

PRESENTE Y FUTURO DEL TAVI

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NOVEDADES EN 2015. ESTADO ACTUAL

PARTNER 1. 5 años de seguimiento



Symptomatic Severe Aortic Stenosis

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

Total = 1,057 patients

N = 699

High Risk

2 Parallel Trials:
Individually Powered

Yes

**ASSESSMENT:
Transfemoral Access**

No

Transfemoral (TF)

Transapical (TA)

1:1 Randomization

N = 244

N = 248

1:1 Randomization

N = 104

N = 103

TF TAVR

VS

SAVR

TA TAVR

VS

SAVR

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

Inoperable

N = 358

**ASSESSMENT:
Transfemoral Access**

Yes

No

1:1 Randomization

N = 179

N = 179

Not In Study

TF TAVR

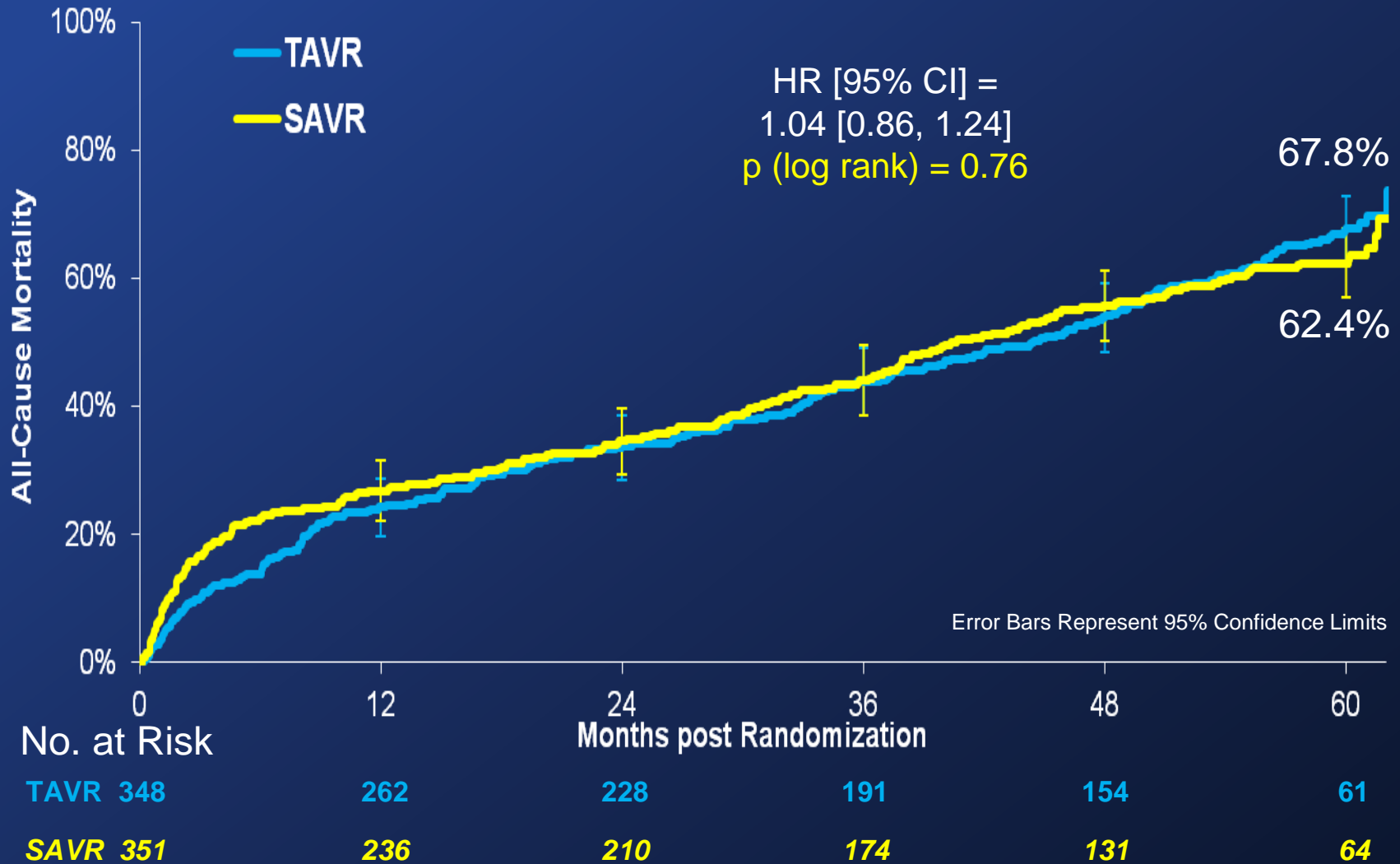
VS

Standard
Therapy

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

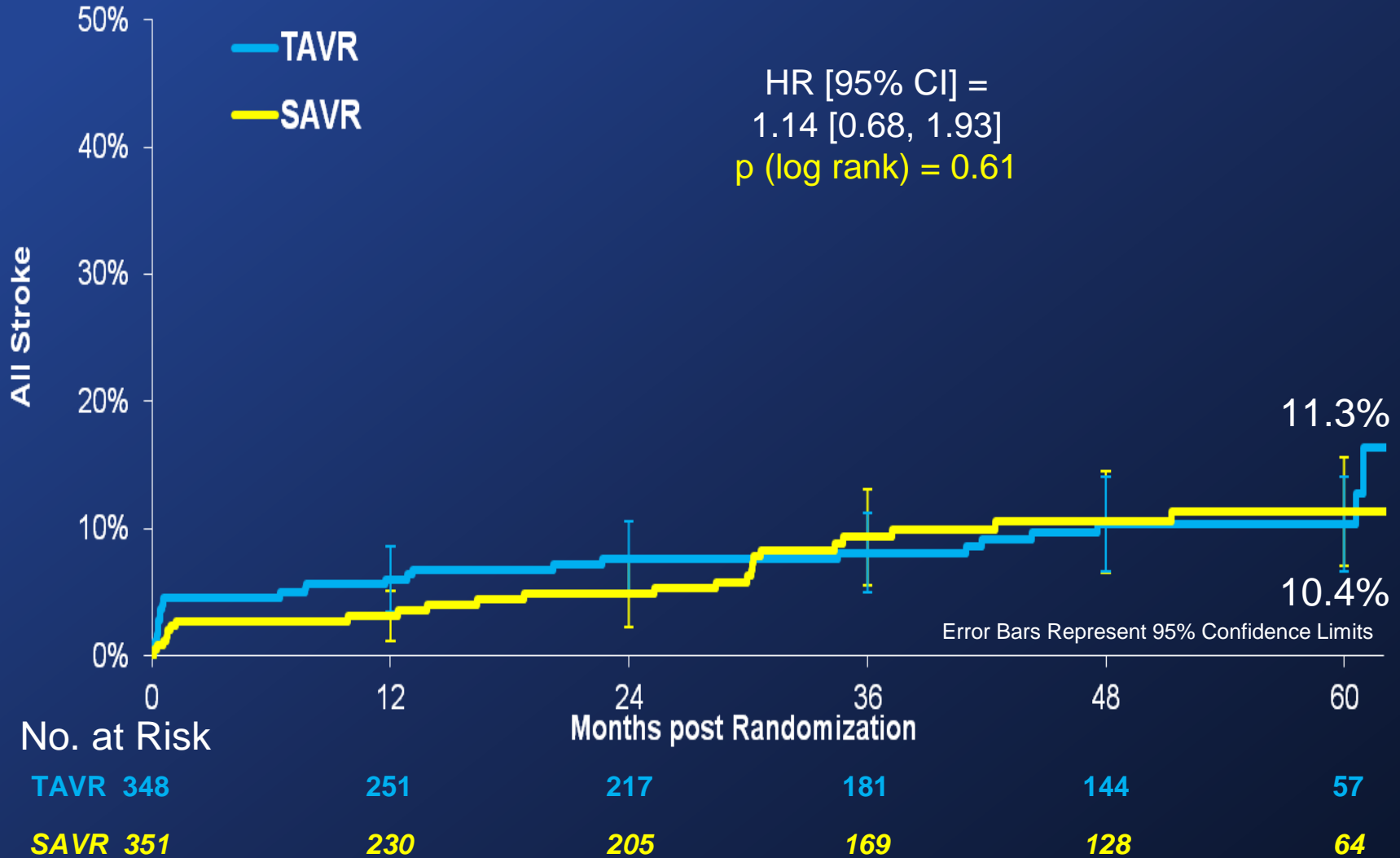
All-Cause Mortality (ITT)

All Patients



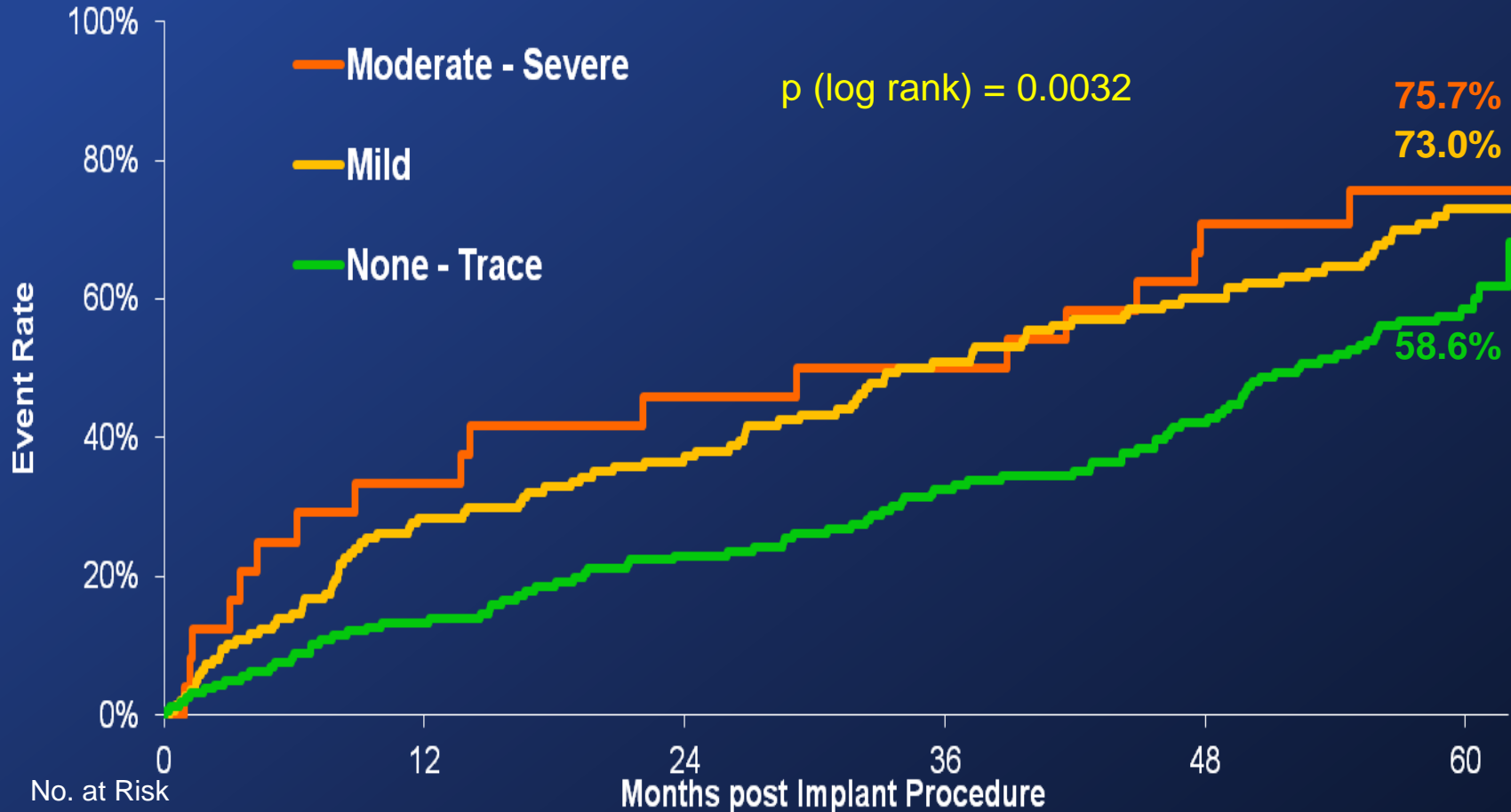
All Stroke (ITT)

