Implante Transcatéter Valvular Aórtico (TAVI):

Podremos Ampliar las Indicaciones?

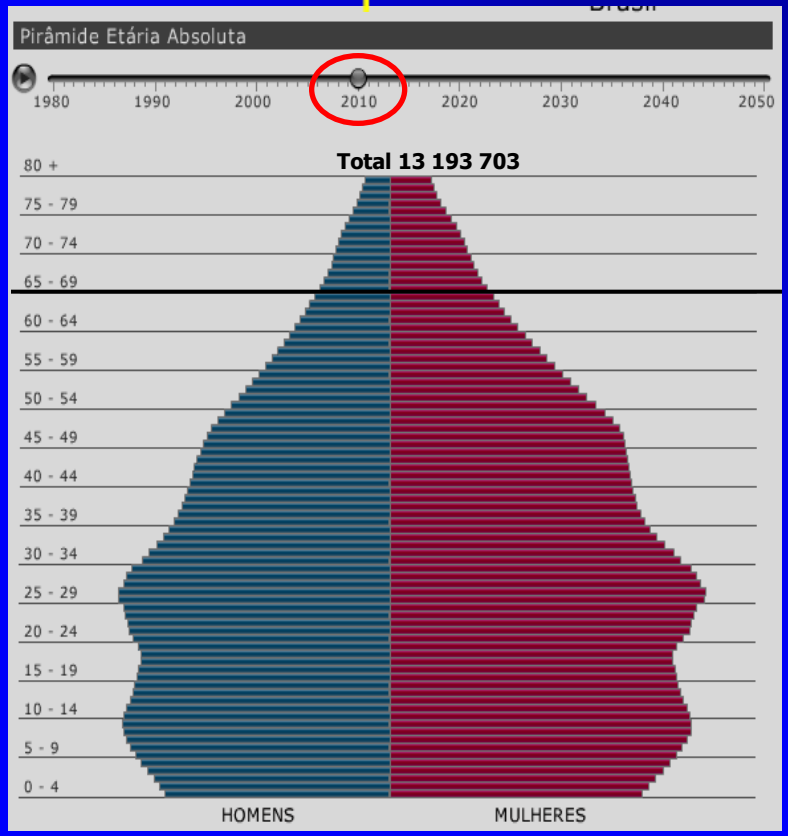
SOCIEDAD LATINOAMERICANA DE CARDIOLOGIA INTERVENCIONISTA

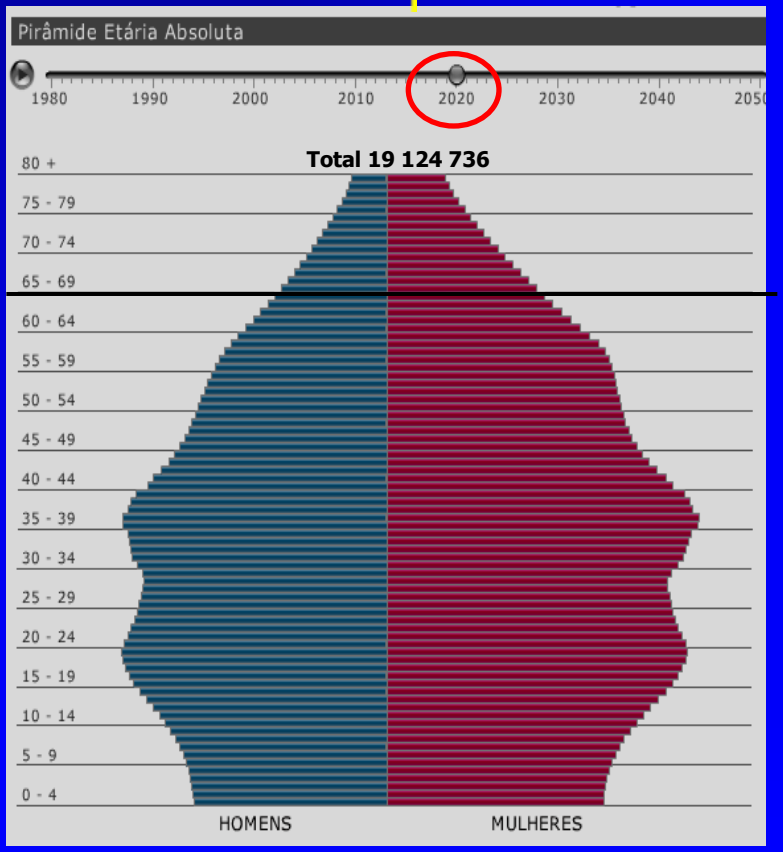
SOLACI

População Anciana > 65 años

Demográfia

+ 44%





Dados IBGE/2008 – www.ibge.gov.br

Implante Valvar Aórtico
Prótesis Edwards Sapien

2005 – Percutaneous Valve Technologies → Edwards Lifesciences

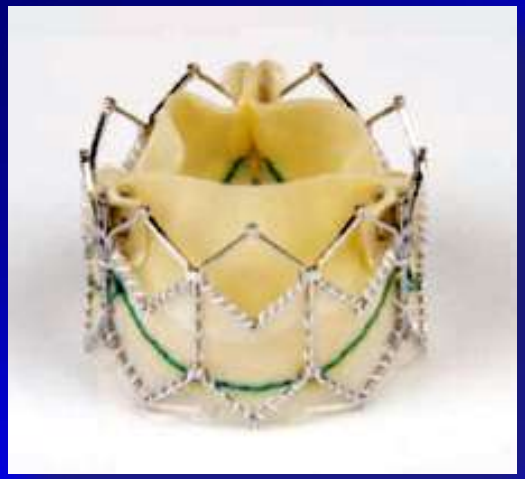
Equine Pericardial Valve

Single size 23mm

Edwards Sapien THV
Acero Inoxidable
Pericardio Bovino

23 e 26 mm
Introductor 22 F e 24 F

Edwards Sapien XT
Cromo Cobalto
Pericardio Bovino



20/23/26/29 mm
Introductor 18 F

Edwards Sapien 3
Cromo Cobalto
Pericardio Bovino

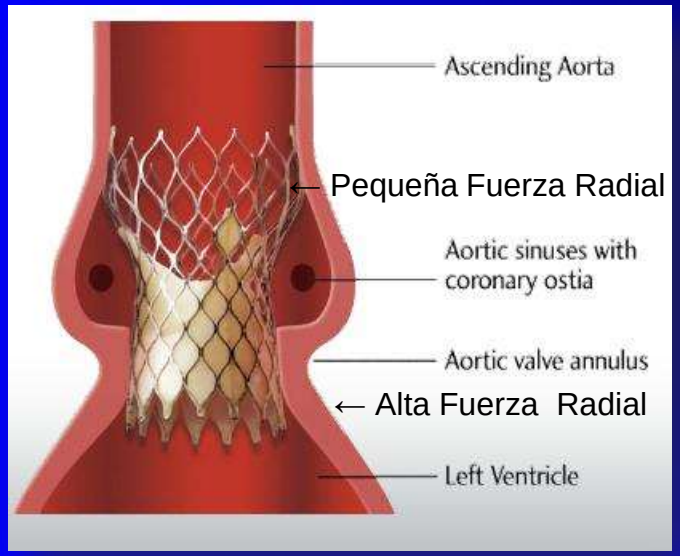
Tereftalato de Polietileno - PET

23/26/29 mm
Introdutor 14 - 16 F

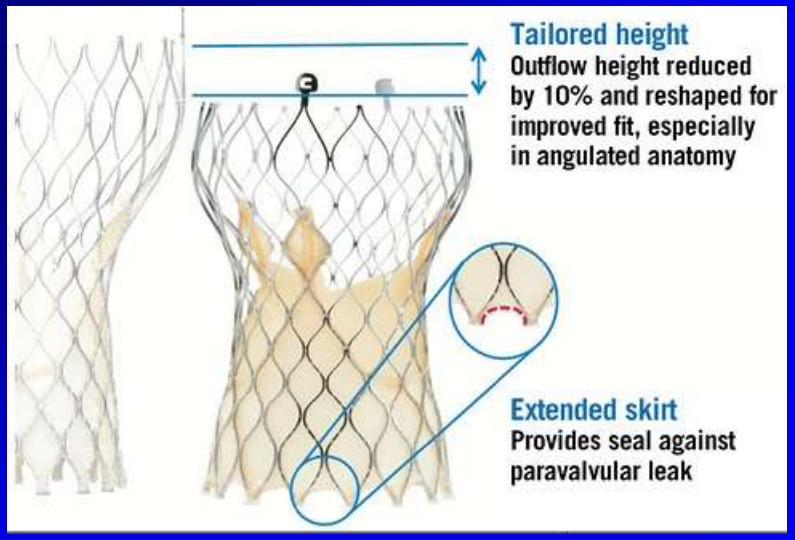
CoreValve ReValving System

Características

- **Stent Autoexpansível de Nitinol - Folletos de Pericardio Porcino**
- **Tamaños - 26, 29 e 31 mm - Introductor 18 F**



Core Valve Evolut R



- **Permite la recaptura y reposicionamiento**
- **Tecnología TrueFit - Mayor adaptación en anatomías mas anguladas**

Mejor coaptación en el anillo valvar non circular

- **AOT – Tratamiento antimineralizante → ↓ calcificación precoz y tardía**

Implante Transcateter CoreValve

Resultados del Procedimiento

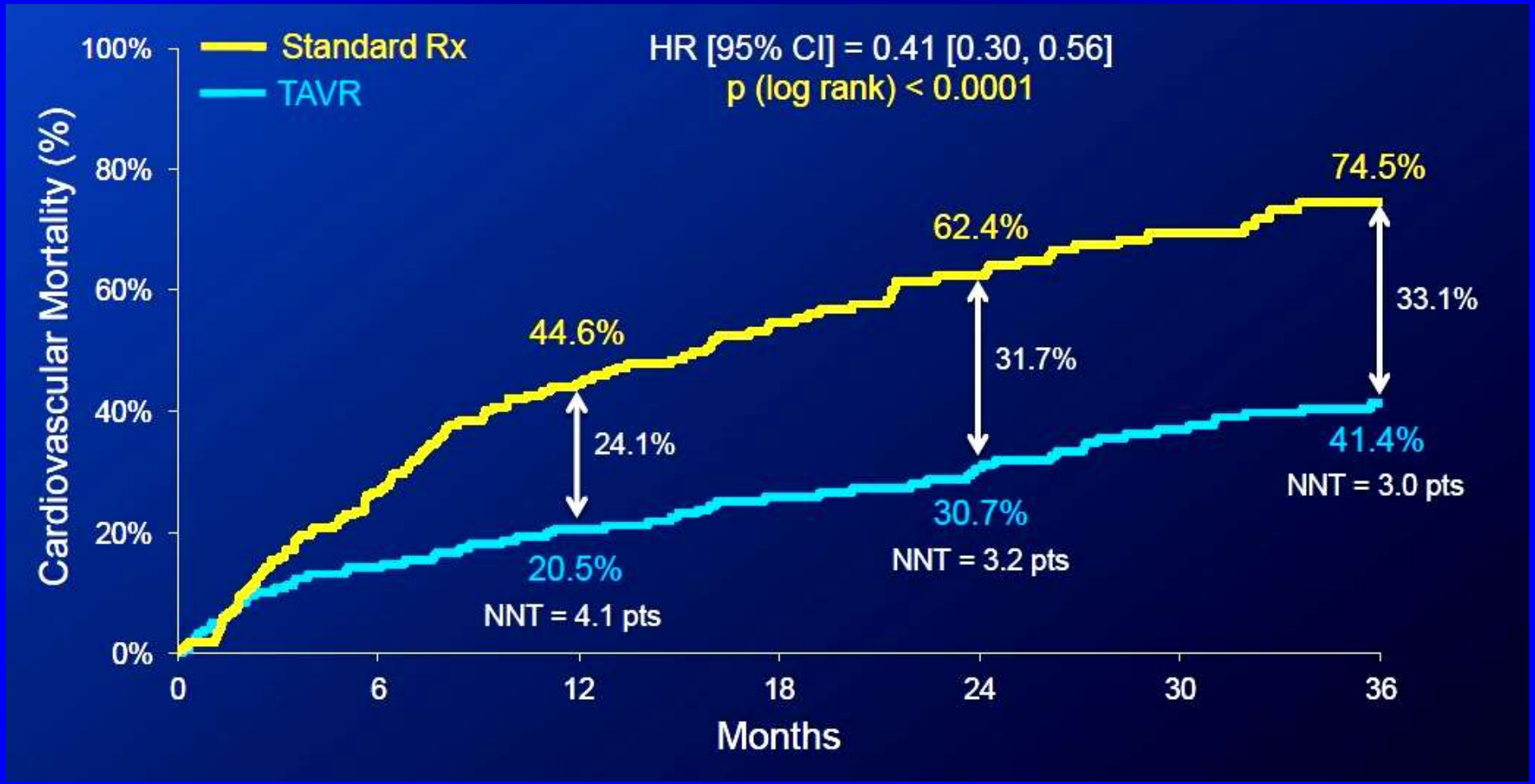
	25 F n = 10	21 F n = 24	18 F n = 102
Artéria Ilíaca Artéria Subclávia Artéria Femoral	10 (100%) 0 0	0 2 (8,3%) 22 (91,7%)	0 1 (1%) 100 (99%)*
Éxito do Procedimiento	7 (70%)	19 (70,8%)	101 (91,2%)*
Muerte	1 (10%)	2 (8,3%)	0*
AVC	1 (10%)	1 (4,2%)	3 (2,9%)
IAM	0	1 (4,2%)	1 (1%)
ECCAM	2 (20%)	4 (16,7%)	4 (3,9%)**
Taponamiento Cardíaco	0	0	2 (2%)
Marca – Passo Definitivo	1 (10%)	3 (13,6%)	30 (33,3%)

