ESTENOSIS AÓRTICA. EPIDEMIOLOGIA

La prevalencia de la estenosis aórtica es de un 4-5% in en personas mayores de 75 años

La estenosis aórtica es la valvulopatía más frecuente en Europa y USA

Hay más de 300.000 pacientes con estenosis aórtica severa en el mundo.

Más de un 30% de los pacientes con estenósis aórtica severa y sintomáticos no son referidos o están contraindicados para un reemplazo quirúrgico de la válvula

De los pacientes tratados con cirugía, muchos de ellos tienen un alto riesgo de moribilidad/mortalidad del procedimeinto

[1] Grube, et al. Percutaneous Aortic Valve Replacement for Severe Aortic Stenosis in High-Risk Patients Using the Second- and Current Third- Generation Self-Expanding CoreValve Prosthesis. American College of Cardiology J. 2007; 69–76.
[2] Iung B, et al. A prospective survey of patients with valvular HD in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur Heart J*. 2003;24(13):1231-43.
[3] Charlson E, Decision-making and outcomes in severe symptomatic AS. Journal of heart valve dis 15(3):312-21, 2006.

HISTORIA NATURAL

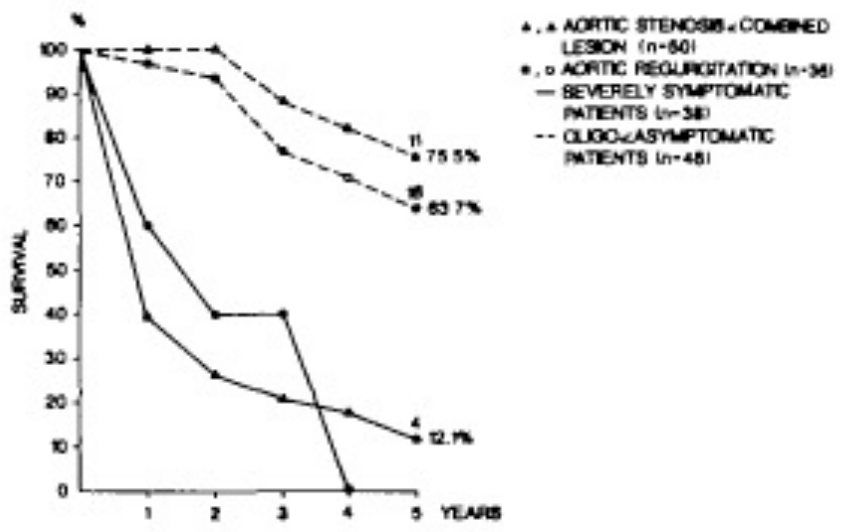


Figure 5 Event-free survival in haemodynamically severe aortic stenosis and combined lesion as well as aortic regurgitation in severely symptomatic and asymptomatic or mildly symptomatic patients.

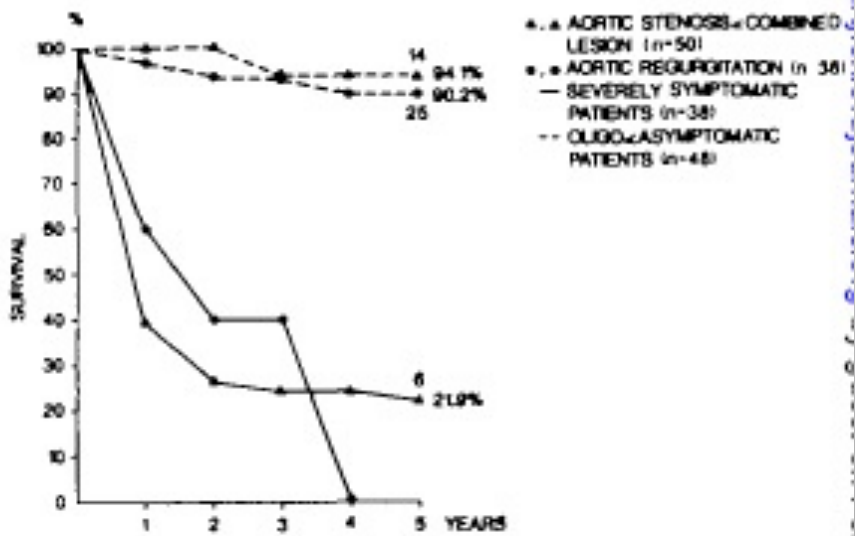
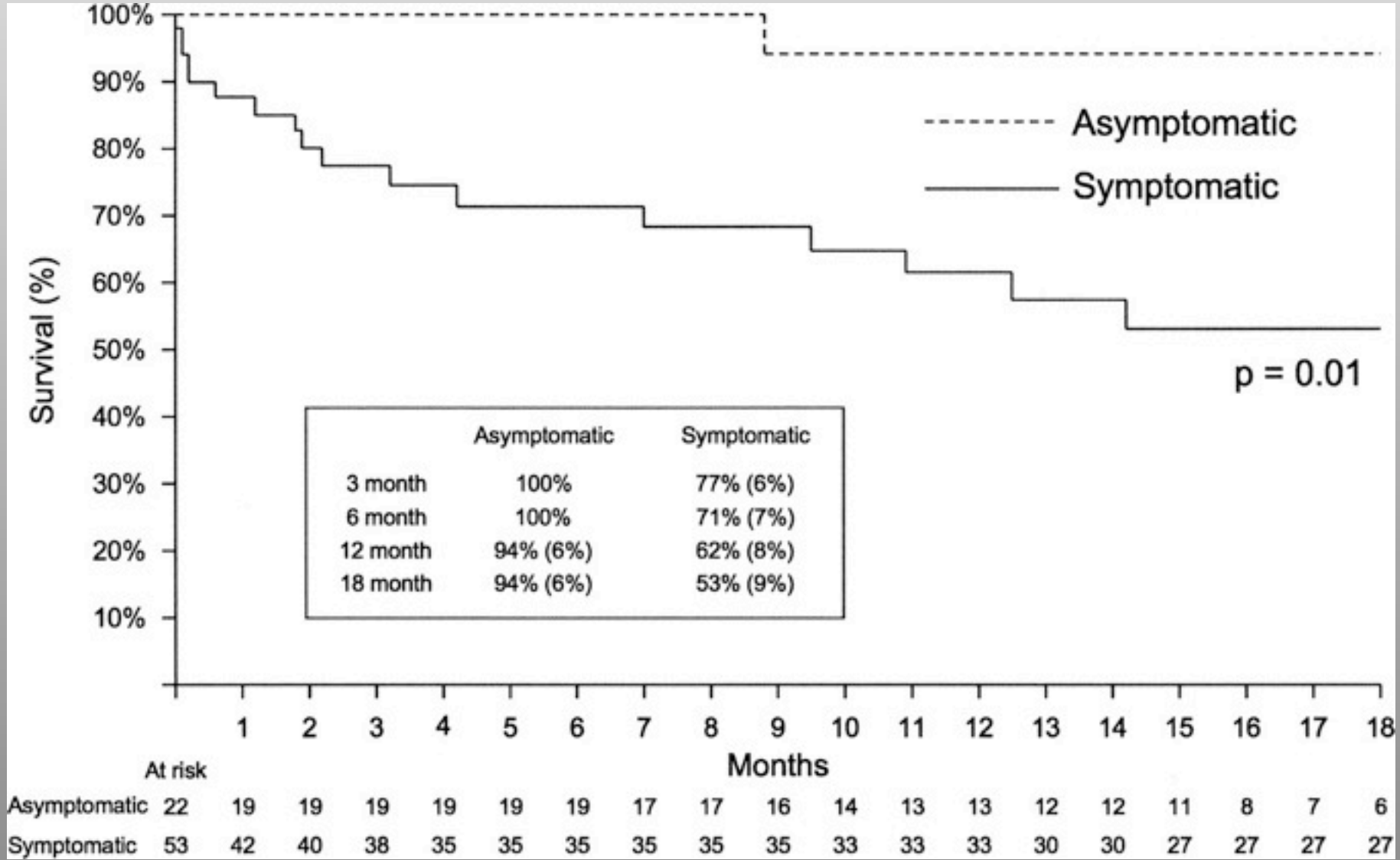


Figure 6 Effective survival in haemodynamically severe aortic stenosis and combined lesion as well as aortic regurgitation in severely symptomatic and asymptomatic or mildly symptomatic patients.

