



XXIII Jornadas SOLACI
9^o Región Centroamérica y el Caribe
7 y 8 de Agosto de 2014



TAVI:
Comparación con resultados de Cirugía



Sociedad Puertorriqueña de
CARDIOLOGÍA
INTERVENCIONAL

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San Juan, Puerto Rico

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(5411) 4954-7173



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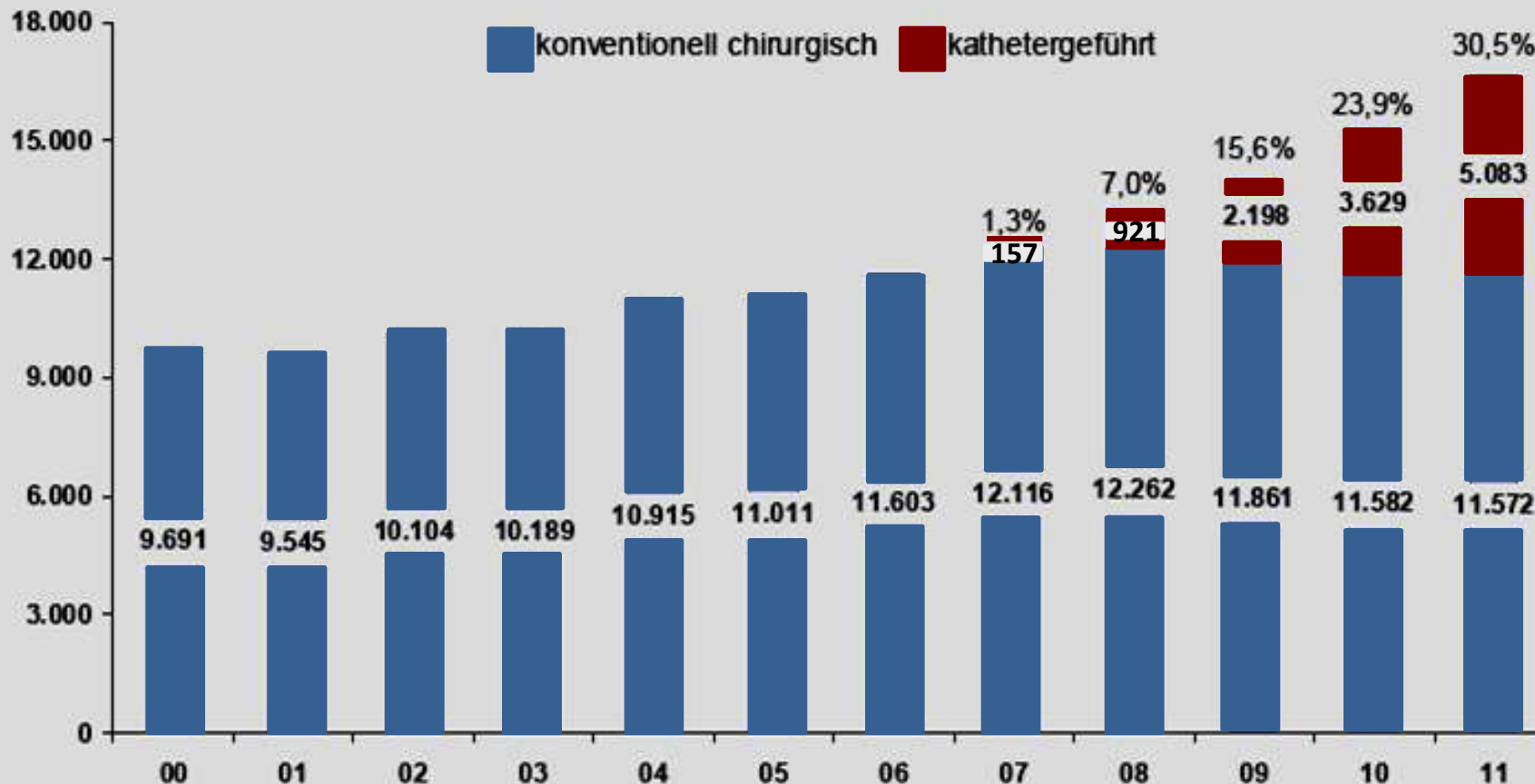
NO TENGO CONFLICTO DE INTERESES

PARA ESTA PRESENTACION



Isolierte Implantation einer Aortenklappenprothese 2000 - 2011

+ (2000 ?)
unreported

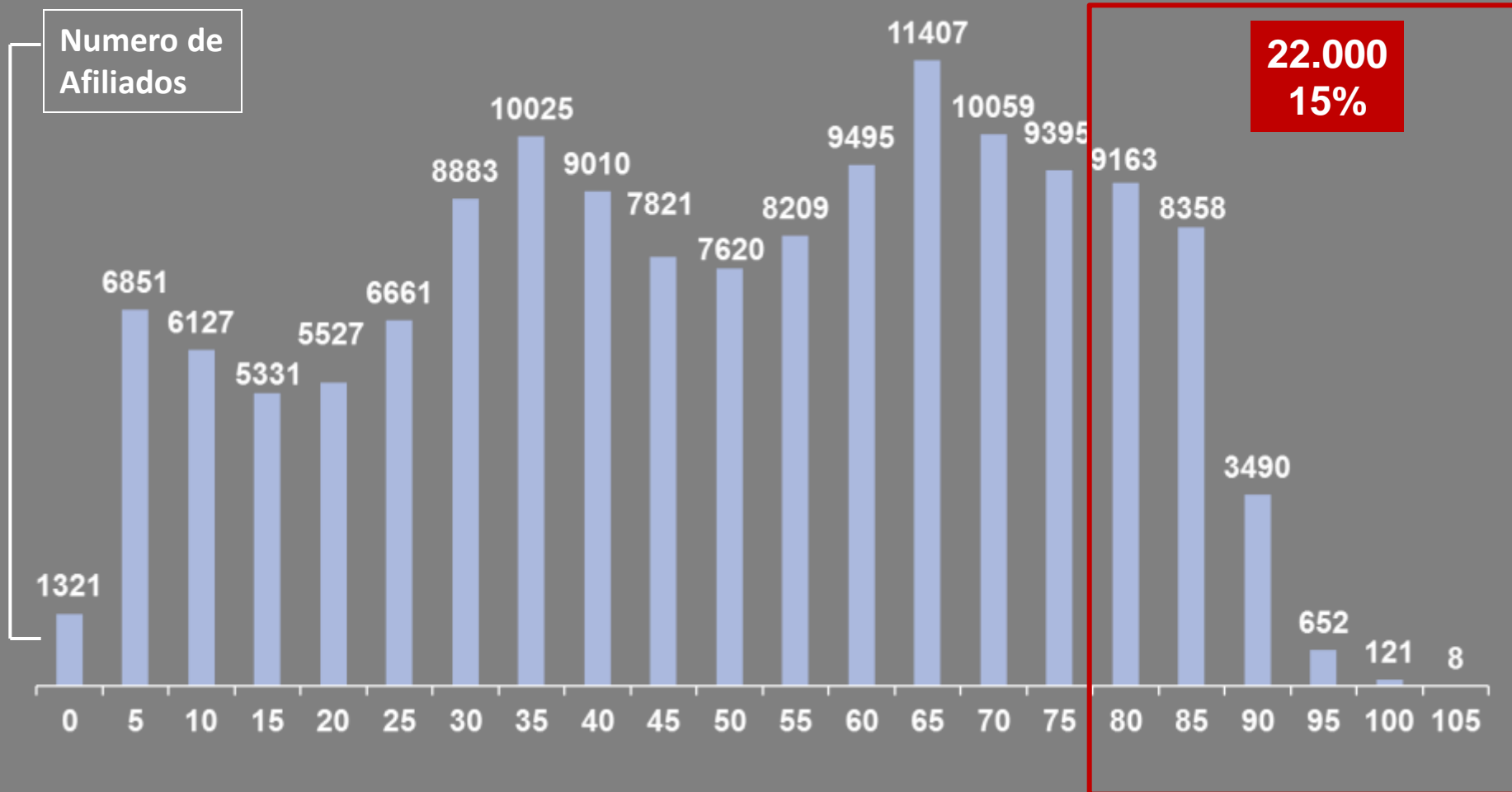


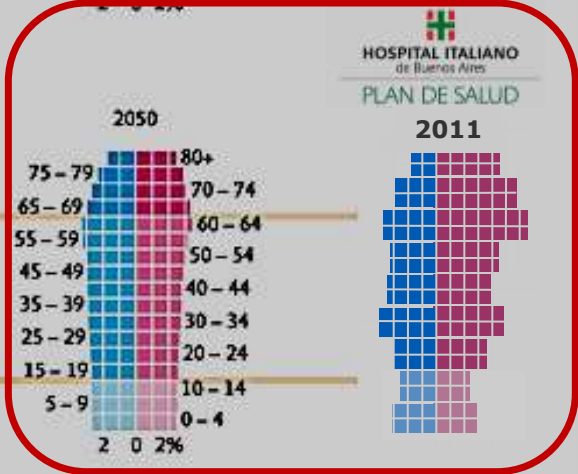
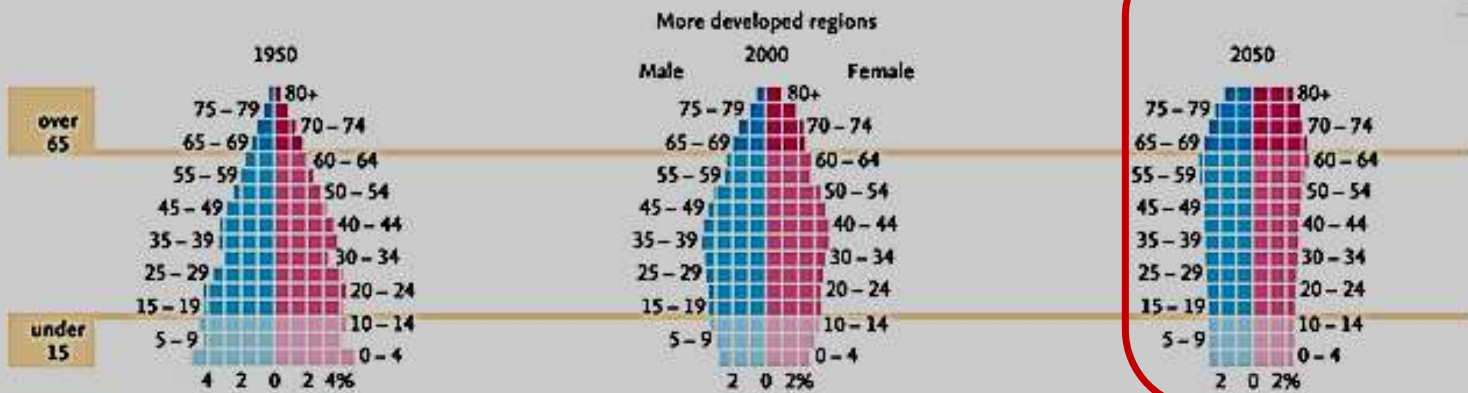
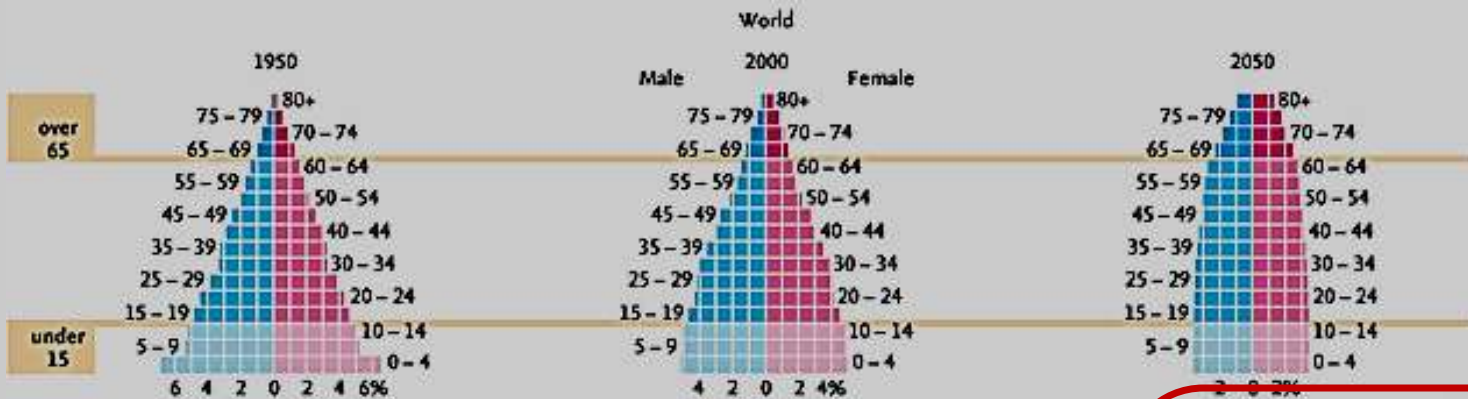