* p =0,003 ** p = 0,008

Grube E. Circulation Cardiovasc Interv 2008;1:167-175

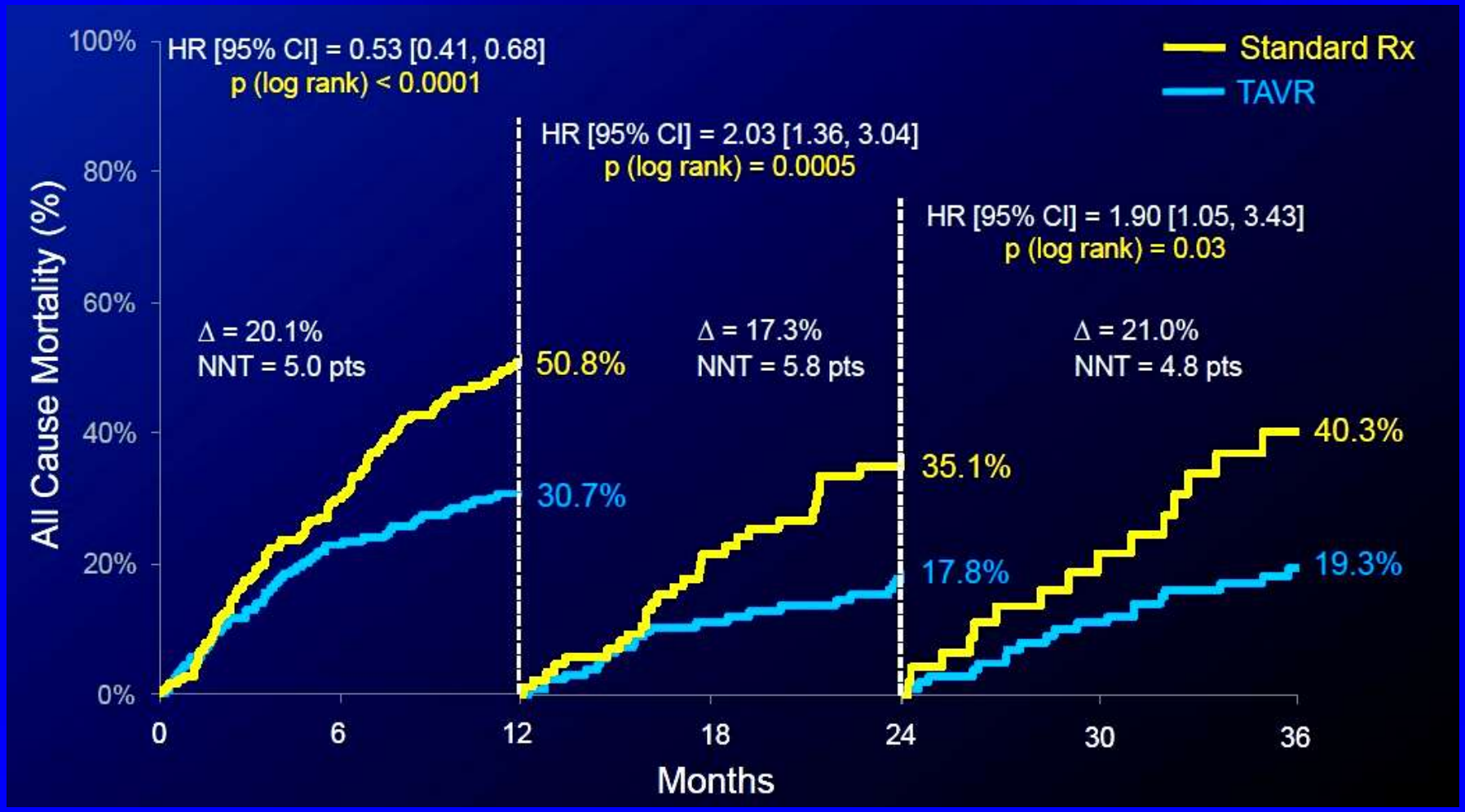
PARTNER TRIAL B

Mortalidad CV



Kapadia S.R. TCT/2012

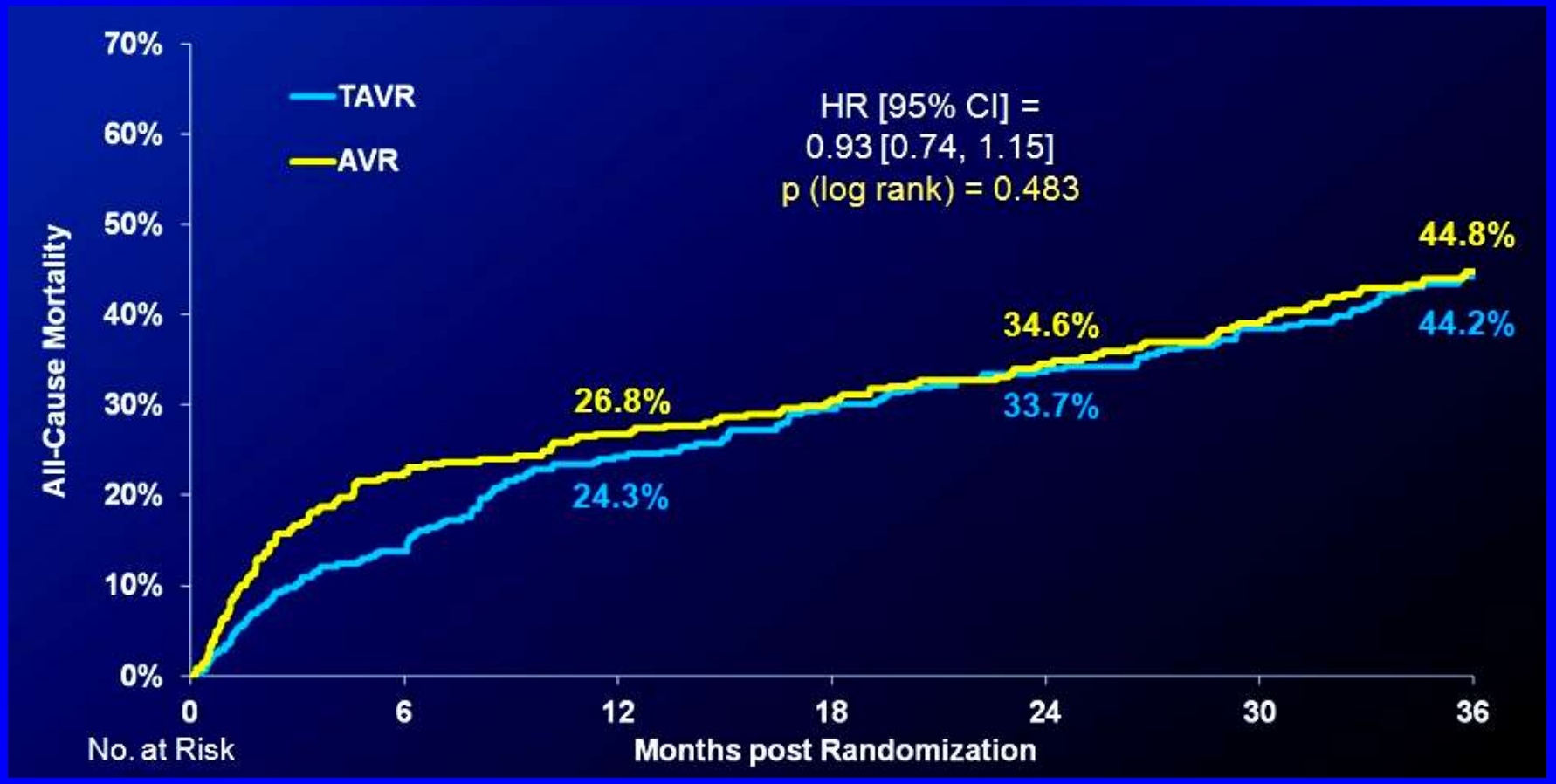
PARTNER TRIAL B
Landmark Analysis



Kapadia S.R. TCT/2012

PARTNER TRIAL A

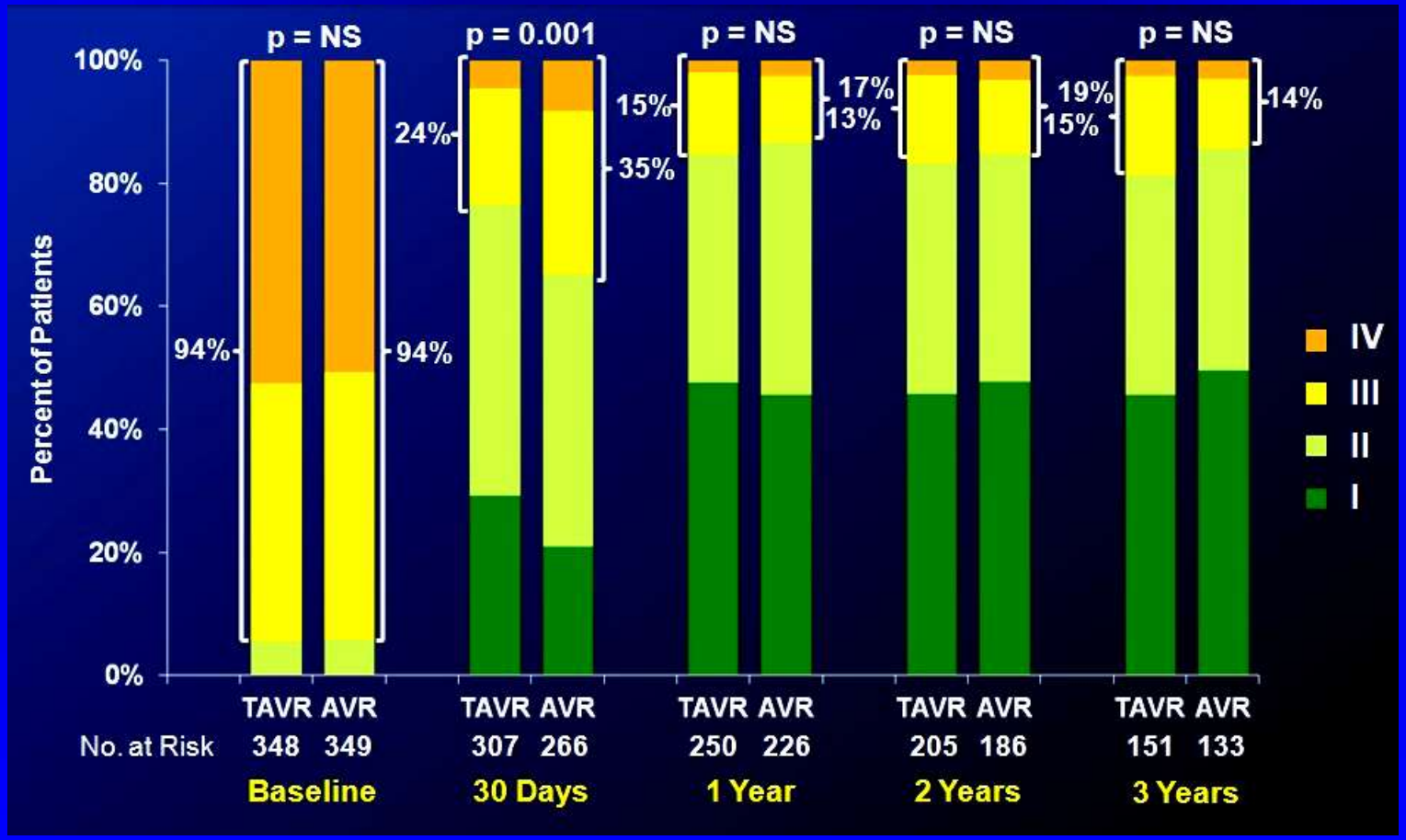
Mortalidad Total - 3 años



Thourani V. ACC/2013

PARTNER TRIAL A

Clase Funcional (NYHA) - 3 años