European Heart Journal (1987) **8**, 471–483

MORTALIDAD



J Am Coll Cardiol, 2007; 50:2018-2019

TTO MEDICO VS CIRUGÍA

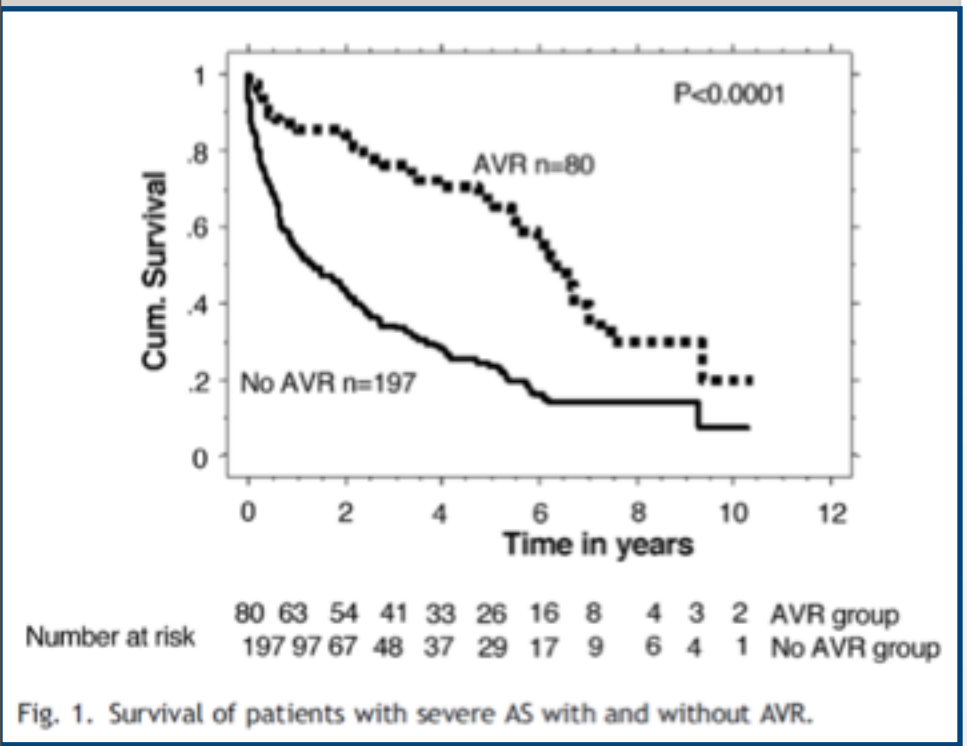
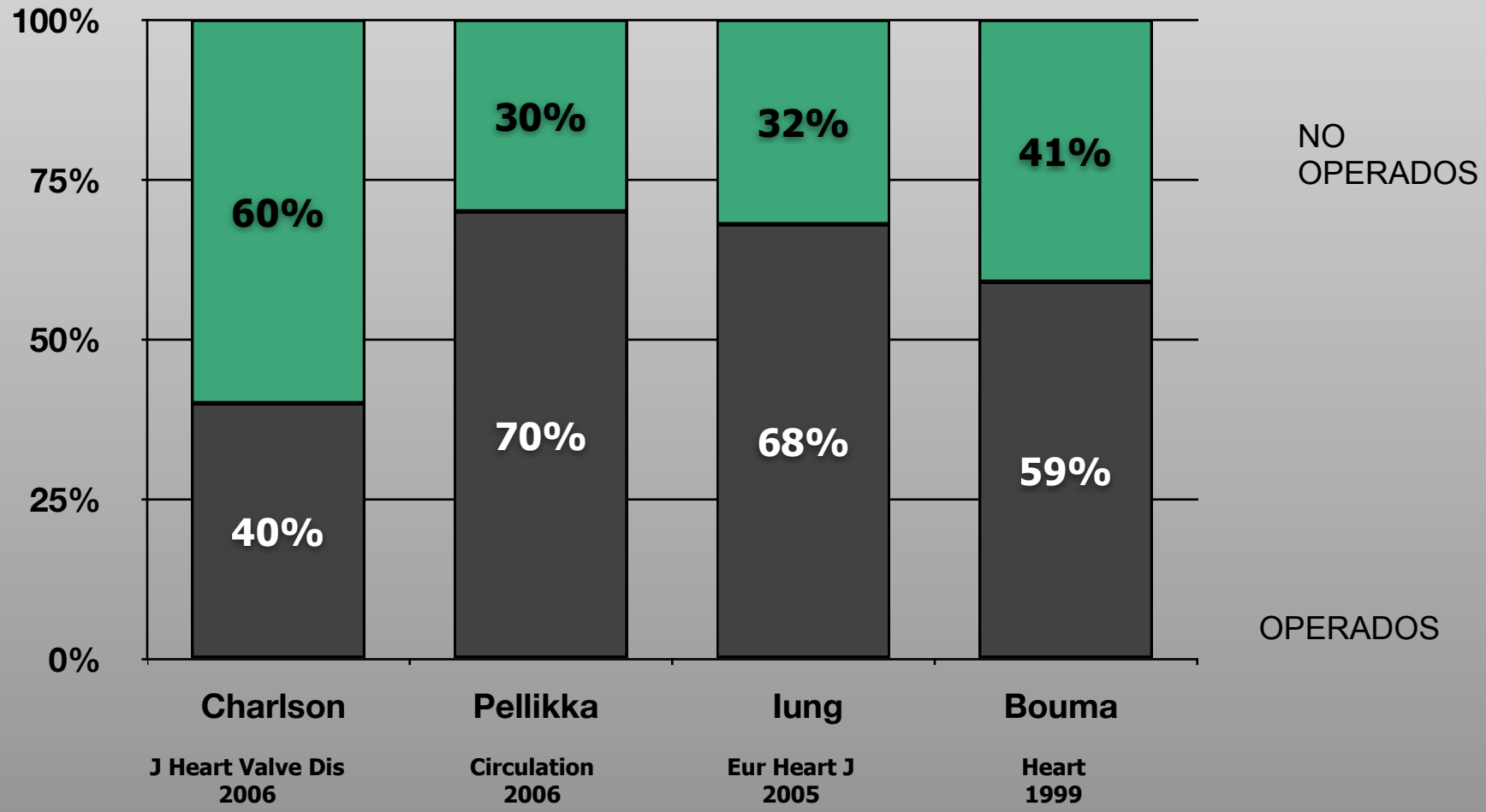


Fig. 1. Survival of patients with severe AS with and without AVR.

- Los pacientes que no tienen un reemplazo quirúrgico tienen una expextativa de vida menor[1]:
  - One-year, 2-year and 5-year survival rates among patients with AVR were 87, 78 and 68%, respectively, compared with 52, 40 and 22%, respectively, in those who had no AVR
- La mortalidad en pacientes sintomáticos no tratados es de alrededor de un 50% a los dos años[2]
- Los pacientes inoperables o de alto riesgo son difíciles de tratar y no y no hay una buena opción.

[1] Varadarajan et al. *European Journal of Cardio-thoracic Surgery* 2006;30;722—727. Charlson E, Decision-making and outcomes in severe symptomatic AS. *Journal of heart valve dis* 15(3):312-21, 2006. PA Pellikka,The natural history of adults with asymptomatic AS. *J Am Coll Cardiol*, 1990; 15:1012-1017. B J Bouma; To operate or not on elderly patients with aortic stenosis: the decision and its consequences *Heart* 1999;82:143.

PACIENTES EXCLUIDOS DE CIRUGÍA



En 2005: 867.030 - 1734060 pacientes no fueron tratados de estenosis aórtica

EDWARDS SAPIEN

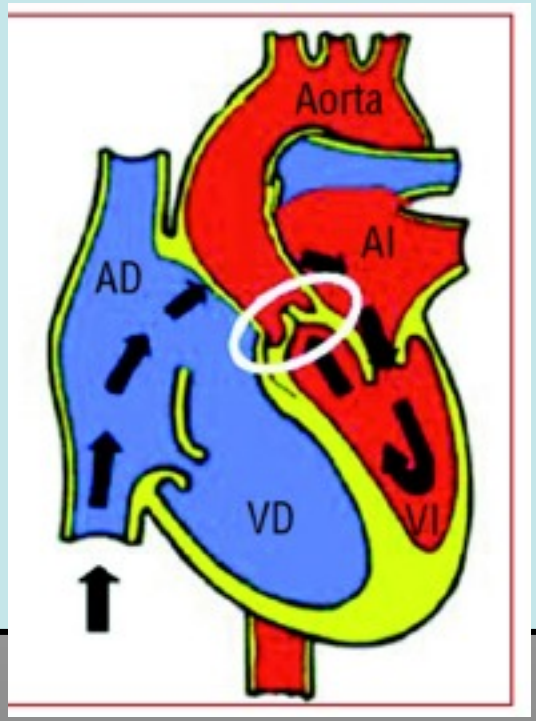
1) PRIMER IMPLANTE EN 2002 POR CRIBIER
2) INICIALMENTE VÁLVULA DE 23 MM DE PERICARDIO EQUINO Y STENT DE ACERO+BALÓN.
3) POSTERIORMENTE PERICARDIO BOVINO, 2 TAMAÑOS, 23 Y 26 MM, SOBRE SOPORTES DE 22 Y 24 FRENCH
4) DESARROLLO DEL CATÉTER RETROFLEX PARA VIA RETRÓGRADA
5) SAPIEN XT 18 F
6) PRIMEROS REGISTROS I-REVIVE, RECAST, REVIVAL II, REVIVE II, SOURCE, PARTNER EU.

Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, Derumeaux G,Anselme F, Laborde F, Leon MB. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation2002;106:3006-3008.7. Cribier A, Eltchaninoff H

EDWARDS SAPIEN. VIA ANTEROGRADA

VENTAJAS

- No problema de acceso vascular
- Fácil cruzar Vao



DESVENTAJAS

- Transeptal
- Procedimiento complicado técnicamente
- Riesgo de IM por
  - Estiramiento loop
  - Laceración mitral

VIA ANTEROGRADA. EXPERIENCIA INICIAL.

- REGISTROS I-REVIVE Y RECAST
- N=36?. Cribier.
- Éxito proc 75%
- Supervivencia 30 días 77%
- Supervivencia 6 meses 63%

Cribier A, Eltchaninoff H, Tron C, Baur F, Agateillo C, Nercolini D, Tapiero S, LitzlerPY, Bessou JP, Vavaliaros V. Treatment of calcific aortic stenosis with thepercutaneous heart valve. Mid-term follow-up from the initial feasibility studies: the french experience. J Am Coll Cardiol 2006;47:1214-23.

EDWARDS SAPIEN. VIA RETROGRADA

- Inicialmente utilizada como bail-out
- Primera publicacion por Webb 25 casos.
- Adoptada como standard tras la introducción del Retroflex
- Actualmente pericardio bovino, falda más larga, tratamiento anticalcificante.