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de Buenos Aires

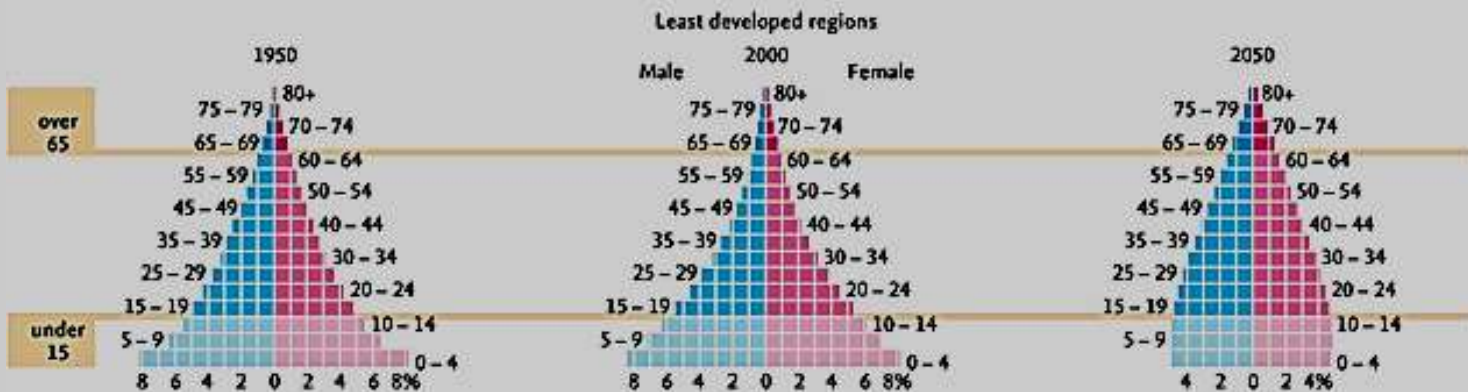
PLAN DE SALUD

Distribución por edades – Año 2011





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de Buenos Aires
PLAN DE SALUD



Predictores de la decisión de no operar considerando el Euroscore

Predictor ⁽¹⁾	“Odds Ratio” (IC al 95%)	p
Edad ⁽²⁾	0.75 (0.69 – 0.81)	<0.0001
QX previa	0.051 (0.01 – 0.29)	0.0007
FEY ⁽³⁾	2.36 (1.05 – 5.28)	0.037
EPOC	0.19 (0.04 – 0.98)	0.047
Situación crítica	0.23 (0.05 – 1.01)	0.052
PSP>60	0.19 (0.04 – 1.05)	0.056
Insuf. Renal	0.26 (0.06 – 1.07)	0.062
Alt. Neurológ	0.21 (0.03 – 1.36)	0.101
Euroscore ⁽⁴⁾	0.31 (0.18 – 0.54)	<0.0001

(1) área bajo la curva ROC de este modelo: 0.895, coeficiente de Akaike 249.96

(2) el “odds ratio” de edad está informado por cada año

(3) la fracción de eyección se la consideró como numérica (1,2,3)

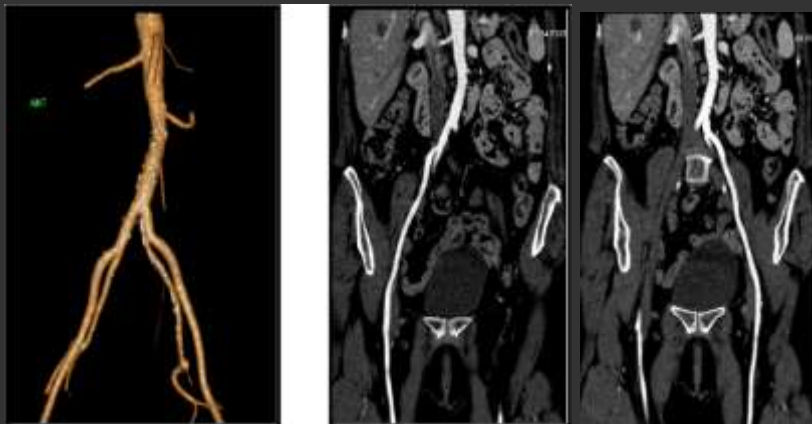
Que es fragilidad?



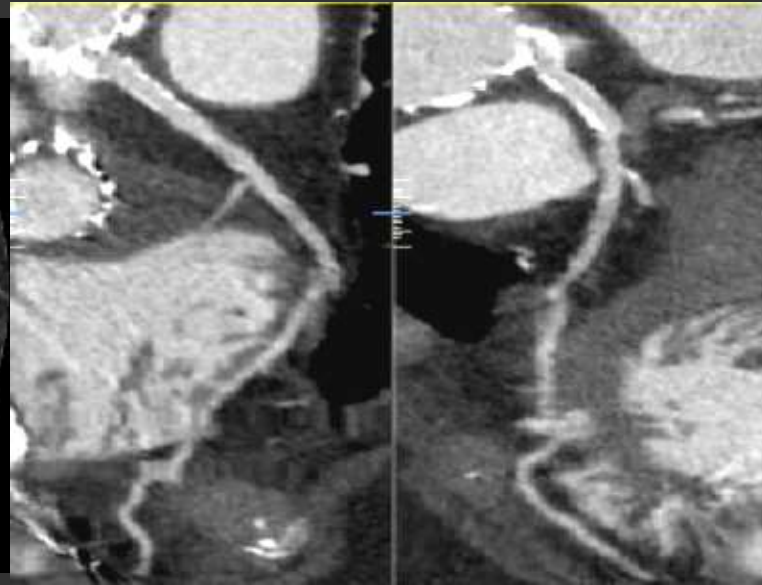
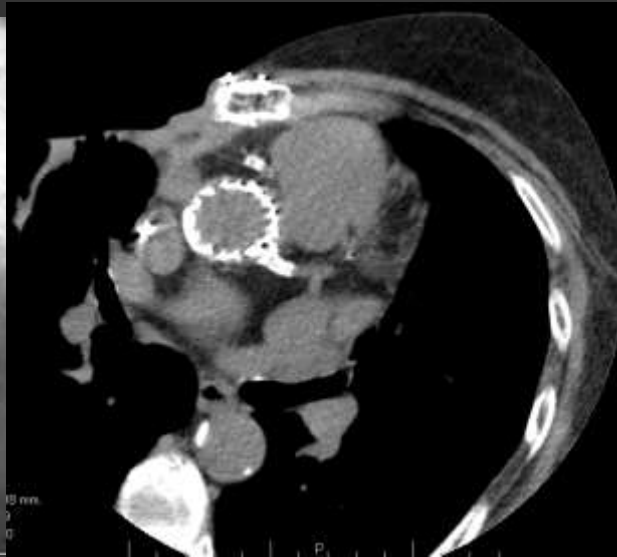
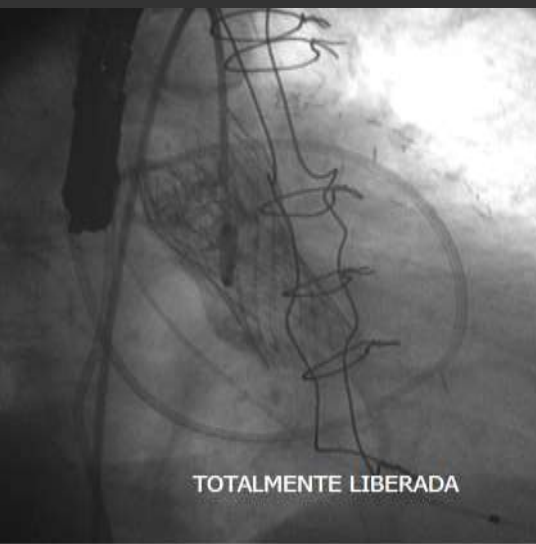
N#	39 p.
Edad	83.7 ± 5.95 a.
Score de Charlson	2.2 ± 1.7
Score de fragilidad de Edmonton	6.7 ± 2.8
Continuaron en plan de TAVI	67%
Se deacartaron para TAVI	33 %
Tx Mx (terapia de destino)	69.6%
BAV (puente)	15.1%
BAV (terapia de destino)	15.1%

Caso TAVI TF

- 68 Mujer
- HTA, DLP, DBT
- Ca de mama (1981) - mastectomía total Derecha, radioterapia y quimioterapia.
- CRM (2003) MIDA, ROM.
- FAC ACO.
- Ostiomielitis, Mediastinitis.
- Tórax lábil.
- Cirugía de reparación torácica con colgajo.
- Enfermedad de tres vasos (2006)
- Puentes ocluidos post irradiación
- Infección torácica.
- ATC TCI con DES 2009**