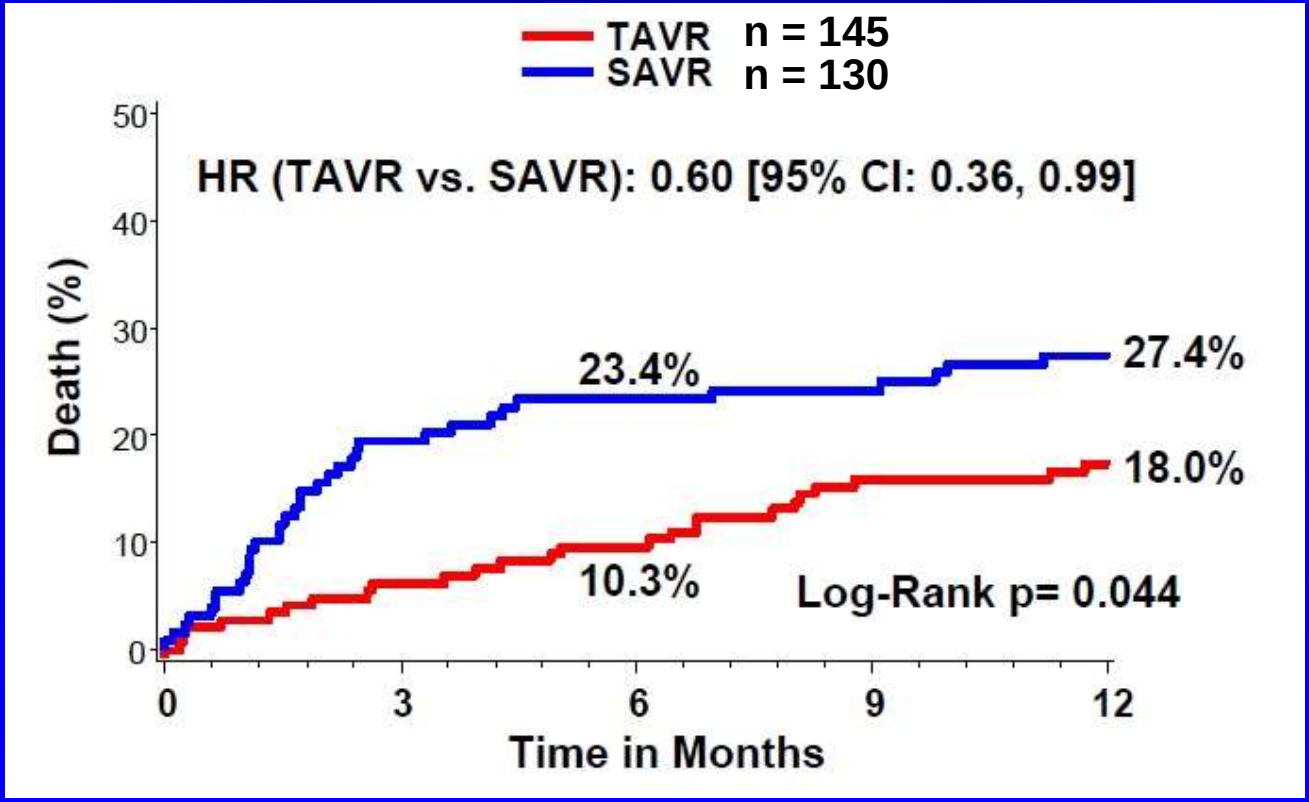


Thourani V. ACC/2013

PARTNER TRIAL A

Diabetes Mellitus

n = 275

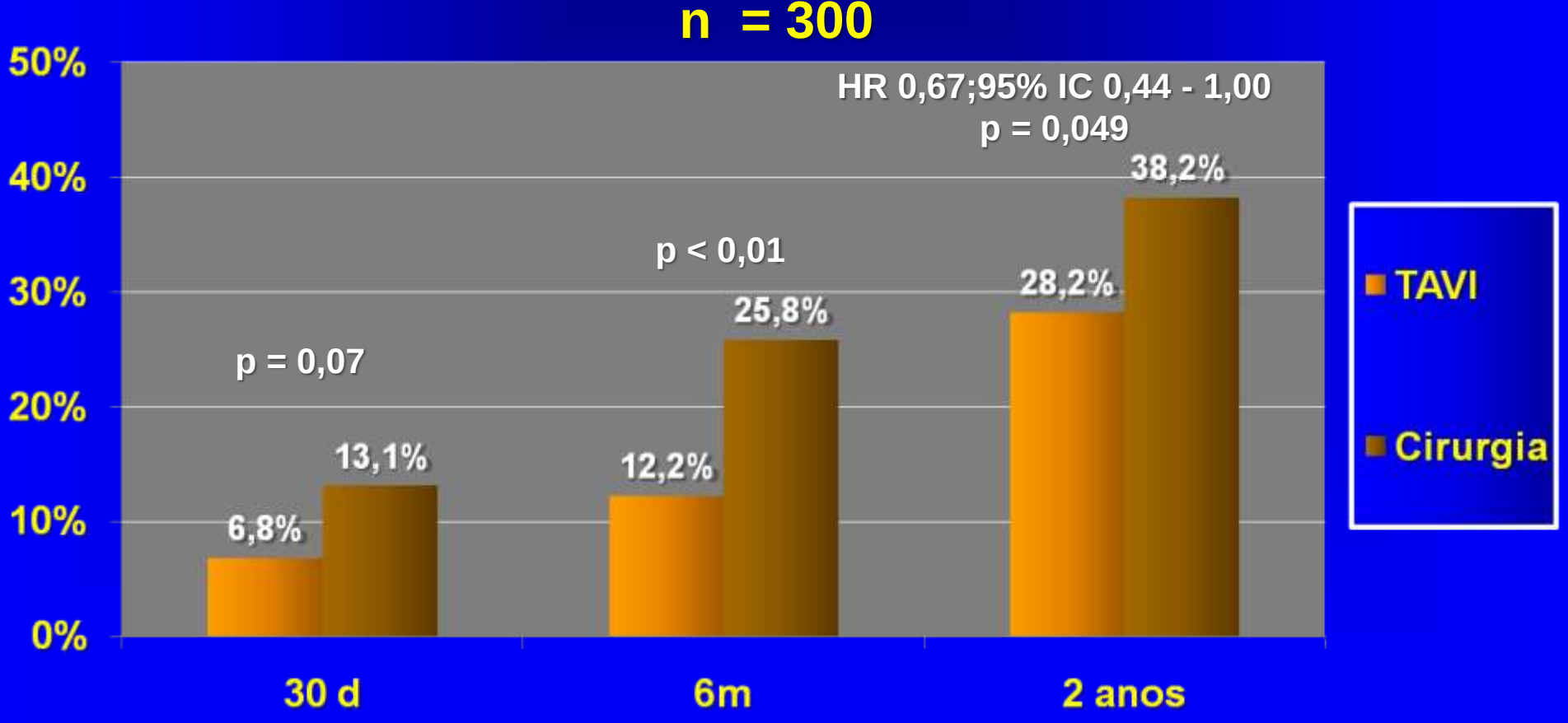


interaction p = 0,048

Lindman B.R. J Am Coll Cardiol 2014;63:1090-99

PARTNER TRIAL A

Mortalidad Total - Sexo Femenino

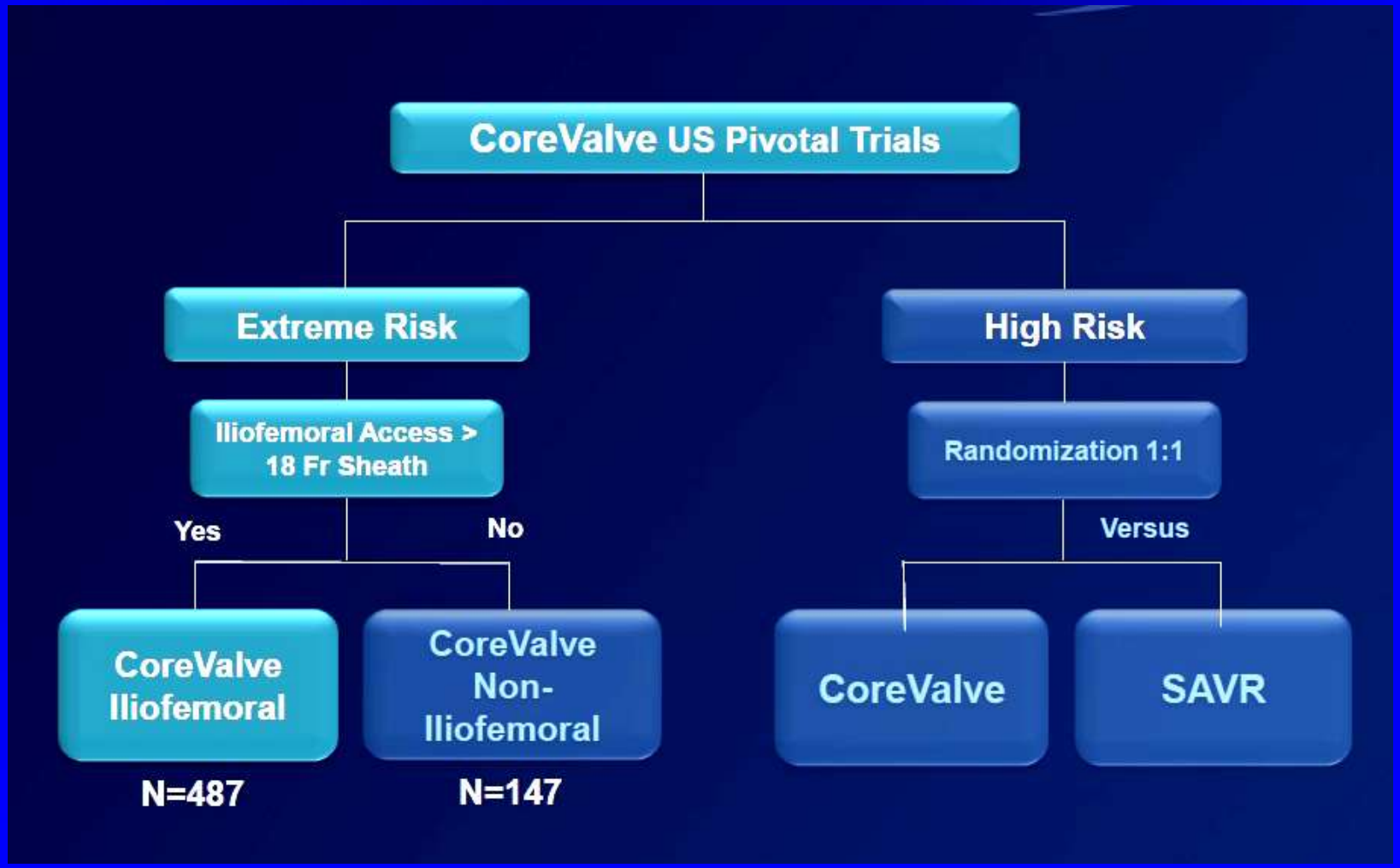


Via Transfemoral – HR 0,55;95% IC 0,32 – 0,93; p = 0,02

Williams M. J Am Coll Cardiol 2014;63:1522-28

CoreValve Pivotal US Trials

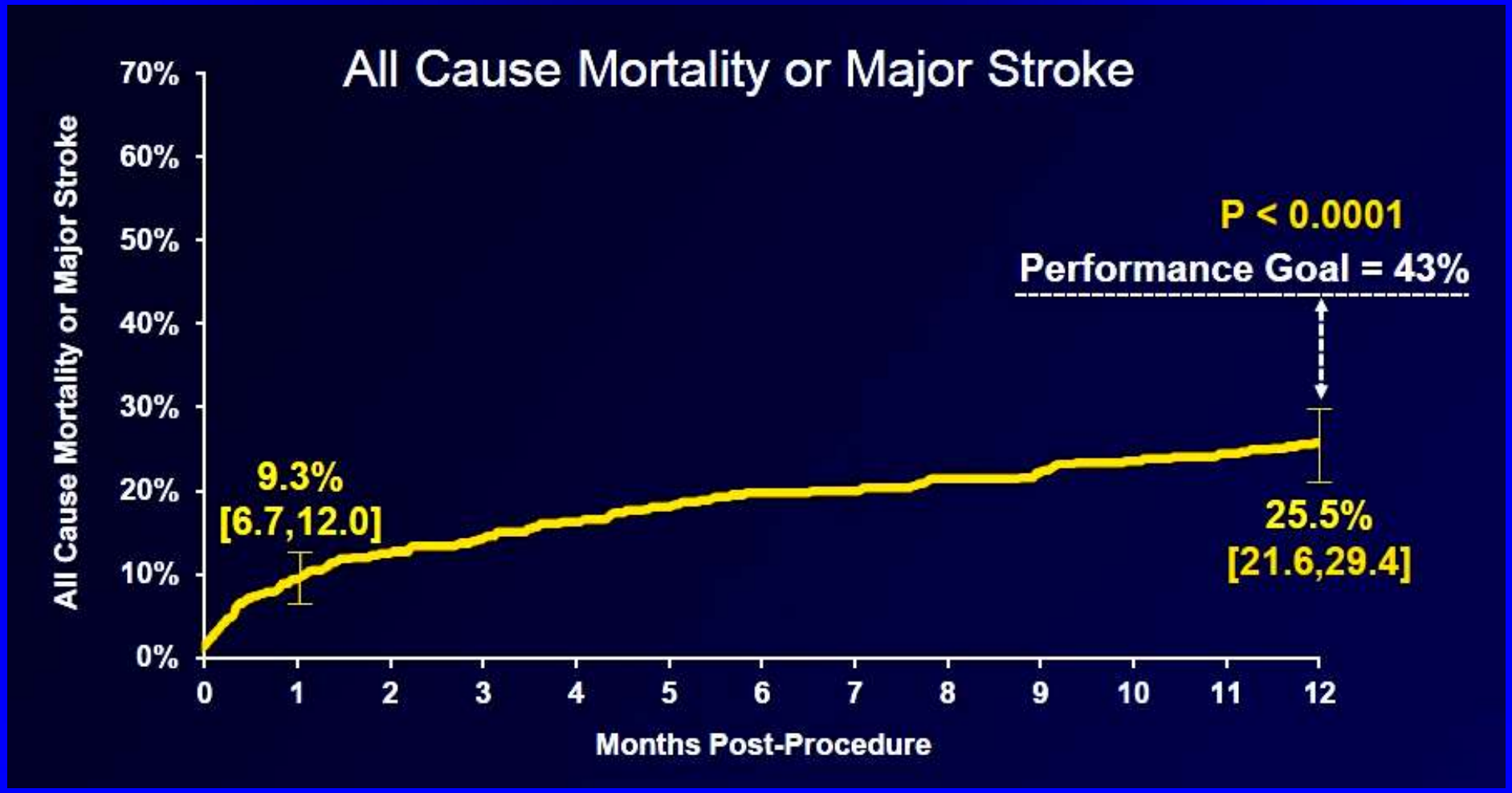
