

Potential conflicts of interest

Speaker's name: Cesar Moris

I have the following potential conflicts of interest to report:

- Research contracts
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest



Disclosure

- Proctor for Corevalve in
 - Europe and Latin America:
- Member advisory board for Medtronic

Corevalve Ibero-American Registry

Cesar Morís

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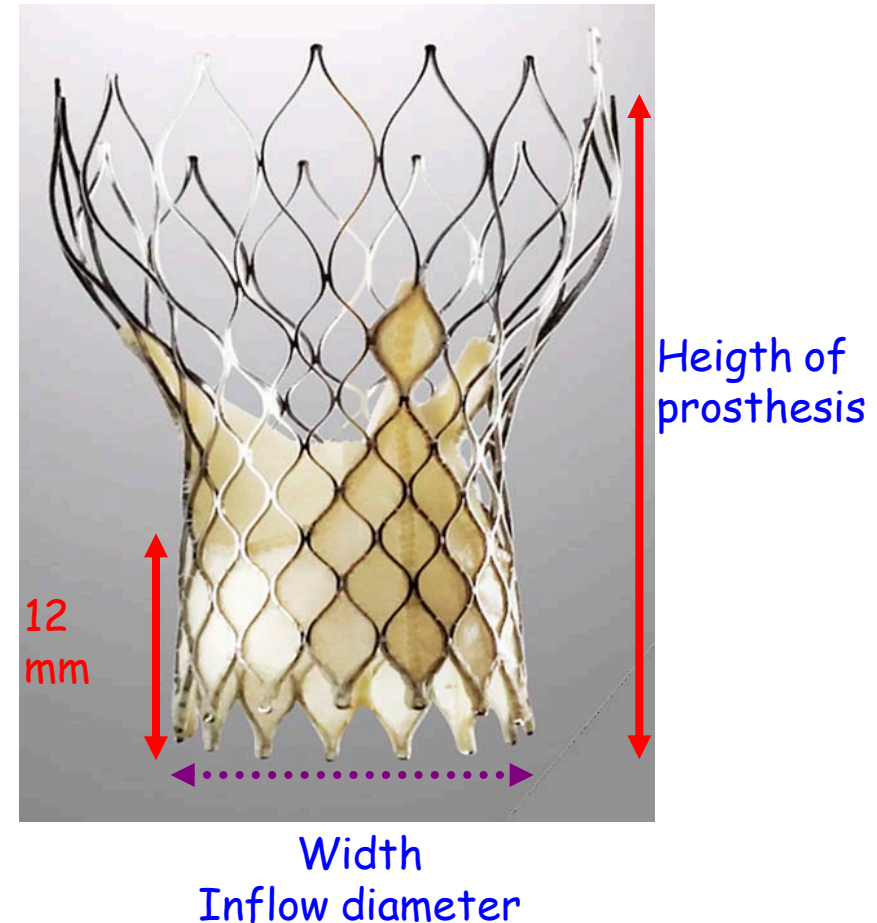
Malaga, Spain

(On behalf of the Ibero-American Registry Investigators)



Background

- ✚ Single layer porcine pericardium
- ✚ Tri-leaflet configuration
- ✚ Scalloped skirt
- ✚ Nitinol frame
- ✚ Supra-annular valve position preserves circularity at level of valve function
- ✚ 18Fr catheter delivery system
- ✚ 3 valve sizes



Objective

To evaluate immediate and long term results of consecutive ‘real world’ inoperable or high risk patients with severe aortic stenosis, treated with percutaneous aortic valve implantation using the Medtronic CoreValve System.

- 1,248 patients enrolled from December 2007 to March 2012
- 43 centers - 9 countries in Europe and Latin America.
- Every patient from each center was included consecutively .
- Clinical endpoints reported according to Valve Academic Research Consortium (VARC)

SPAIN	
Hospital Clínico Universitario Virgen de la Victoria	233
Hospital Universitario Central de Asturias	115
Hospital Clínico Universitário de Santiago	102
Hospital Universitario Gregorio Marañón	85
Hospital Clínico Universitario de Valladolid	67
Hospital Universitario Virgen de las Nieves	37
Hospital Clínico Universitario San Carlos	64
Hospital Universitario de Bellvitge	36
Hospital Carlos Haya	33
Hospital Clínico Universitario de Salamanca	31
Hospital Do Meixoeiro, Vigo	20
Hospital Juan Ramón Jiménez, Huelva	15
Fundación Jiménez Díaz	14
Hospital de León	11
Hospital General de Valencia	11
Hospital de Navarra	4
Hospital de Valme	2
Hospital Fundación Alcorcón	2
Hospital General Universitario de Albacete	2
Hospital General Yagüe	2
Hospital Miguel Servet	2
Total	888

ARGENTINA	
Fundación Favaloro , B Aires	60
Hospital Fernández, B Aires	31
ICBA, Buenos Aires	27
Sanatorio Guemes, B Aires	19
Hospital Español, B Aires	19
Instituto Cardiovascular de Rosario,	8
Hospital Privado de Córdoba,	6
Sanatorio Modelo Burzaco,	5
Hospital D. F. Santojanni, B Aires	2
Hospital Privado Del Sur, Bahía Blanca,	1
Total	178

PORTUGAL	
Hospital Santa Cruz, Lisboa	52
Hospital Santa Marta, Lisboa	22
Hospital de Gaia. Porto	6
Total	80

CHILE	
Clínica Las Condes, Santiago de Chile	17
Hospital del Tórax, Santiago de Chile	10
Total	27

