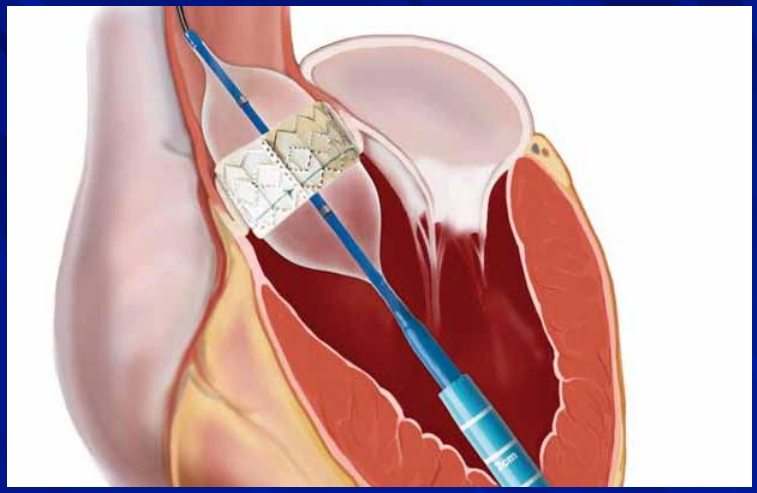
II Jornada d'Atenció Compartida en Cardiologia

Àrea Integral de Salut Barcelona Esquerra



Estat actual del tractament transcatéter d'implantació valvular aòrtica (TAVI). Protocol d'avaluació a l'Hospital Clínic.

Dra. Rut Andrea
Servei de Cardiologia, Hospital Clínic de Barcelona
Grup Clínic de Cardiologia AIS-BE

Barcelona, 7 de noviembre de 2013

Àrea Integral de Salut Barcelona Esquerra

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

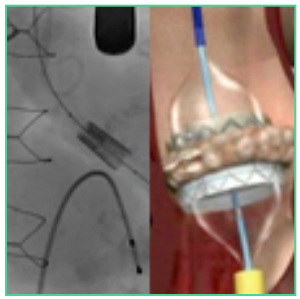
American Heart Association.

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis : First Human Case Description

Alain Cribier, Helene Eltchaninoff, Assaf Bash, Nicolas Borenstein, Christophe Tron, Fabrice Bauer, Genevieve Derumeaux, Frederic Anselme, François Laborde and Martin B. Leon

Circulation. 2002;106:3006-3008; originally published online November 25, 2002;
doi: 10.1161/01.CIR.0000047200.36165.B8

This year's Andreas Gruentzig lecturer Alain Cribier, with below the latest Edwards SAPIEN transcatheter valve.



"Balloon-expandable"

Catheterization and Cardiovascular Interventions 66:465–469 (2005)

VALVULAR HEART DISEASE

Case Report

First Report on a Human Percutaneous Transluminal Implantation of a Self-Expanding Valve Prosthesis for Interventional Treatment of Aortic Valve Stenosis

Eberhard Grube,[1]* MD, FACC, Jean C. Laborde,[2] MD, Bernfried Zickmann,[3] MD, Ulrich Gerckens,[1] MD, Thomas Felderhoff,[4] MD, Barthel Sauren,[3] MD, Andreas Bootsveld,[1] MD, Lutz Buellesfeld,[1] MD, and Stein Iversen,[4] MD

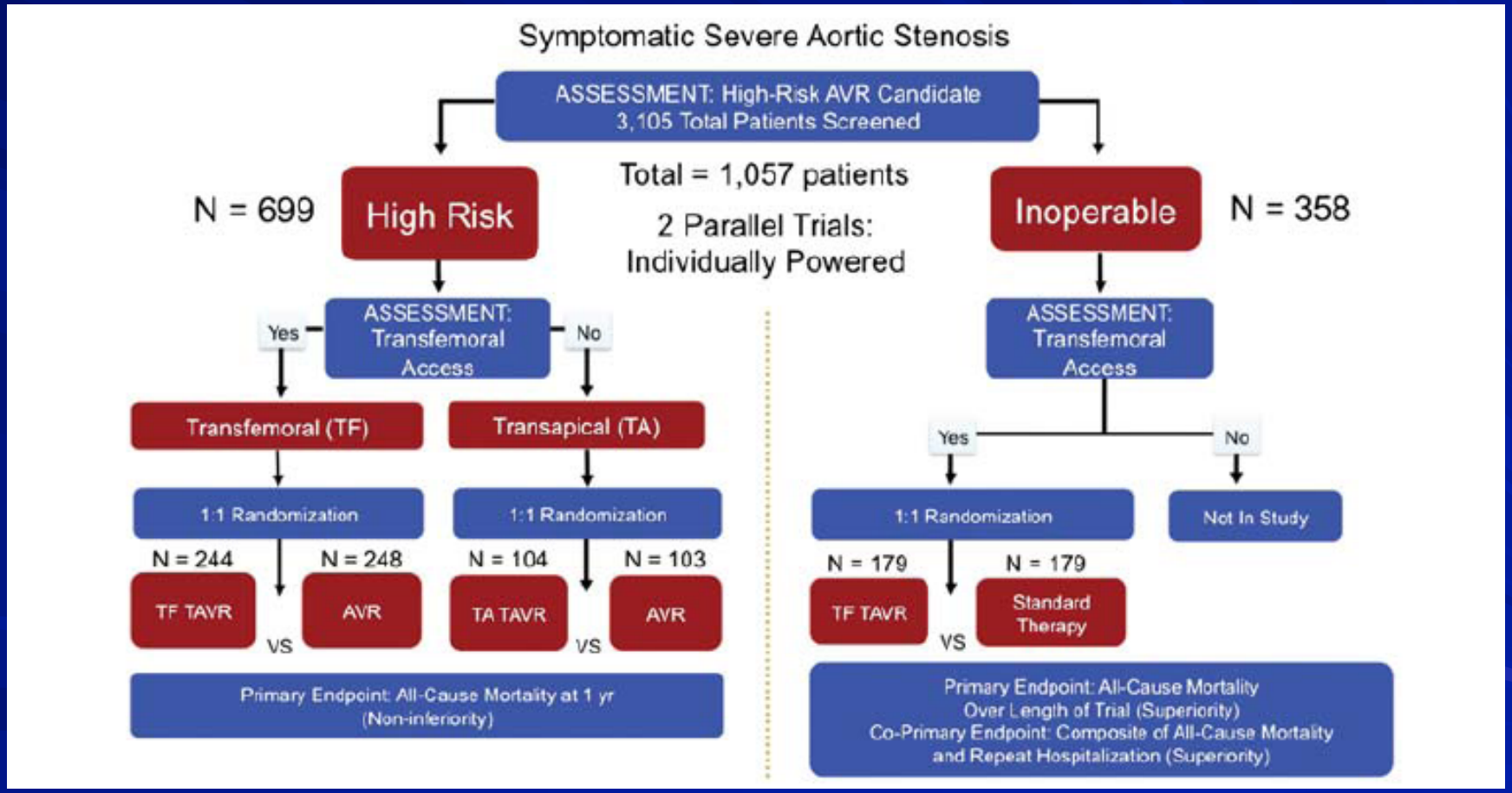
"Self-expanding"

