
	no. of patients (%)			*no. of patients (%)*			*no. of patients (%)*		
Death from any cause or disabling stroke	62 (6.1)	80 (8.0)	0.11	145 (14.5)	160 (16.4)	0.24	192 (19.3)	202 (21.1)	0.33
Death									
From any cause	39 (3.9)	41 (4.1)	0.78	123 (12.3)	124 (12.9)	0.69	166 (16.7)	170 (18.0)	0.45
From cardiac causes	33 (3.3)	32 (3.2)	0.92	70 (7.1)	77 (8.1)	0.40	97 (10.1)	104 (11.3)	0.38
Not from cardiac causes	6 (0.6)	9 (0.9)	0.41	53 (5.6)	47 (5.2)	0.71	69 (7.4)	65 (7.4)	0.98
Neurologic event									
Any event	64 (6.4)	65 (6.5)	0.94	99 (10.1)	93 (9.7)	0.76	121 (12.7)	103 (11.0)	0.25
Transient ischemic attack	9 (0.9)	4 (0.4)	0.17	23 (2.4)	16 (1.8)	0.38	34 (3.7)	20 (2.3)	0.09
Any stroke	55 (5.5)	61 (6.1)	0.57	78 (8.0)	79 (8.1)	0.88	91 (9.5)	85 (8.9)	0.67
Disabling stroke	32 (3.2)	43 (4.3)	0.20	49 (5.0)	56 (5.8)	0.46	59 (6.2)	61 (6.4)	0.83
Nondisabling stroke	23 (2.3)	18 (1.8)	0.43	30 (3.0)	24 (2.5)	0.44	33 (3.4)	27 (2.9)	0.51
Rehospitalization	64 (6.5)	62 (6.5)	0.99	142 (14.8)	135 (14.7)	0.92	183 (19.6)	156 (17.3)	0.22
Death from any cause or rehospitalization	99 (9.8)	101 (10.2)	0.78	234 (23.4)	225 (23.3)	0.97	303 (30.5)	281 (29.6)	0.67
Death from any cause, any stroke, or rehospitalization	140 (13.9)	153 (15.3)	0.37	274 (27.4)	276 (28.3)	0.64	344 (34.6)	326 (33.9)	0.75
Myocardial infarction	12 (1.2)	19 (1.9)	0.22	24 (2.5)	29 (3.0)	0.47	33 (3.6)	37 (4.1)	0.56
Major vascular complication	80 (7.9)	51 (5.0)	0.008	84 (8.4)	54 (5.3)	0.007	86 (8.6)	55 (5.5)	0.006
Life-threatening or disabling bleeding	105 (10.4)	442 (43.4)	<0.001	151 (15.2)	460 (45.5)	<0.001	169 (17.3)	471 (47.0)	<0.001
Acute kidney injury	13 (1.3)	31 (3.1)	0.006	32 (3.4)	48 (5.0)	0.07	36 (3.8)	57 (6.2)	0.02
New atrial fibrillation	91 (9.1)	265 (26.4)	<0.001	100 (10.1)	272 (27.2)	<0.001	110 (11.3)	273 (27.3)	<0.001
New permanent pacemaker	85 (8.5)	68 (6.9)	0.17	98 (9.9)	85 (8.9)	0.43	114 (11.8)	96 (10.3)	0.29
Endocarditis	0	0	—	7 (0.8)	6 (0.7)	0.84	11 (1.2)	6 (0.7)	0.22
Aortic-valve reintervention	4 (0.4)	0	0.05	11 (1.2)	4 (0.5)	0.10	13 (1.4)	5 (0.6)	0.09
Coronary obstruction	4 (0.4)	6 (0.6)	0.53	4 (0.4)	6 (0.6)	0.53	4 (0.4)	6 (0.6)	0.53

Leon MB et al. N Engl J Med 2016;374:1609-20.

NOTION Trial

	Index Hospitalization* or 30 Days†			1 Year		
	TAVR	SAVR	p Value	TAVR	SAVR	p Value
Major, life threatening, or disabling bleeding*	16 (11.3)	28 (20.9)	0.03			
Cardiogenic shock*	6 (4.2)	14 (10.4)	0.05			
Major vascular complications*	8 (5.6)	2 (1.5)	0.10			
Acute kidney injury stage II or III*	1 (0.7)	9 (6.7)	0.01			
All-cause death†	3 (2.1)	5 (3.7)	0.43	7 (4.9)	10 (7.5)	0.38
Cardiovascular death†	3 (2.1)	5 (3.7)	0.43	6 (4.3)	10 (7.5)	0.25
Neurological events†	4 (2.8)	4 (3.0)	0.94	7 (5.0)	8 (6.2)	0.68
Stroke†	2 (1.4)	4 (3.0)	0.37	4 (2.9)	6 (4.6)	0.44
Transient ischemic attack†	2 (1.4)	0 (0)	0.17	3 (2.1)	2 (1.6)	0.71
MI†	4 (2.8)	8 (6.0)	0.20	5 (3.5)	8 (6.0)	0.33
Valve endocarditis†	1 (0.7)	0 (0)	0.33	4 (2.9)	2 (1.6)	0.47
New-onset or worsening AF†	24 (16.9)	77 (57.8)	<0.001	30 (21.2)	79 (59.4)	<0.001
Permanent pacemaker implantation†	46 (34.1)	2 (1.6)	<0.001	51 (38.0)	3 (2.4)	<0.001

Thyregod HGH et al. J Am Coll Cardiol 2015;65:2184-94.