REGISTROS EDWARDS-SAPIEN RETROGRADA

REGISTRO SOURCE

- 305 pacientes via femoral
- 95% éxito procedimiento
- Supervivencia 30 días 94%

REGISTRO PARTNER EU

- Registro observacional europeo
- 54 pacientes transfemoral (67 TA)
- 92% supervivencia 30 días y 90% 6 meses

REGISTROS IMPORTANTES

Table I Demographics and outcome data of published single- and multicentre registries of TAVI using the Edwards Sapien and Medtronic CoreValve prostheses

	Year of publication	Type of TAVI	Study design	Device	Total patients, *n*	Age, years	Logistic EuroScore, %	Procedural success, %	Procedural mortality, %	30-day mortality, %	30-day stroke, %
Lichtenstein et al.	2006	TA	Single centre	Edwards	7		35	100	–	14	0
Cribier et al.	2006	TF	Single centre	Edwards	36		~27	75	7.4	22.2	3.7
Webb et al.	2006	TF	Single centre	Edwards	18		26.2 ± 13.1	77.8	0	11.1	–
Grube et al.	2006	TF/TS	Single centre	CoreValve	25		11	84	–	20	12
Walther et al.	2007	TA	Multicentre	Edwards	59		27	93.2	13.6	13.6	3.4
Webb et al.	2007	TF	Single centre	Edwards	50		28	86	2	12	4
Grube et al.	2007	TF/TS	Multicentre (2)	CoreValve	86		21.7 ± 12.6	88	6	12	10
Svensson et al.	2008	TA	Multicentre	Edwards				90	22.5	17.5	0
Piazza et al.	2008	TF/TS	Multicentre	CoreValv				97	1.5	8	1.9
Grube et al.	2008	TF/TS	Single centre	CoreValv				–	0	10.8	2.9
Walther et al.	2008	TA	Single centre	Edwards	50		27.6 ± 12.2	94	0	8	0
Webb et al.	2009	TF/TA	Single centre	Edwards	168		28.6	94.1	1.2	11.3	4.2
Himbert et al.	2009	TF/TA	Single centre	Edwards	75		26 ± 13	93.3	–	10	4
Osten et al.	2009	TF/TA	Single centre	Edwards	46		25.3	91	2.2	6.5	6.5
Thielmann et al.	2009	TF/TA	Single centre	Edwards	39		44.2 ± 12.6	97	2.6	17.9	–
Bleiziffer et al.	2009	TF/TA/TS	Single centre	Edwards/CoreValve	203		22 ± 14	–	–	11.2	7
Buellesfeld et al.	2010	TF/TS	Multicentre (2)	CoreValve	168		± 15.4	90.5	–	11.9[a]	–
Thomas et al.	2010	TF/TA	Multicentre (34)	Edwards	1038		25.7 (TF)/29.1 (TA)	93.8	–	8.5	2.5
Rodés-Cabau et al.	2010	TF/TA	Multicentre (6)	Edwards	339		–	93.3	1.7	10.4	2.3
Petronio et al.	2010	TF/TS	Multicentre (13)	CoreValve	514		20.1	98.6	0.8	5.4	1.8
Tchetche et al.	2010	TF	Multicentre (2)	Edwards/CoreValve	45	81.8 ± 4.2	25.2 ± 8.4	97.8	2.2	4.4	0

20.000 TAVI

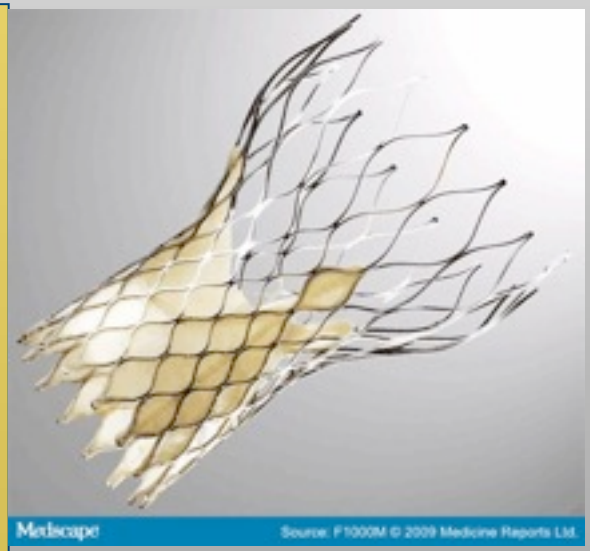
[a]In hospital.
TA, transapical; TAVI, transcatheter aortic valve implantation; TF, transfemoral; TS, transsubclavian.

EDWARDS. ENSAYOS EN MARCHA

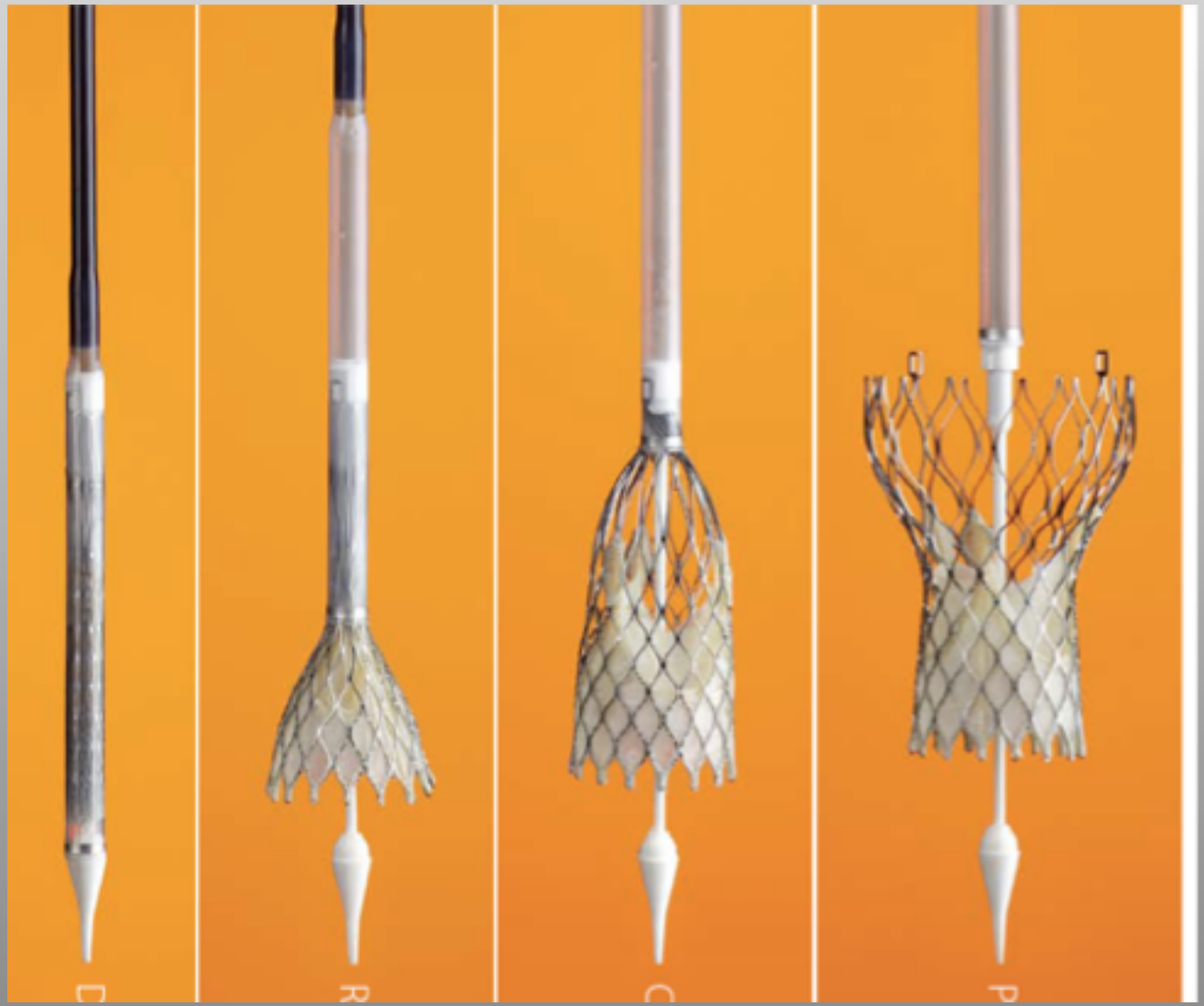
NOMBRE	TIPO	N	PAIS
PARTNER	ENSAYO COMPARATIVO 2 RAMAS	1040	USA CANADA ALEMANIA
SOURCE XT	REGISTRO		ITALIA, MULTICENT.
PREVAIL EU	ENSAYO SEGURIDAD XT	150	MULTICENT EUROPA
PREVAIL JAPAN	ENSAYO SEGURIDAD XT	69	JAPON
PREVAIL TA	ENSAYO PILOTO XT APICAL	150	USA, ALEMANIA, UK, AUSTRIA

COREVALVE

- Válvula de pericardio porcino
- Stent autoexpandible de nitinol
- 2 tamaños: 26 y 29 mm.
- Inicialmente 24 F, luego 21 F. Finalmente 18 French. Vía retrógrada.



COREVALVE. DISEÑO



COREVALVE

- Primera publicación 2006, Grube/Laborde
- Desde entonces unas 10.000 Corevalve.

PRIMER REGISTRO:

-25 pacientes.

-24 French, extracorpórea.

-Éxito 88%, MACE 32%, muerte 20%

COREVALVE. PRIMEROS REGISTROS

	GRUBE 21+18	PIAZZA 18	LABORDE 18
PACIENTES	86	112	1243
ÉXITO PROC	74	97	98
MORT PROC	6	1.5	1.7
MORT 30D	12	8	6.7
MARCAPASOS		9.3	12
ACV	10	0.6	1.7

ENSAYO PARTNER

- Estenosis aórtica severa sintomática (área <0.8, GM>40 ó vel>4m/seg).
- Disnea II-IV
- STS>10% u otra comorbilidad grave.

OPERABLES

INOPERABLES (RIESGO>50%)

RAMA QUIRÚRGICA

VS CATÉTER

RAMA FARMACOLOGICA

VS CATÉTER

ENSAYO PARTNER (RAMA MÉDICA)

358 PACIENTES

TTO MEDICO VS EDWARDS

OBJETIVO PRIMARIO: MUERTE

OBJETIVOS 2ARIOS:

-TIEMPO LIBRE DE INGRESOS O MUERTE

-NYHA

-HOSPITALIZACION

-IAM, ACV, IRA, VASCULAR, SANGRADO

-TEST 6 MINUTOS

-FUNCIÓN VALVULAR

CRIT. EXCLUSION

- bicúspide
- IAM
- Enf coronaria severa
- LVEF<20%
- anillo < 18 mm O > 25 mm,
- IM severa
- AIT o ACV 6 meses antes
- IRC severa.