Evidència actual

- Registres: → "real-world"
  - Edwards
  - CoreValve
  - Nacionals mixtes

- Assaigs clínics:
  - PARTNER IB, NEJM 2010
  - PARTNER IA, NEJM 2011

Disseny PARTNER I



PARTNER B: Inoperables
TAVI vs. tractament mèdic

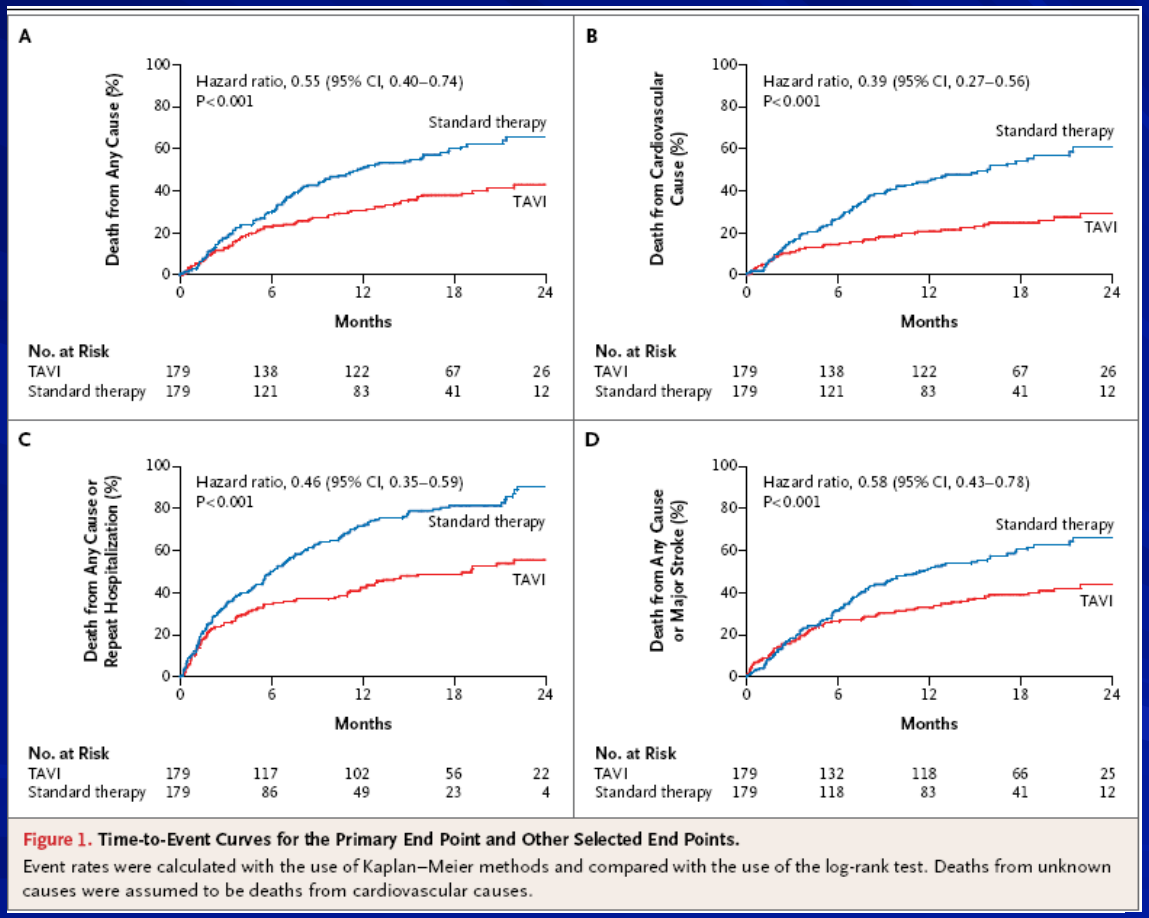


Figure 1. Time-to-Event Curves for the Primary End Point and Other Selected End Points.
Event rates were calculated with the use of Kaplan–Meier methods and compared with the use of the log-rank test. Deaths from unknown causes were assumed to be deaths from cardiovascular causes.

Smith et al. Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients. NEJM 2011.

Makkar RR et al. Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis. NEJM 2012.

PARTNER A: Alt risc quirúrgic TAVI vs. RVAo

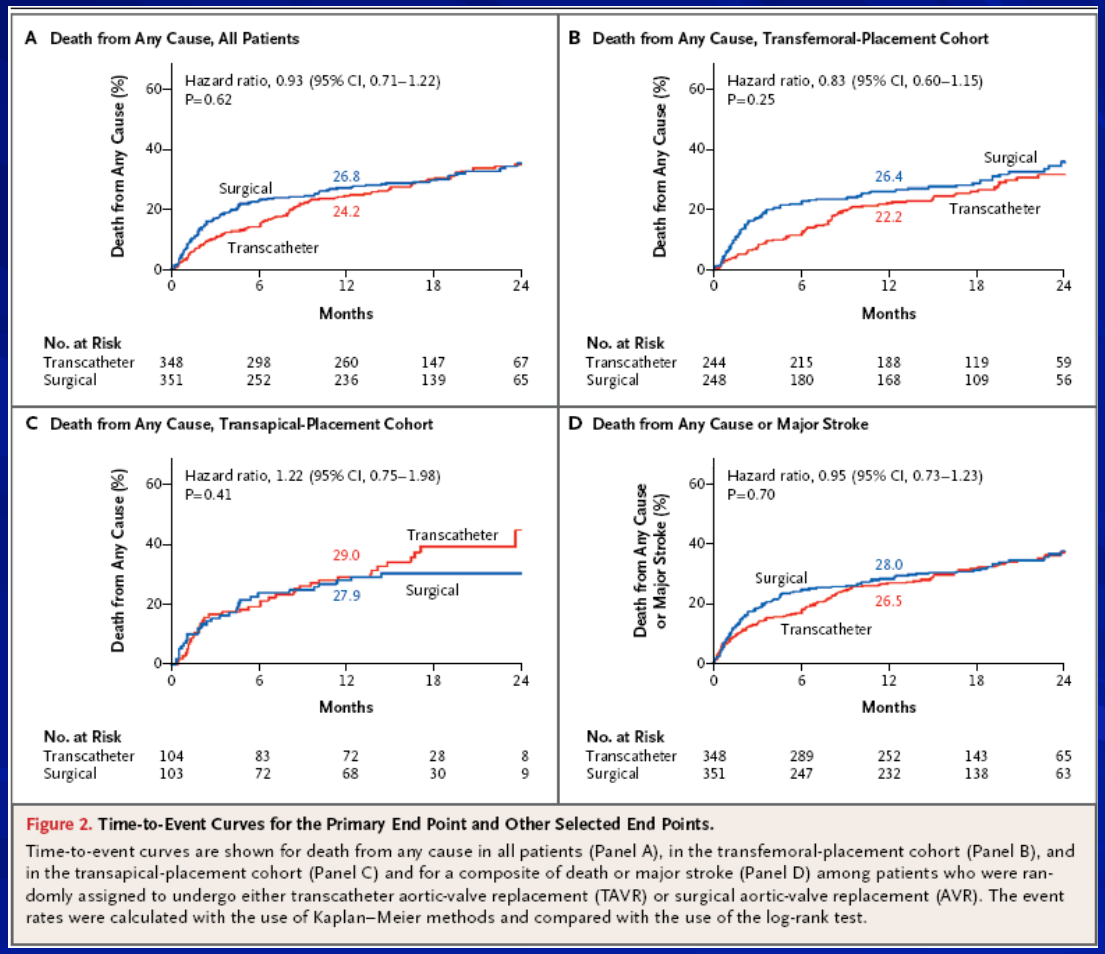


Figure 2. Time-to-Event Curves for the Primary End Point and Other Selected End Points.

Time-to-event curves are shown for death from any cause in all patients (Panel A), in the transfemoral-placement cohort (Panel B), and in the transapical-placement cohort (Panel C) and for a composite of death or major stroke (Panel D) among patients who were randomly assigned to undergo either transcatheter aortic-valve replacement (TAVR) or surgical aortic-valve replacement (AVR). The event rates were calculated with the use of Kaplan–Meier methods and compared with the use of the log-rank test.

Smith et al. Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients. NEJM 2011.

Kodali SK et al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. NEJM 2012.

Complicacions 1er mes

Table 2. Clinical Outcomes at 30 Days and 1 Year in the Intention-to-Treat Population.*

Outcome	30 Days			1 Year		
	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value
	no. of patients (%)			*no. of patients (%)*		
Death						
From any cause	12 (3.4)	22 (6.5)	0.07	84 (24.2)	89 (26.8)	0.44
From cardiac causes	11 (3.2)	10 (3.0)	0.90	47 (14.3)	40 (13.0)	0.63
Repeat hospitalization	15 (4.4)	12 (3.7)	0.64	58 (18.2)	45 (15.5)	0.38
Death or repeat hospitalization	25 (7.2)	33 (9.7)	0.24	120 (34.6)	119 (35.9)	0.73
Stroke or transient ischemic attack						
Either	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
Transient ischemic attack	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
Stroke						
Minor	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84
Major	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07
Death from any cause or major stroke	24 (6.9)	28 (8.2)	0.52	92 (26.5)	93 (28.0)	0.68
Myocardial infarction	0	2 (0.6)	0.16	1 (0.4)	2 (0.6)	0.69
Vascular complication						
Any	59 (17.0)	13 (3.8)	<0.001	62 (18.0)	16 (4.8)	<0.001
Major	38 (11.0)	11 (3.2)	<0.001	39 (11.3)	12 (3.5)	<0.001
Acute kidney injury						
Creatinine >3 mg/dl (265 μmol/liter)	4 (1.2)	4 (1.2)	0.95	12 (3.9)	8 (2.7)	0.41
Renal-replacement therapy	10 (2.9)	10 (3.0)	0.95	18 (5.4)	20 (6.5)	0.56
Major bleeding	32 (9.3)	67 (19.5)	<0.001	49 (14.7)	85 (25.7)	<0.001
Endocarditis	0	1 (0.3)	0.42	2 (0.6)	3 (1.0)	0.63
New-onset atrial fibrillation†	30 (8.6)	56 (16.0)	0.006	42 (12.1)	60 (17.1)	0.07
New pacemaker	13 (3.8)	12 (3.6)	0.89	19 (5.7)	16 (5.0)	0.68

Smith et al. Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients. NEJM 2011.