Diseño del Estudio



Popma J. J Am Coll Cardiol 2014;63:1972-1981

CoreValve Pivotal US Trials

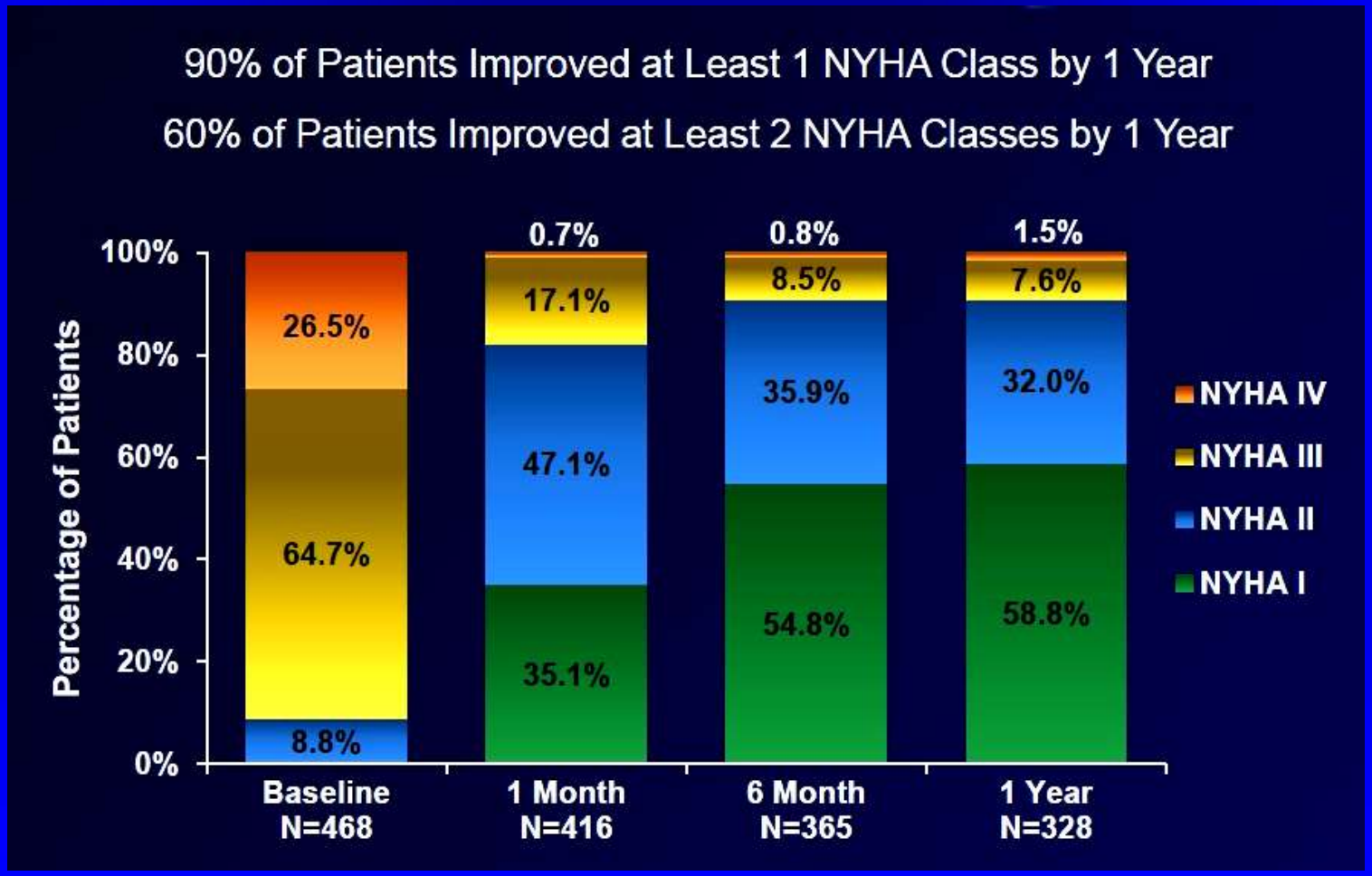
Endpoint Primario



Popma J. J Am Coll Cardiol 2014;63:1972-1981

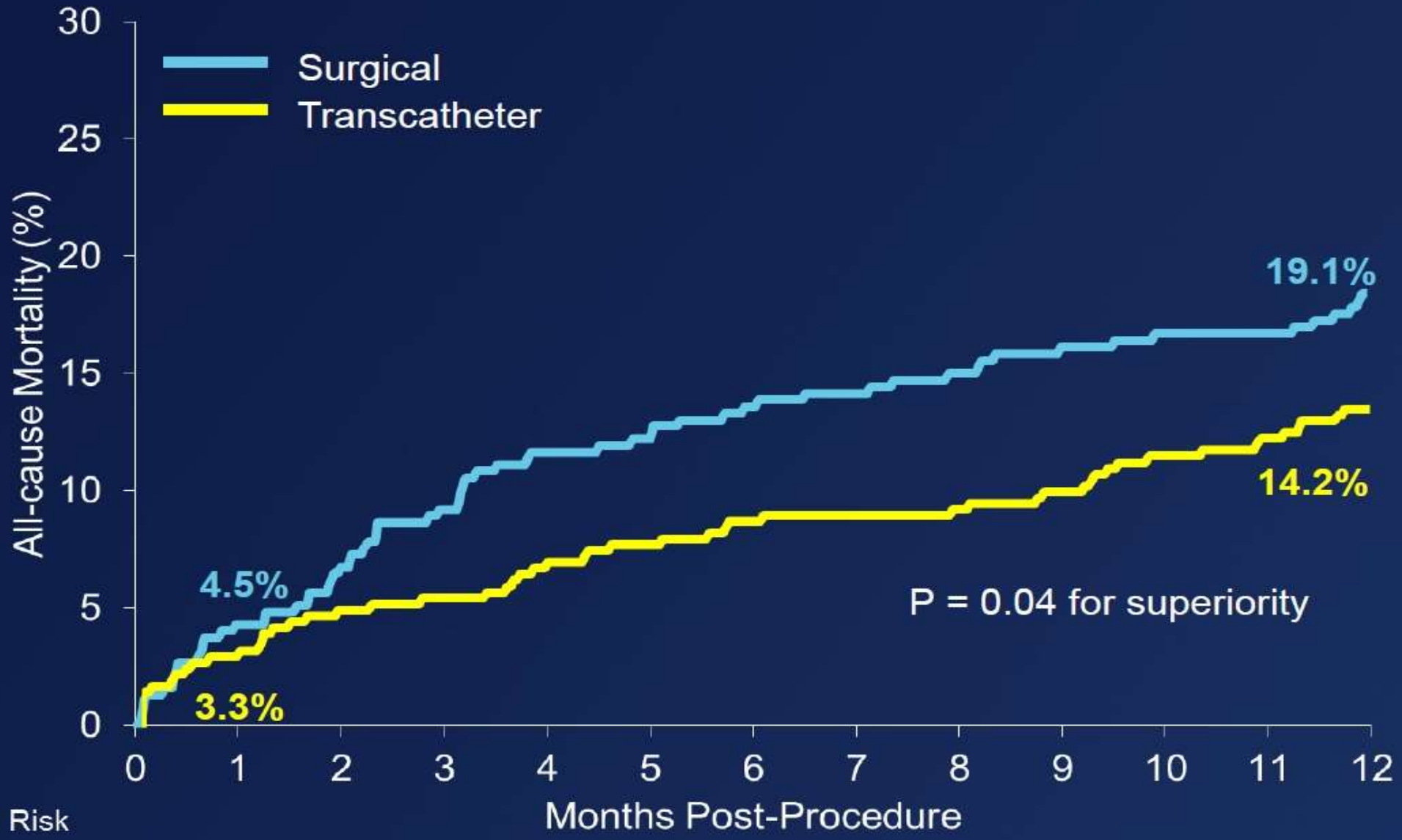
CoreValve Pivotal US Trials

Clase Funcional - NYHA



Popma J. J Am Coll Cardiol 2014;63:1972-1981

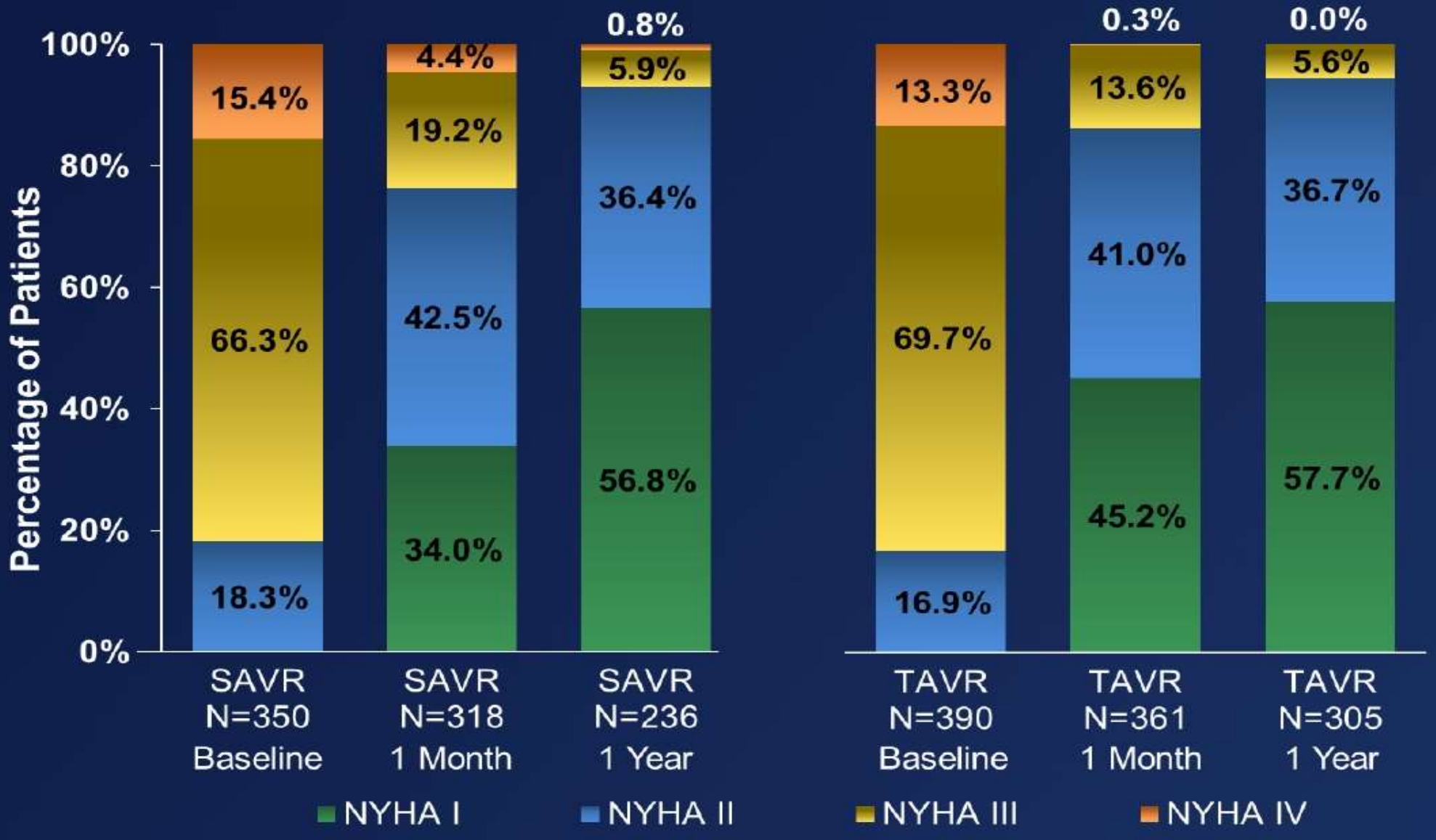
Primary Endpoint: 1 Year All-cause Mortality