Seguimiento a 1 año



Seguimiento a 3 años

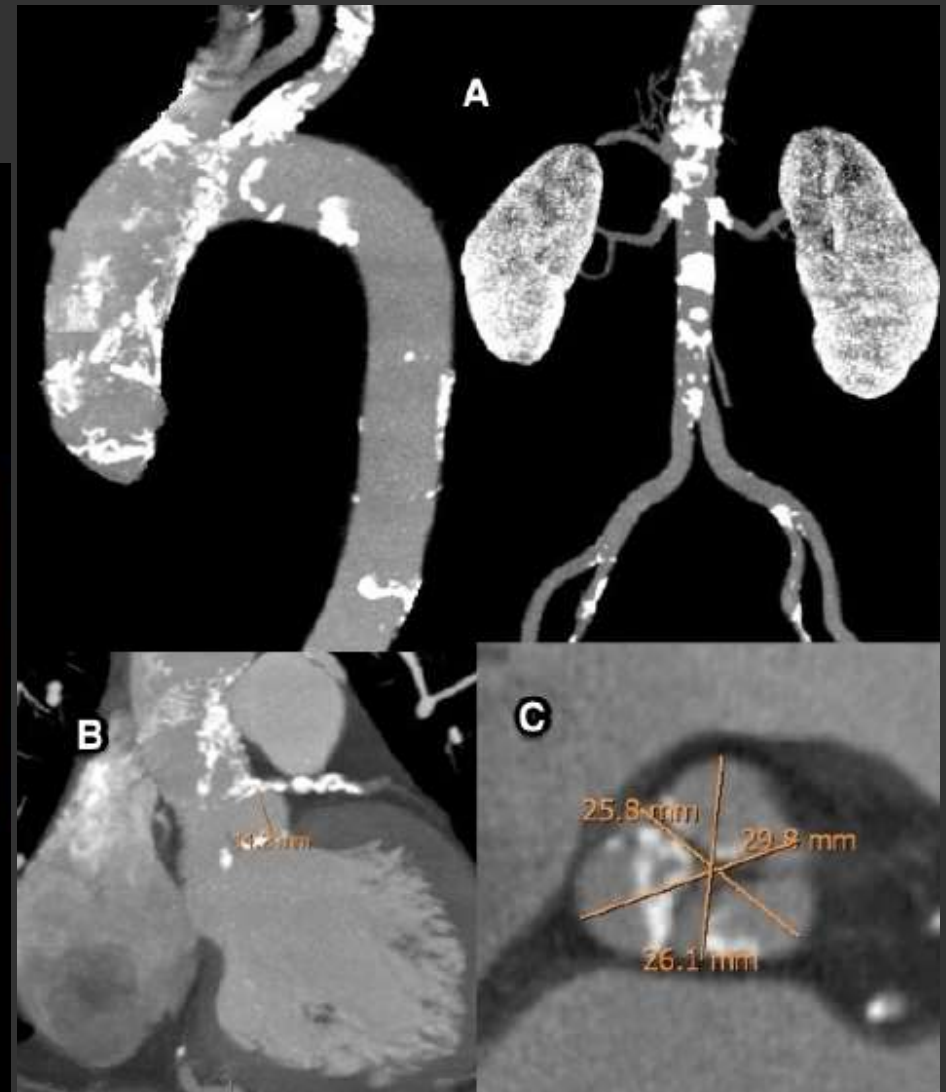


▪ ♀ 72 años

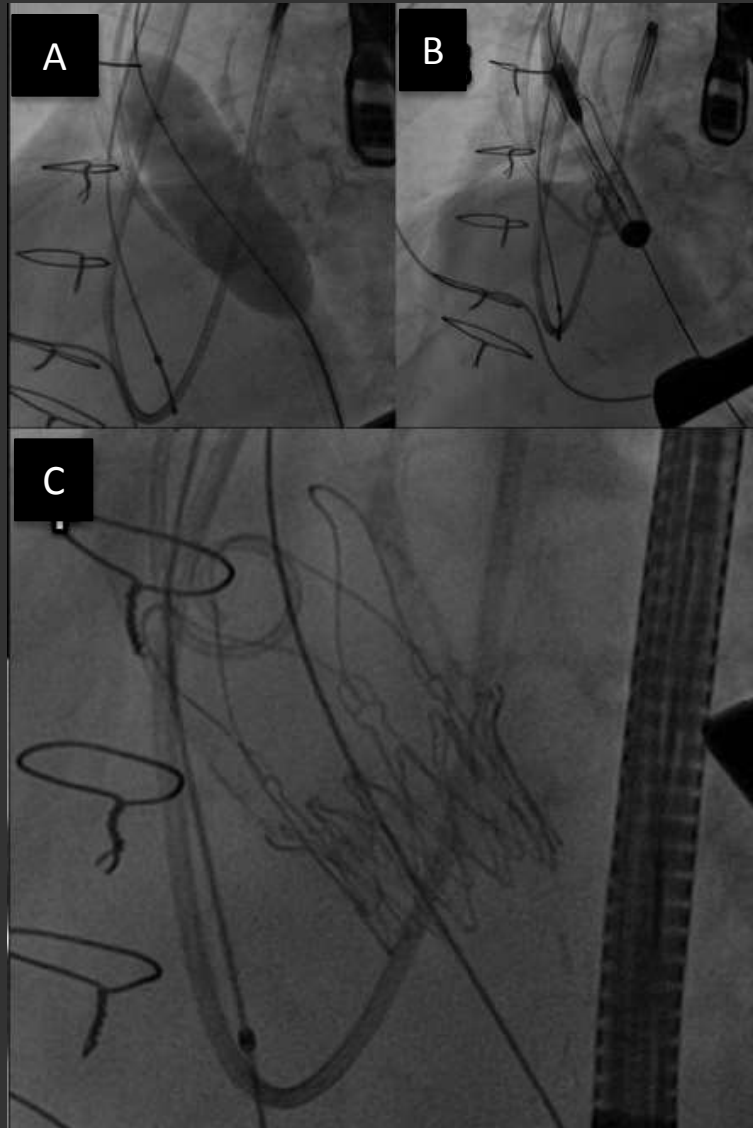
▪Euro SCORE Log: 33 ± 12.5

▪Euro SCORE II: 10.5 ± 0.5

▪STS: 8.08 ± 1



TAVI TRANSAPICAL

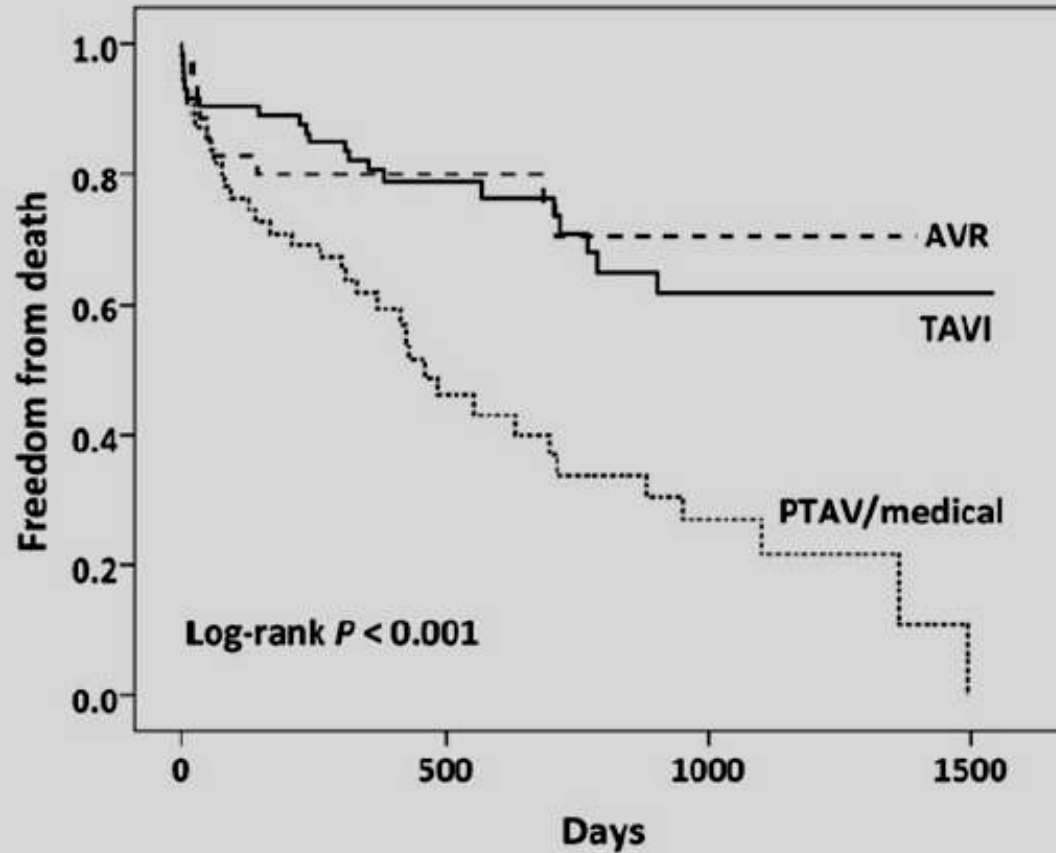


- A: Valvuloplastía con balón de 23 mm
- B: Posicionamiento de la bioprótesis
- C: Bioprótesis ACURATE TA liberada
- D: Hemostasia del apex