Predictors mortalitat a la TAVI

Artículo original

Predictores de mortalidad hospitalaria y a medio plazo tras el reemplazo valvular aórtico transcatéter: datos del registro nacional TAVI 2010-2011☆

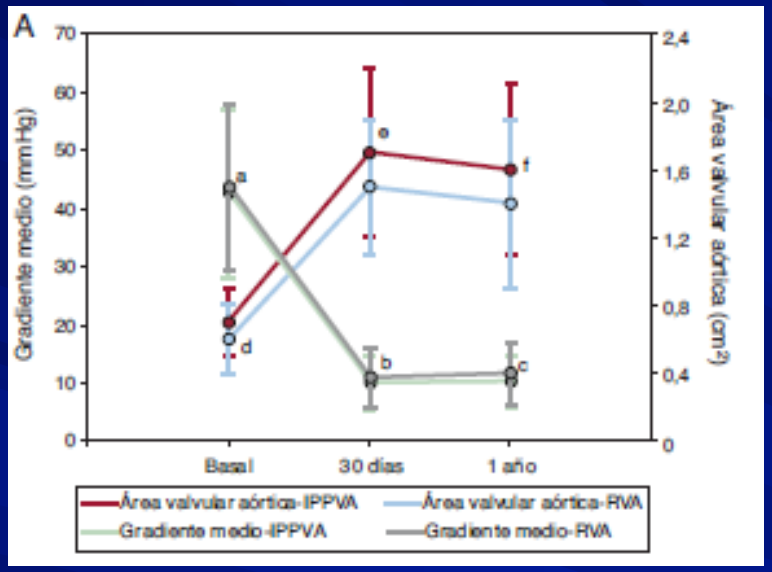
Manel Sabaté[a,*], Sergio Cánovas[b], Eulogio García[c], Rosana Hernández Antolín[c], Luis Maroto[c], José María Hernández[d], Juan H. Alonso Briales[d], Antonio J. Muñoz García[d], Enrique Gutiérrez-Ibañes[e], Jorge Rodríguez-Roda[e] y colaboradores del Grupo Nacional TAVI◇

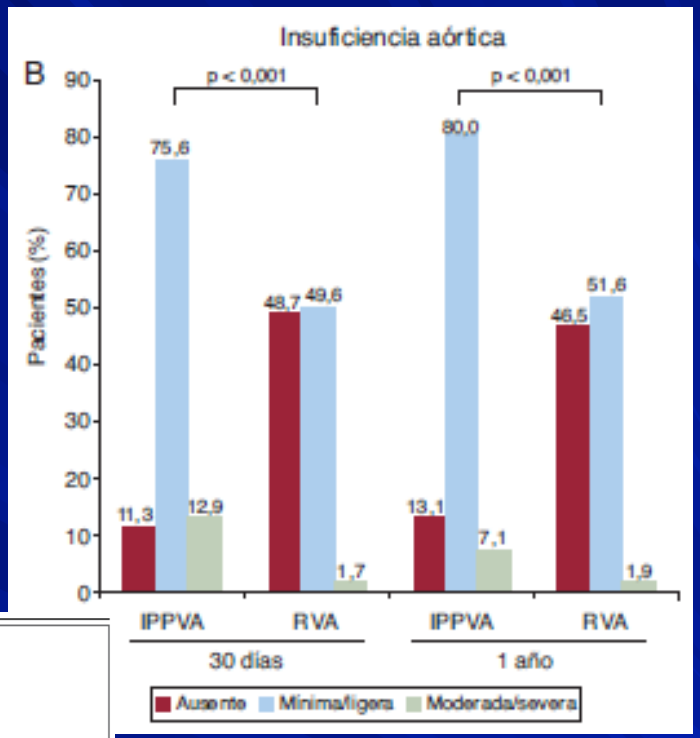
Predictores de mortalidad a medio plazo

	Univariable, HR (IC95%)	p	Multivariable, HRa (IC95%)	p
Sexo femenino	0,77 (0,59-0,99)	0,04		
Enfermedad vascular periférica	1,77 (1,28-2,46)	0,001	1,80 (1,27-2,56)	0,002
Arritmia completa por FA	1,57 (1,20-2,06)	0,001	1,78 (1,34-2,38)	0,0001
Creatinina plasmática	1,19 (1,05-1,35)	0,02	1,18 (1,04-1,35)	0,02
FEVI	0,99 (0,98-1,00)	0,04	0,99 (0,98-1,00)	0,05
Edwards frente a CoreValve	1,19 (0,95-1,55)	0,19		
Apical frente a no apical	1,34 (0,99-1,81)	0,07		
IAo postoperatoria moderada-grave	2,84 (1,91-4,23)	0,0001	2,78 (1,77-4,37)	0,0001
Conversión a cirugía	5,05 (2,82-9,03)	0,0001	3,60 (1,65-7,88)	0,005

Manel Sabate et al. Predictores de mortalidad hospitalaria y a medio plazo tras el reemplazo vlavular aórtico transcatéter: datos del registro nacional TAVI 2010-2011. Rev Esp Cardiol 2013, in press.

Evolució ecocardiogràfica i funcional





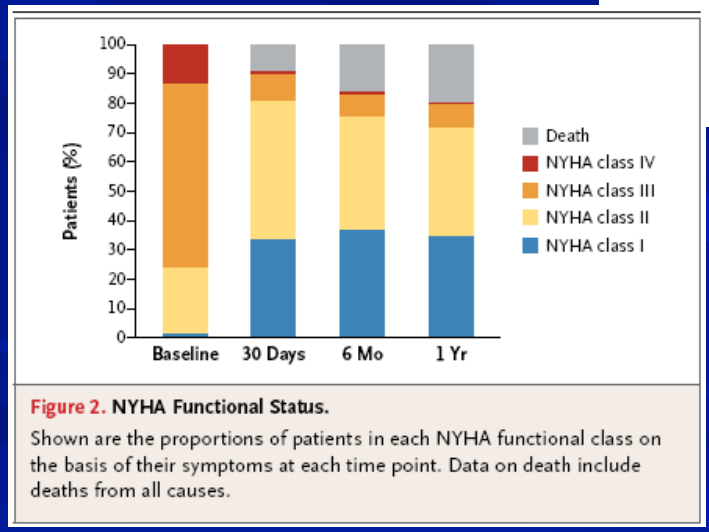


Figure 2. NYHA Functional Status.

Shown are the proportions of patients in each NYHA functional class on the basis of their symptoms at each time point. Data on death include deaths from all causes.

Rodés-Cabau et al. Indicaciones de prótesis aórtica percutánea después del estudio PARTNER. Rev Esp Cardiol 2012;65:208-214.

Gilard et al. Registry of transcatheter aortic-valve implantation in high risk patients. N Engl J Med 2012.