Table 2. Clinical Outcomes at 30 Days and 1 Year.*

Outcome	30 Days			1 Year		
	TAVI (N=179)	Standard Therapy (N=179)	P Value†	TAVI (N=179)	Standard Therapy (N=179)	P Value†
	no. of patients (%)			*no. of patients (%)*		
Death						
From any cause	9 (5.0)	5 (2.8)	0.41	55 (30.7)	89 (49.7)	<0.001
From cardiovascular cause‡	8 (4.5)	3 (1.7)	0.22	35 (19.6)	75 (41.9)	<0.001
Repeat hospitalization§	10 (5.6)	18 (10.1)	0.17	40 (22.3)	79 (44.1)	<0.001
Death from any cause or repeat hospitalization§	19 (10.6)	22 (12.3)	0.74	76 (42.5)	126 (70.4)	<0.001
Stroke or TIA						
All	12 (6.7)	3 (1.7)	0.03	19 (10.6)	8 (4.5)	0.04
TIA	0	0	—	1 (0.6)	0	1.00
Stroke						
Minor	3 (1.7)	1 (0.6)	0.62	4 (2.2)	1 (0.6)	0.37
Major	9 (5.0)	2 (1.1)	0.06	14 (7.8)	7 (3.9)	0.18
Death from any cause or major stroke	15 (8.4)	7 (3.9)	0.12	59 (33.0)	90 (50.3)	0.001
Myocardial infarction						
All	0	0	—	1 (0.6)	1 (0.6)	1.00
Periprocedural	0	0	—	0	0	—
Vascular complications						
All	55 (30.7)	9 (5.0)	<0.001	58 (32.4)	13 (7.3)	<0.001
Major	29 (16.2)	2 (1.1)	<0.001	30 (16.8)	4 (2.2)	<0.001
Acute kidney injury						
Creatinine >3 mg/dl (265 μmol/liter)¶	0	1 (0.6)	1.00	2 (1.1)	5 (2.8)	0.45
Renal-replacement therapy‖	2 (1.1)	3 (1.7)	1.00	3 (1.7)	6 (3.4)	0.50
Major bleeding	30 (16.8)	7 (3.9)	<0.001	40 (22.3)	20 (11.2)	0.007
Cardiac reintervention						
Balloon aortic valvuloplasty	1 (0.6)**	2 (1.1)	1.00	1 (0.6)	66 (36.9)††	<0.001
Repeat TAVI‡‡	3 (1.7)	NA	—	3 (1.7)	NA	—
Aortic-valve replacement	0	3 (1.7)	0.25	2 (1.1)**	17 (9.5)	<0.001
Endocarditis	0	0	—	2 (1.1)	1 (0.6)	0.31
New atrial fibrillation	1 (0.6)	2 (1.1)	1.00	1 (0.6)	3 (1.7)	0.62
New pacemaker	6 (3.4)	9 (5.0)	0.60	8 (4.5)	14 (7.8)	0.27

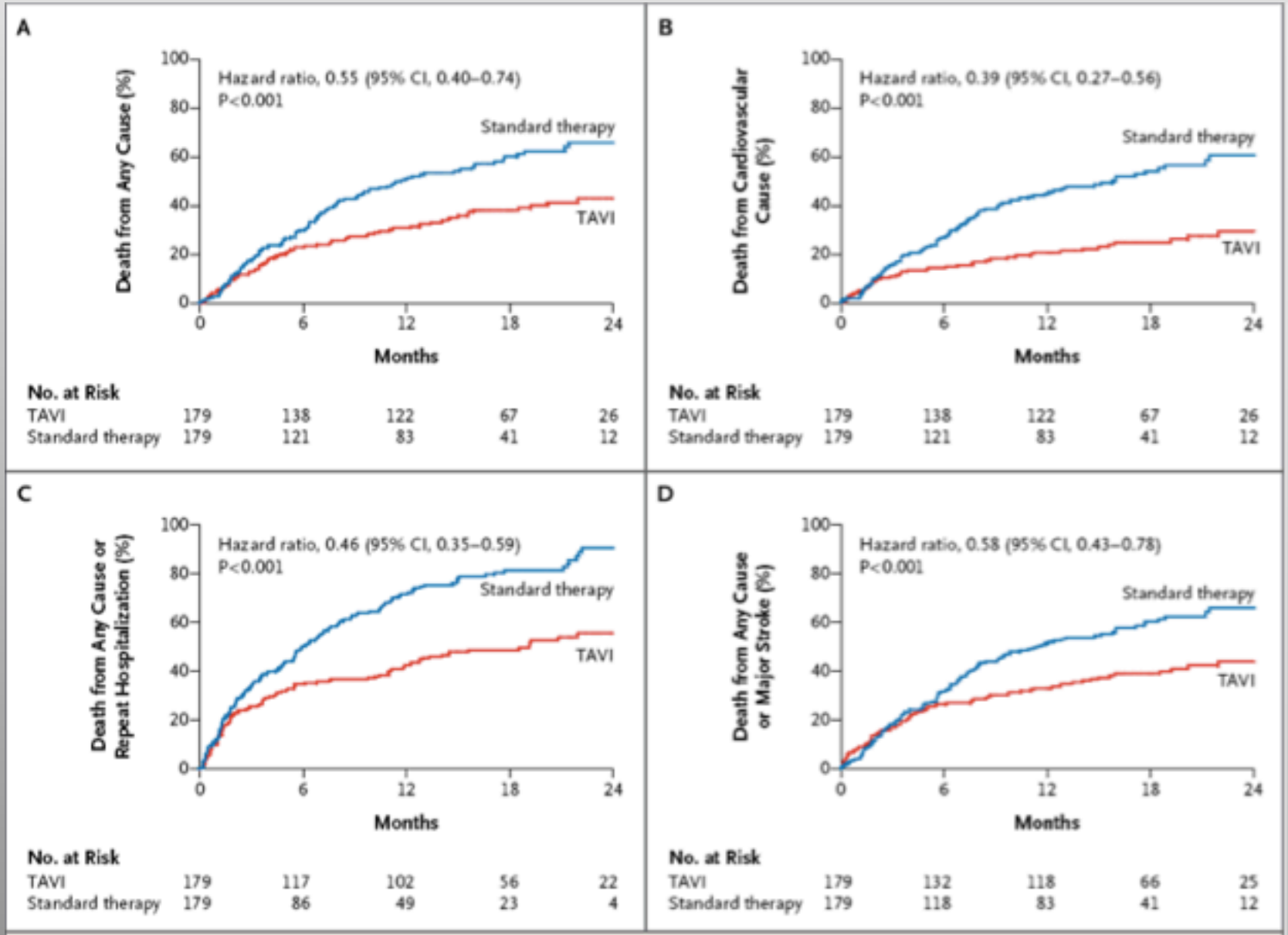


Figure 1. Time-to-Event Curves for the Primary End Point and Other Selected End Points.

Event rates were calculated with the use of Kaplan–Meier methods and compared with the use of the log-rank test. Deaths from unknown causes were assumed to be deaths from cardiovascular causes.

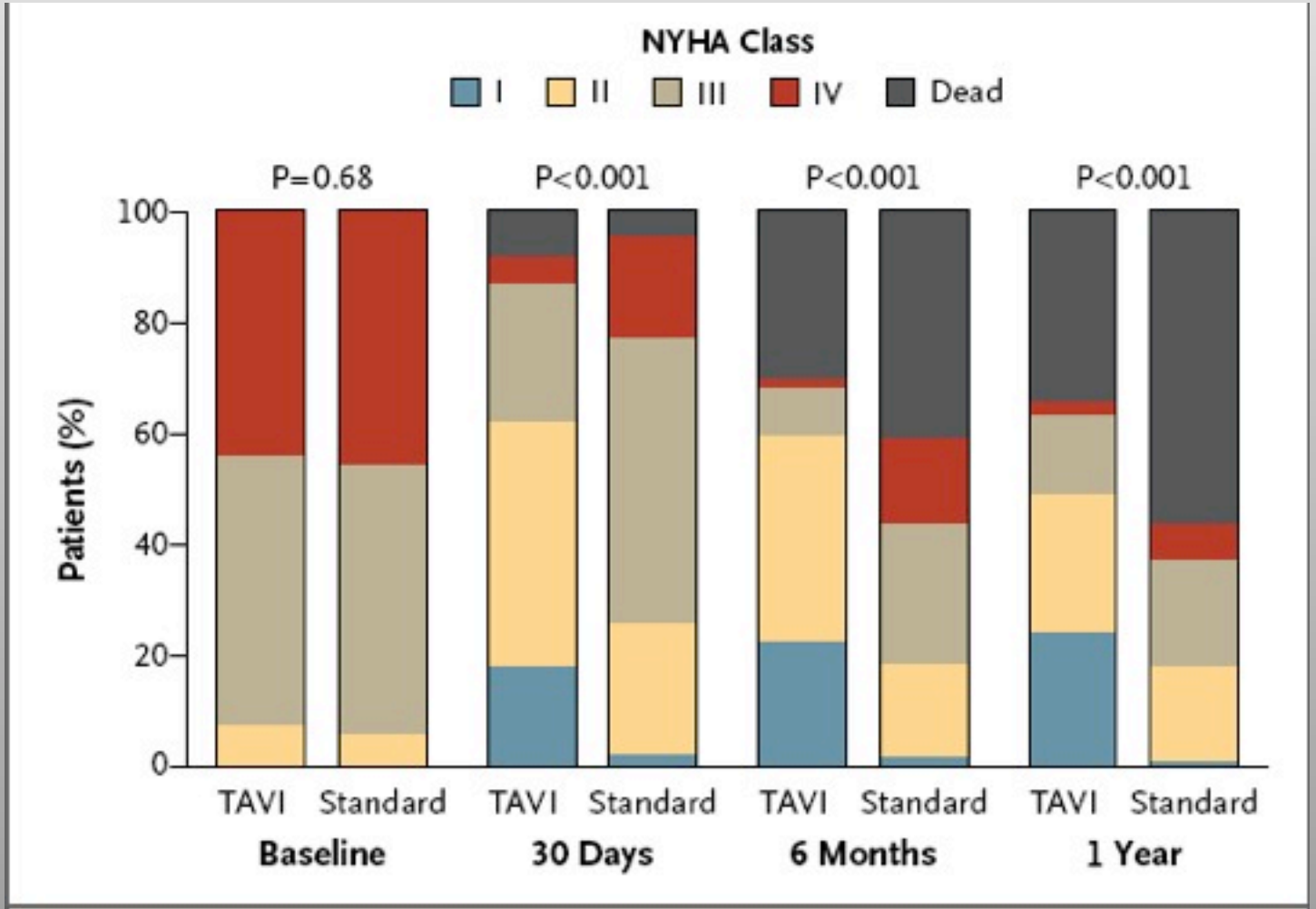


Figure 3. Symptom Status over Time.