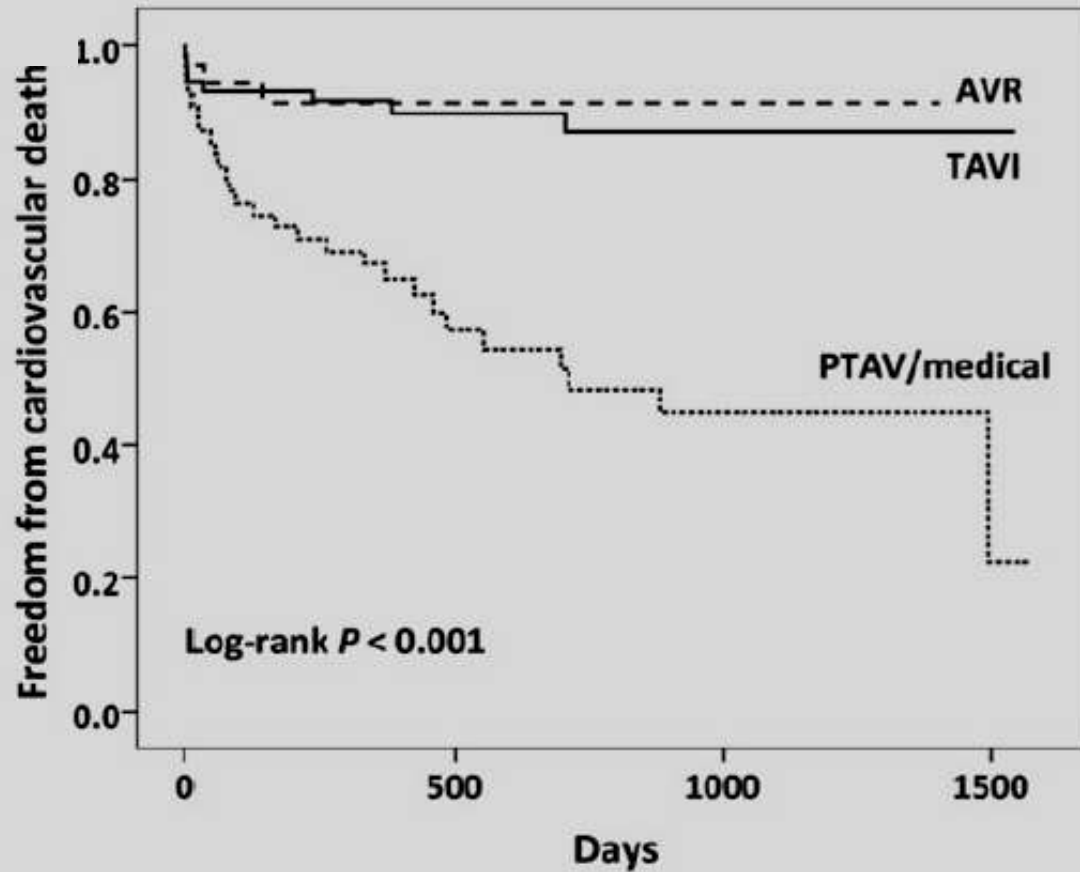


Bioprosthesis ACURATE TA
Transapical approach

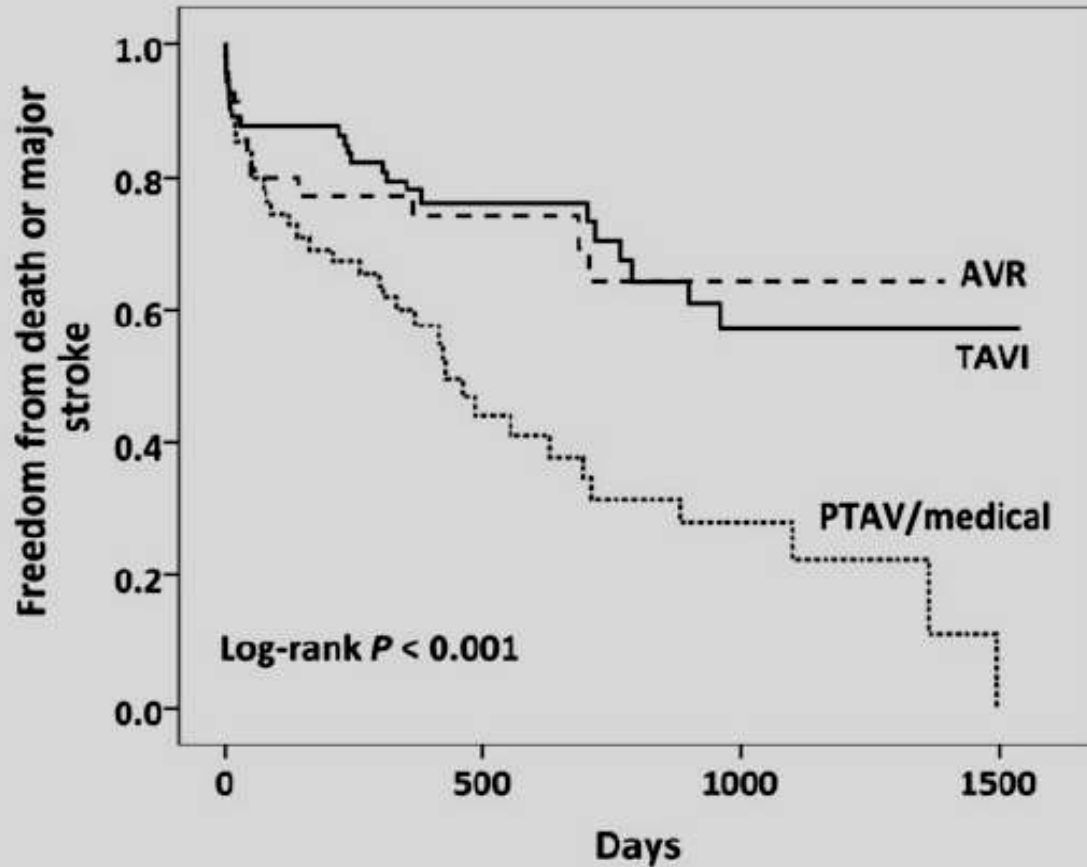
All-comer high-risk patients with aortic valve stenosis



All-comer high-risk patients with aortic valve stenosis



All-comer high-risk patients with aortic valve stenosis



PARTNER Study Design

Symptomatic Severe Aortic Stenosis

ASSESSMENT: High-Risk AVR Candidate
3,105 Total Patients Screened

A

B

Total = 1,057 patients

2 Parallel Trials:
Individually Powered

N = 699

High Risk

N = 358

Inoperable

**ASSESSMENT:
Transfemoral
Access**

Yes

No

**ASSESSMENT:
Transfemoral
Access**

Yes

No

Transfemoral (TF)

Transapical (TA)

1:1 Randomization

1:1 Randomization

N = 244

N = 248

N = 104

N = 103

TF TAVR

AVR

VS

TA TAVR

AVR

VS

1:1 Randomization

Not In Study

N = 179

N = 179

TF TAVR

**Standard
Therapy**

VS

**Primary Endpoint: All-Cause Mortality at 1 yr
(Non-inferiority)**

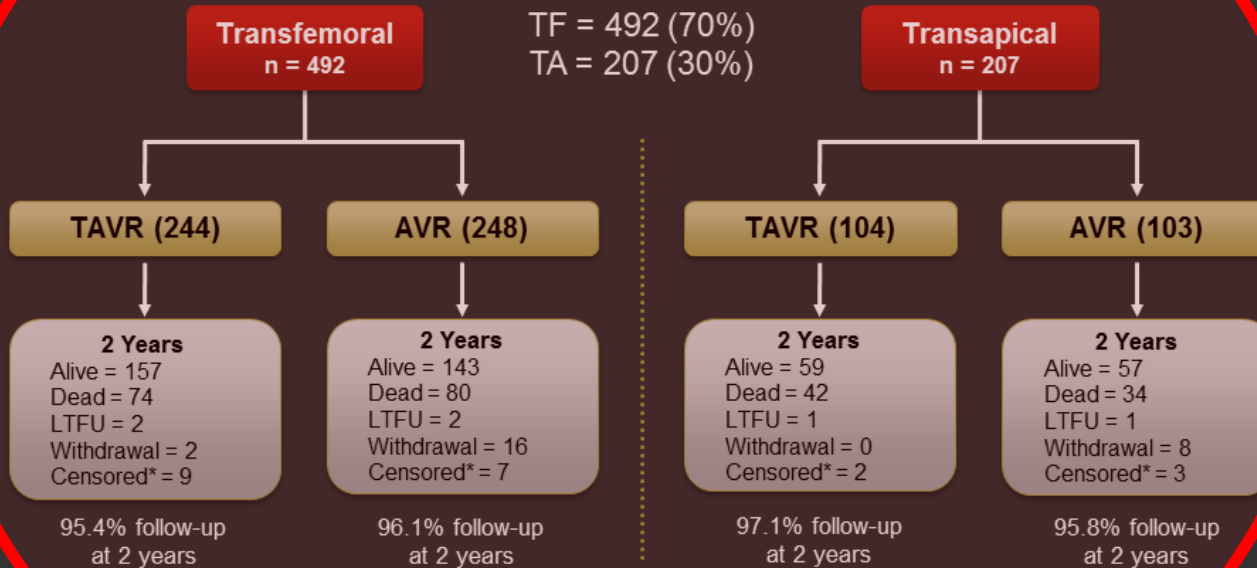
**Primary Endpoint: All-Cause Mortality
Over Length of Trial (Superiority)**
**Co-Primary Endpoint: Composite of All-Cause Mortality
and Repeat Hospitalization (Superiority)**

PARTNER Study Design

Symptomatic Severe Aortic Stenosis

Study Flow-High risk pts

Randomized = 699 patients



*Censored = Patient is alive at last contact but no information available within follow-up window

B
able N = 358

MENT: **Transfemoral**
ss
No
Not In Study

(Non-inferiority)

All-Cause Mortality
Over Length of Trial (Superiority)
Co-Primary Endpoint: Composite of All-Cause Mortality and Repeat Hospitalization (Superiority)

PARTNER US (A)

Baseline Patient Characteristics Demographics (ITT)

Characteristic	TAVR (n = 348)		AVR (n = 351)		p-value
	n		n		
Age – years (Mean ± SD)	348	83.6 ± 6.8	349	84.5 ± 6.4	0.07 ✓
Male	201	57.8%	198	56.7%	0.82
STS Score (Mean ± SD)	347	11.8 ± 3.3	349	11.7 ± 3.5	0.61
NYHA Class III or IV	328	94.3%	328	94.0%	0.79

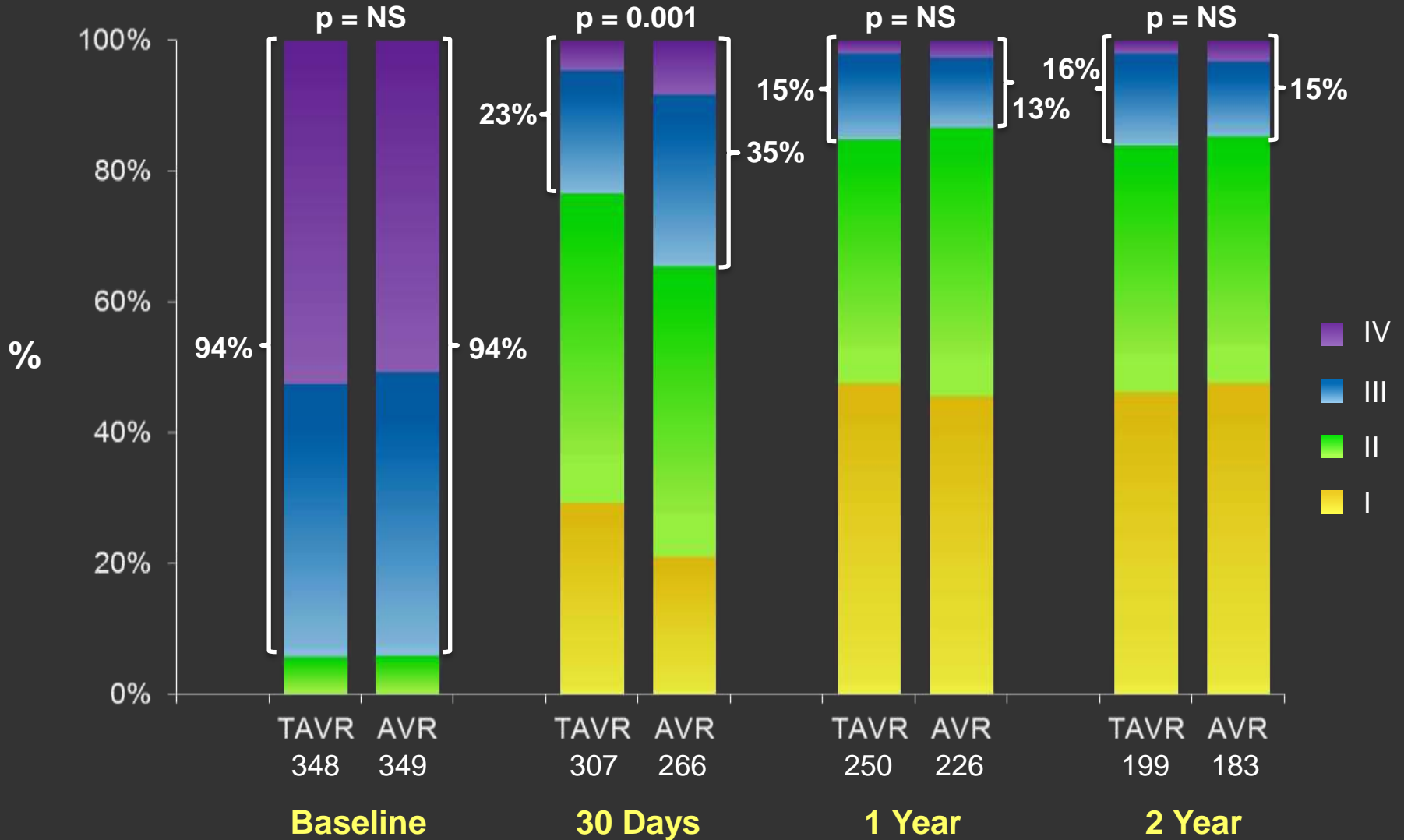
PARTNER US (A)
Baseline Patient Characteristics
Other Co-morbidities (ITT)