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ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2012.08.960

Long-Term Outcomes After Transcatheter Aortic Valve Implantation

Insights on Prognostic Factors and Valve Durability From the Canadian Multicenter Experience

Josep Rodés-Cabau, MD,* John G. Webb, MD,† Anson Cheung, MD,† Jian Ye, MD,†

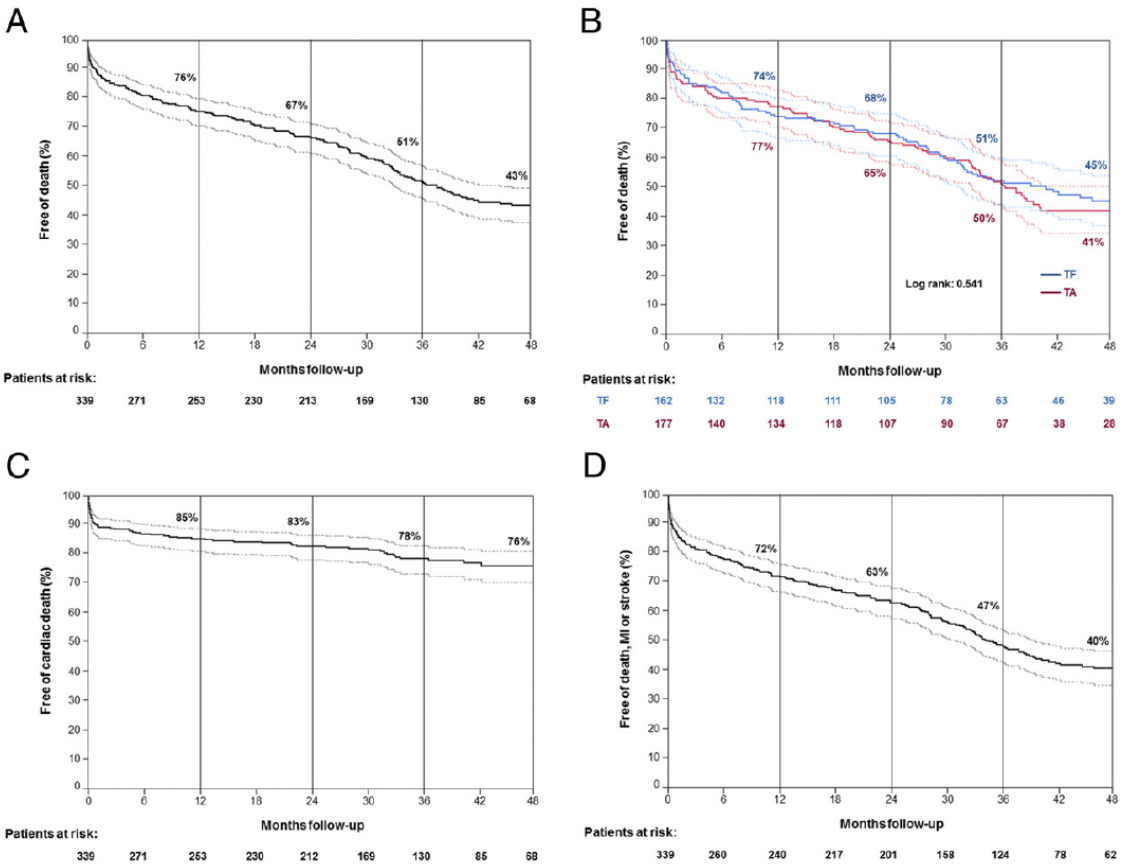


Figure 1 Kaplan-Meier Survival Curves up to 4-Year Follow-Up

(A) Percentage of patients free of death up to 4-year follow-up. **(B)** Survival curves up to 4-year follow-up, depending on the approach (transfemoral [TF], transapical [TA]). **(C)** Percentage of patients free of cardiac death up to 4-year follow-up. **(D)** Percentage of patients free of death, stroke, or myocardial infarction up to 4-year follow-up.

European Heart Journal (2012) 33, 2451–2496
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Table 11 Recommendations for the use of transcatheter aortic valve implantation

Recommendations	Class[a]	Level[b]	Ref[c]
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C	
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B	99
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.	IIa	B	97

AS = aortic stenosis; AVR = aortic valve replacement; TAVI = transcatheter aortic valve implantation.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting class I (A + B) and IIa + IIb (A + B) recommendations.

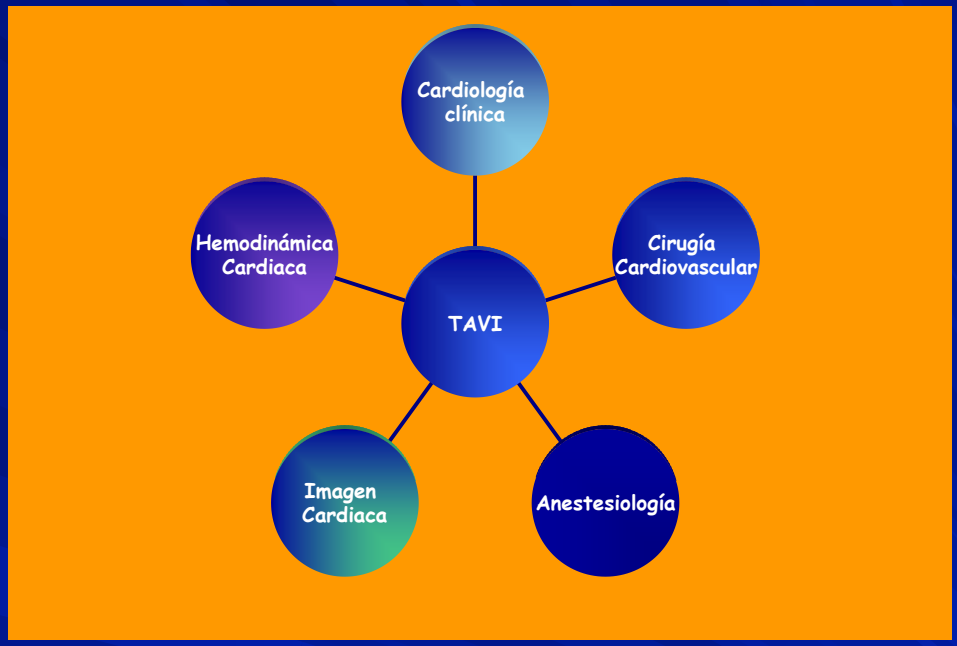
Table 10 Contraindications for transcatheter aortic valve implantation

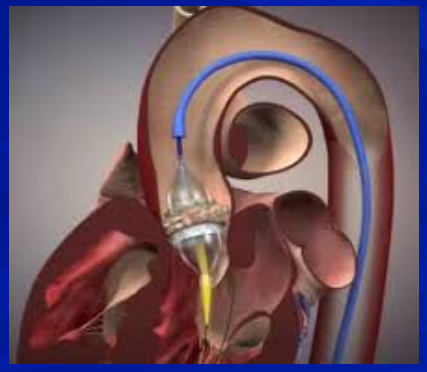
Absolute contraindications
Absence of a 'heart team' and no cardiac surgery on the site
Appropriateness of TAVI, as an alternative to AVR, not confirmed by a 'heart team'
Clinical
Estimated life expectancy <1 year Improvement of quality of life by TAVI unlikely because of comorbidities Severe primary associated disease of other valves with major contribution to the patient's symptoms, that can be treated only by surgery
Anatomical
Inadequate annulus size (<18 mm, >29 mm[a])
Thrombus in the left ventricle
Active endocarditis
Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuses)
Plaques with mobile thrombi in the ascending aorta, or arch
For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity)
Relative contraindications
Bicuspid or non-calcified valves
Untreated coronary artery disease requiring revascularization
Haemodynamic instability
LVEF <20%
For transapical approach: severe pulmonary disease, LV apex not accessible

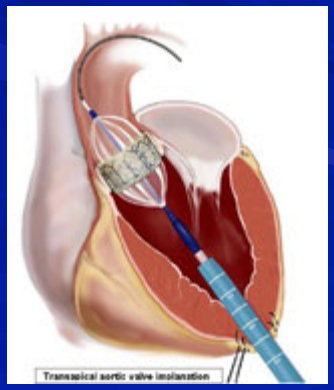
AVR = aortic valve replacement; LV = left ventricle; LVEF = left ventricular ejection fraction; TAVI = transcatheter aortic valve implantation.
[a]Contraindication when using the current devices.