Symptom status according to New York Heart Association (NYHA) class is shown at baseline and at 30 days, 6 months, and 1 year among patients randomly assigned to transcatheter aortic-valve implantation (TAVI) or standard therapy (Standard).

ESTUDIO PREVIO. ECOCARDIOGRAMA

-Válvula aórtica: anatomía, calcio, gradientes, área, regurgitación.

-Aorta: ANILLO, sinusal, altura seno, UST, ascendente, angulación, salida coronarias

-VI: tamaño, hipertrofia, FEVI, TSVI, trombos

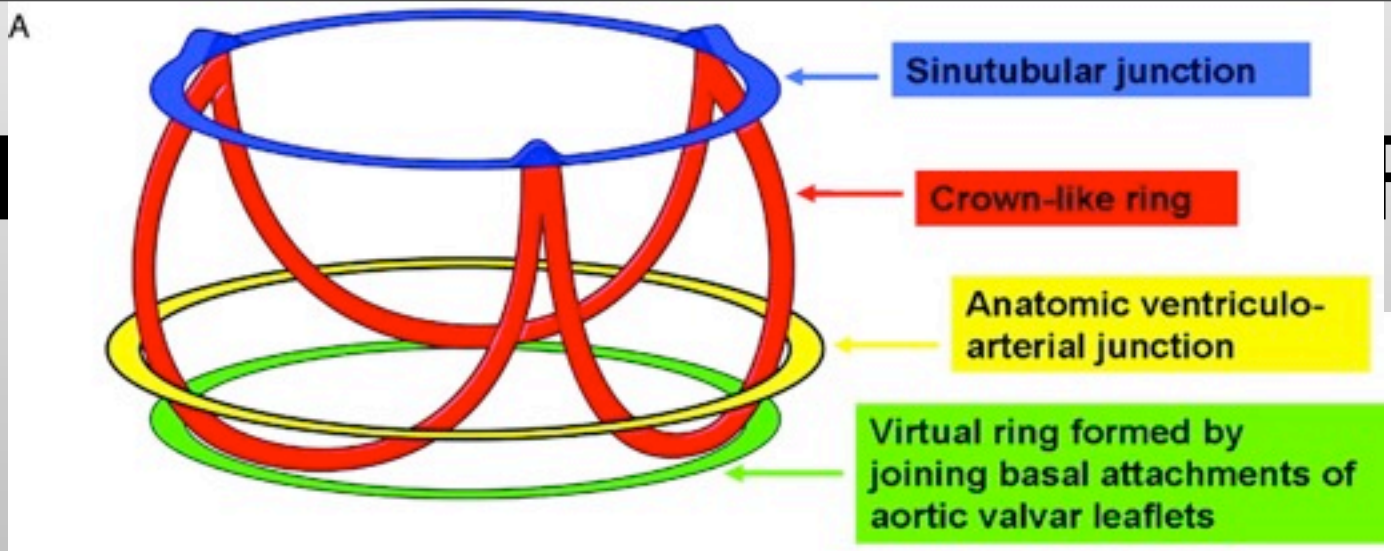
-AI: trombos

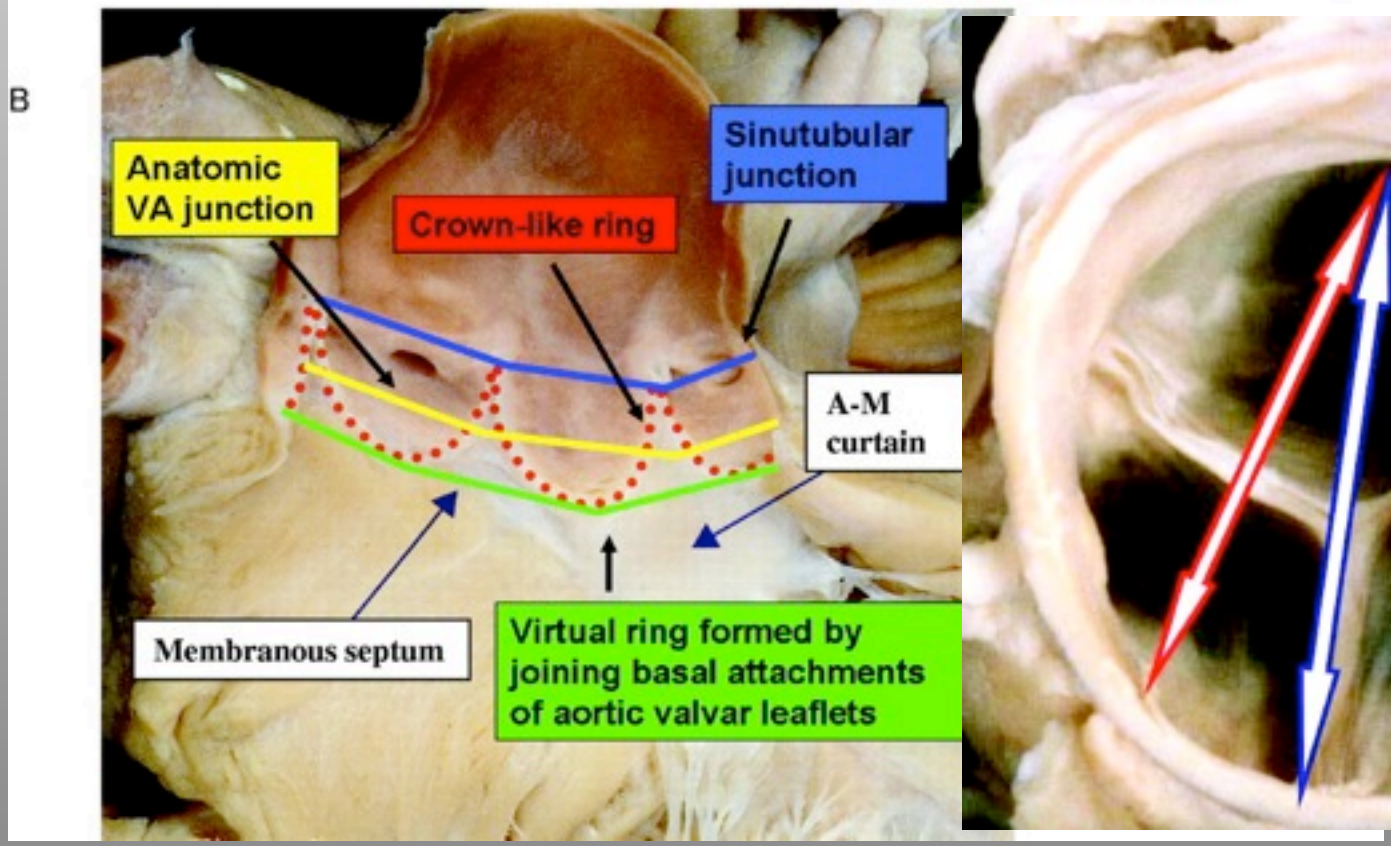
-Mitral: regurgitación, estenosis, distancia al anillo aortico, prótesis