No. at Risk													
Surgical	357	341				297							274
Transcatheter	390	377				353							329

Adams D.H. N Engl J Med 2014;370:1790-98

NYHA Class Survivors

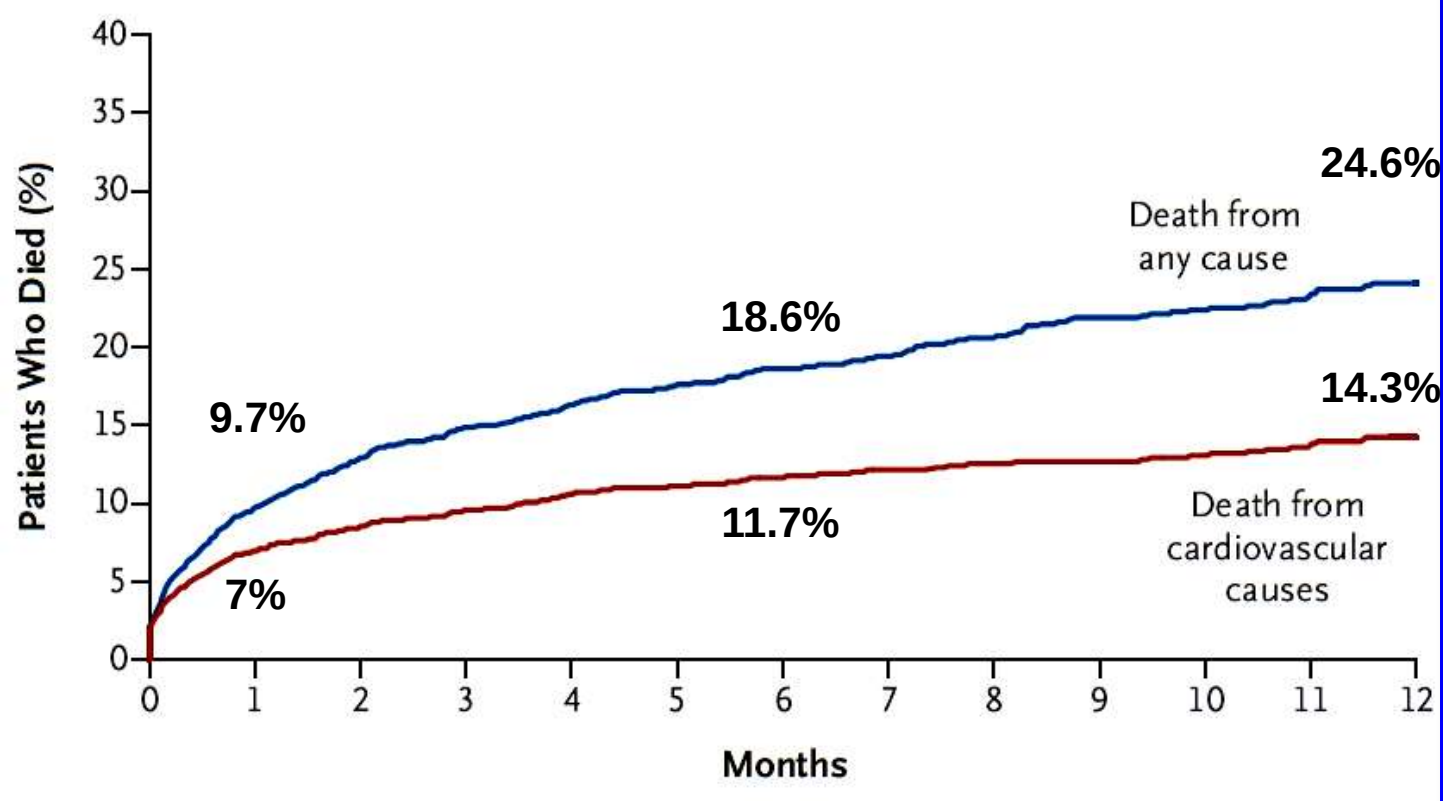


French Registry 2

Mortalidad - 1 año

Enero/2010 - Octubre/2011 35 centros n = 3.195

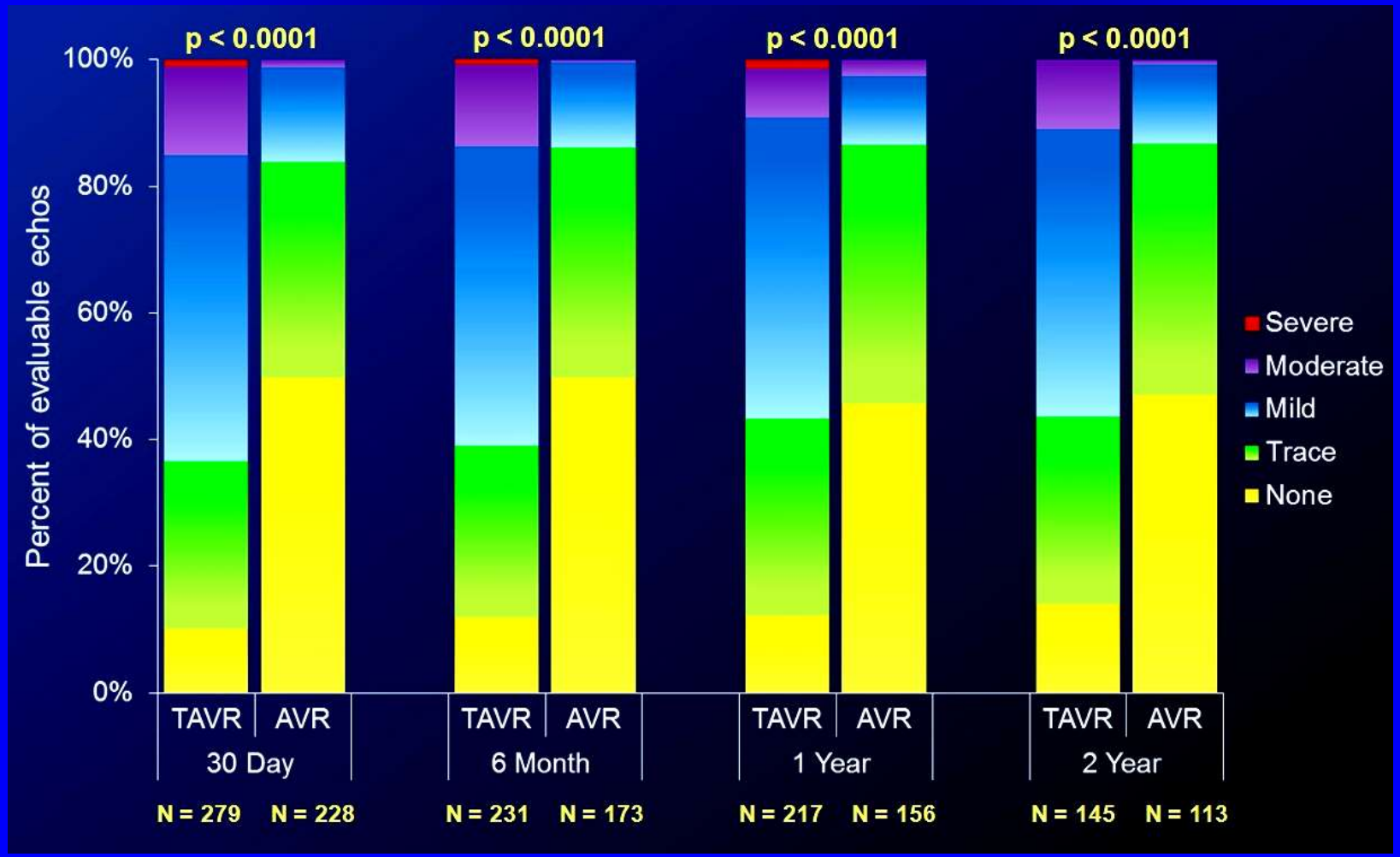
Euroscore Logístico – 21,9 ± 14,3% STS Score – 14,4 ± 12%