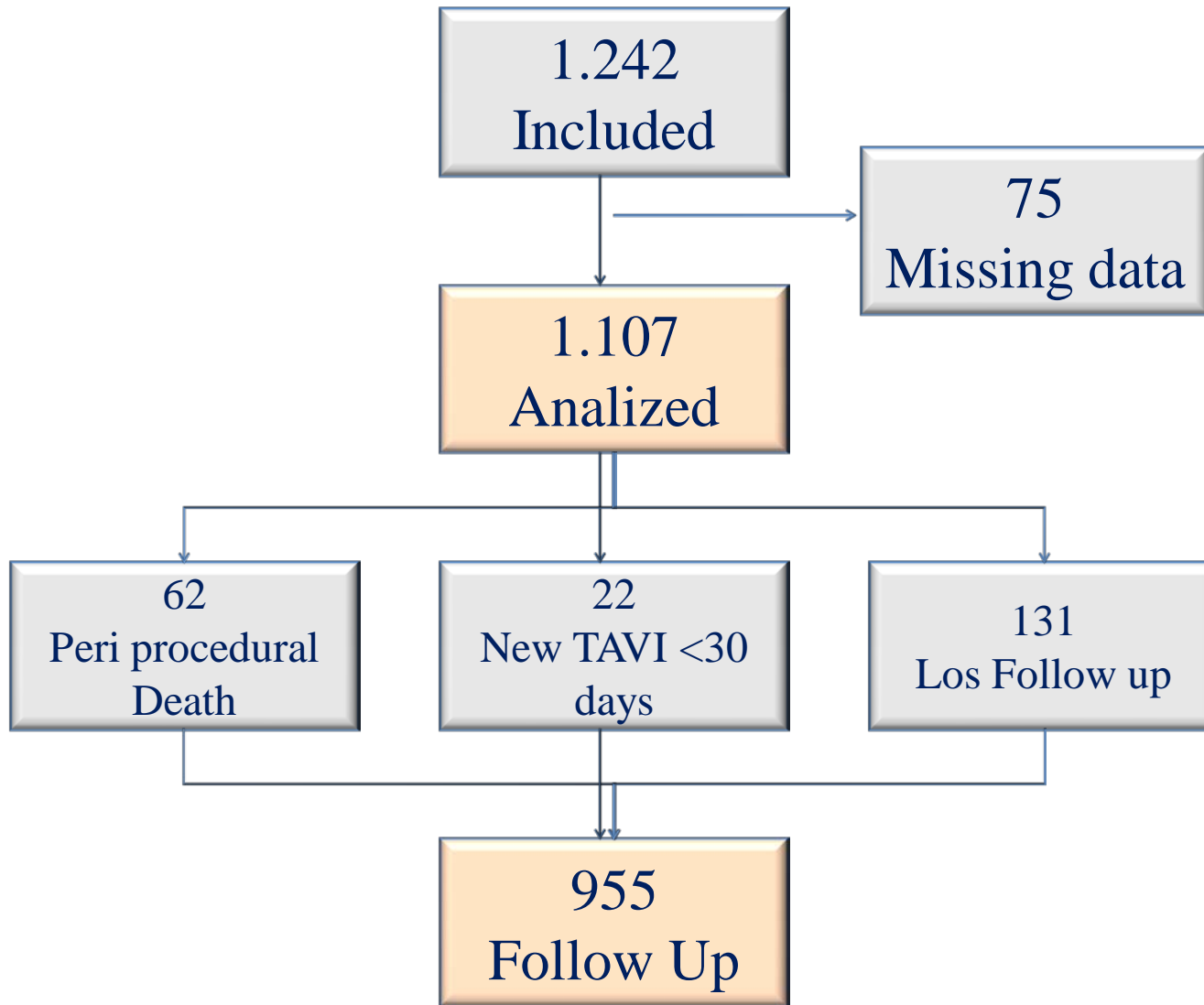
COLOMBIA	
Fundación Cardio infantil de Bogotá,	14
Fundación Cardiovascular , Bucaramanga,	13
Total	27

VENEZUELA	
Hospital Clínico de Caracas,	18
Hospital Universitario de Maracaibo,	1
Total	19

REPUBLICA DOMINICANA	
CEDIMAT ,Santo Domingo	16
Total	16

PERU	
Hospital Rebagliati, Lima	6
Total	6

Methods



Baseline characteristics

N=1.170			
Age (years)	81,4±6,3	Renal Failure	22,3%
Logistic EuroScore	17,8±13,1	Creatinin >200mmol/L	5,3%
Male	54,7%	COPD	34,6%
Diabetes	32,8%	NYHA III-IV	79,8%
Prior Revascularization	29,9%	Porcelain aorta	6,6
Stroke/TIA	11%	Pacemaker	8,5%
Prior MI	11,4%	Afib	21,4%
Arteriopathy	13,5%	CAD (50%)	35,7%
Severe Pulmonary HTP	19,3%	Mitral Reg, mod-sev	18,7%
LVEF < 40%	14,5%		