-Tricúspide: regurgitación, presión pulmonar

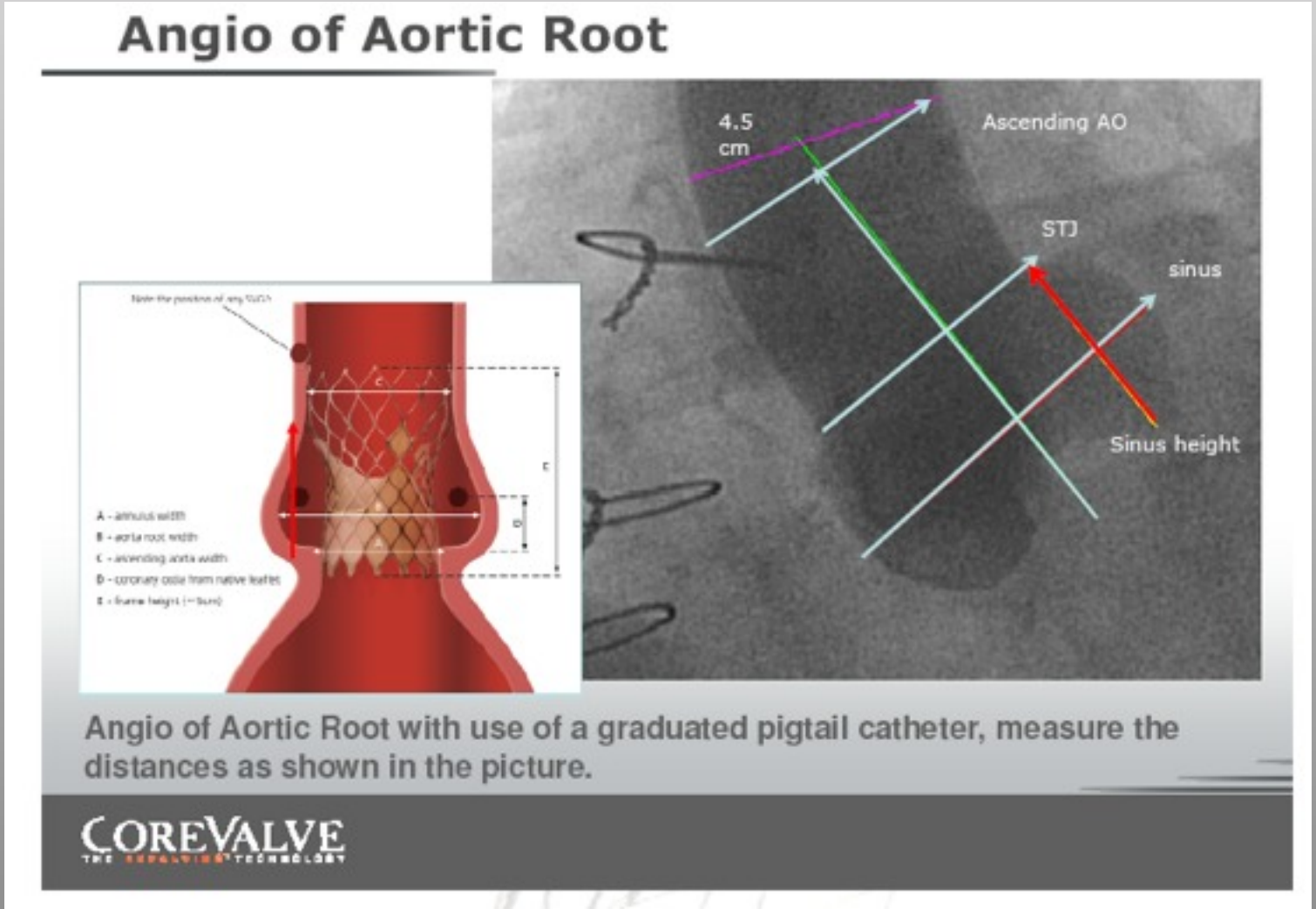
-Derrame pericárdico

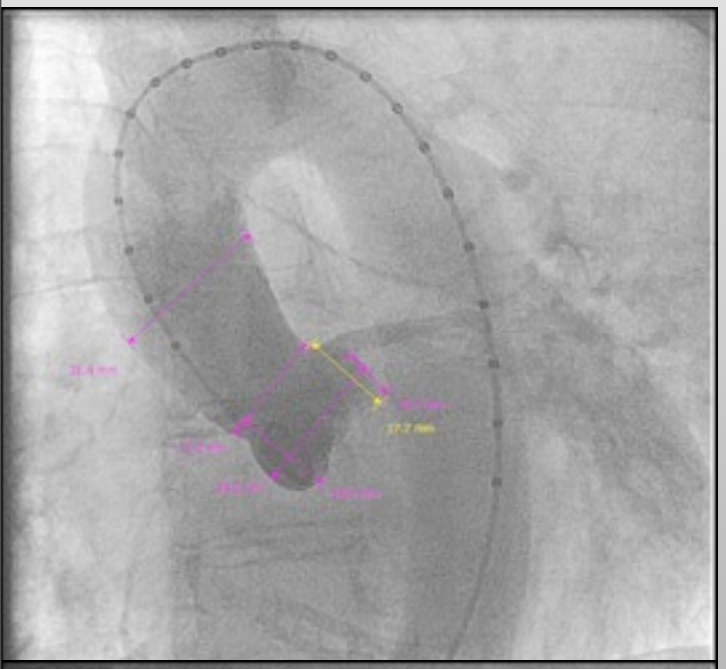
RDIO


A
Sinutubular junction
Crown-like ring
Anatomic ventriculo-arterial junction
Virtual ring formed by joining basal attachments of aortic valvar leaflets


B
Anatomic VA junction
Crown-like ring
Sinutubular junction
A-M curtain
Membranous septum
Virtual ring formed by joining basal attachments of aortic valvar leaflets

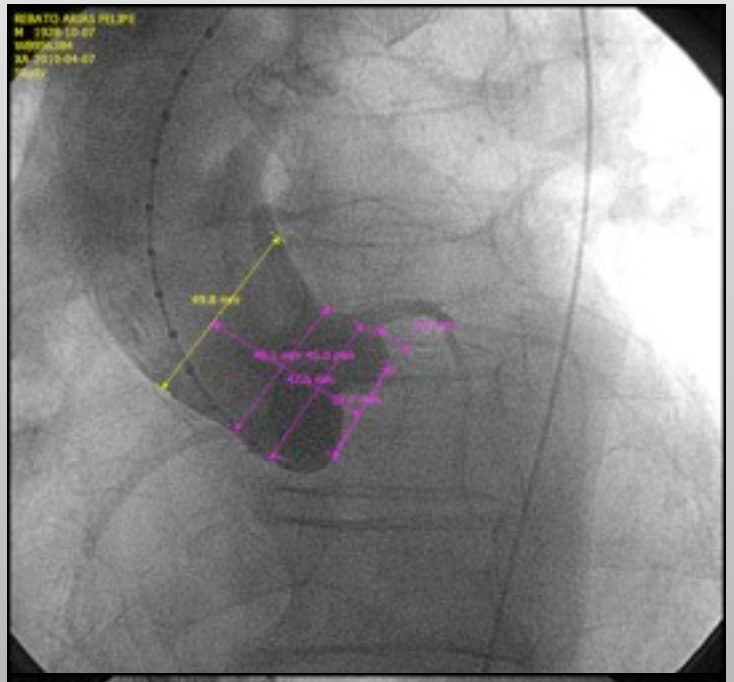
AORTOGRAFIA

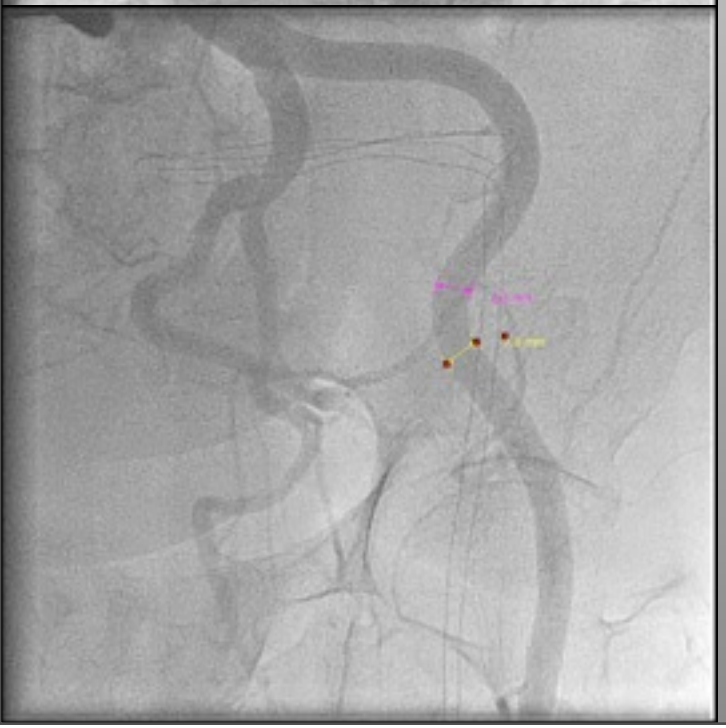




ANGULACION

DIÁMETROS





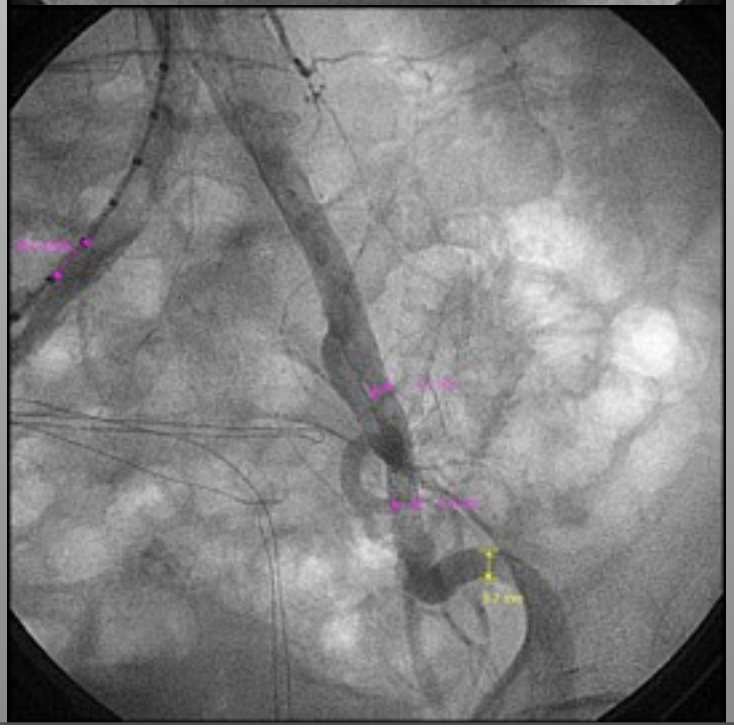
CALIBRE

TORTUOSIDAD

ENFERMEDAD

BIFURCACION

CALCIO



PROCEDIMIENTO. LINEAS GENERALES

- Sedación sin IOT. Anestesista
- 2 arterias femorales, una vena femoral
- Acceso percutáneo sin cut-down
- Cierre percutáneo con Prostar
- Marcapasos provisional 48 horas
- Medida HV pre y post procedimiento.