Gilard M. N Engl J Med 2012;366:1705-15

PARTNER TRIAL A

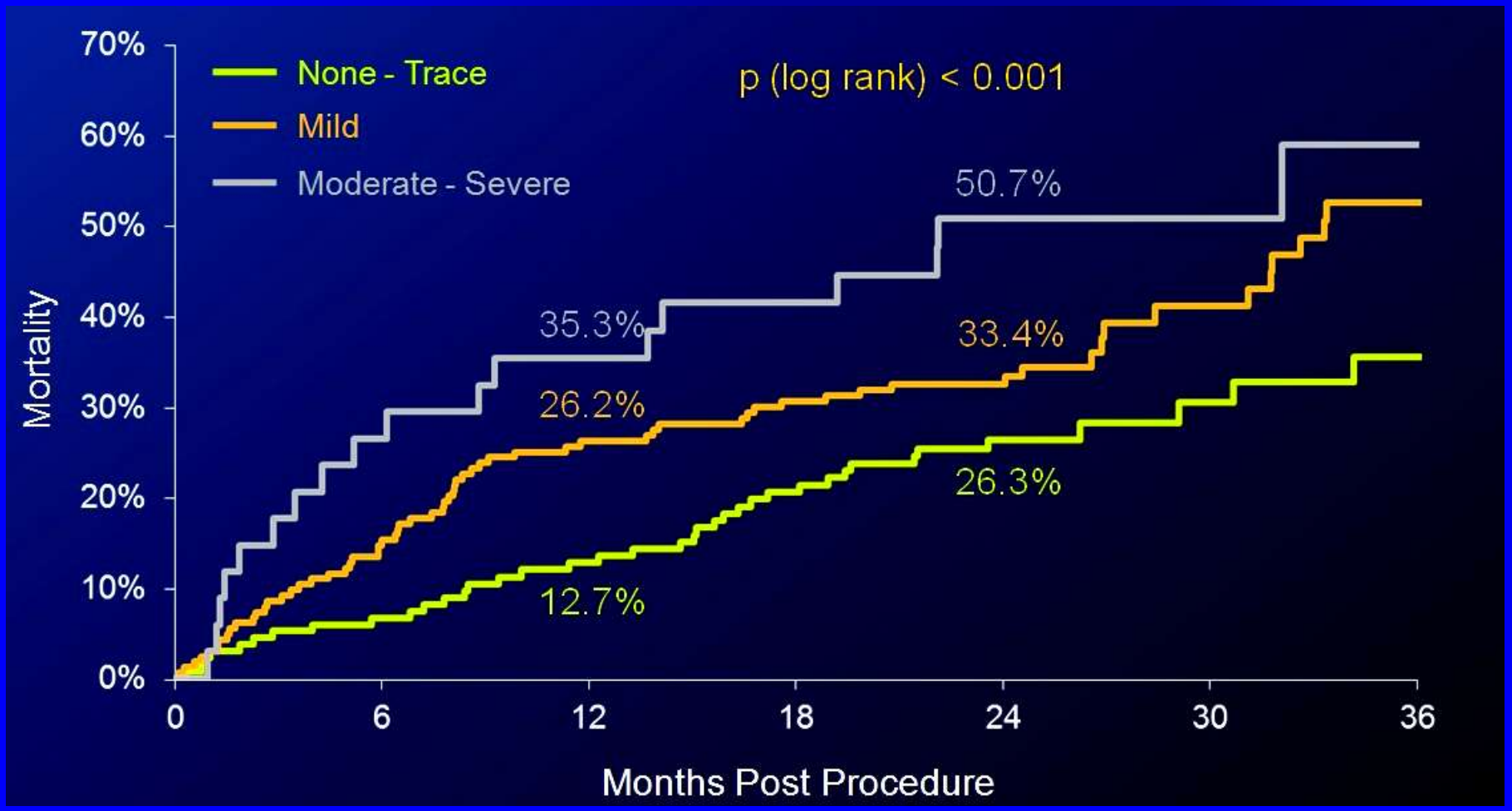
Grado de Insuficiencia Aórtica



Kodali SK. N Engl J Med 2012;366:1686-95

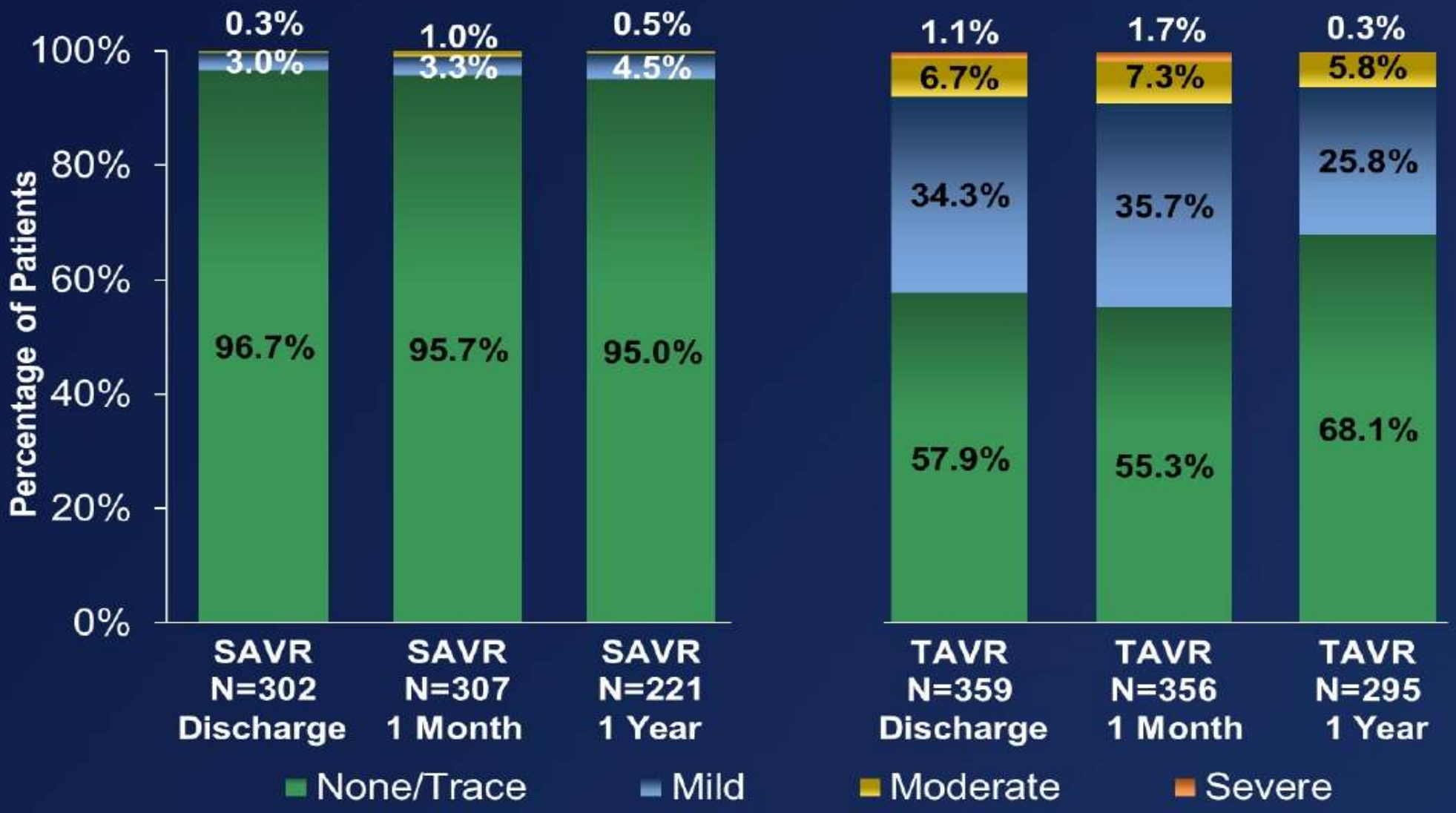
PARTNER TRIAL A

Regurgitación Aórtica vs Mortalidad (TAVR)



Kodali SK. N Engl J Med 2012;366:1686-95

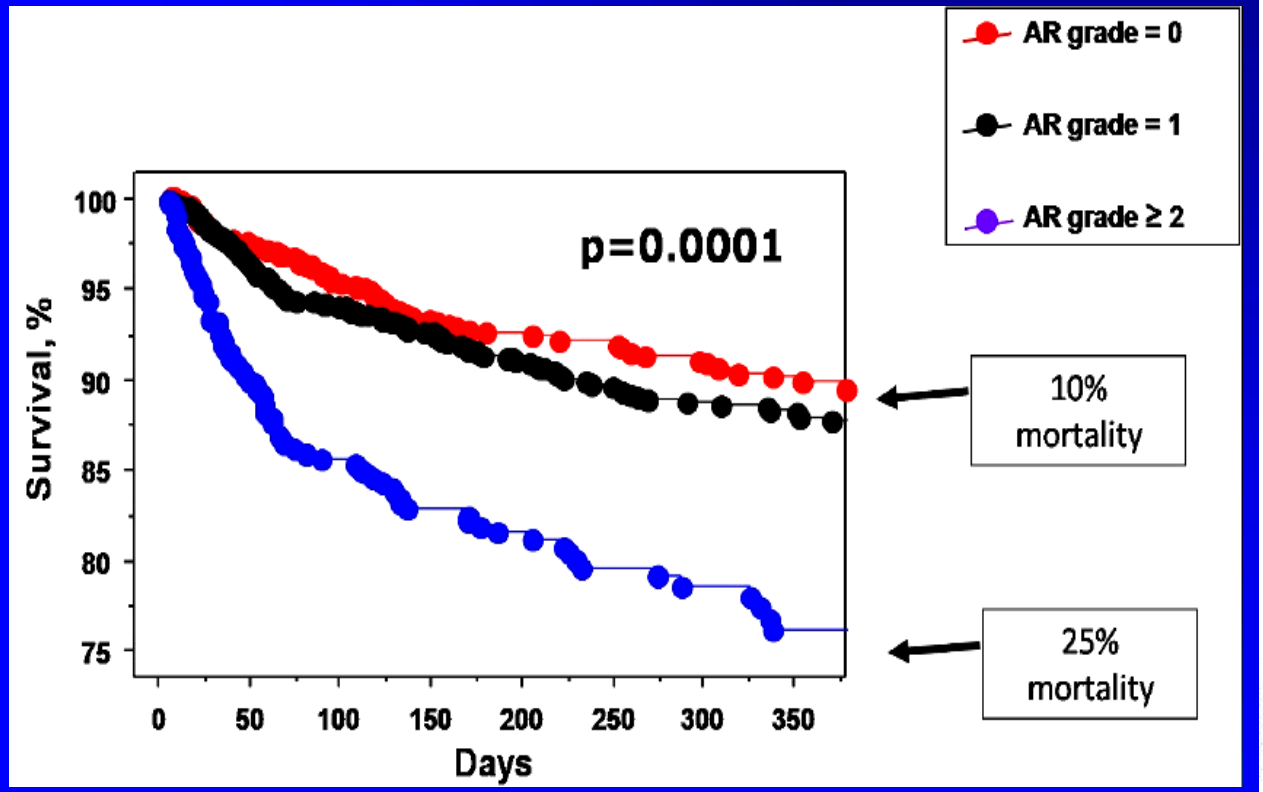
Paravalvular Regurgitation

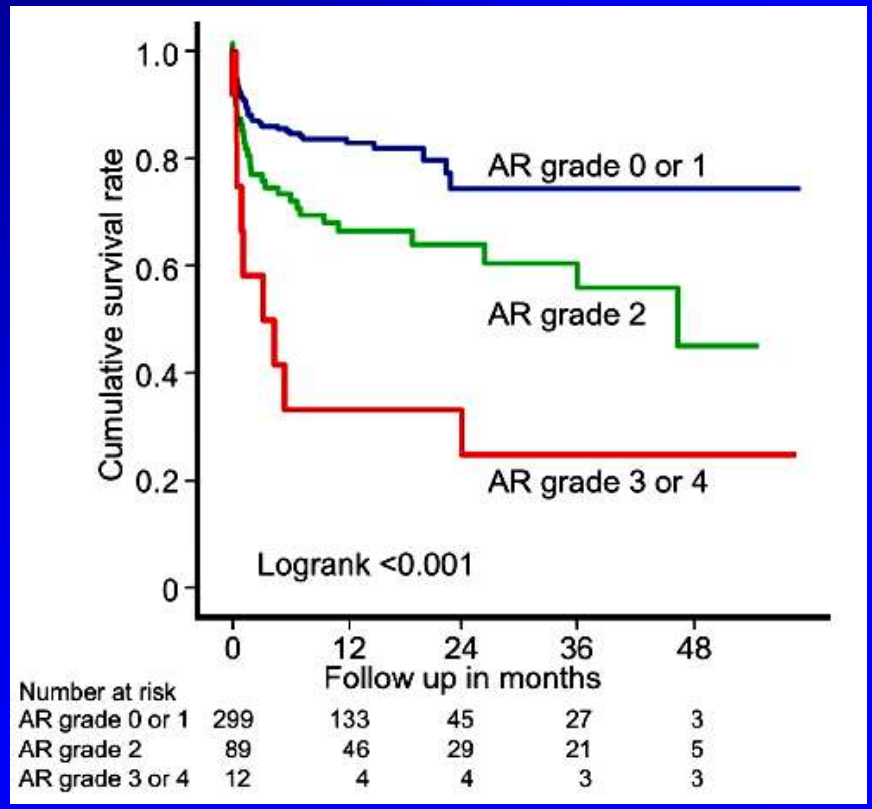


There was significantly lower PVL with SAVR over TAVR at each time point (P<0.001)