<i>Characteristic</i>	<i>TAVR</i> <i>(n = 348)</i>		<i>AVR</i> <i>(n = 351)</i>		<i>p-value</i>
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	
COPD – Any	152	43.7	151	43.0	0.88
COPD – O₂ dependent	38	17.3	38	16.6	0.90
Creatinine >2mg/dL	37	10.8	22	6.4	0.04 ✓
Atrial fibrillation	81	40.7	75	43.6	0.60
Pacemaker implant	69	19.8	76	21.8	0.58
Pulmonary hypertension	126	42.7	111	36.8	0.15

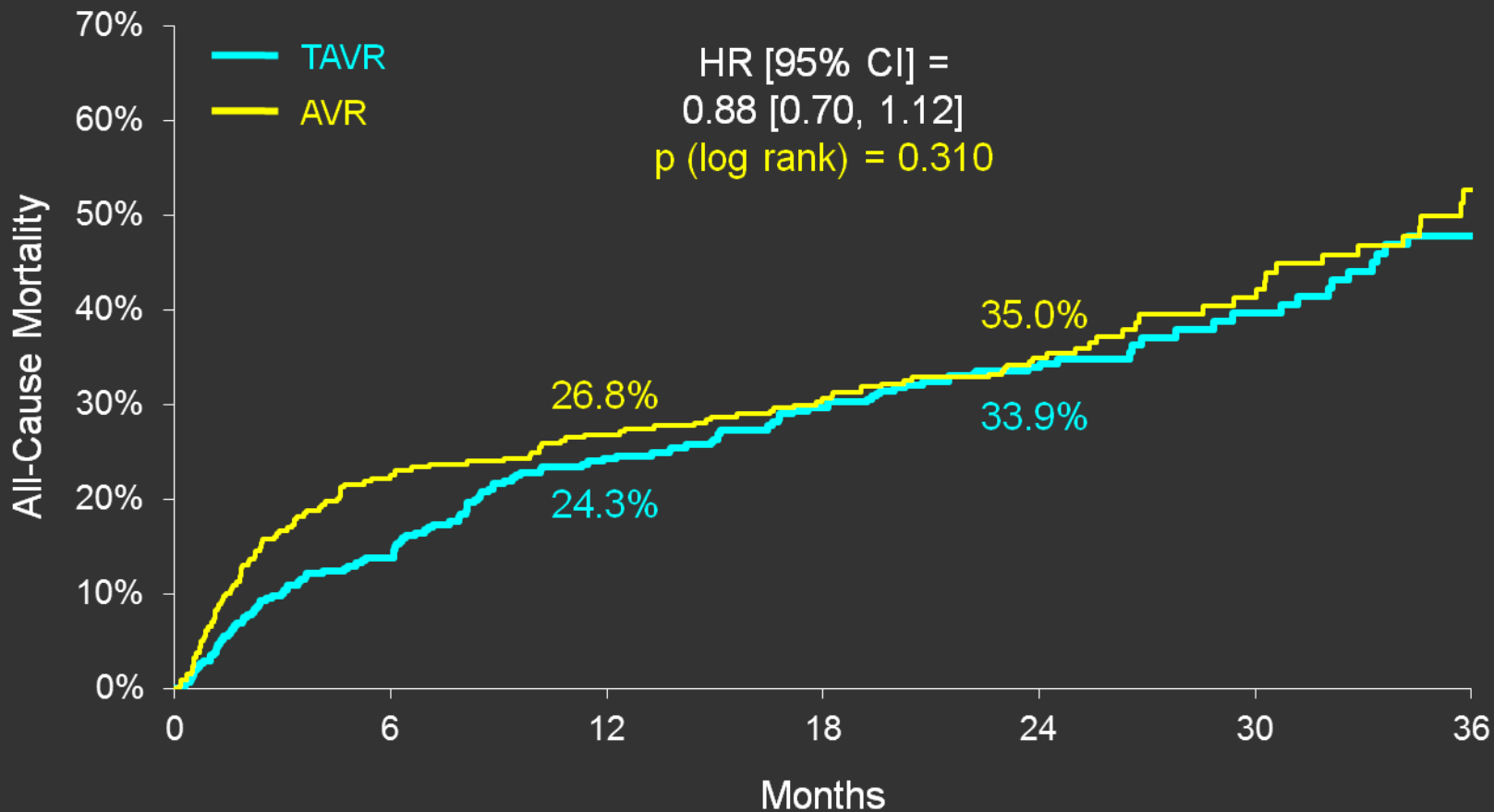
Multivariate Baseline Predictors of Mortality by Treatment Arm

TAVR	<i>Hazard Ratio [95% CI]</i>	<i>p-value</i>
Body Mass Index (kg/m ²)	0.93 [0.90-0.97]	<0.001
Mean Gradient (mmHg/10)	0.82 [0.72-0.94]	0.003
Baseline Creatinine	1.06 [1.00-1.13]	0.044
Prior Vascular Surgery or Stent	1.85 [1.01-3.39]	0.045
AVR		
Prior CABG	0.57 [0.40-0.82]	0.002
STS Risk Score	1.07 [1.02-1.12]	0.004
Liver Disease	2.59 [1.16-5.43]	0.020
Moderate/Severe MR	1.77 [1.17-2.68]	0.006

NYHA Class Survivors (ITT)



PARTNER US (A) Primary Endpoint: All-Cause Mortality (ITT)



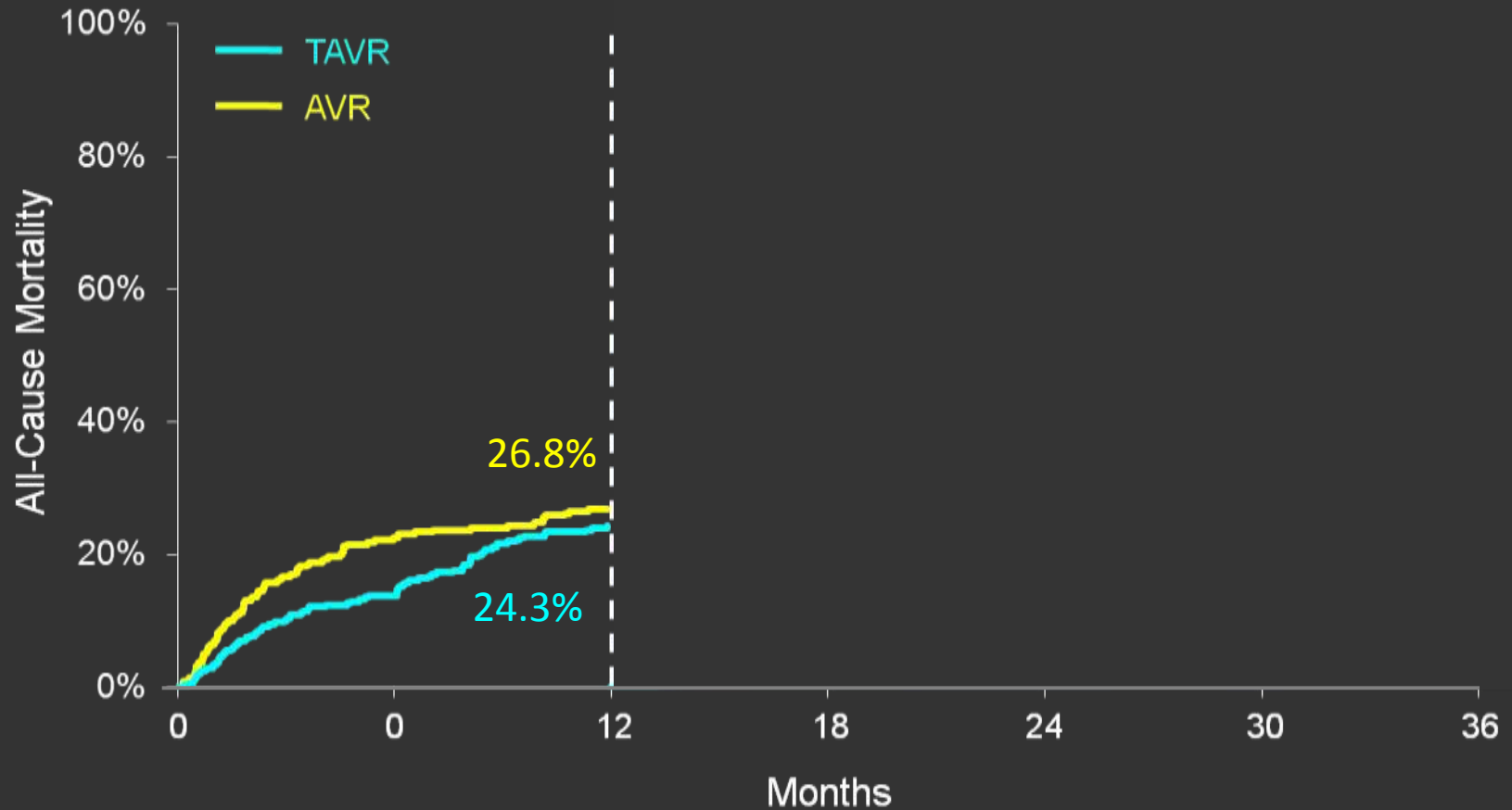
Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

PARTNER US (A)

All-Cause Mortality (ITT)