Table 4 Procedural and clinical events

Procedural results	
Technical successful	98.4% (684/695)
Conversion to open heart surgery	0.7% (5/695)
Unsuccessful termination of the procedure	0.9% (6/695)
Gradient after the procedure (mmHg)[a]	5 (0–8)
Residual aortic insufficiency	72.4% (499/689)
none	27.6% (190/689)
Grade 1	54.9% (378/689)
Grade 2	15.2% (105/689)
Grade 3	2.0% (14/689)
Grade 4	0.3% (2/689)
Implantation of a pacemaker	39.3% (262/667)
Clinical course	
Time at intensive care unit (days)[a]	2 (1–3)
Groin problems	19.5% (130/668)
With need of transfusion	17.1% (115/671)
Severe	4.0% (27/668)
Need for haemodynamic support (IABP or ECLS[b])	1.8% (12/656)
Pericardial tamponade	1.8% (12/670)
Aortic dissection	0.4% (3/670)
Coronary ischaemia	0.1% (1/670)
Myocardial infarction	0.3% (2/673)
Stroke	2.8% (19/670)
Pulmonary embolism	1.3% (9/670)
In-hospital death	8.2% (57/697)
30 day death	12.4%

[a]Median (quartiles).
[b]IABP, intra aortic balloon pump; ECLS, extra corporal life support.

REGISTRO ALEMÁN 2010

697 PACIENTES 2009-2010

84% COREVALVE

European Heart Journal (2011) **32**, 198–204
doi:10.1093/eurheartj/ehq339

REGISTRO FRANCÉS 2010

Table 3 Early complications (one patient could have more than one event)

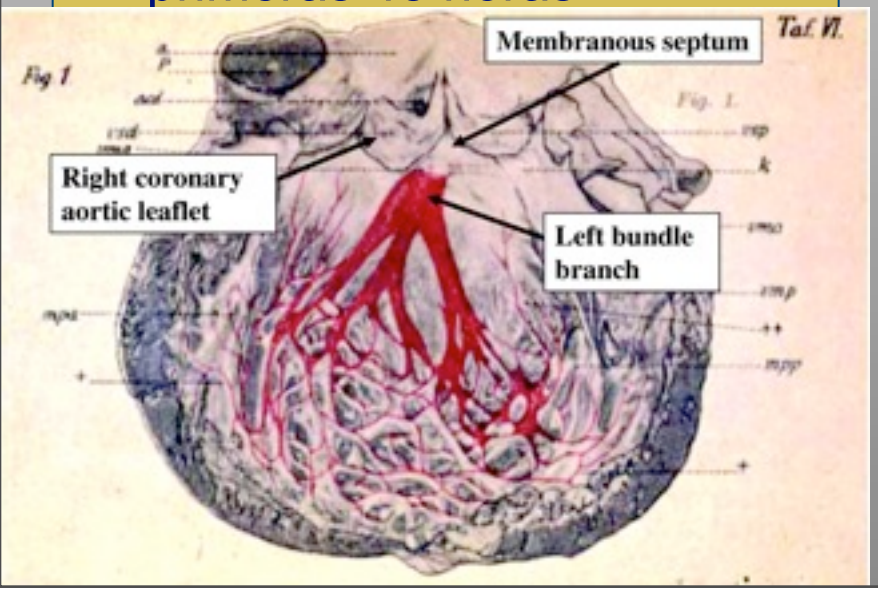
Approach and type of valve	Total (*n* = 244)	TF Edwards[a] (*n* = 95)	TF CoreValve (*n* = 66)	TA Edwards (*n* = 71)	SC CoreValve (*n* = 12)
Thirty-day mortality	31 (12.7)	8 (8.4)	10 (15.1)	12 (16.9)	1 (8.3)
Tamponade	5 (2.0)	2 (2.1)	2 (3.0)	0	1 (8.3)
Stroke	9 (3.6)	4 (4.2)	3 (4.5)	2 (2.8)	0
Coronary occlusion	3 (1.2)	2 (2.0)	1 (1.5)	0	0
New pacemaker	29 (11.8)	5 (5.3)	17 (25.7)	4 (5.6)	3 (25.0)
Vascular complications: Total	16 (7.3)	6 (6.3)	5 (7.5)	4 (5.6)	1 (8.3)
Aortic rupture	2 (0.8)	2 (2)	0	0	0
Iliofemoral dissection	8 (3.2)	4 (4.2)	3 (4.5)	1 (1.4)	0
Thrombosis/distal embolization	3 (1.2)	0	0	2 (2.8)	1 (8.3)
Retroperitoneal haematoma	2 (0.8)	0	2 (3.0)	0	0
LV apex bleeding (re-surgery)	1 (0.4)	NA	NA	1 (1.4)	NA
Renal failure requiring dialysis	4 (1.6)	1 (1.0)	1 (1.5)	2 (2.8)	0
Infection[b]	7 (2.8)	1 (1.0)	1 (1.5)	5 (7.0)	0
Transfusion (≥1 blood units)	52 (21.3)	8 (8.4)	9 (13.6)	25 (27.4)	10 (83.3)

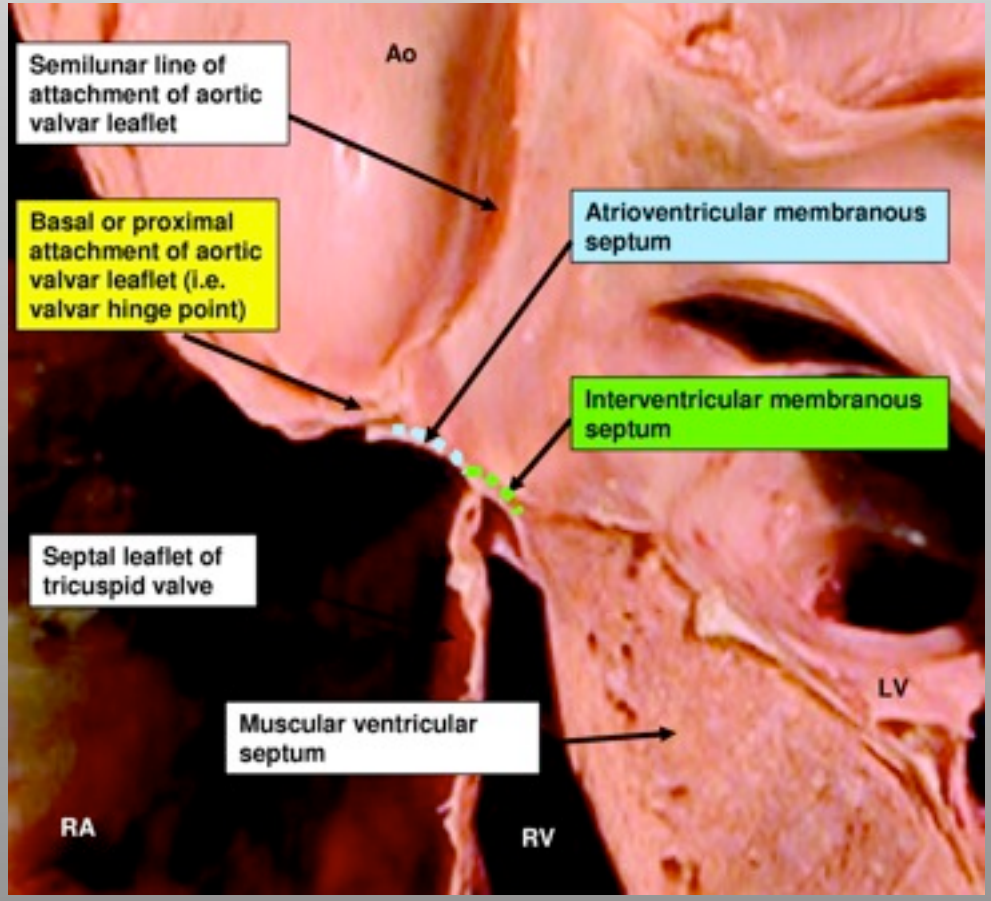
Values are given in *n* (%).
NA, not applicable.
[a]Including one retroperitoneal implantation.
[b]Pulmonary in five; erisypele in one, unknown in one.

European Heart Journal (2011) **32**, 191–197
doi:10.1093/eurheartj/ehq261

PROBLEMAS ESPECIALES: BLOQUEO AV

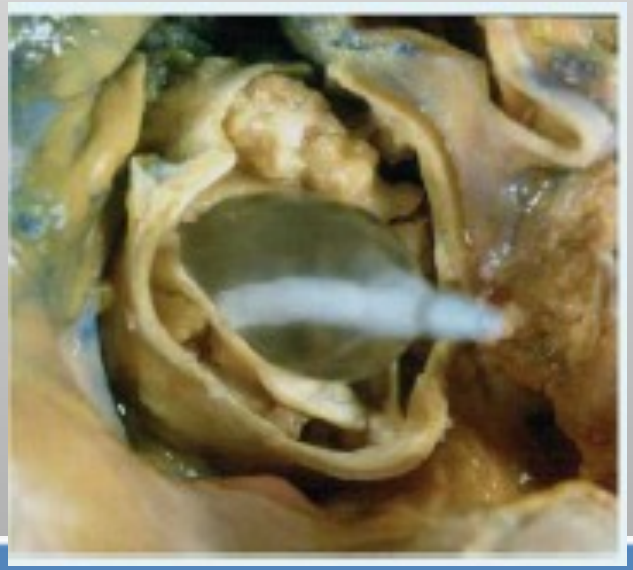
- Frecuencia entre 5 y 39 (25%)
- Más frecuente en Corevalve
- Relacionado con profundidad de la prótesis, HVI, calcio, BRD
- Habitualmente en las primeras 48 horas