Baseline characteristics

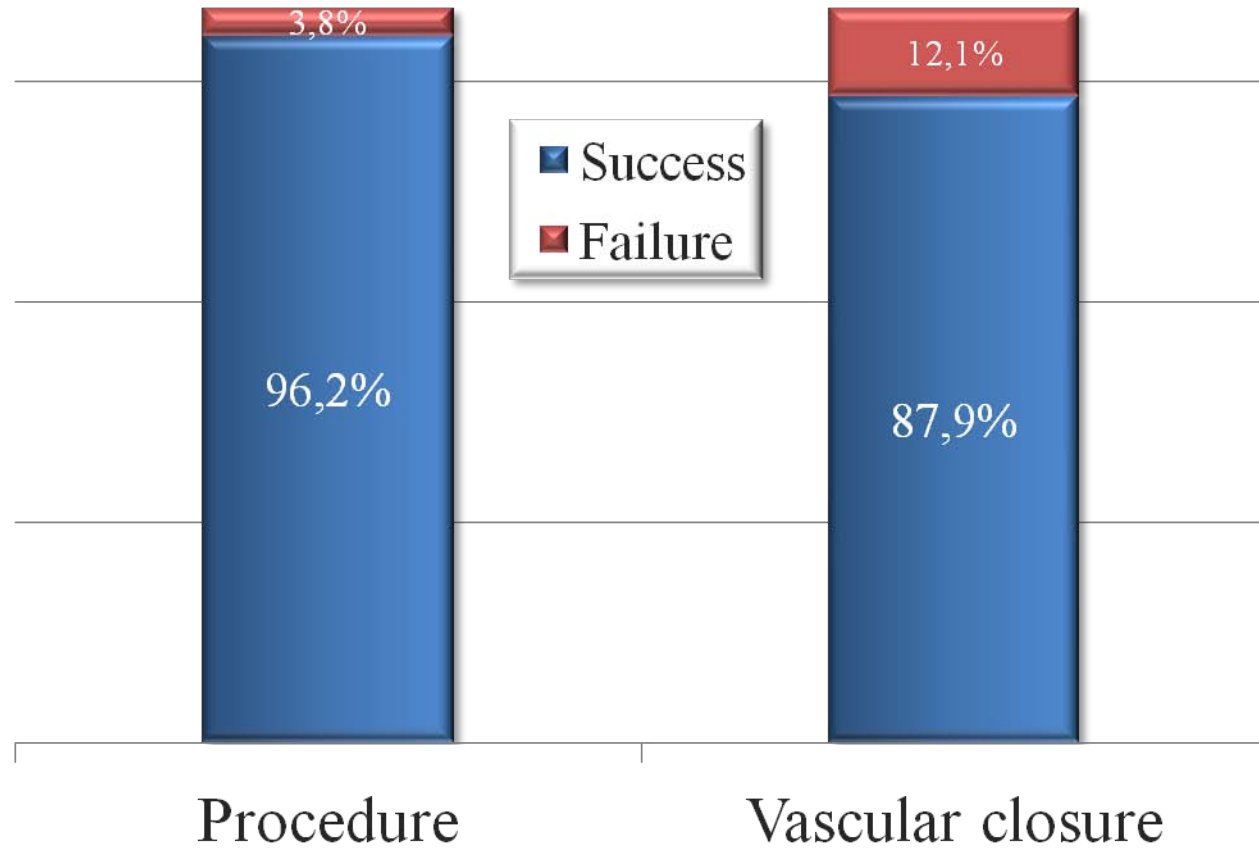
Euroscore relevant factors

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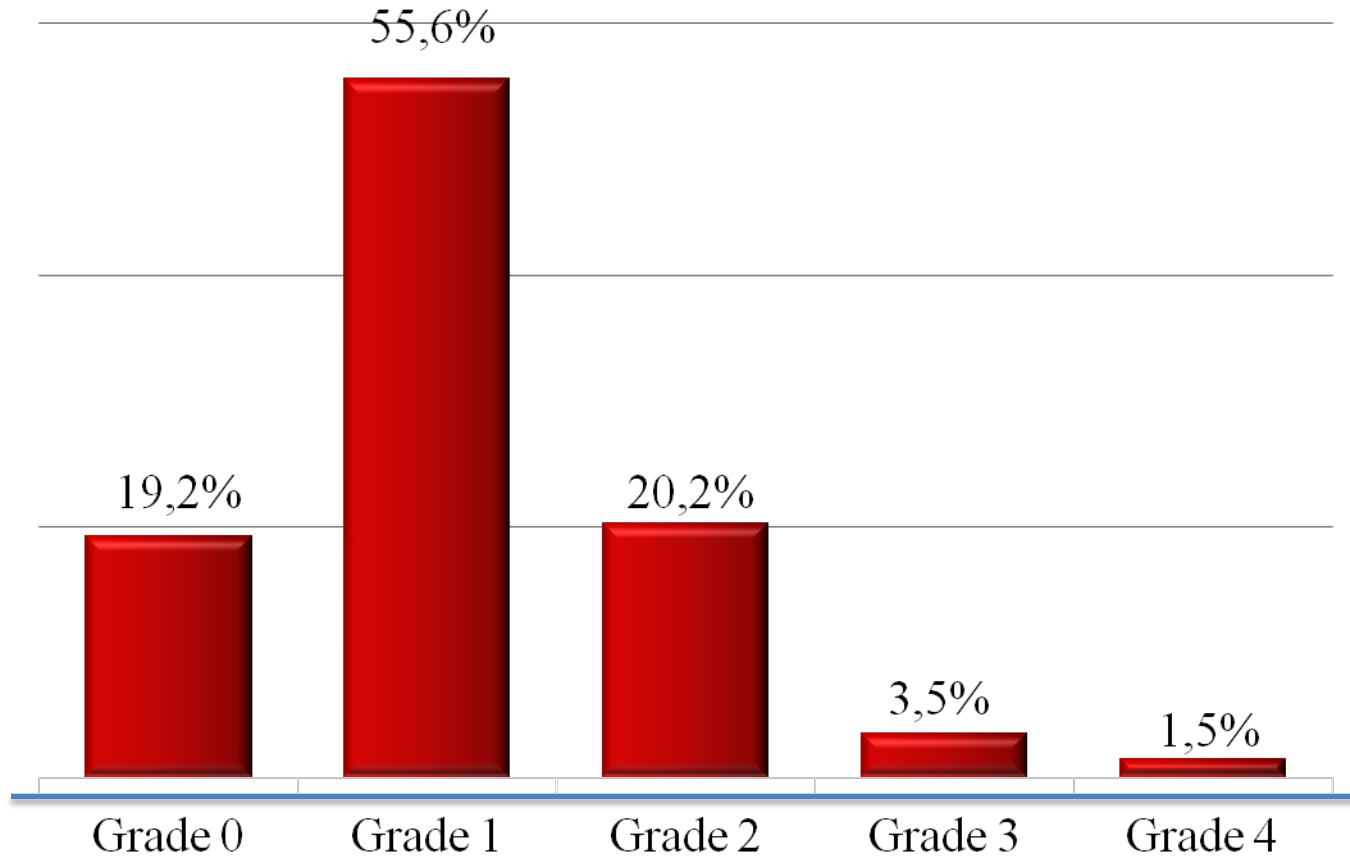
Procedure