TAVI

Regurgitación Aórtica vs Mortalidad



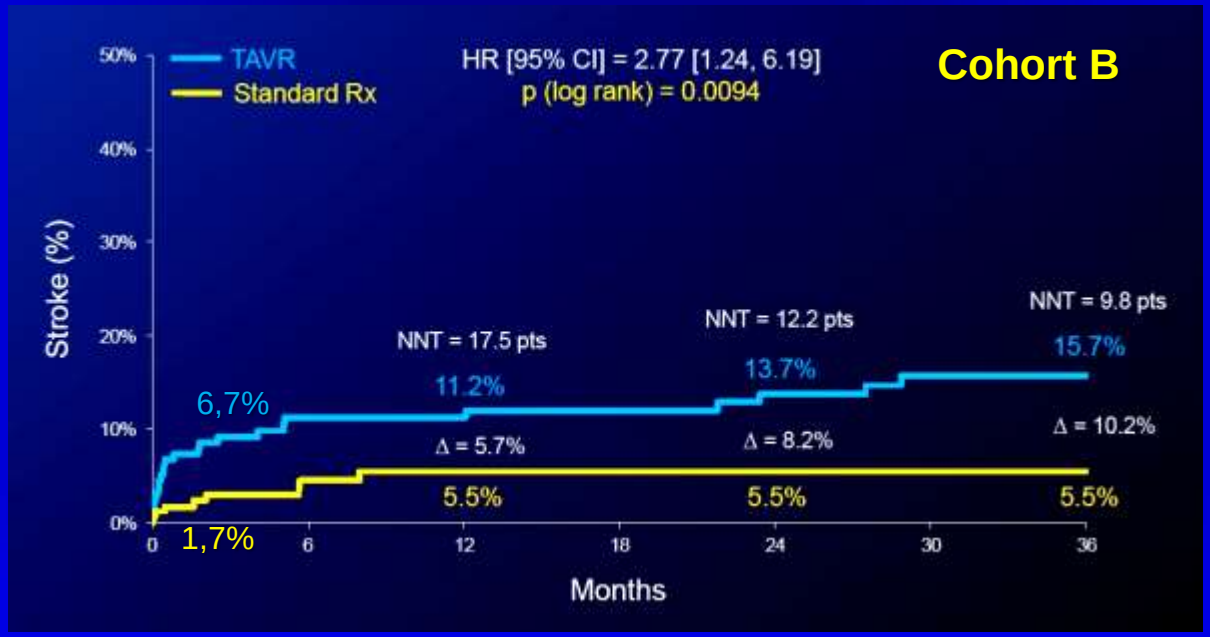


Registro Frances 2
Van Belle TCT/2012

Instituto Cardiovascular de Paris
Hayashida K. JACC Intv 2012;12:1247-56

PARTNER TRIAL

AVC

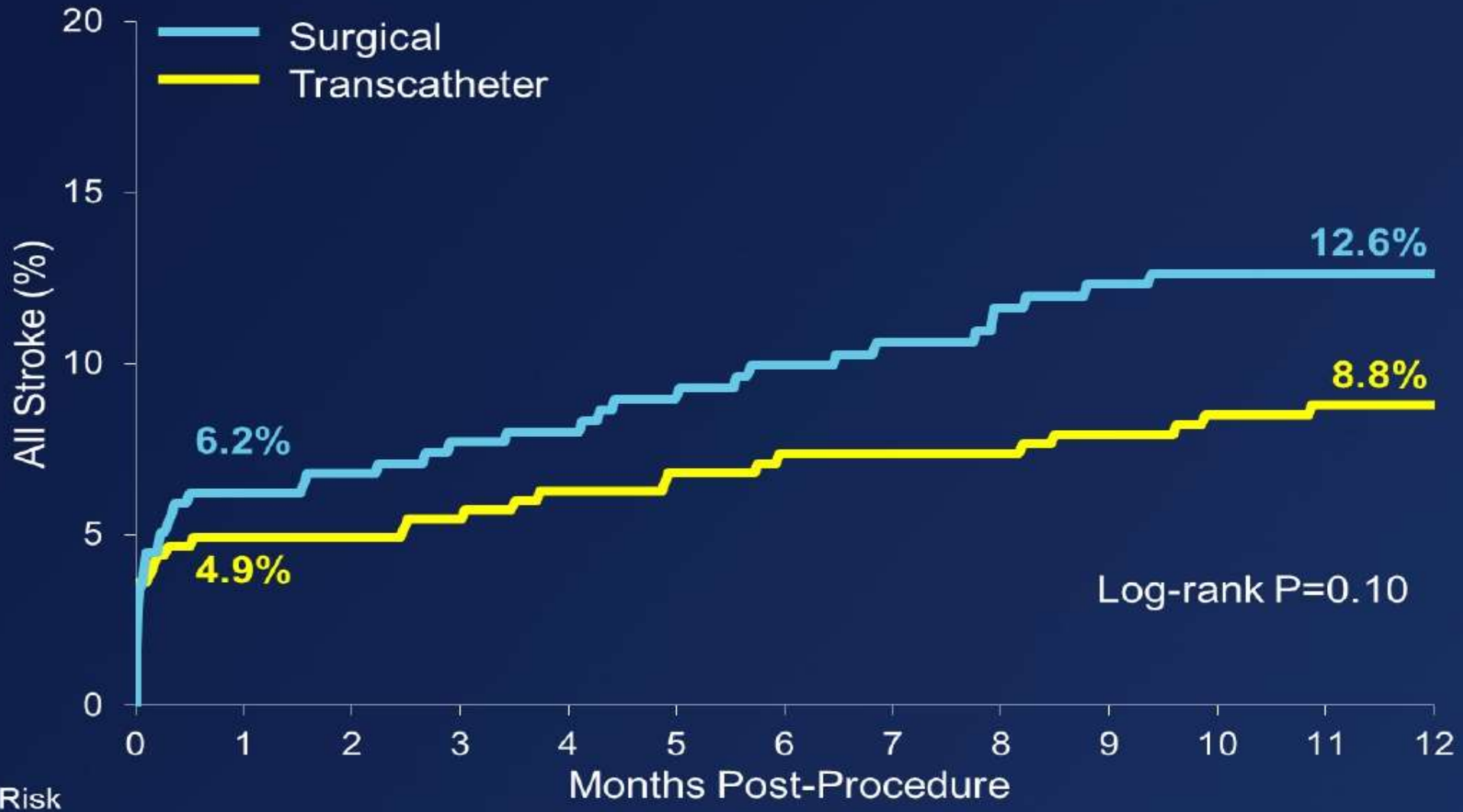


Cohort A

3 años	TAVR n = 348	Cirugía n = 351	p
ACV	8,2%	9,3%	0,763
Muerte/ACV	47,1%	45,9%	0,839

Kapadia S.R. TCT/2012 Thourani V. ACC/2013

All Stroke

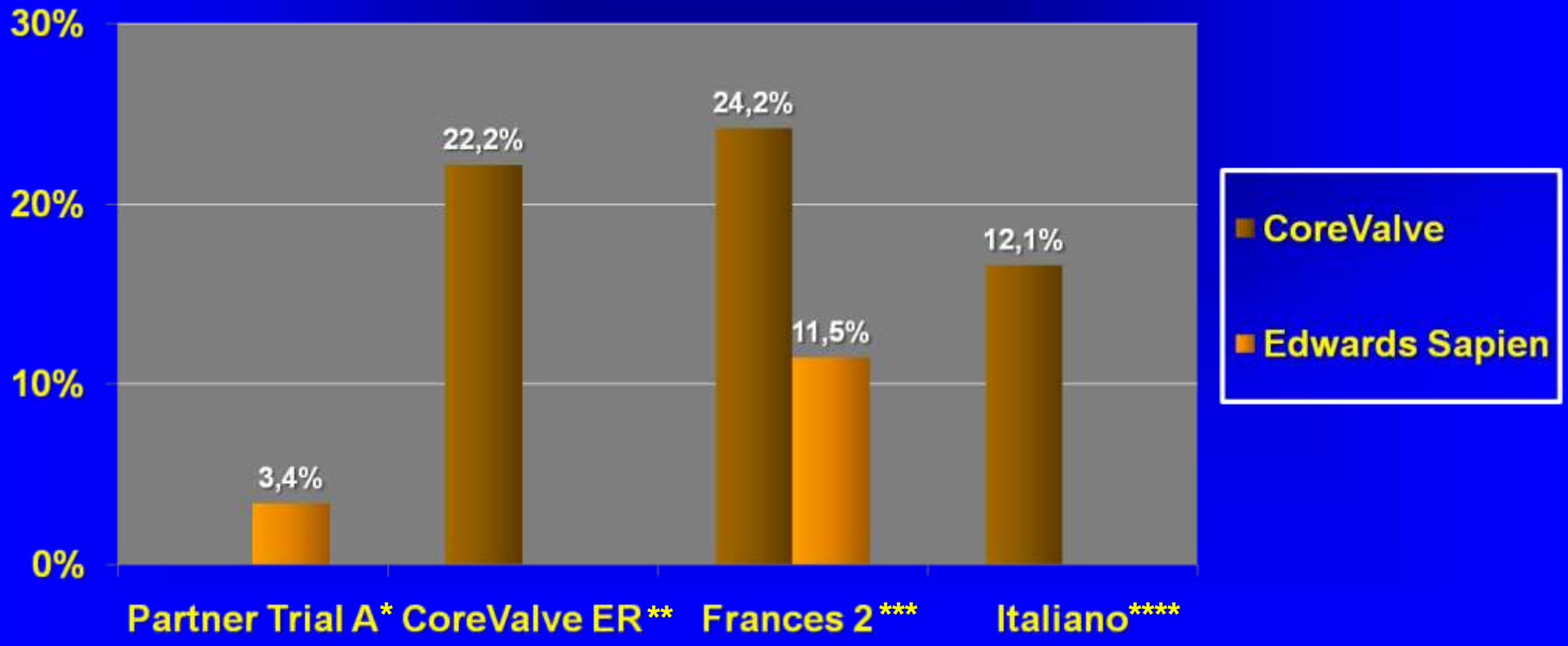


No. at Risk												
Surgical	357	322				274						249
Transcatheter	390	363				334						314