All Patients



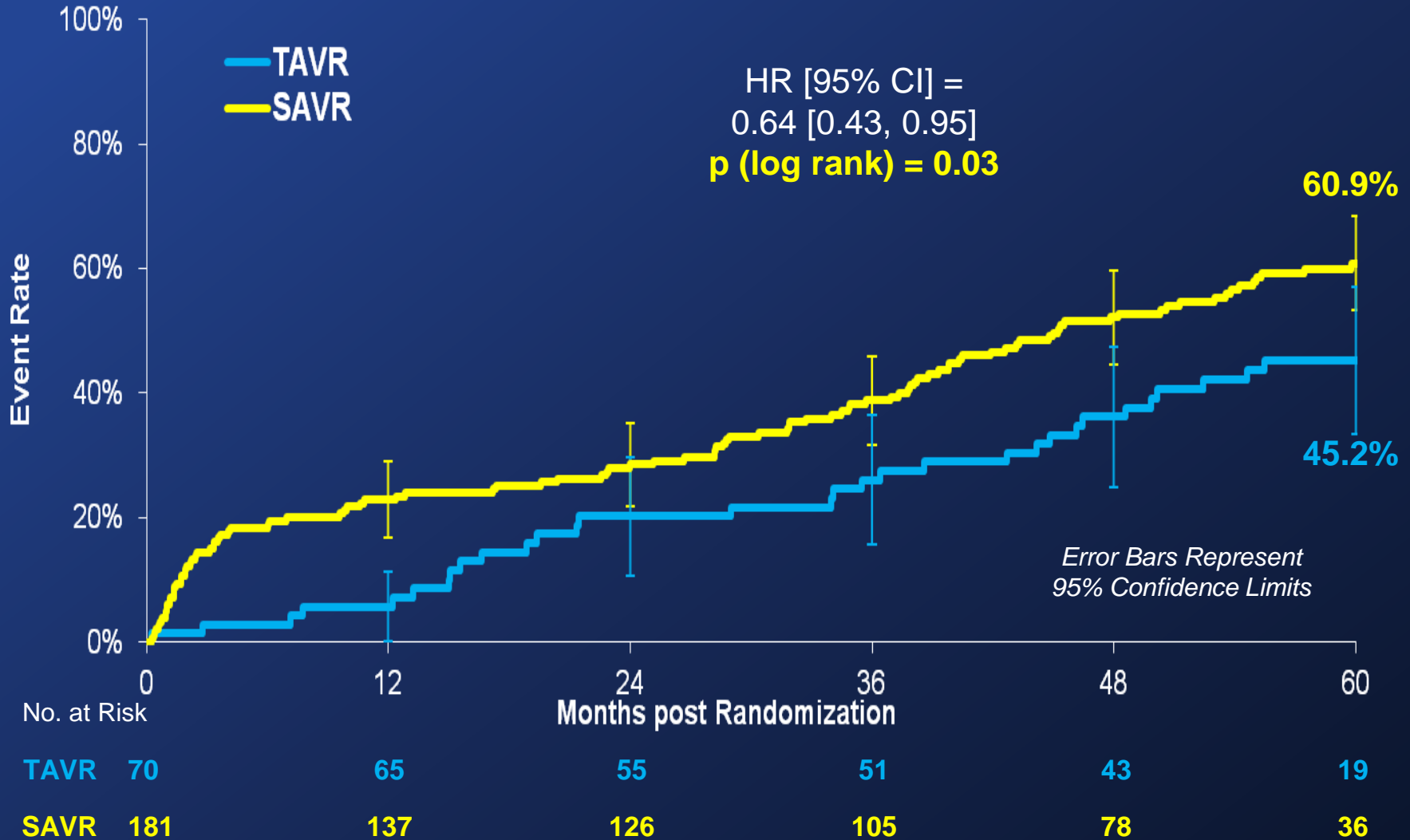
Mortality and Post Procedural PVL

TAVR Patients



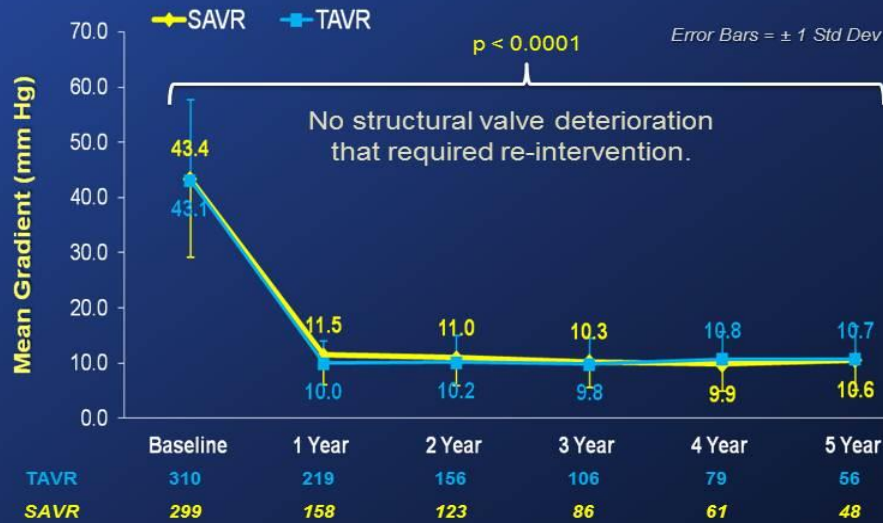
M-S	24	16	13	12	7	2
Mild	137	98	84	65	52	11
N-T	158	135	120	105	88	34