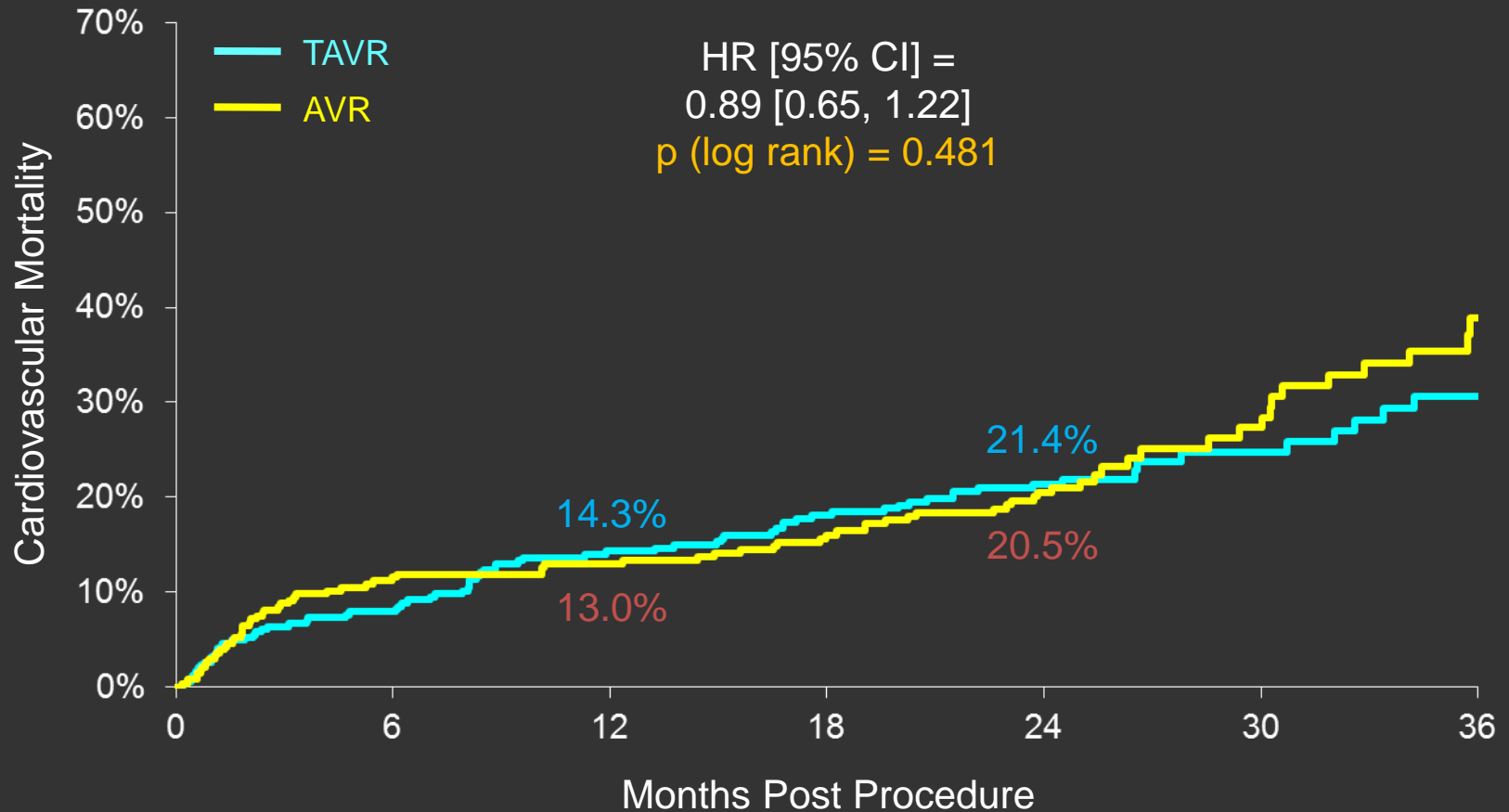
Landmark Analysis



Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

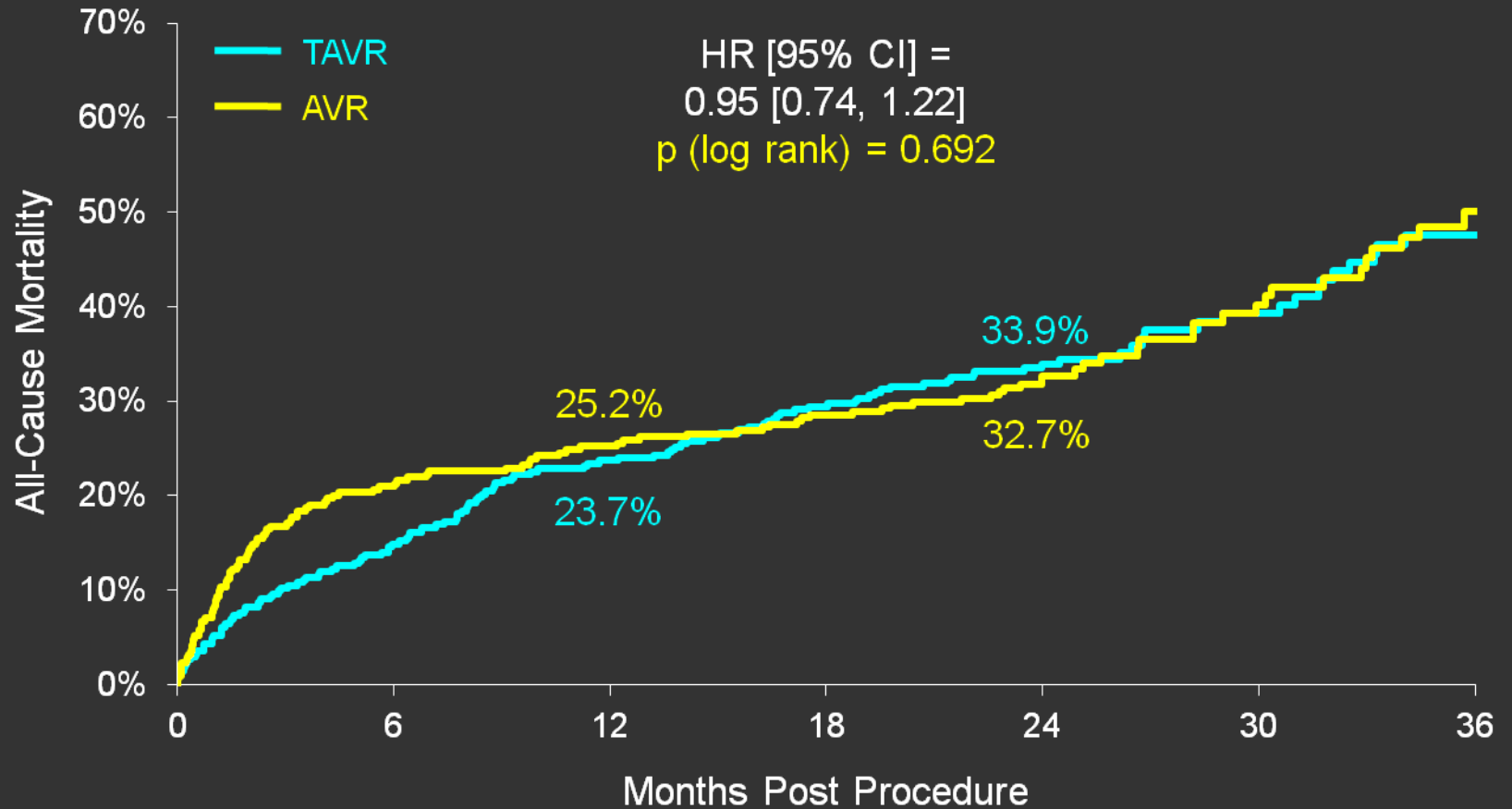
PARTNER US (A) Primary Endpoint: Cardiovascular Mortality (ITT)



Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

PARTNER US (A) All-Cause Mortality (AT)



Numbers at Risk

TAVR	344	291	259	232	155	70	29
AVR	313	243	229	211	143	63	28

PARTNER-B

Complicaciones con el TAVI vs. Tratam. Estándar

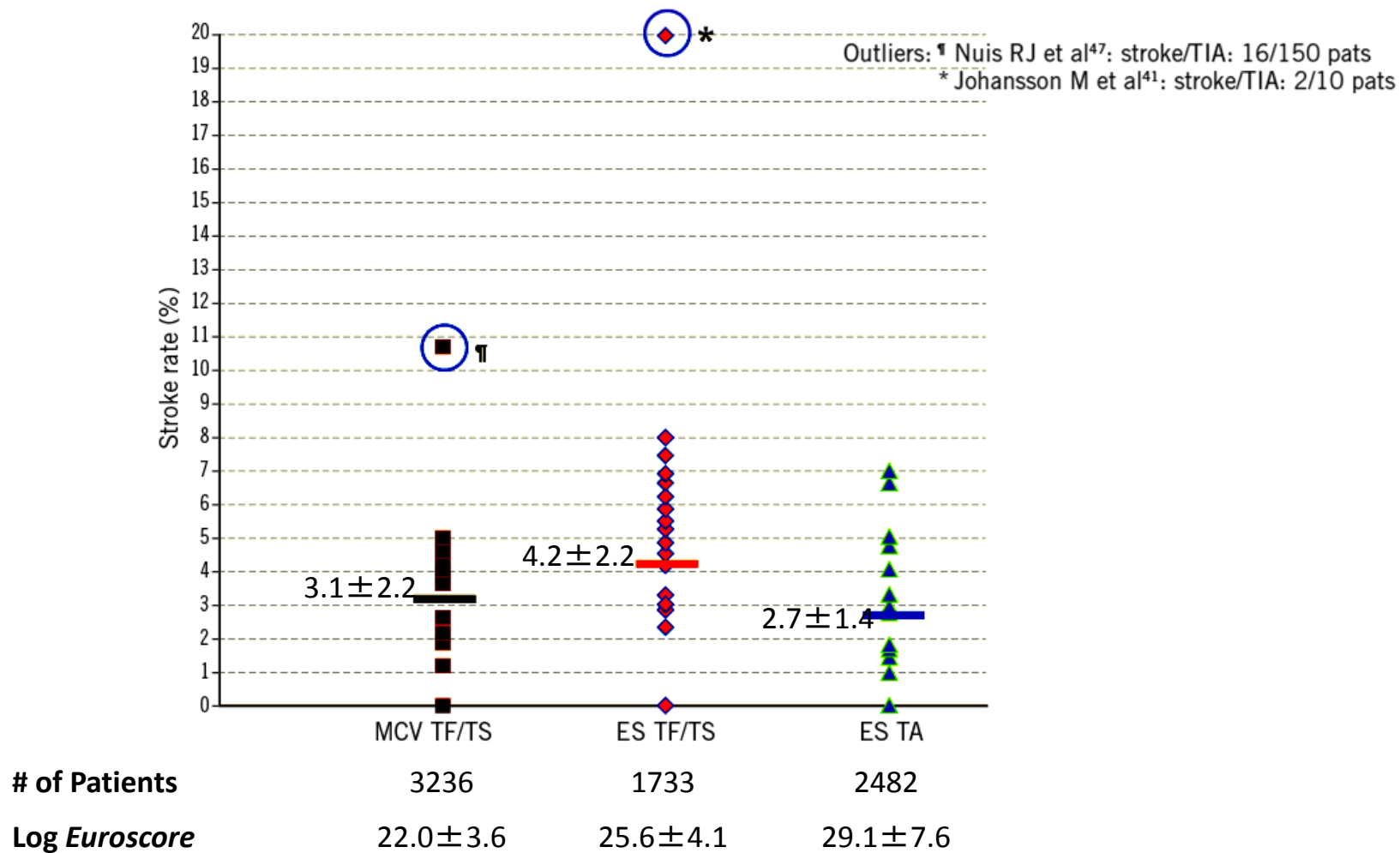
Resultados	30 días		1 año	
	TAVI	TE	TAVI	TE
▪ ACV mayor	5.0%	1.1% (p =.06)	7.8%	3.9% (p =.18)
▪ ACV (FDA)	7.3%	1.7% (p =.02) ✓		
▪ Compl. Vasculares				
Todas	30.7%	5.0% (p <.001) ✓	32.4%	7.3% (p <.001)
Mayores	16.2%	1.1% (p <.001) ✓	16.8%	2.2% (p <.001)
▪ Sangrado mayor	16.8%	3.9% (p <.001) ✓	22.3%	11.2% (p =.007)
▪ Terapia de Diálisis	1.1%	1.7% (p =1.0)	1.7%	3.4% (p =0.50)
▪ Nuevo Marcapaso	3.4%	5.0% (p =0.60) ✓	4.5%	7.8% (p =0.27)