N=1.170			
Vascular access:		Post-dilatation	18,5%
Femoral	95,0%		
Axillary/subclavian	4,9%		
Direct aortic	0,1%	Another aortic position	2,6%
Prosthesis size		Valve-in-valve	4%
26mm	54,1%		
29mm	44,7%		
31mm	0,9%		
No	0,3%		

Procedural Success



Post-procedure Aortic Regurgitation



Complications (VARC)

In-hospital Mortality 7,3%

Procedural complication (%)	29,7%	In-hospital complication (%)	44%
Conversion to surgery	0,6	Hemorrhage	9,2
Tamponade	1,6	TIA	1,2
Coronary obstruction	0,7	Stroke	
Cardiac arrest	2,6	Rankin < 2	0,3
Aortic annulus rupture	0,4	Rankin ≥ 2	1,0
Aortic dissection	0,2	Kidney Injury (RIFLE)	
MI	0,6	Stage 1	4,6
Vascular Access	9,8	Stage 2	2,3
Pseudoaneurysm	2,4%	Stage 3	2,6
		Pacemaker	24,7%

Complications (VARC)

In-hospital Mortality 7,3%

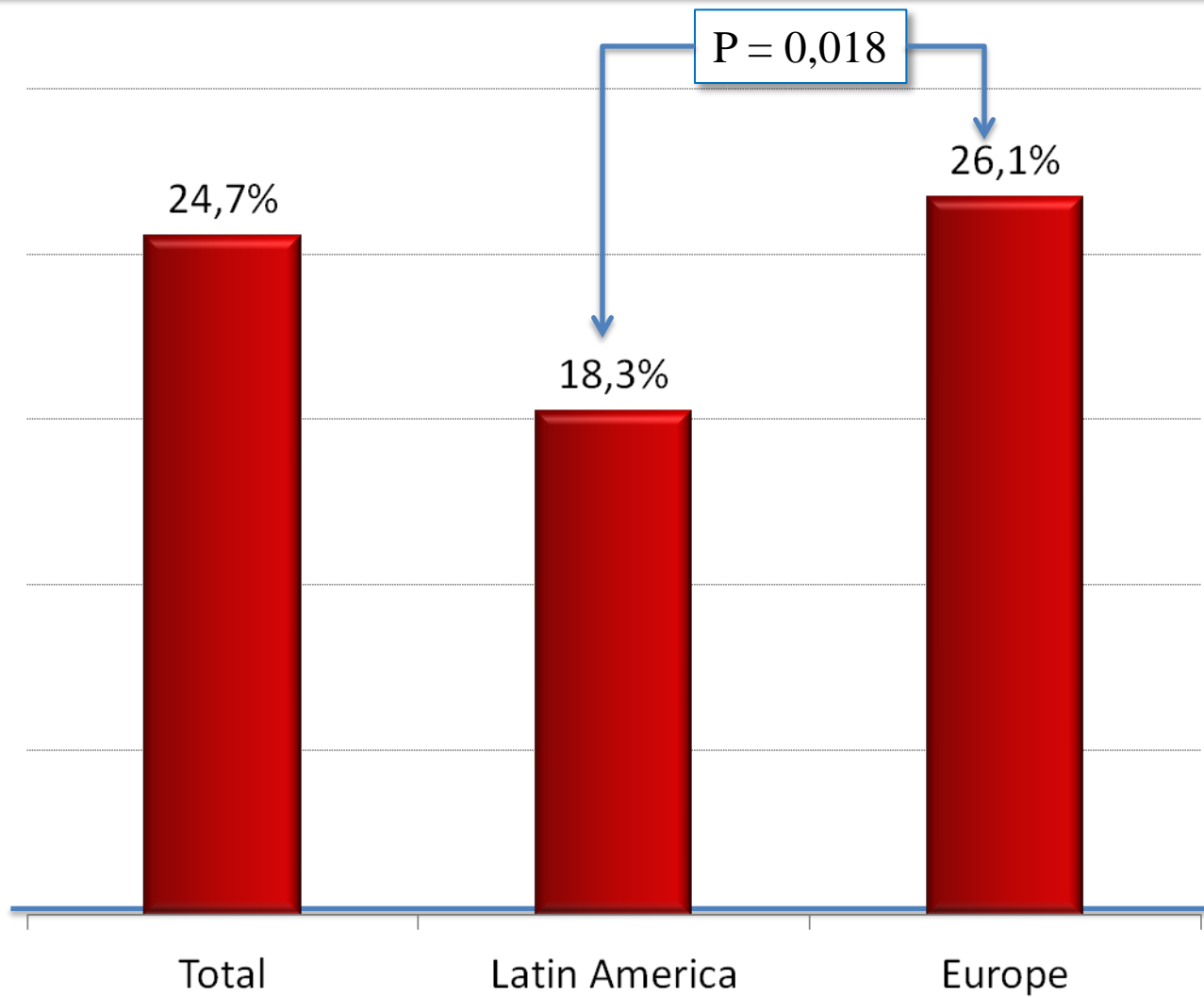
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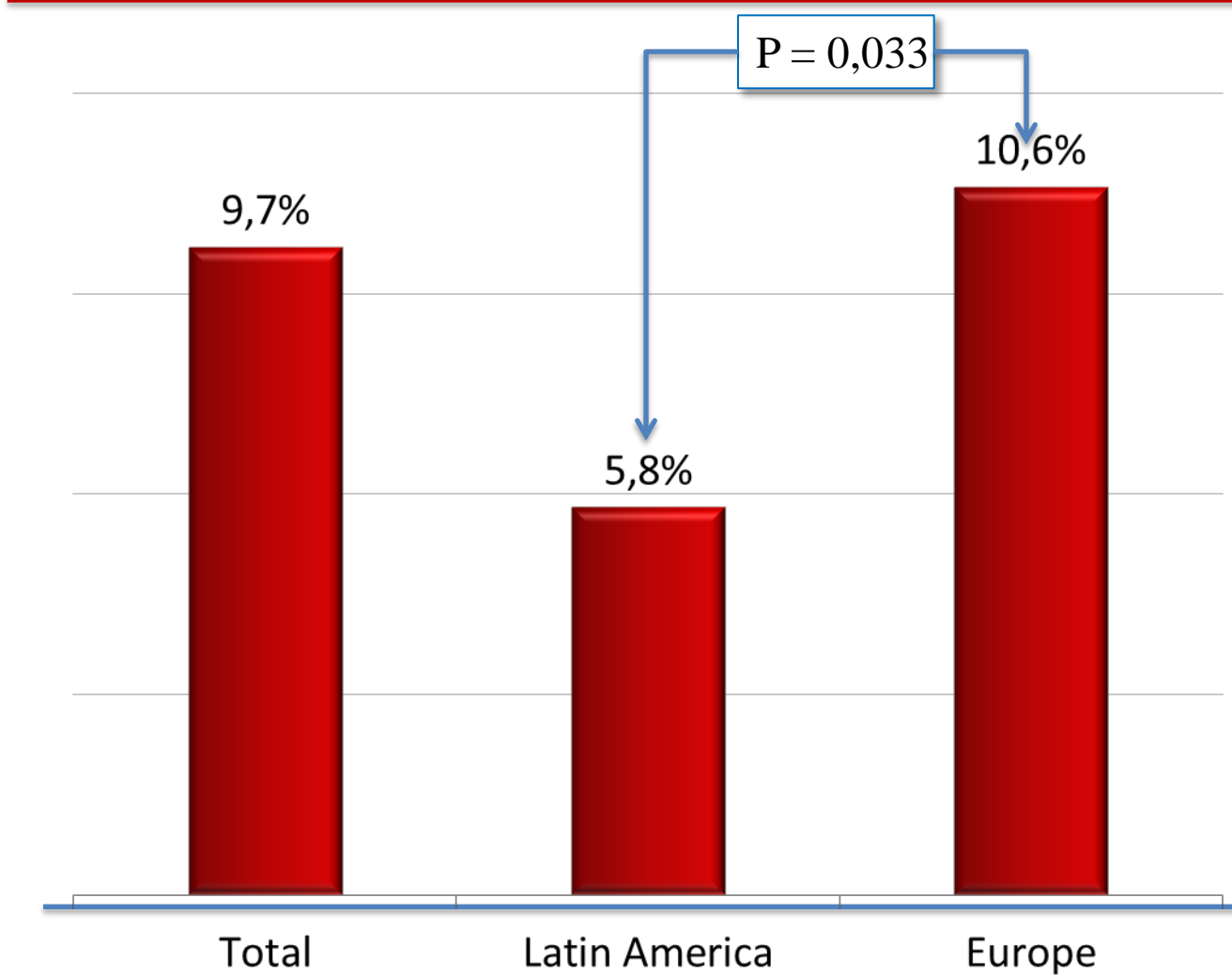
Permanent Pacemaker Implantation