Mortality and None-Trace Total AR Transfemoral Patients



Echocardiographic Results

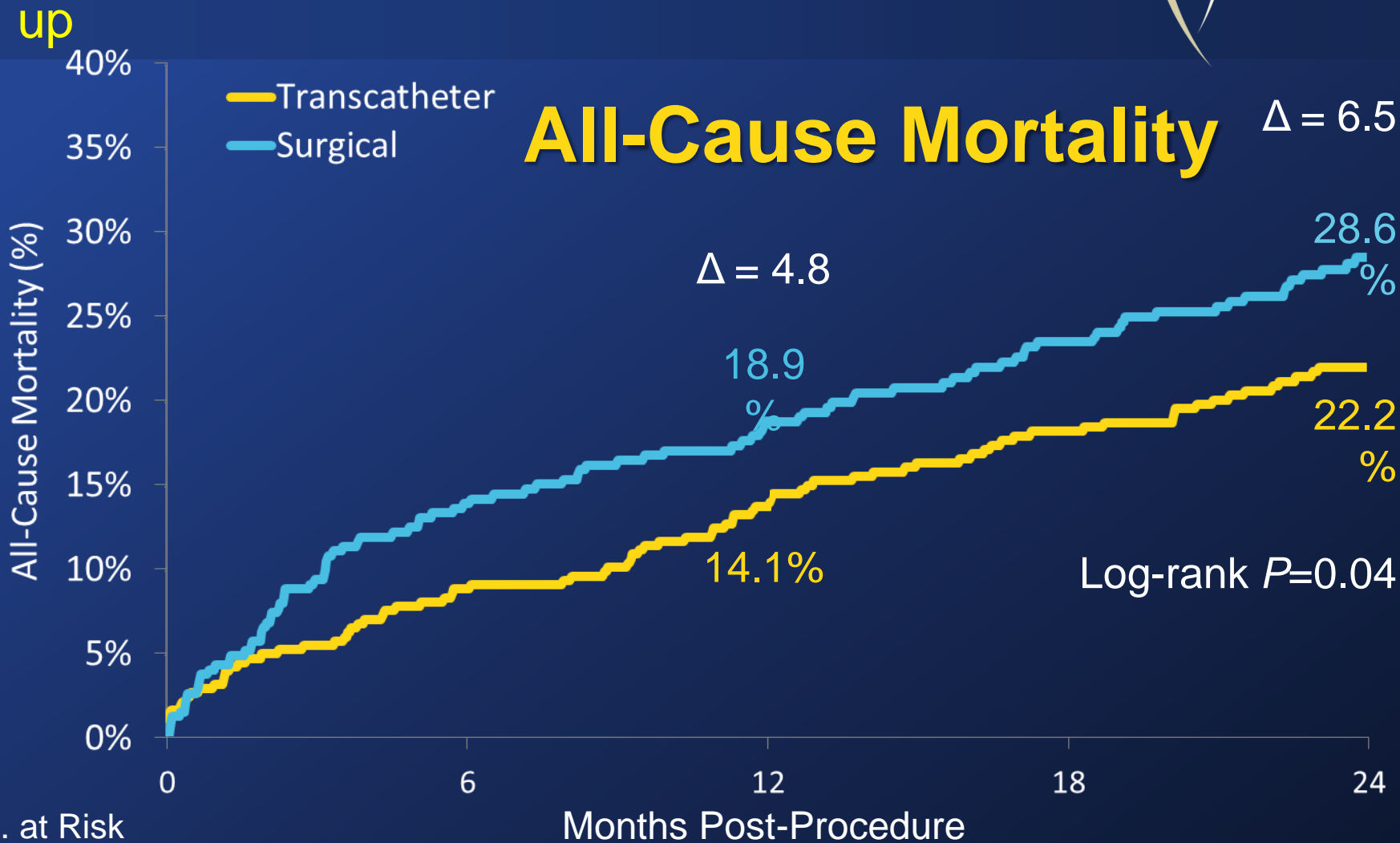
Aortic Valve Mean Gradient



Aortic Valve Area



COREVALVE US Pivotal Trial. 2 years follow up

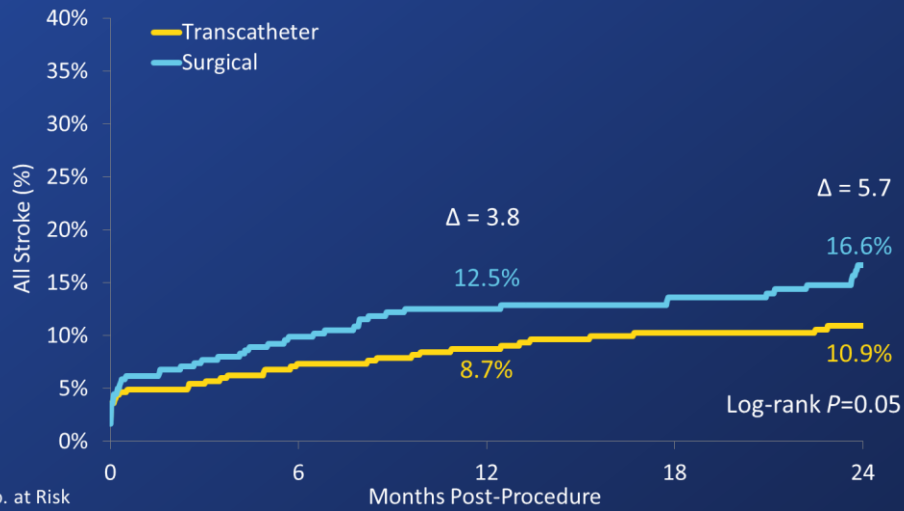


No. at Risk	0	6	12	18	24
Transcatheter	391	378	354	334	219
Surgical	35	343	304	282	191