PARTNER-A – TAVI vs. Remp. VAo. en cirugía en Alto Riesgo

Complicaciones del TAVI vs. RVAo

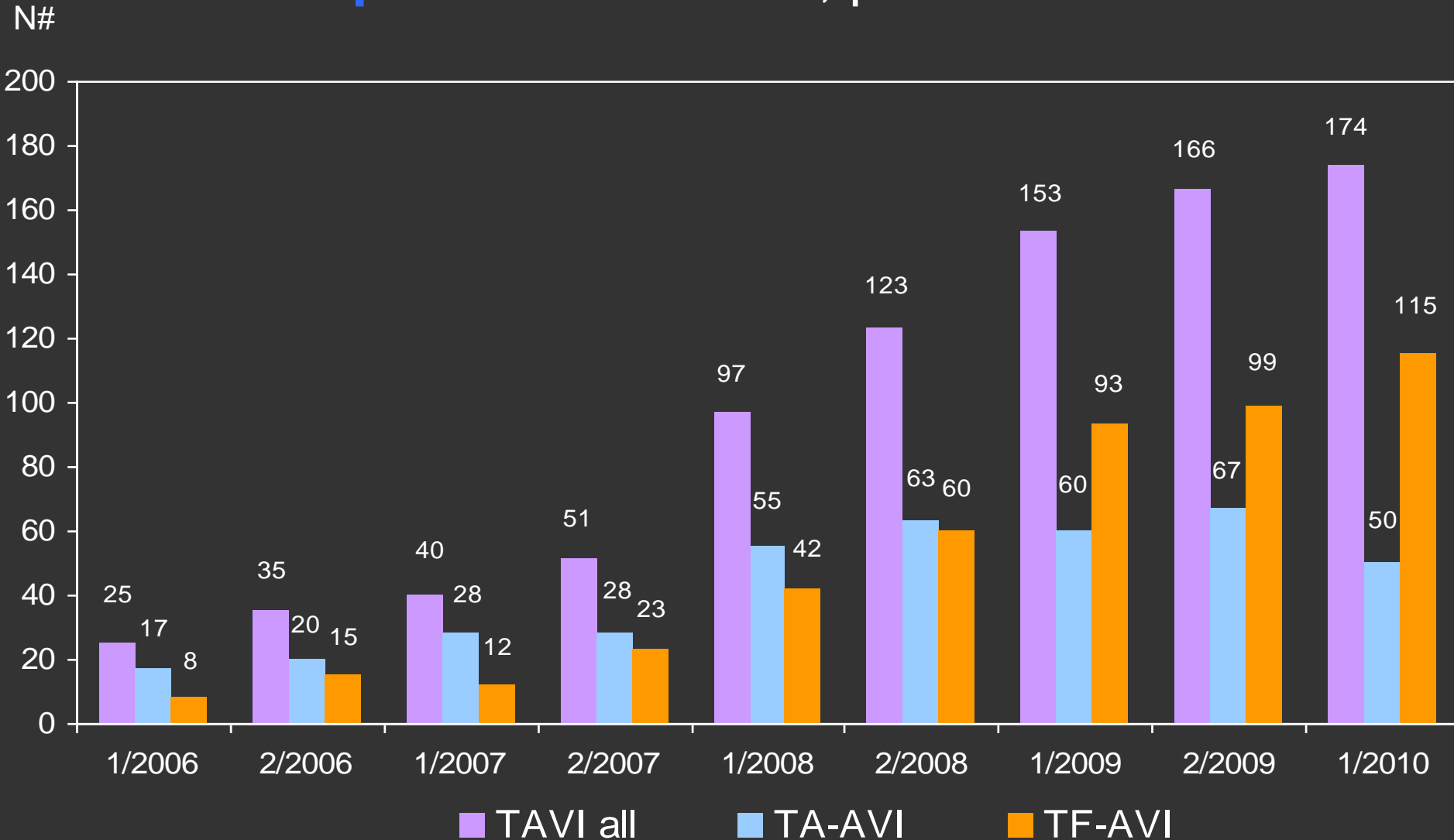
Resultados	30 días		1 año	
	TAVI	RVAo	TAVI	RVAo
▪ ACV o AIT	5.5%	2.4% (p .04) ✓	8.3% ✓	4.3% (p .04)
▪ ACV mayor	3.8%	2.1% (p .20) ✓	5.1% ✓	2.4% (p .07)
▪ Compl. Vasculares				
Todas	17.0%	3.8% (p <.001) ✓	18.0% ✓	4.8% (p <.001)
Mayores	11.0%	3.2% (p <.001) ✓	11.3% ✓	3.5% (p <.001)
▪ Sangrado mayor	9.3%	19.5% (p <.001) ✓	14.7% ✓	25.7% (p <.001)
▪ Terapia de Diálisis	2.9%	3.0% (p .95)	5.4%	6.5% (p 0.56)
▪ Nuevo Marcapaso	3.8%	3.6% (p 0.89)	5.7%	5.0% (p 0.68)

Risk of stroke after transcatheter aortic valve implantation (TAVI): a meta-analysis of 10,037 published patients



TAVI program (Leipzig):

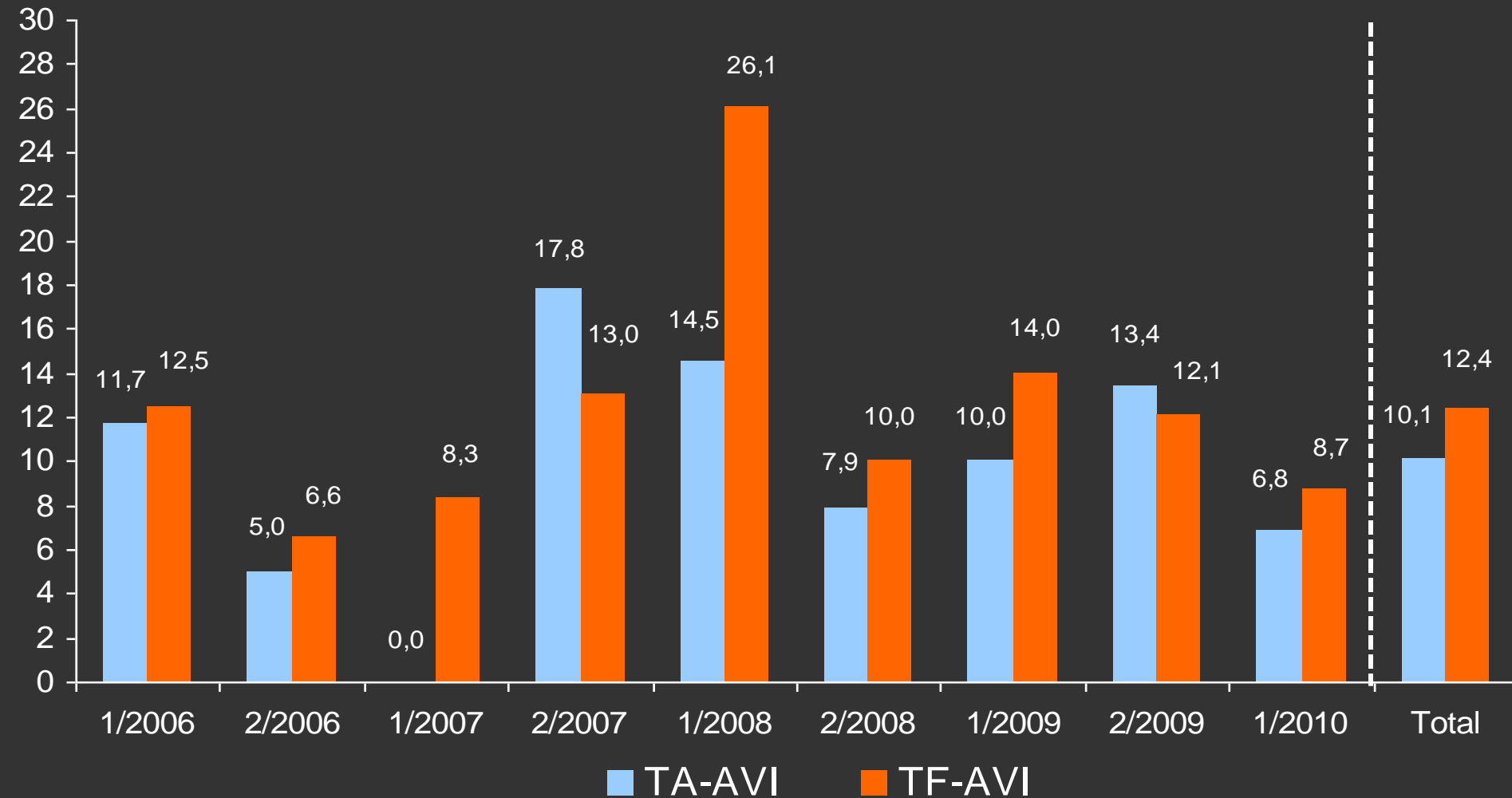
apical \Leftrightarrow **femoral**, procedures



All comers TAVI (Leipzig): Mortality ($n \sim 800$)

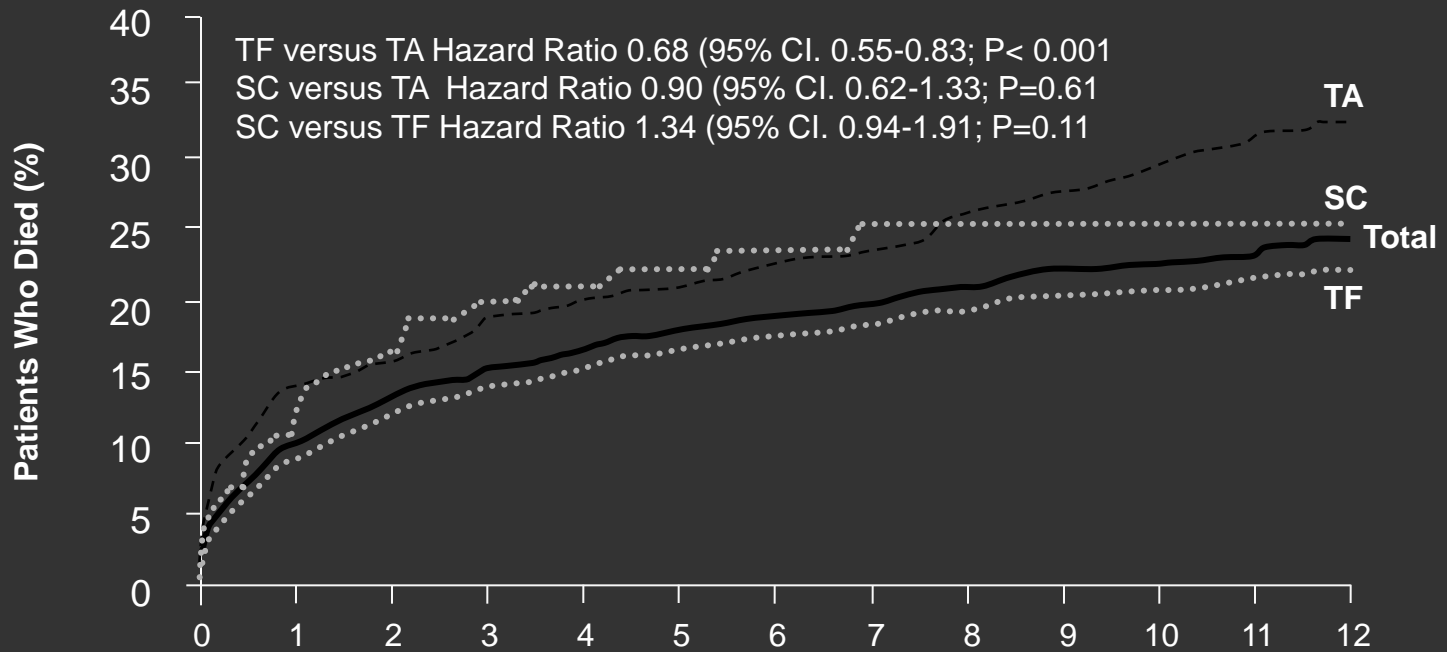
apical \Leftrightarrow femoral

Hospital
Mortality (%)





Vía de Acceso y Mortalidad



# at Risk	Months			
Total	3195	2420	1207	402
TA	567	439	239	54
TF	2361	1794	908	329
SC	184	131	52	19

Gilard M, Eltchaninoff H y col. NEJM 2012;366:1705-15
 Registry of Transcatheter Aortic Valve Implantation in High Risk patients
 France 2.