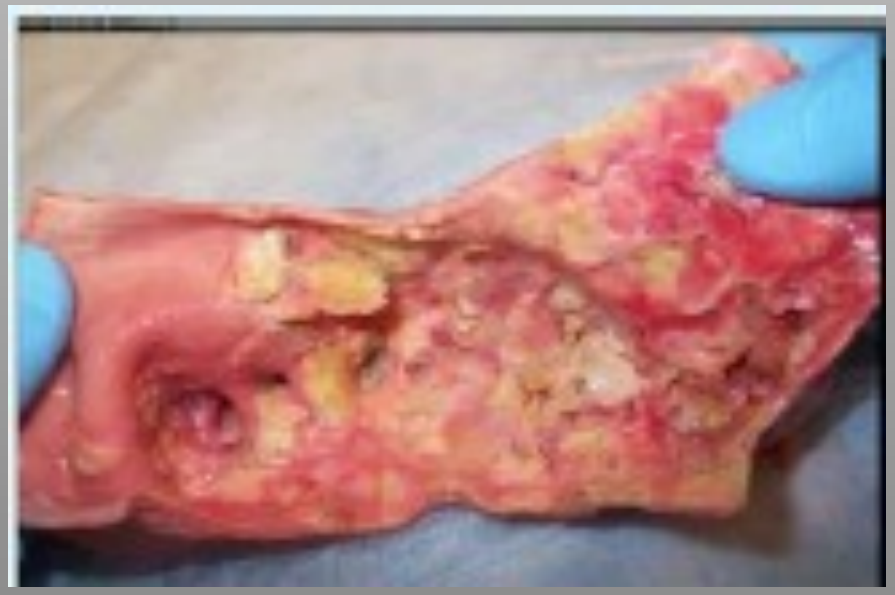


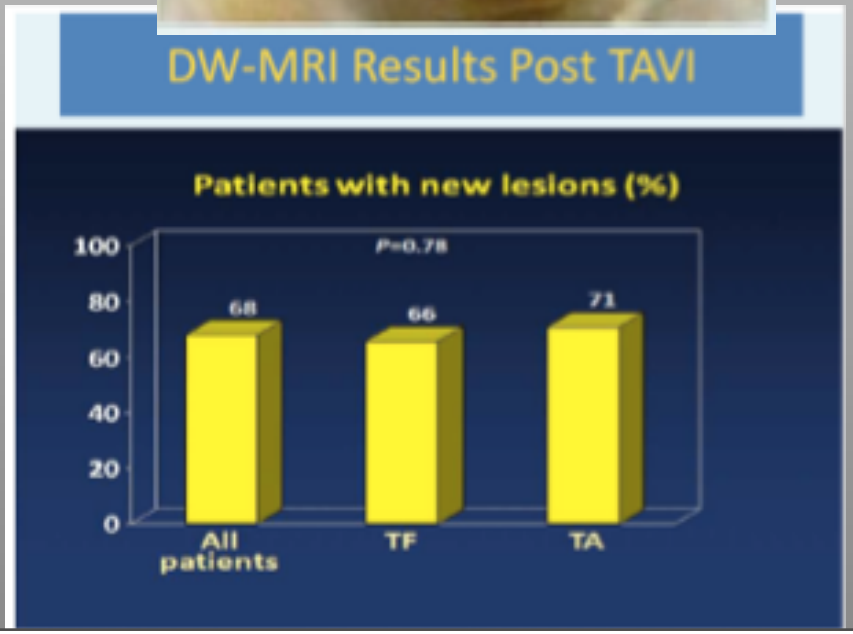


PROBLEMAS ESPECIALES: ACV

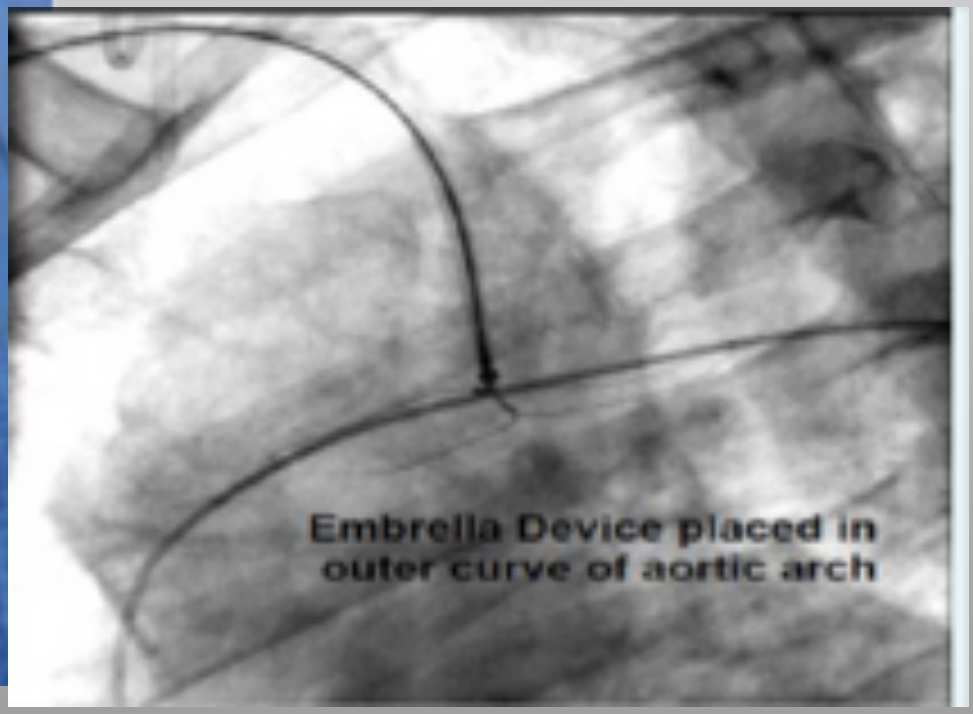
- Frecuencia 2-8% clínico. Más de 50% por RM
- Multifactorial: trombo, placas aorta, rotura válvula, bajo gasto…
- Difícil prevención. Dispositivos protectores en fase de piloto.
- No diferencias femoral / apical



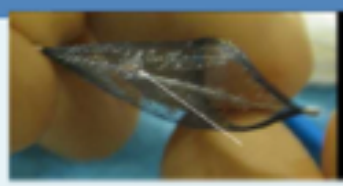


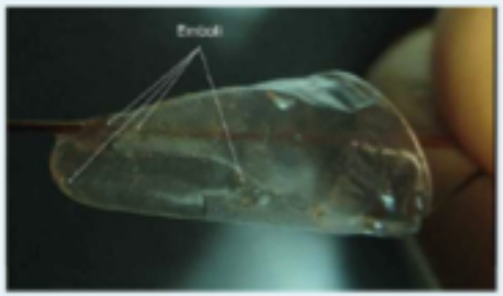


EMBRELLA



Claret Dual Filter





PROBLEMAS ESPECIALES. COMPLICACIONES VASCULARES

- 5-20% aproximadamente
- Más frecuente en Edwards
- Menos frecuente con nuevos dispositivos 18 F.
- Importante selección de pacientes, imagen.

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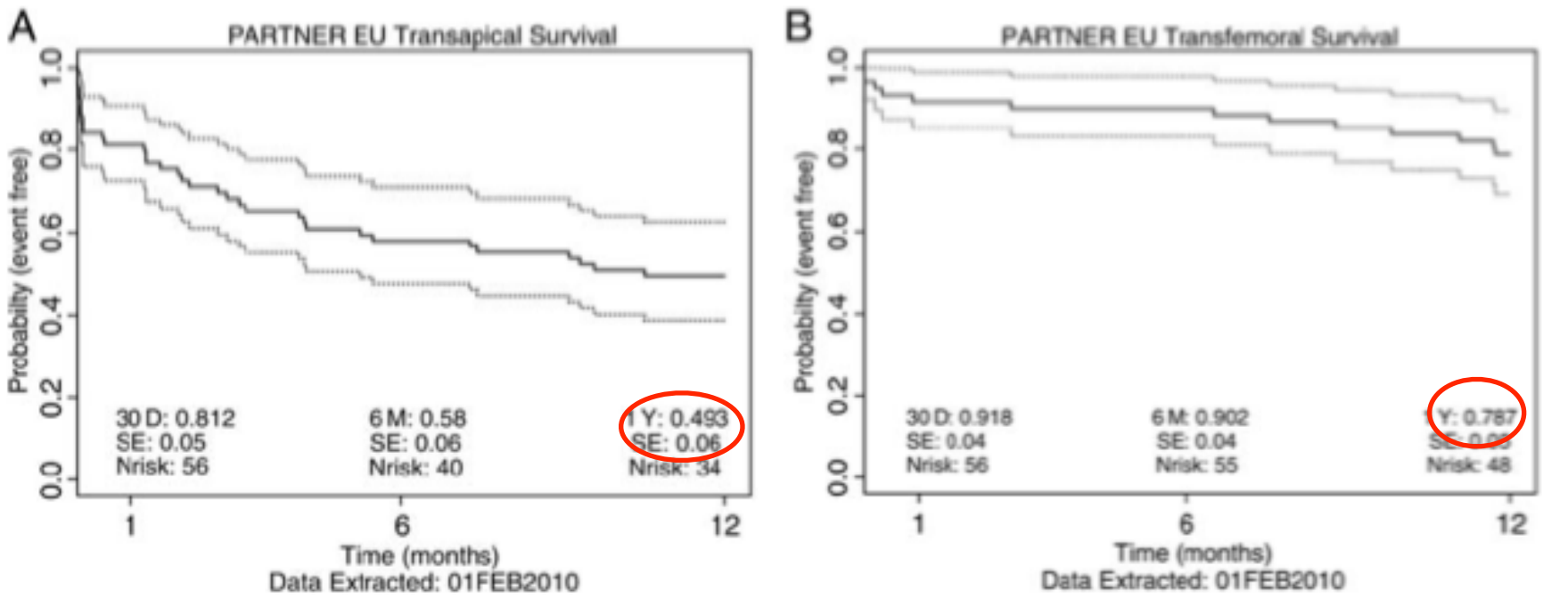
FASTTRACK

One year follow-up of the multi-centre European PARTNER transcatheter heart valve study



igure 2 (*A*) Overall survival for transapical patients. (*B*) Overall survival for transfemoral patients.

CONCLUSIONES

- Tecnología emergente, aún en evolución
- Población objetivo extensa
- Suficientes datos de seguridad y factibilidad.
- Curva de aprendizaje importante
- Resultados en nuestro centro similares a series descritas
- Escasos datos comparativos, ensayos pendientes.
- Probablemente ampliar población en próximos años, idealmente en marco aleatorizado
- Problemas pendientes: estandarización, durabilidad, complicaciones (ACV, marcapasos), cooperación.