Stroke

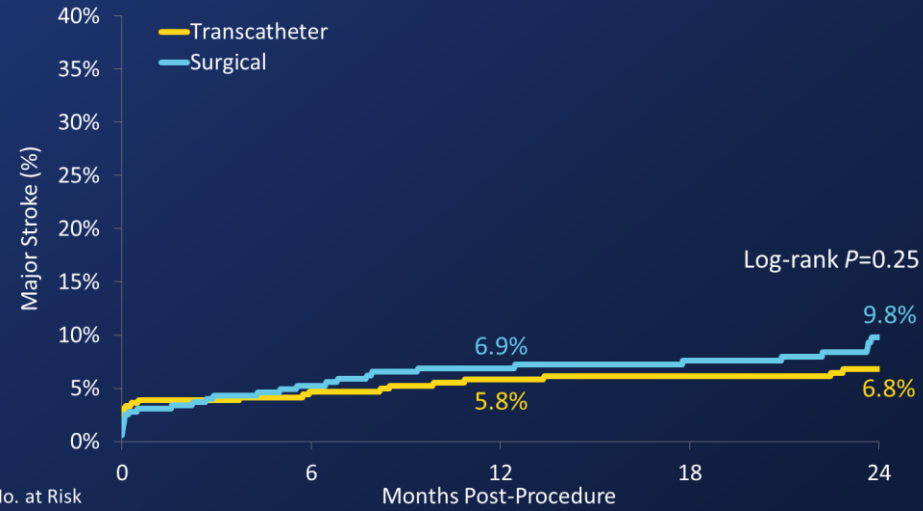


All Stroke



No. at Risk	0	6	12	18	24
Transcatheter	391	364	335	318	205
Surgical	359	324	281	256	169

Major Stroke



No. at Risk	0	6	12	18	24
Transcatheter	391	368	345	326	214
Surgical	359	335	296	271	184