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de Buenos Aires

*Instituto de Medicina
Cardiovascular*

N#	60 p.
Edad	80.75 ± 8.6 a(46-94)
Euroscore Log.	25.6 ± 11
STS	7.4 ± 4.3
	% (n)
TF	60 (36p)
TIIáico	5 (3)
TSubclavio	3.3 (2)
Tao	5 (3)
TA	26.6 (16)
Mortalidad 30días	11.6 (7)
Mortalidad a 1 año	23.3 (24)
MP definitivo	11.6 (7)
Leak paravalvular >2+	16 (10)
ACV	1.6 (1)
Complicaciones vasculares	0 (0)

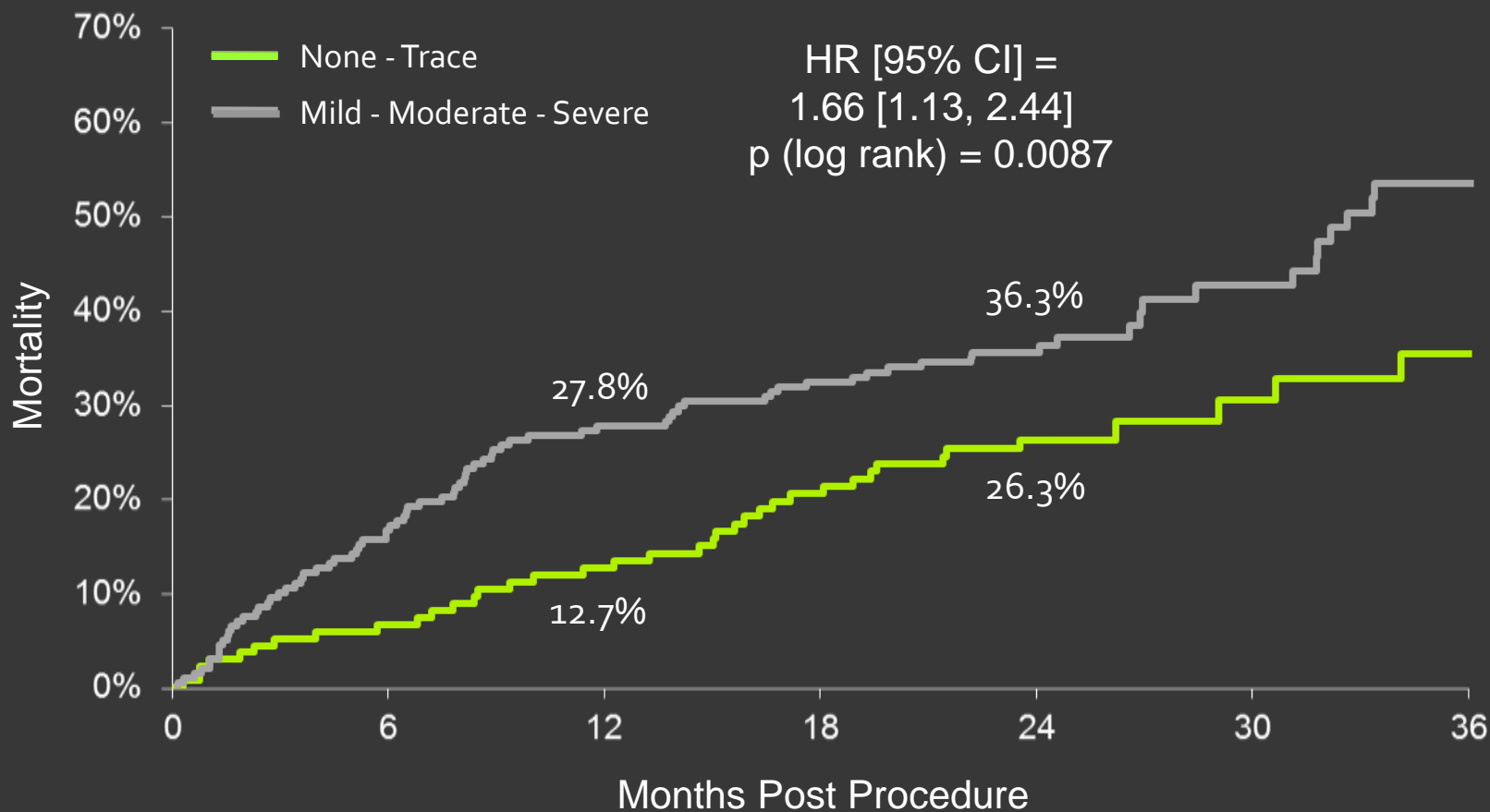
73.4% Retrógrado

26.6% Anterógrado

?



Total AR and Mortality TAVR Patients (AT)

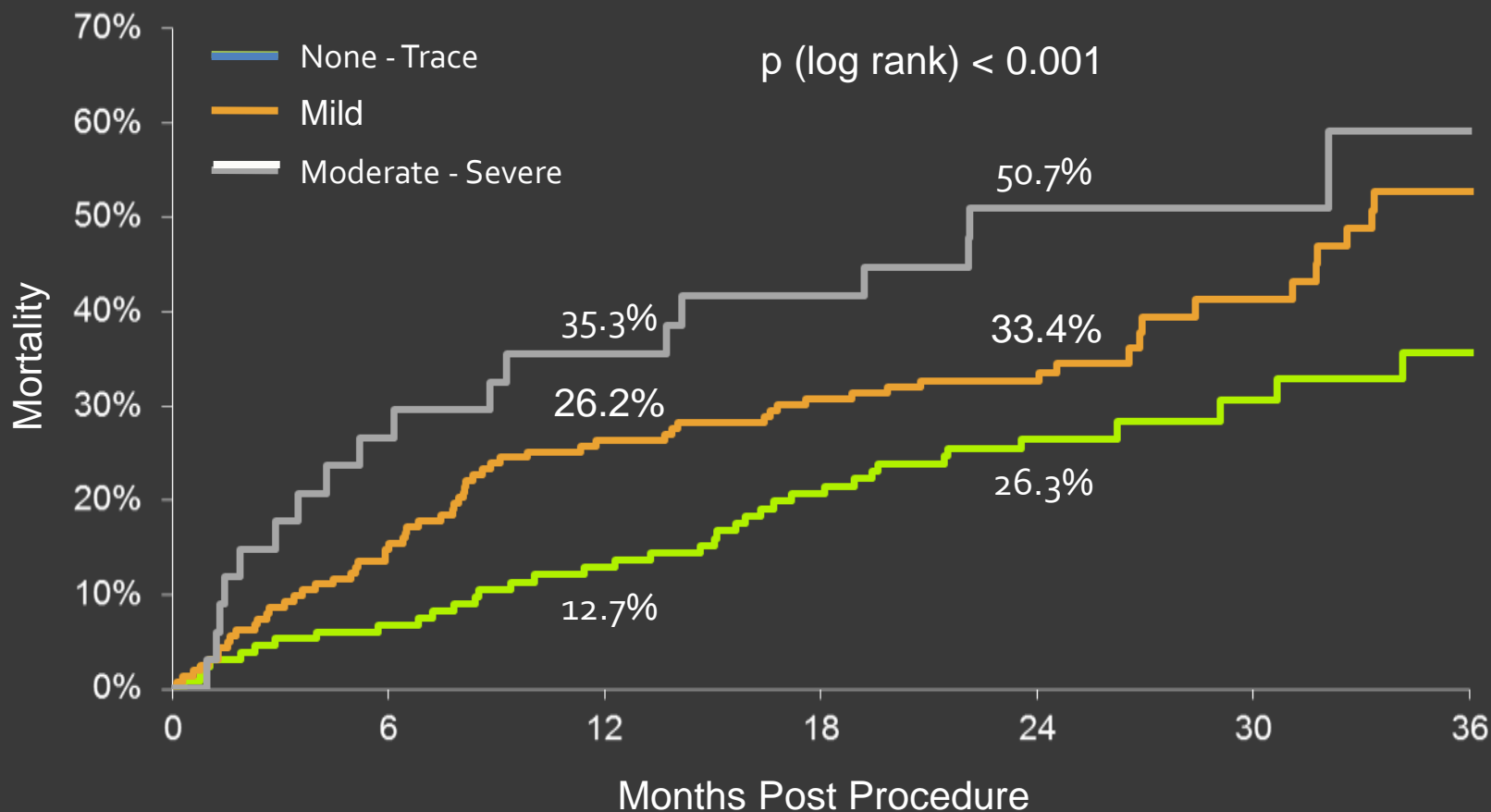


Numbers at Risk

	0	6	12	18	24	30	36
None-Tr	135	125	115	101	68	31	11
Mild-Mod- Sev	199	164	143	130	86	39	18



Total AR and Mortality TAVR Patients (AT)



Numbers at Risk

	0	6	12	18	24	30	36
None-Tr	135	125	115	101	68	31	11
Mild	165	139	121	111	71	33	16
Mod-Sev	34	25	22	19	15	6	2

Evolución de las bioprótesis



 **Sadra**
MEDICAL
Boston
Scientific

 **JENAVALVE**
Designed with the patient at heart

ACURATE TA™
symetis 

DIRECT FLOW
MEDICAL, INC.


Medtronic
ENGAGER

SAPIEN3™
 **Edwards**

- ✓ No hay diferencias en mortalidad a 3 años
- ✓ Durabilidad indeterminada
- ✓ Stroke sigue siendo mayor que con cirugía convencional
- ✓ Aun el “leak” moderado esta relacionado con peor sobrevida
- ✓ Requiere marcapaso definitivo en el 12% con ES y 28% con MCV
- ✓ Tiene más complicaciones vasculares
- ✓ Contar con TODOS los posibles accesos puede reducir Stroke y complicaciones vasculares (“Heart Team”)
- ✓ Los nuevos modelos podrían reducir la posibilidad de “leaks”



NOTHING IS AS STRONG
AS TEAM SPIRIT