Programa TAVI - HCB

- Inici Febrer de 2010
- Creació equip multidisciplinar
- Consulta monogràfica
- Protocol
- Accés transfemoral i transapical







Sel·lecció dels pacients

- Consulta monogràfica especialitzada:
  - Avaluació clínica: indicació, risc quirúrgic (EuroScore).
  - Avaluació funcional:
    - Índex de mobilitat-dependència de Barthel
  - Avaluació comorbilitats:
    - Índex comorbilitat Charlson
- Estudi anatòmic:
  - Ecocardiograma
  - Coronariografia i angiografia ilio-femoral
  - Angio-TC aorta
- Comitè Multidisciplinar

Indicacions TAVI

CLÍNIC
BARCELONA
Hospital Universitari

PROGRAMA DE IMPLANTACIÓN DE VÁLVULA AÓRTICA TRANSCATÉTER (TAVI)

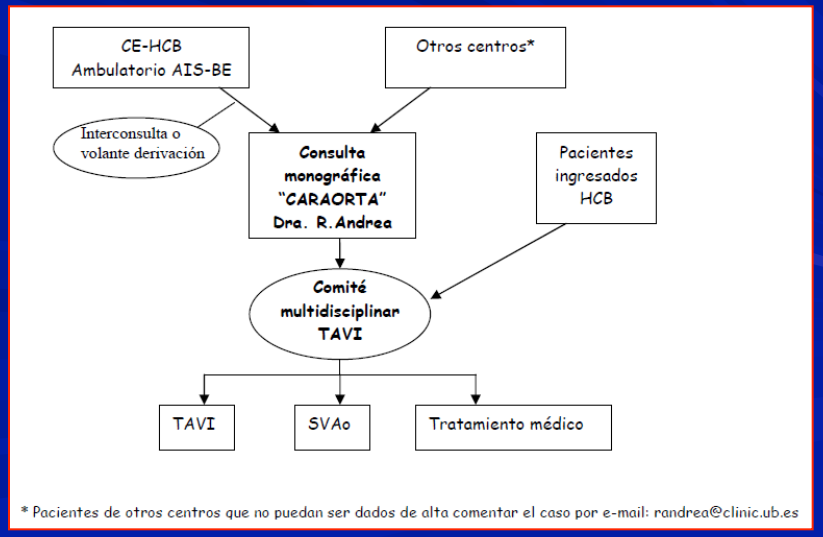
Indicaciones

La válvula cardiaca transcatéter Edwards SAPIEN, está indicada en pacientes con:

- ESTENOSIS AÓRTICA GRAVE CALCIFICADA SINTOMÁTICA, sobre válvula nativa o prótesis biológica, que requiera recambio valvular

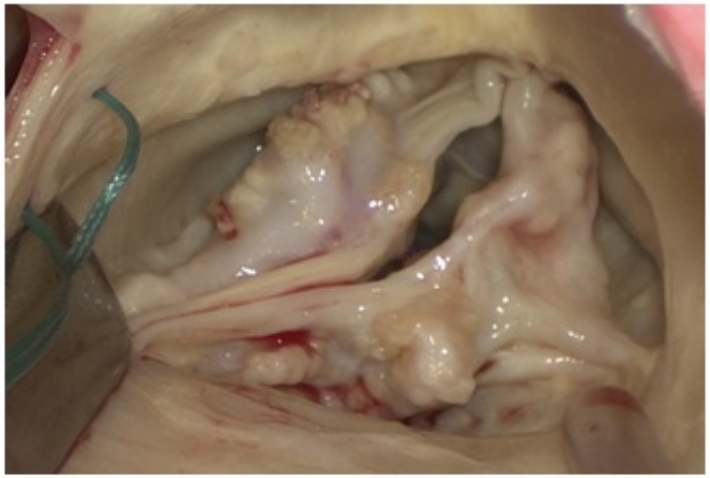
+

- CONTRAINDICACIÓN PARA CIRUGIA CONVENCIONAL o ALTO RIESGO DE MORTALIDAD QUIRÚRGICA (EUROSCORE>15-20%)

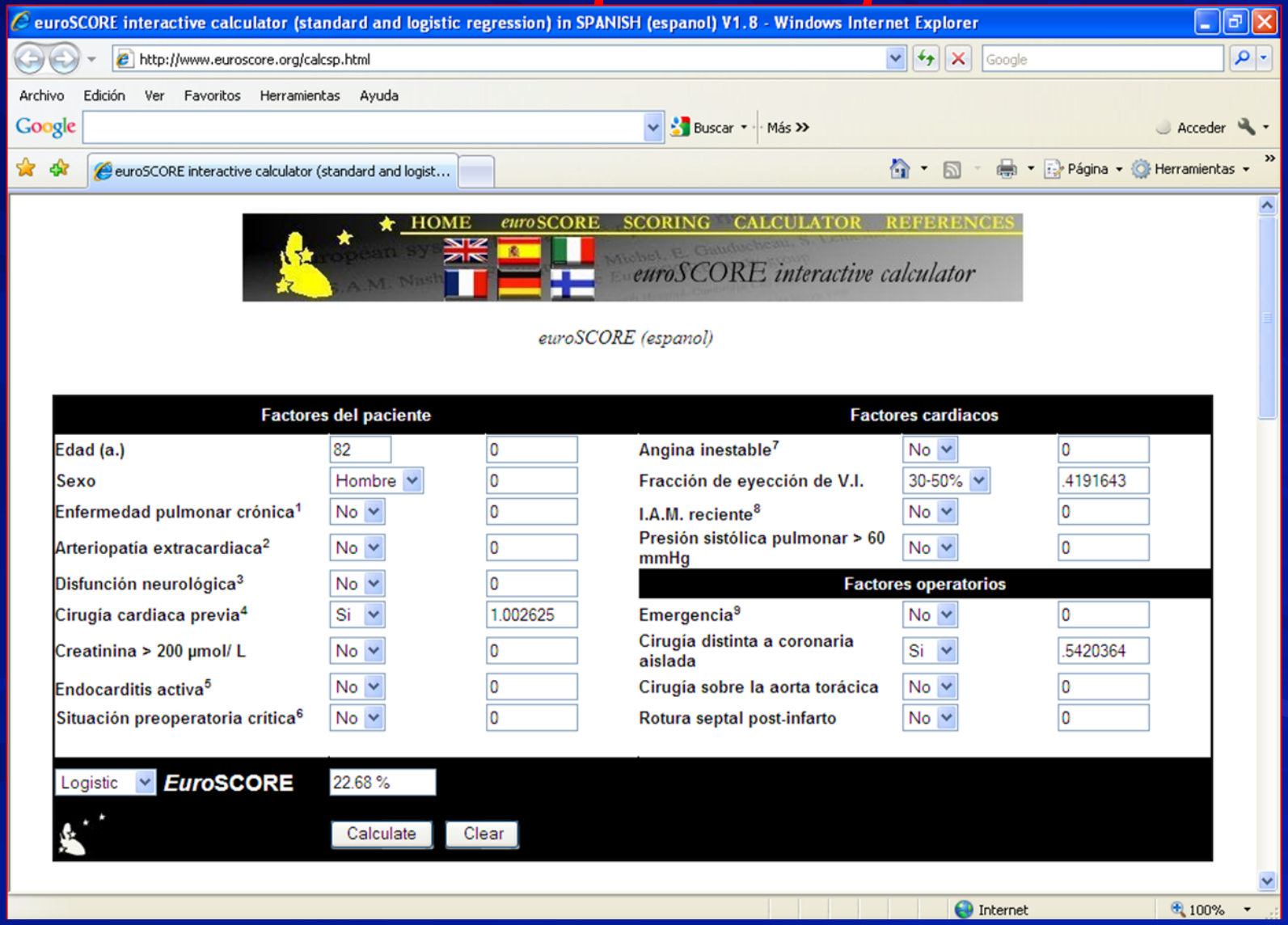


Avaluació clínica

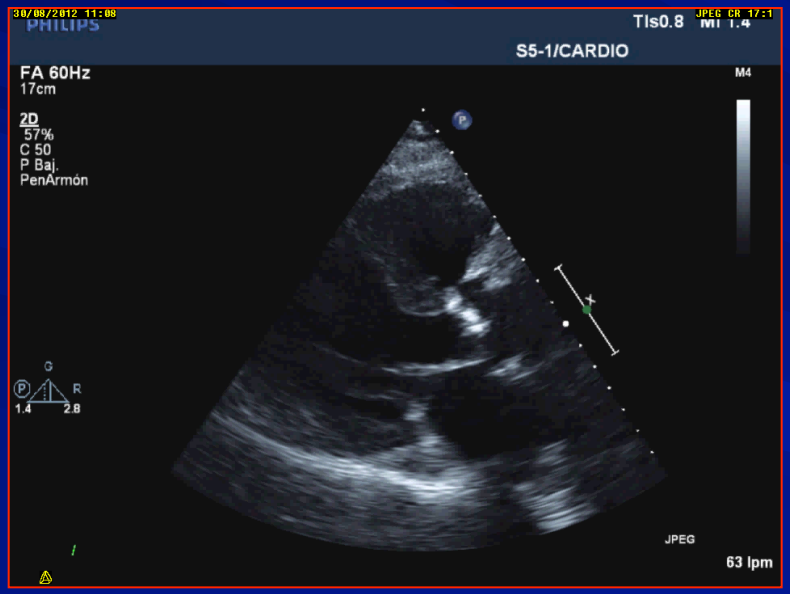
Figure 1: Aortic valve stenosis (intraoperatively)