Early Procedural Results

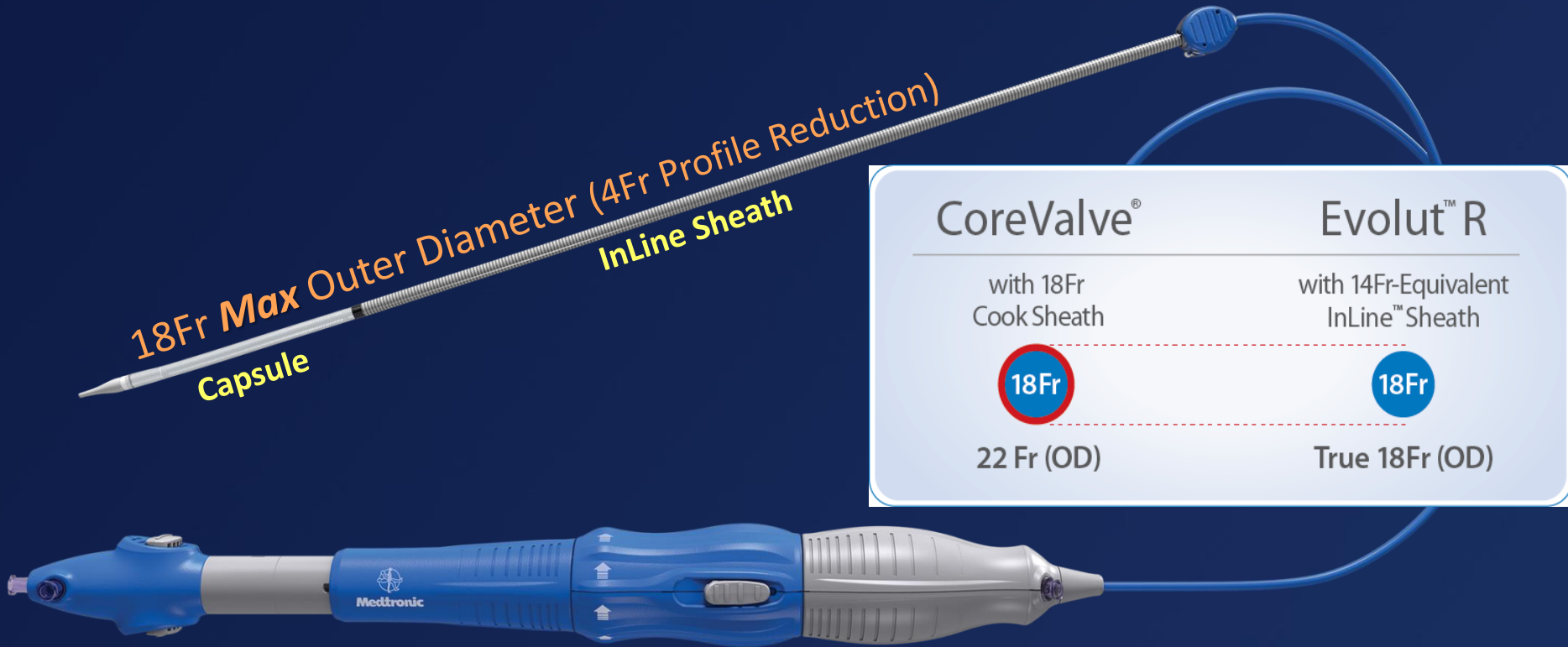
From the CoreValve Evolut R CE Study

Lowest Delivery Profile, 14Fr-Equivalent

System with InLine Sheath across All Valve Sizes

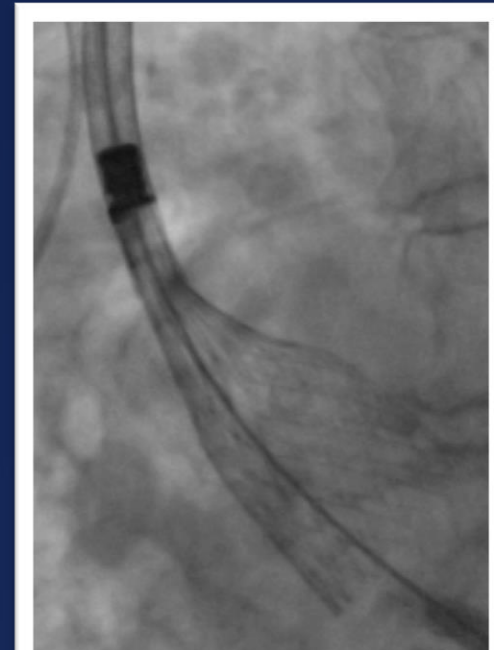
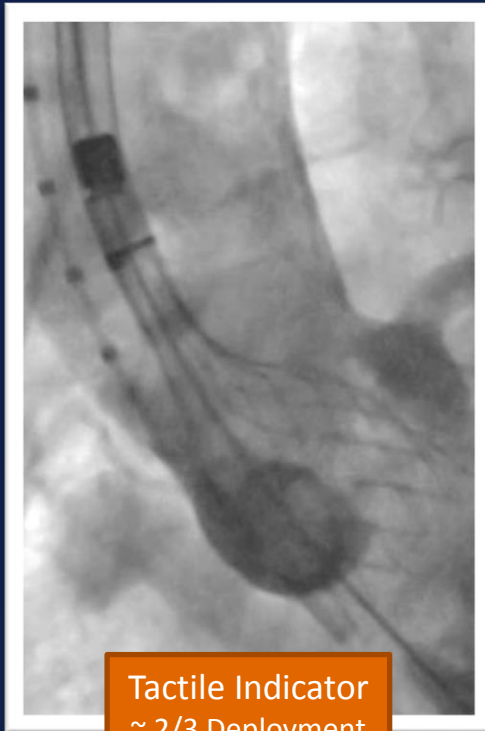
*Improves Access and Reduces Risk of Major Vascular Complications**

NOW Indicated for Minimum Transarterial Access Vessel Diameters ≥ 5.0 mm!



- Sheath to Femoral Artery Ratio (SFAR) great than 1.05 predicted higher rates of VARC major vascular complications. Hayashida K, et al. Transfemoral aortic valve implantation. JACC Intv 2011;4(8):851-8.

Positioning Accuracy: Ability to Recapture and Reposition



* Up to 80% deployment

Clinical Performance

Event, %	N=60
Absence of procedural mortality	100.0 (60/60)
Correct positioning of 1 valve in proper location	98.3 (59/60)
Mean gradient < 20 mm Hg or peak velocity < 3m/sec	98.3 (59/60)

* Effective orifice area could not be determined in 5 patients to calculate patient prosthesis mismatch.

† First time reporting of device success according to VARC-2 criteria

Outcomes

Procedural Event Rates (%)* N=60

Annular rupture [†]	0.0
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Coronary artery obstruction requiring intervention [†]	0.0
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Valve dysfunction requiring reintervention	0.0
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Device embolization	0.0
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30 Day Event Rates (%)*

All-cause mortality	0.0
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All stroke	0.0
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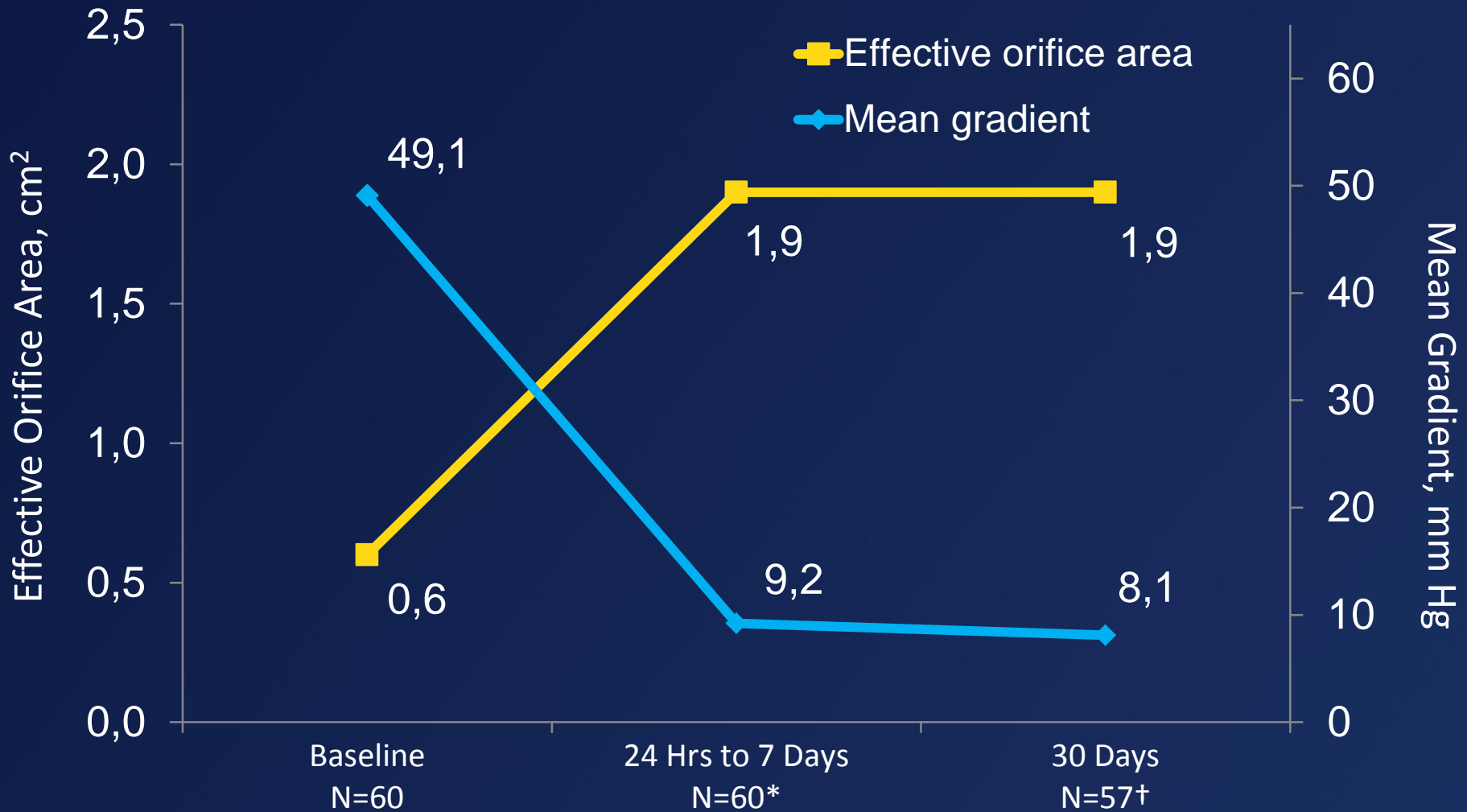
Moderate or severe PVL	3.4
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Permanent pacemaker implantation	11.7
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* Percentages obtained from Kaplan Meier estimates