Adams D.H. N Engl J Med 2014;370:1790-98

Implante Transcateter Valvar Aórtico

Necesidad de MP Definitivo - 30 días



* Smith C.R. N Engl J Med 2011;364:2187-98

** Adams D.H. N Engl J Med 2014;370:1790-98

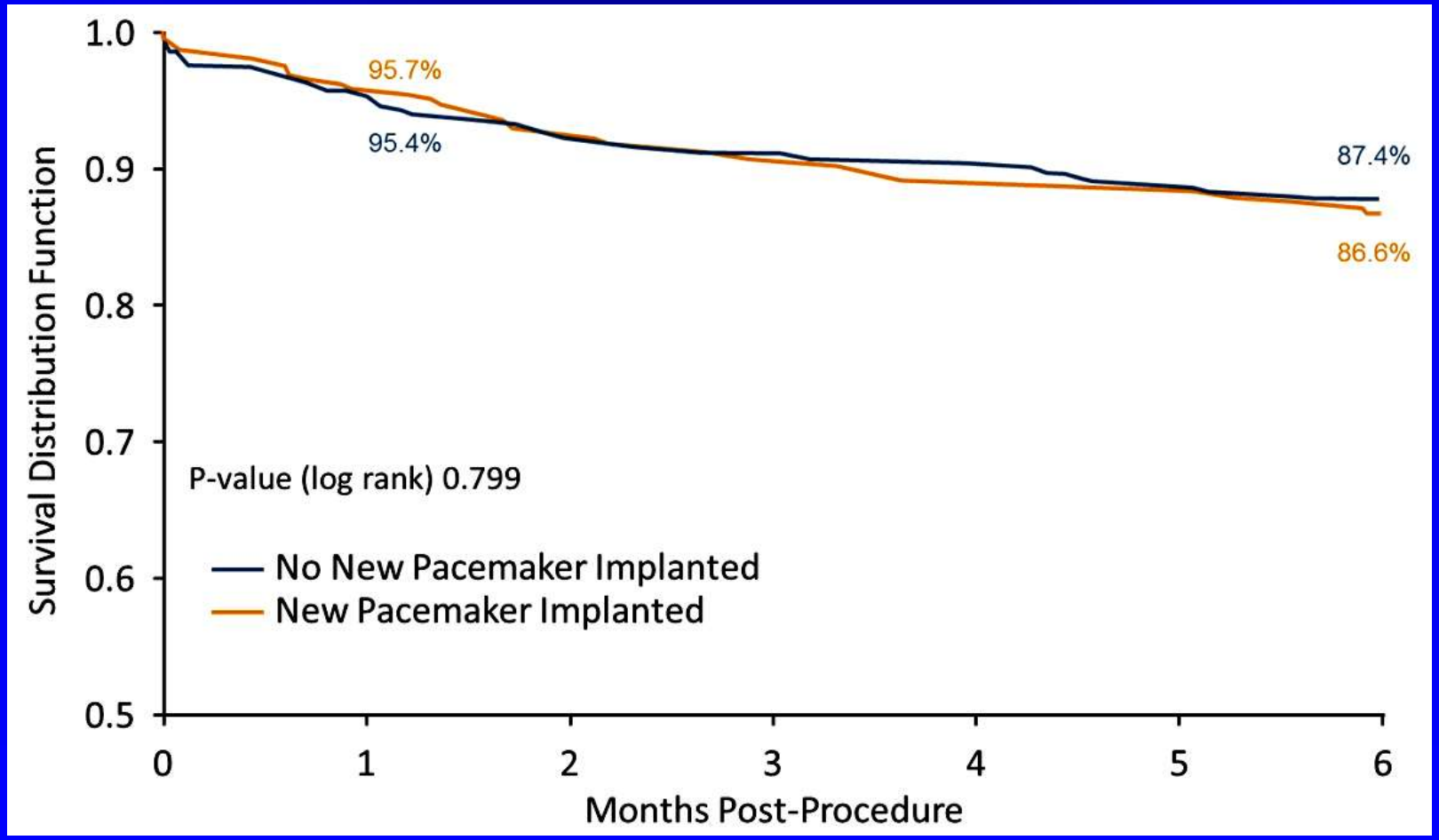
*** Eltchaninoff H. TVT/2013

**** Tamburino C. TVT/2013

ADVANCED REGISTRY

Marca-Paso vs Mortalidad

n = 1.015



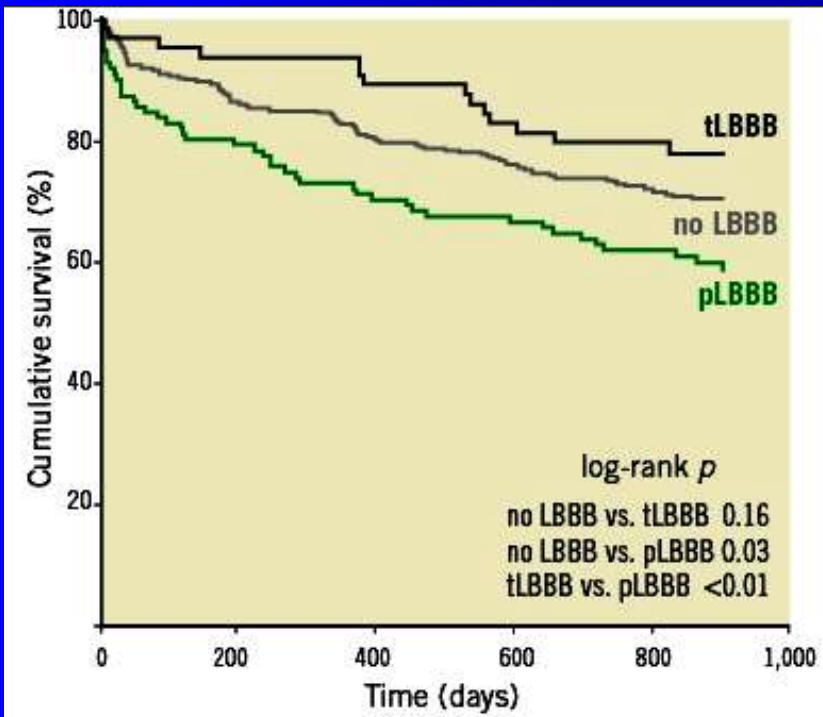
Linke A. TCT/2012

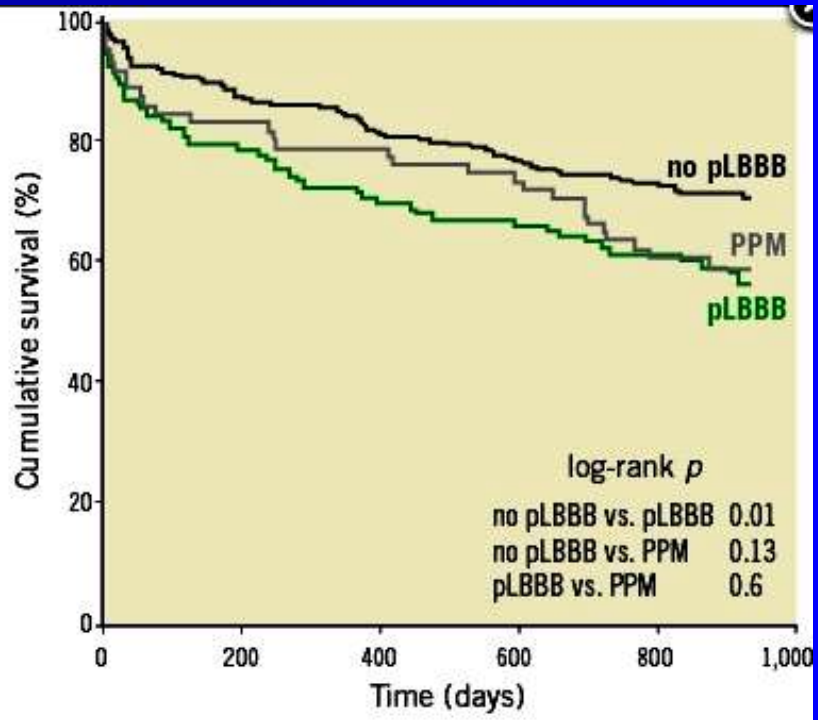
Disturbios de Conducción (BRI)

Sobrevivencia

n = 476 5 centros (Holanda e Canadá) Δt – 898 dias

BRI – 36,8% CV – 53,8% vs ES - 21,7% (p<0,001)





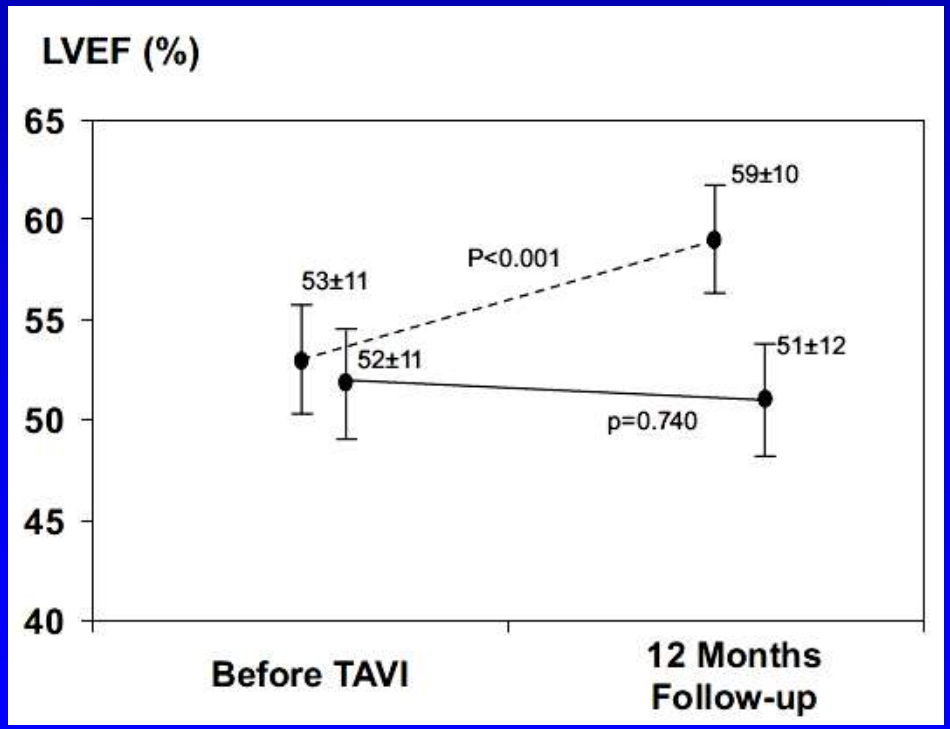
Houthuizen P. Eurointervention 2014;9:1142-50

Disturbios de Conducción

Sobrevivencia

n = 90 2 centros Alemanha

BRI o PPM = 39 Sin defectos de conducción = 51



Houthuizen P. JACC Intv 2012;12:1257-63

CoreValve® SURTAVI Trial
Study Design

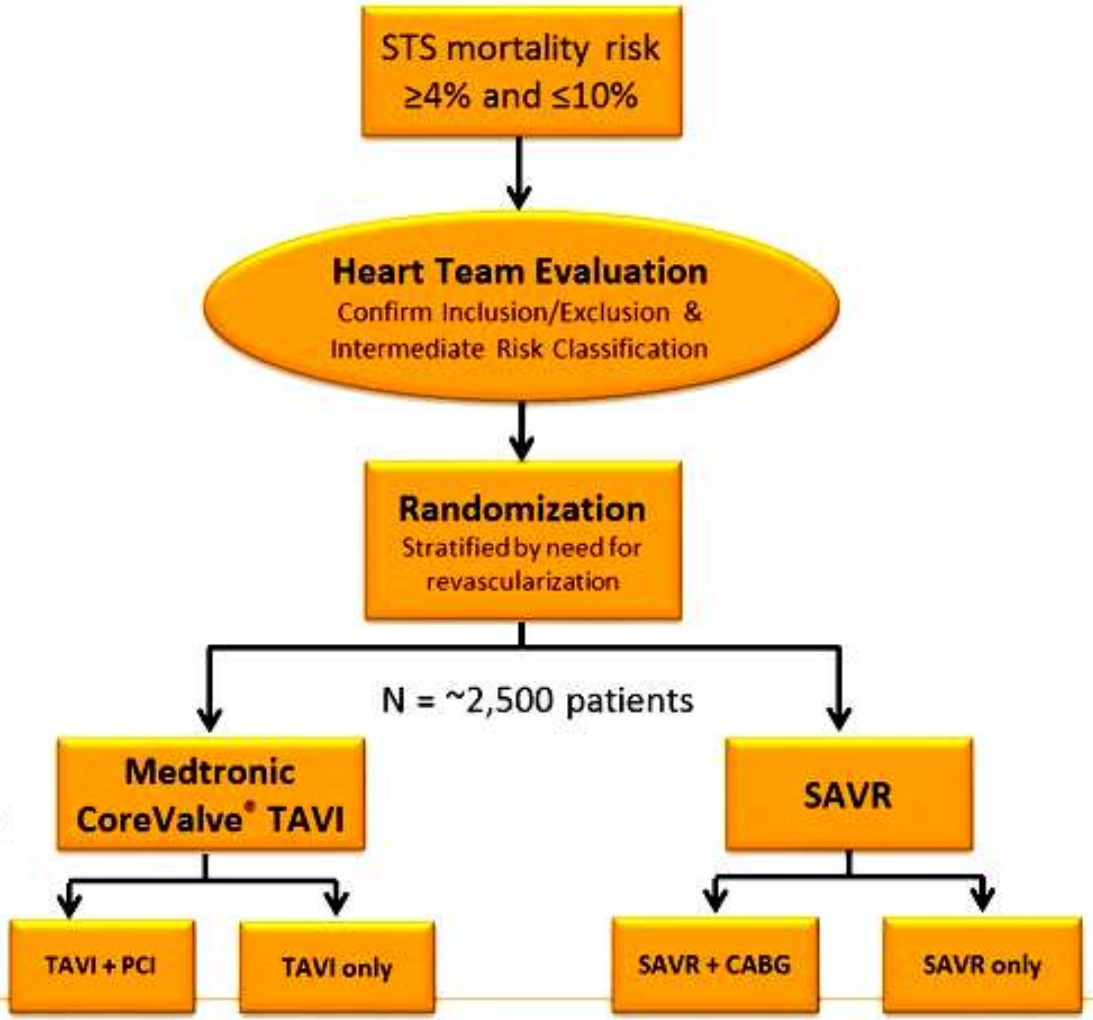
Randomized 1:1, non-inferiority study

The trial will ultimately be conducted at up to 75 worldwide centers

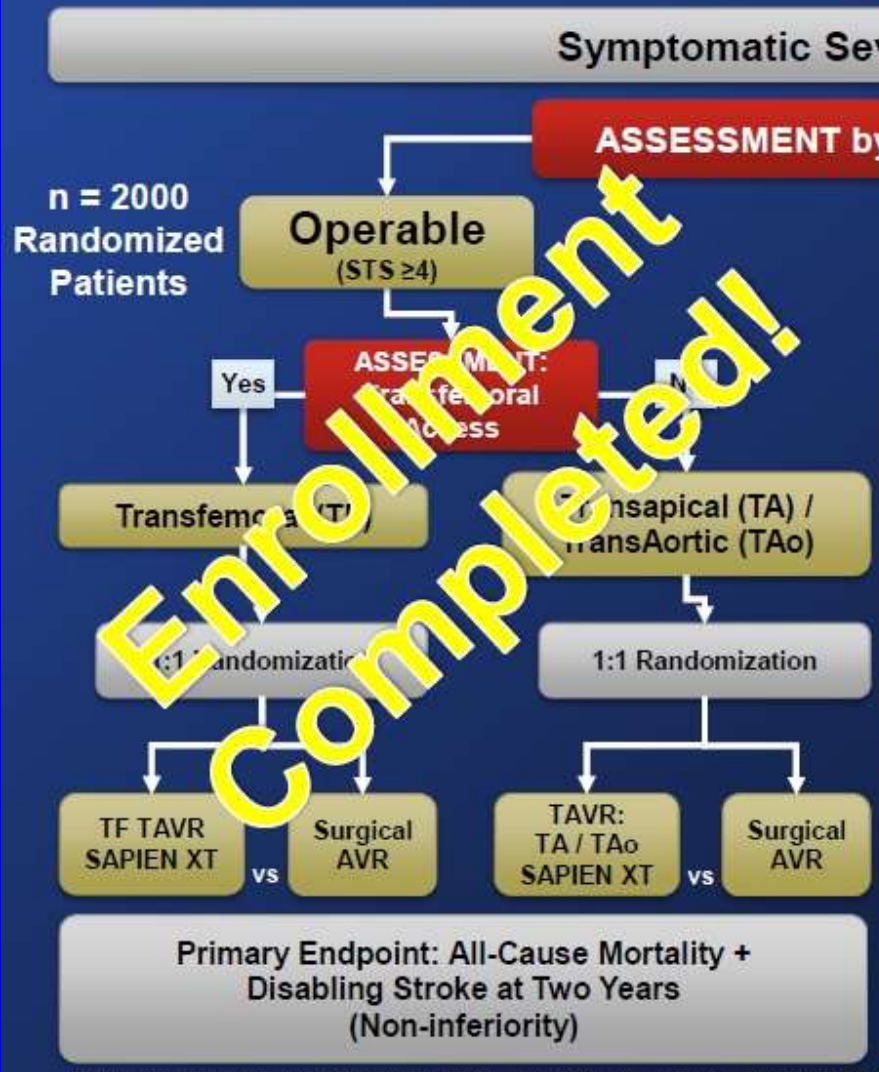
- **Europe**
- **Canada**
- **United States**

Long-term follow-up through 5 years

Approx 2,500 total number of trial subjects



The PARTNER IIA Trial
Study Design



- *2011 patients enrolled in 22 months!*
- *Mean STS ~6%*
- *~75% TF access*

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association®

2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Rick A. Nishimura, Catherine M. Otto, Robert O. Bonow, Blase A. Carabello, John P. Erwin III, Robert A. Guyton, Patrick T. O'Gara, Carlos E. Ruiz, Nikolaos J. Skubas, Paul Sorajja, Thoralf M. Sundt III and James D. Thomas

3.5. Choice of Intervention

Class I

TAVR is recommended in patients who meet an indication for AVR (Section 3.4) who have a prohibitive risk for surgical AVR (Section 2.5 in the full-text guideline) and a predicted post-TAVR survival greater than 12 months (72, 73). *(Level of Evidence: B)*

Class IIa

TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR (Section 3.4) and who have high surgical risk for surgical AVR (Section 2.5 in the full-text guideline) (74, 75). *(Level of Evidence: B)*

Nishimura R.A. Circulation 2014;63:e57–e185