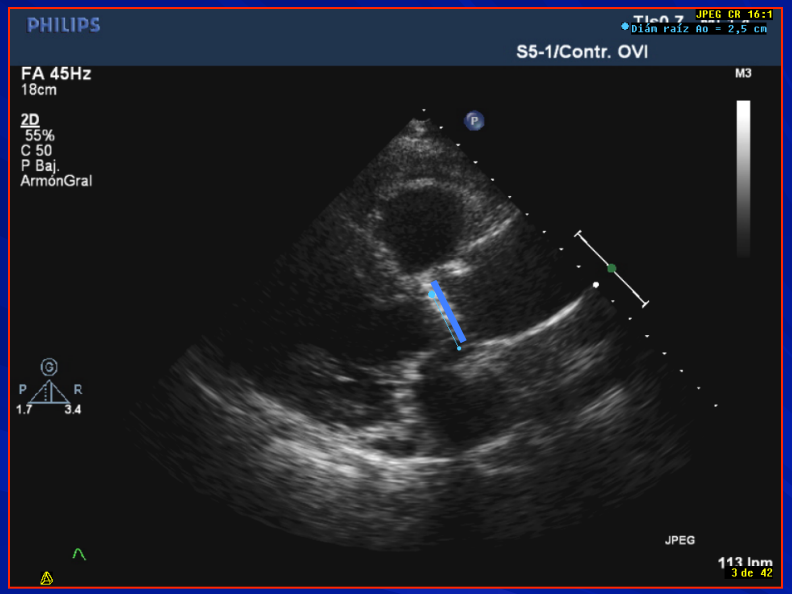


Risc quirúrgic



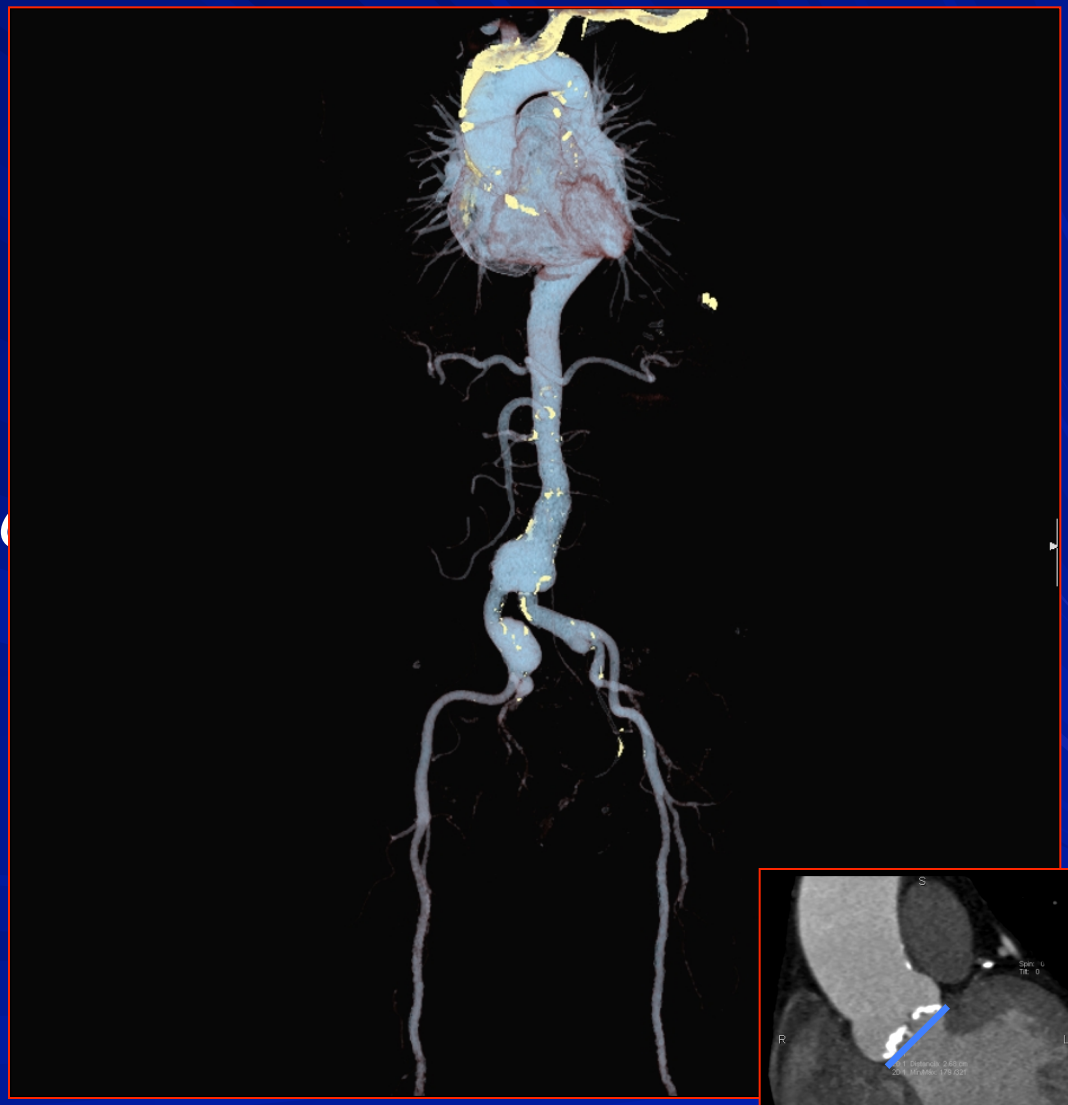
Ecocardiograma



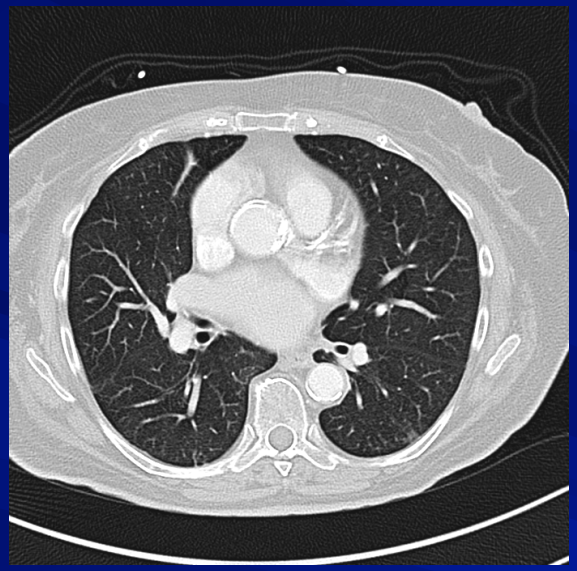


Angio-TC aorta

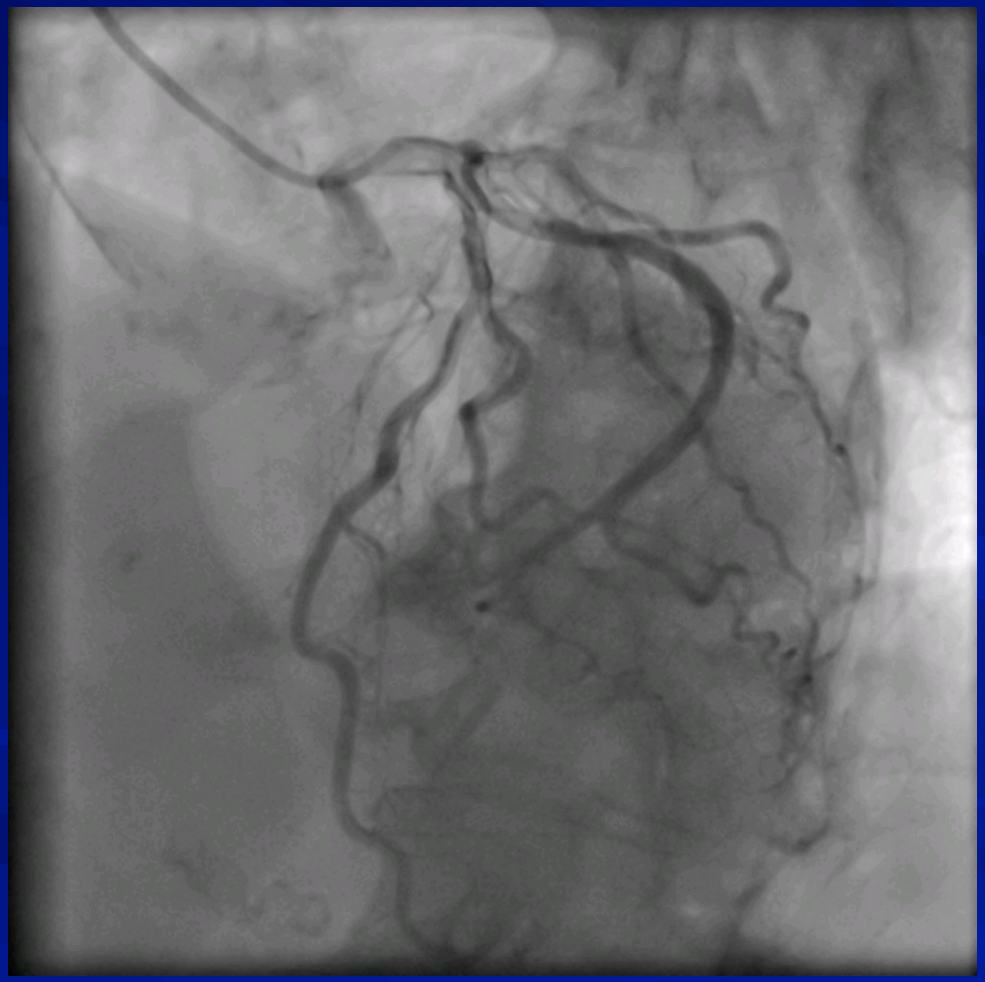
- Distància anell aòrtic-TC
- Distància anell aòrtic-CD
- Diàmetre anell aòrti
- Eix ilio-femoral:
  - Tortuositat
  - Calcificació
  - Diàmetre