[†] Medtronic data on file.

Valve Performance



*Mean AV gradient was available in 60 patients; EOA in 55

†AV gradient available in 57 patients, EOA in 54

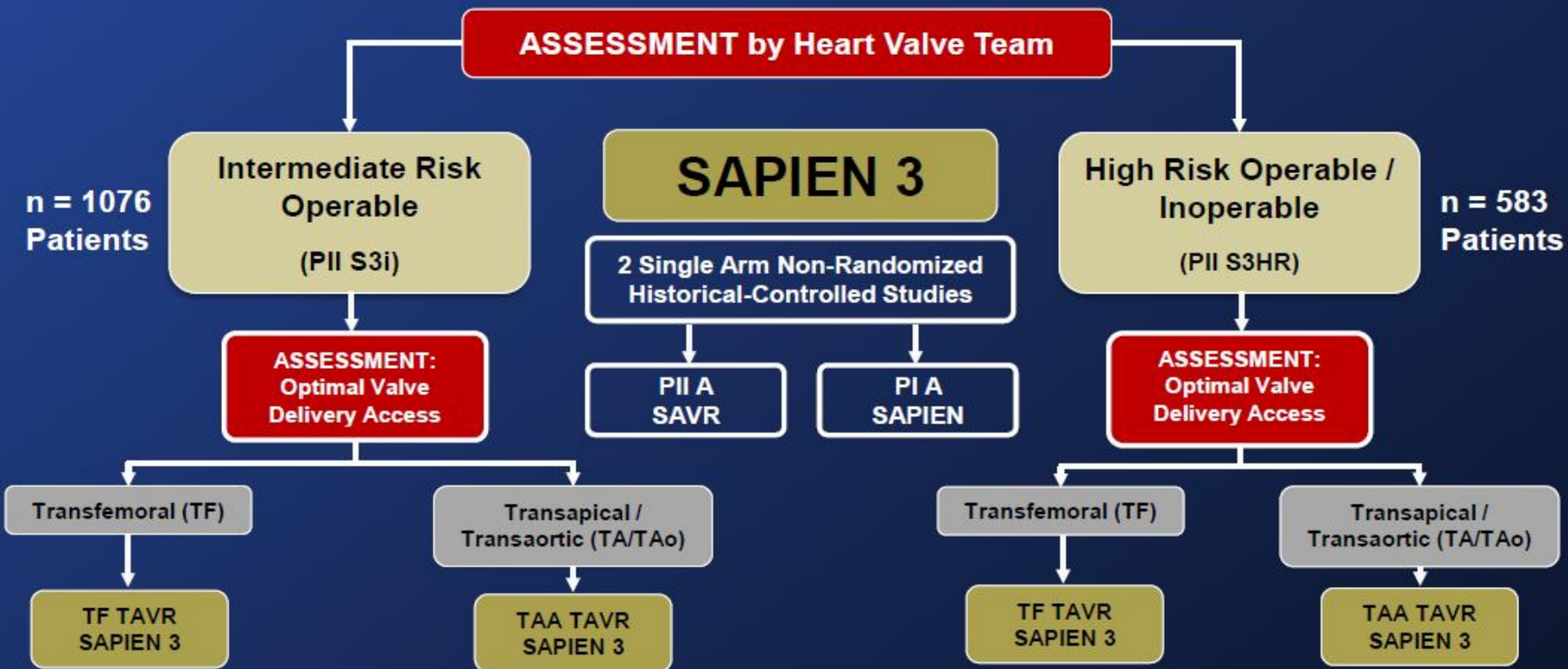
- **PARTNER 5 años:** la primera generación de la Sapien tiene resultados similares a la cirugía en pacientes de alto riesgo quirúrgico. La función valvular se mantiene a los cinco años sin deterioro
- **CoreValve High-Risk 2 años:**
 - TAVI se mantiene superior a cirugía (mortalidad a 2 años)
 - Menor tasa de ACV con TAVI, si bien los ACV graves son similares en ambos grupos
 - La hemodinámica valvular es superior en la válvula percutánea que en la quirúrgica a los 2 años, sin datos de disfunción
- **Evolut R:** Los resultados clínicos a 30 días demuestran ausencia de mortalidad y ACV un porcentaje bajo de insuficiencia aórtica paravalvular moderada o severa y marcapasos