In-hospital combined safety endpoint

Combined safety endpoint	85,8%
All-cause mortality	7,3%
Major stroke	1,0%
Major bleeding (Life-threatening or disabling)	4,1%
Acute Kidney Injury Stage 3	2,6%
Peri-procedural MI	0,6%
Major vascular complication	3,7%

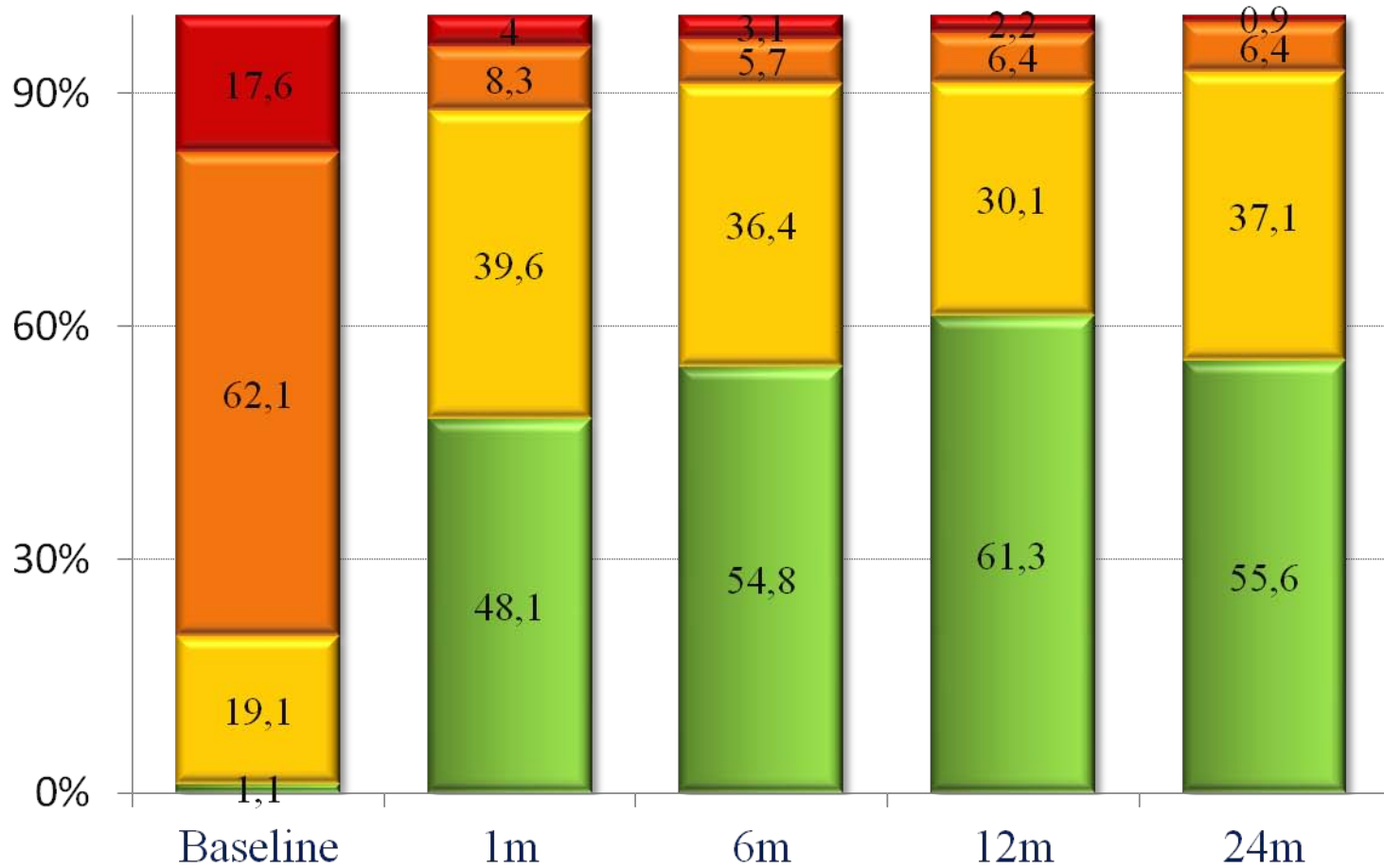
Vascular access complications



Device success

Successful vascular acces, delivery, deployment of device and retrieval of delivery system	1.143/1.170 (97,9%)
Correct position of device in the correct anatomic position	1.166/1.170 (99,6%)
Aortic valve gradient < 20mmHg	1.126/1.147 (98,16%)
No grade III-IV Aortic Regurgitation	1.128/1.170 (96,4%)
Only one valve implanted in the proper anatomic location	1.114/1.170 (95,2%)