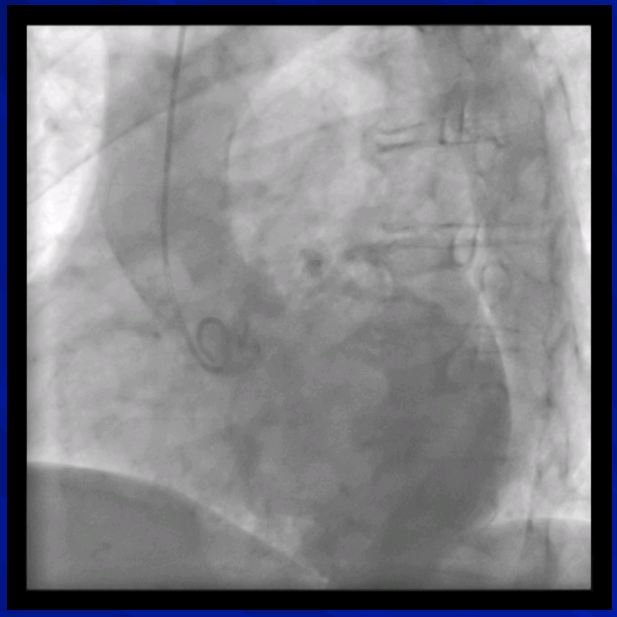


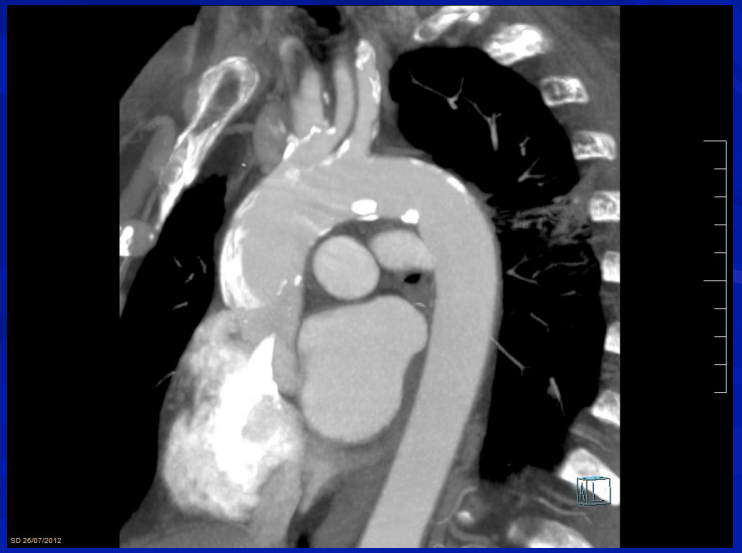
Angio-TC aorta

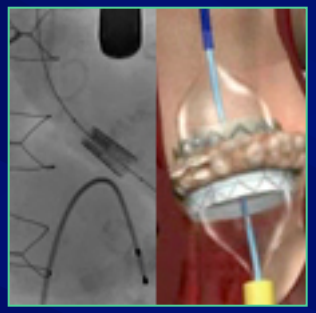


Coronariografia i calcificació aorta









Multidisciplinar TAVI Heart Team

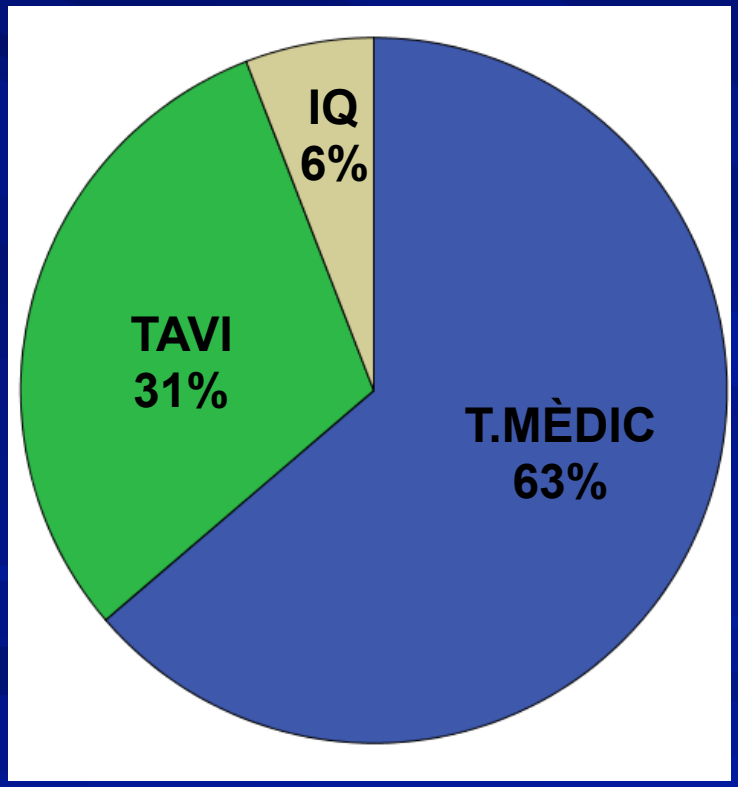
CLÍNIC BARCELONA Hospital Universitari

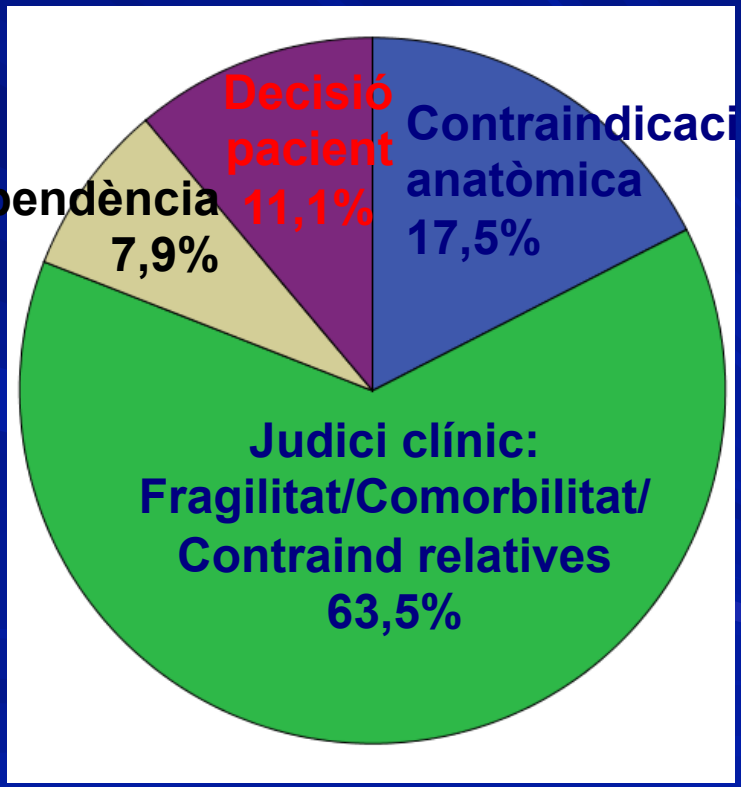
TAVI

Cardiologia Clínica	Hemodinàmica Cardíaca	Cirurgia Cardiovascular	Anestesiologia	Imatge Cardíaca
Rut Andrea Carles Falces	Manel Sabaté Victoria Martín Xavi Freixa Mónica Masotti	Manel Castellà Clemente Barriuso Salvador Ninot	Guillermina Fita Irene Rovira	Bàrbara Vidal

Avaluació mostra CARAORTA

- N = 103 pacients



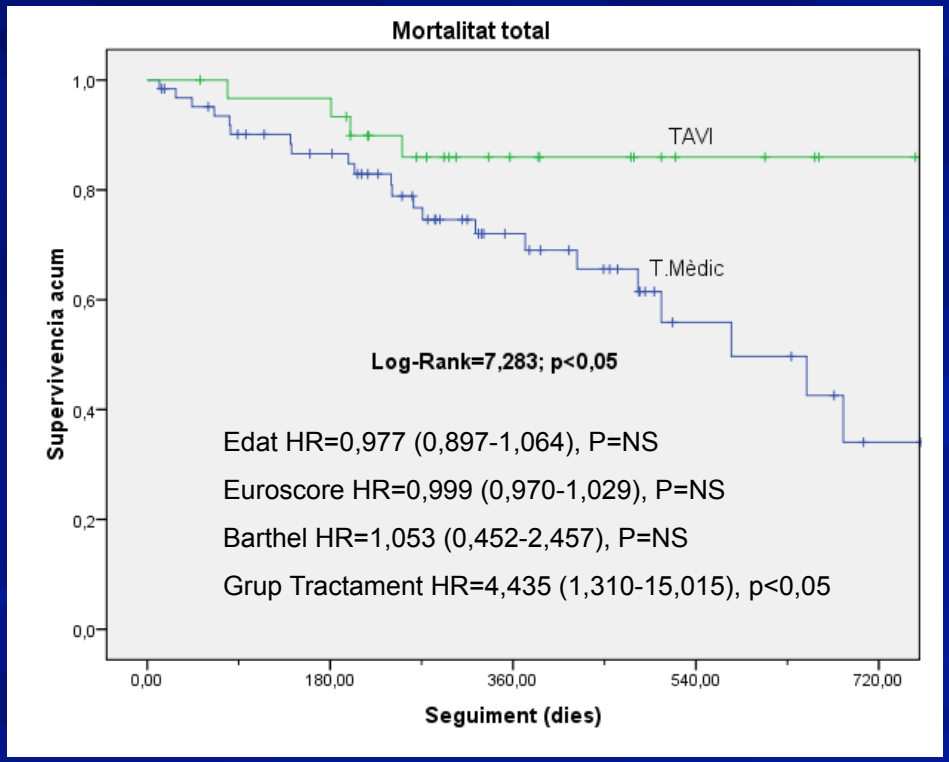


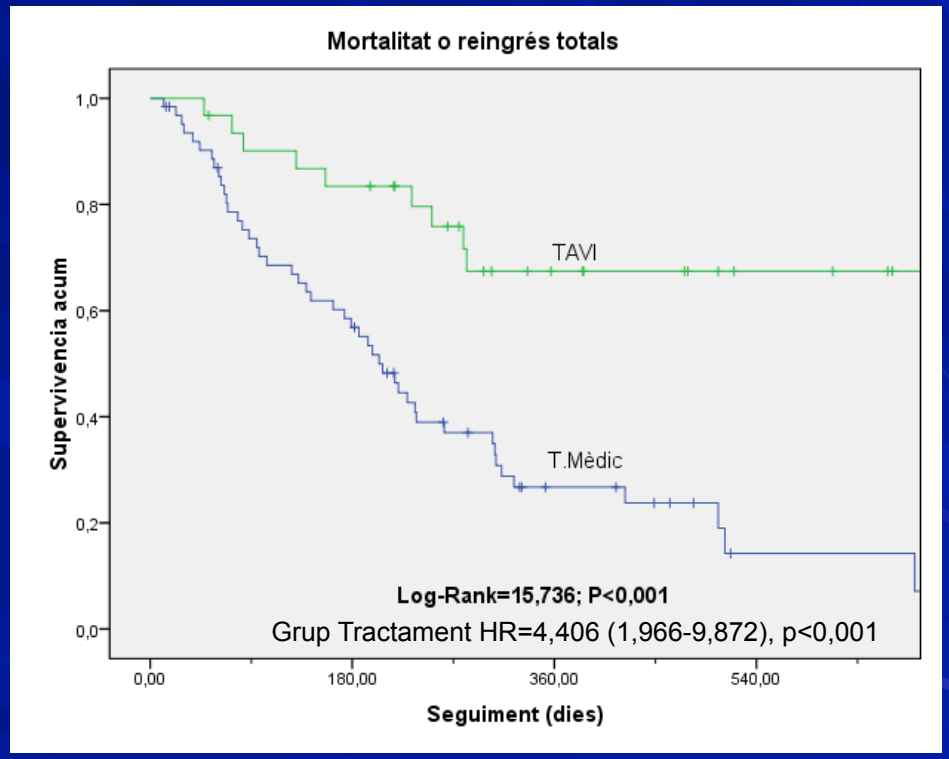
Característiques basals

	TAVI	Mèdic	p
Edat	77±8	83±4	< 0,001
Sexe (♂)	48%	31%	NS
Barthel < 80	0%	55,8%	< 0,001
Charlson	4,5	4,8	NS
FG (ml/min,MDRD)	66,3	57,9	NS
AVA (cm2)	0,723	0,716	NS
GP (mmHg)	76/46	74/44	NS
FE (%)	53%	52%	NS
EuroScore log (%)	14.9±12.6	20.5±12.5	0,043

Sobrevida

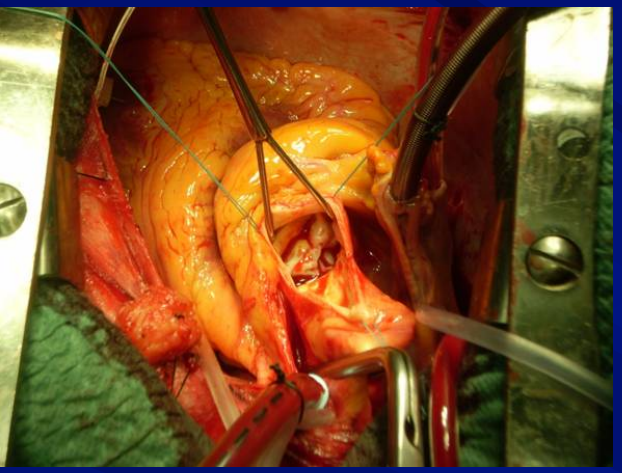
- Seguiment mig = 12 ± 7,7 mesos





Mortalitat : 33% vs. 14%

Mort o reingrés: 73% vs. 33%




Gràcies !
SD 26/07/2012