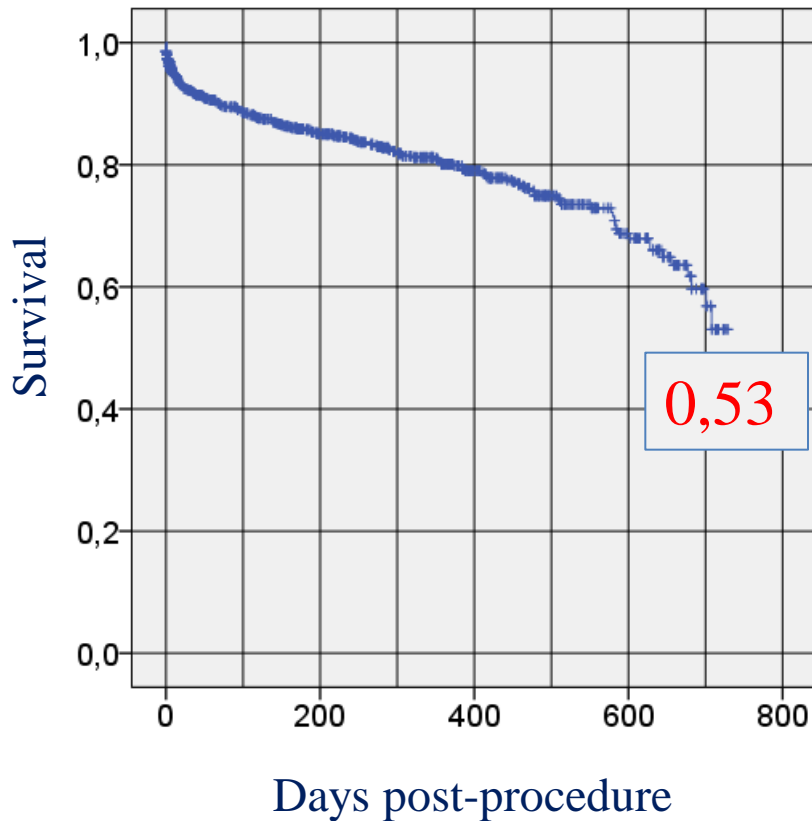
NYHA Class at F UP



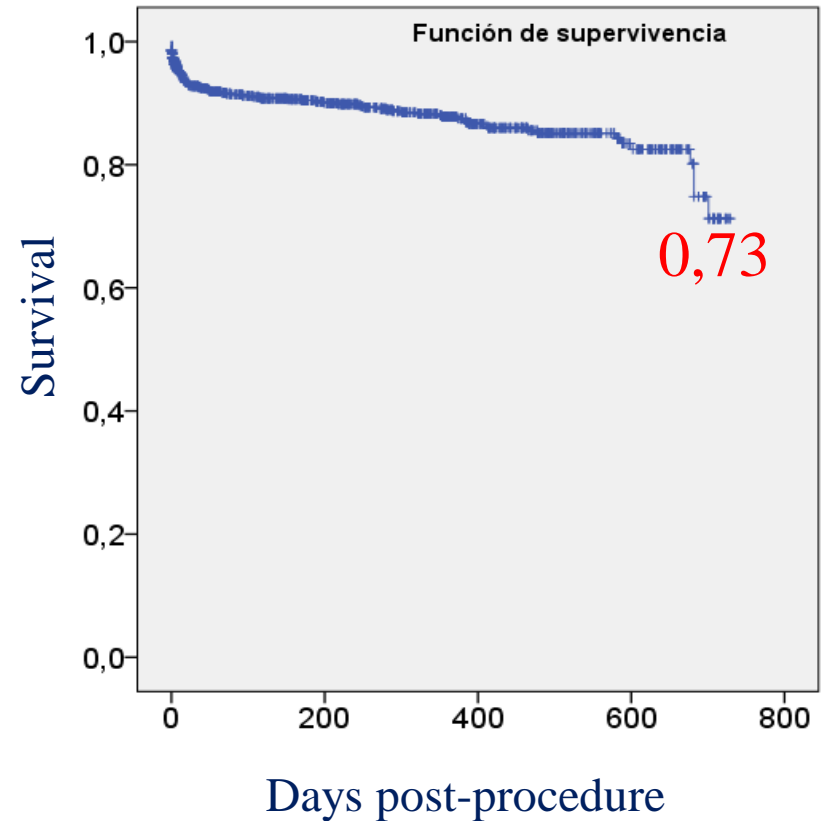
Mortality

Kaplan-Meier estimates of freedom from mortality

All causes



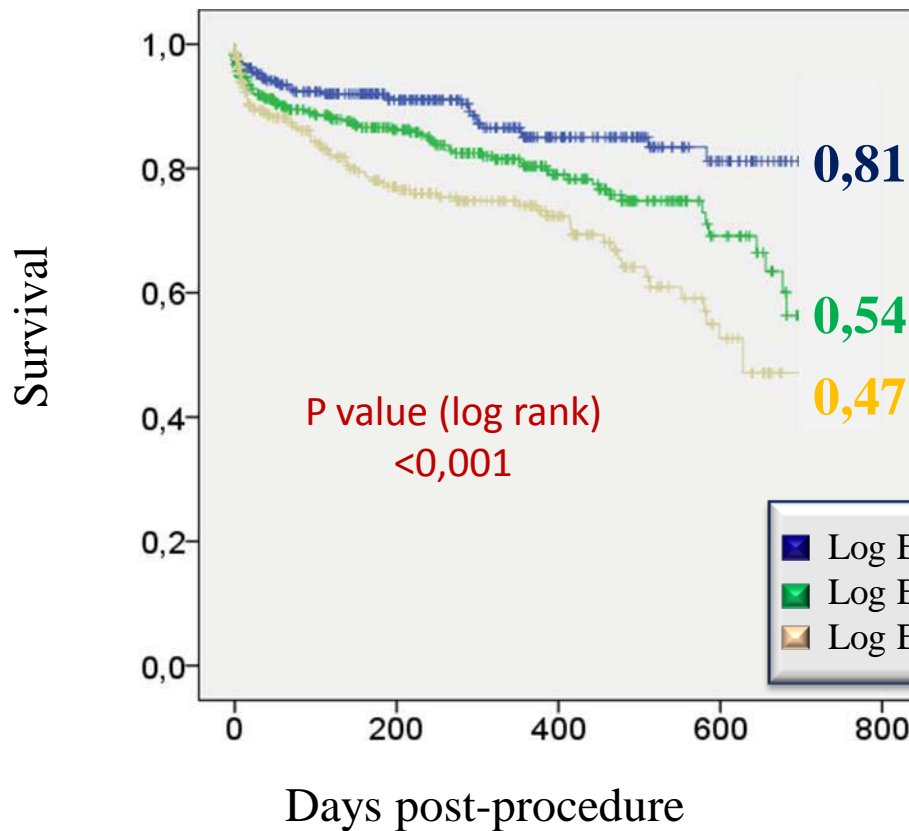
Cardiac



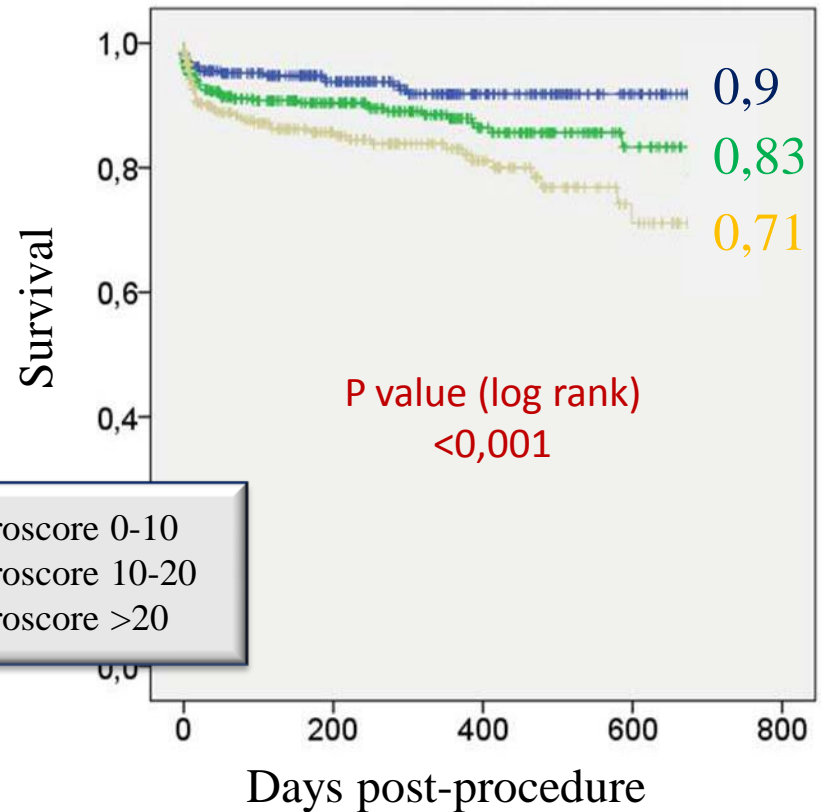
Mortality by Euroscore

Kaplan-Meier estimates of freedom from mortality

All causes



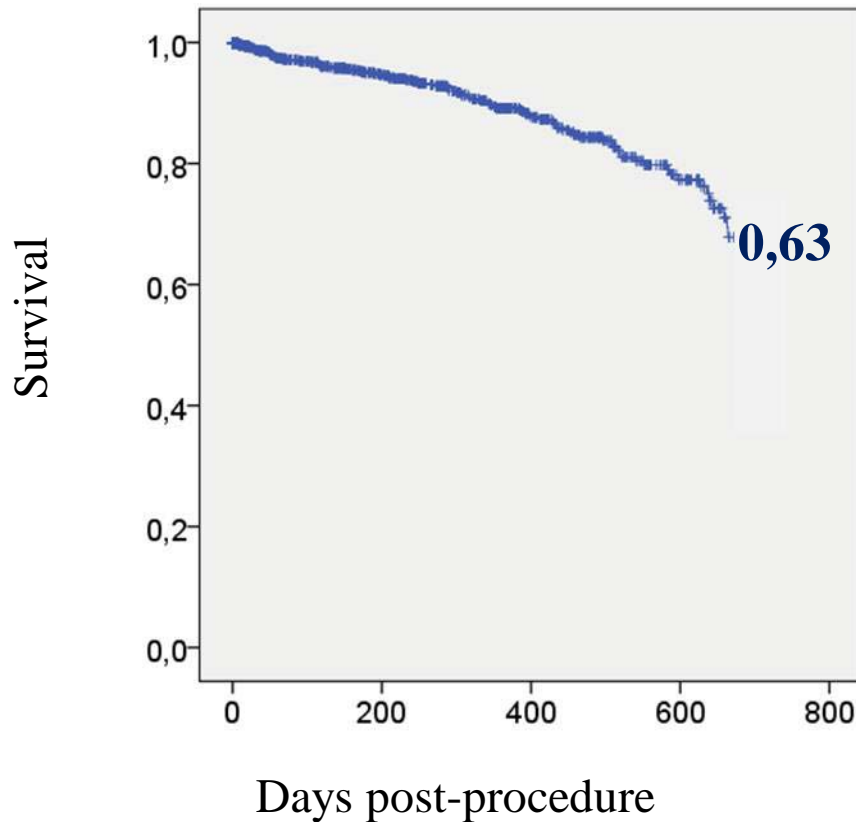
Cardiac



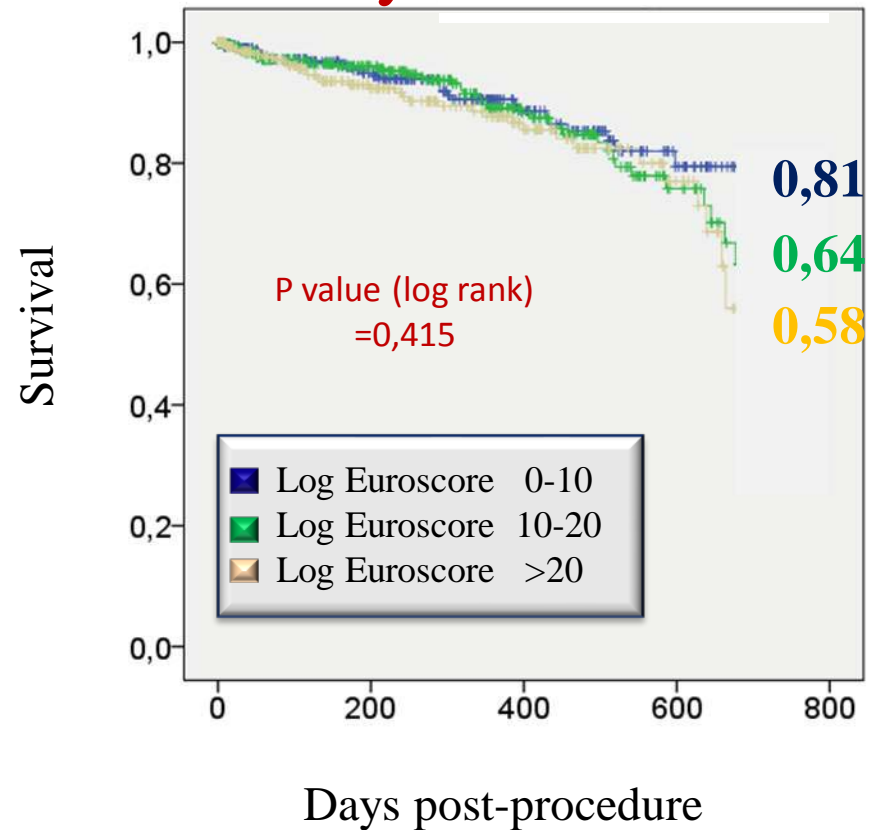
Hospital admission (cardiac causes)

Kaplan-Meier estimates of freedom from rehospitalization

Total



By Euroscore



- ✚ The Ibero American registry, has the important following limitations:
 - ✚ Initial patients data was collected retrospectively
 - ✚ Death and MACE were not adjudicated
 - ✚ Cerebrovascular events were not adjudicated by an independent neurologist

- ✚ The Ibero American registry, a large study shows that treatment of 'real world' inoperable and frail, high-risk patients with the Medtronic CoreValve is even during the learning curve in many centers:
 - ✚ Feasible
 - ✚ Safe
 - ✚ Associated with:
 - ✚ an improvement in aortic valve function
 - ✚ An improvement in functional status
 - ✚ low stroke and mortality rates at 1 month and follow-up

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Thank You
Ibero American Registry centers and
specias thanks to
Dra. del Valle
for her cooperation in the elaboration
of this results

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