The PARTNER II S3 Trial


Study Design



Symptomatic Severe Aortic Stenosis



Evolution of the Edwards Balloon-Expandable Transcatheter Valves




Cribier-Edwards

2002



SAPIEN

2006



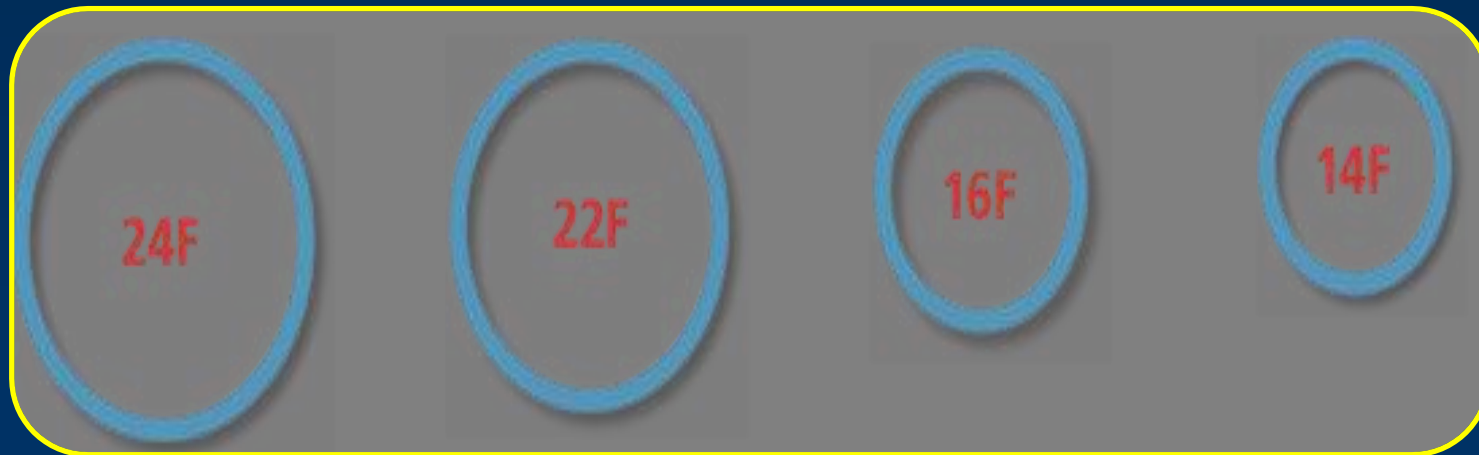
SAPIEN XT

2009



SAPIEN 3

2013



* Sheath compatibility for a 23 mm valve

Key Inclusion Criteria



- Risk determined by STS score and heart team:
 - **High Risk / Inoperable (S3HR)**: STS score > 8 or heart team determination
 - **Intermediate Risk (S3i)**: STS score between 4 and 8 or heart team determination
- Severe aortic stenosis determined by echocardiography:
 - Valve area $< 0.8 \text{ cm}^2$ or Valve area index $< 0.5 \text{ cm}^2/\text{m}^2$ **and** mean gradient $> 40\text{mmHg}$ or peak velocity $> 4 \text{ m/s}$

Study Flow: S3HR & S3i

30 Day Patient Status

S3HR

n = 583

13 Deaths

n = 570
SAPIEN 3

0 Withdrawal
3 LTFU

**567 / 570 or 99.5% follow-up
visits performed at 30 Days**

S3i

n = 1076

12 Deaths

n = 1064
SAPIEN 3

0 Withdrawal
5 LTFU

**1059 / 1064 or 99.5% follow-up
visits performed at 30 Days**

Baseline Patient Characteristics

S3HR Patients

N = 583

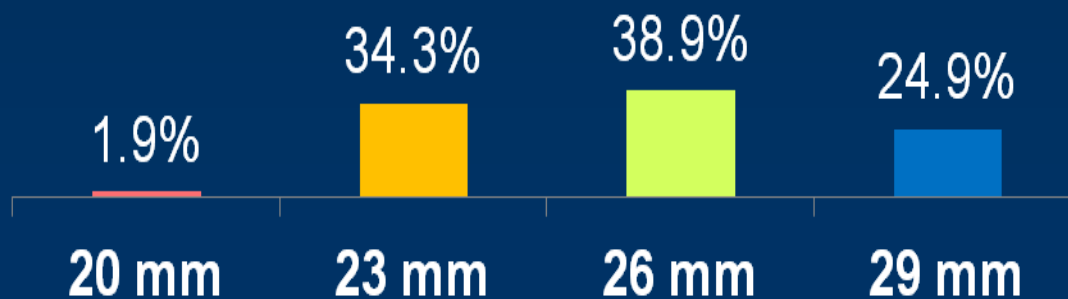
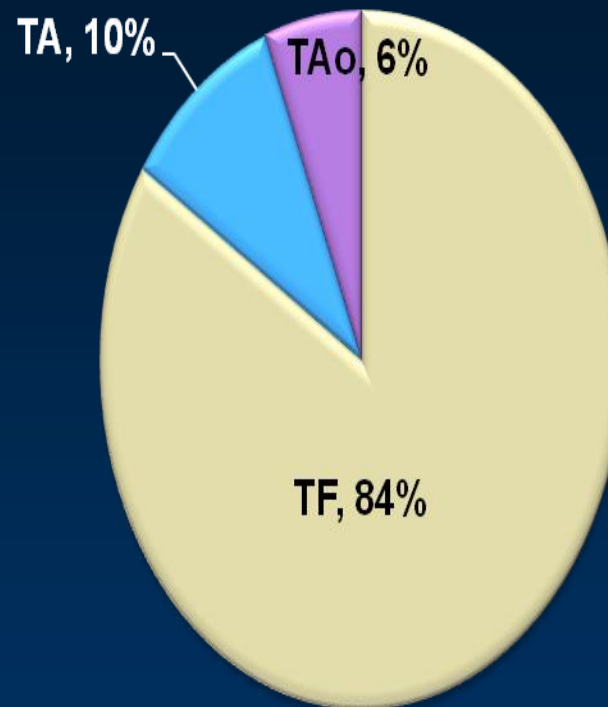
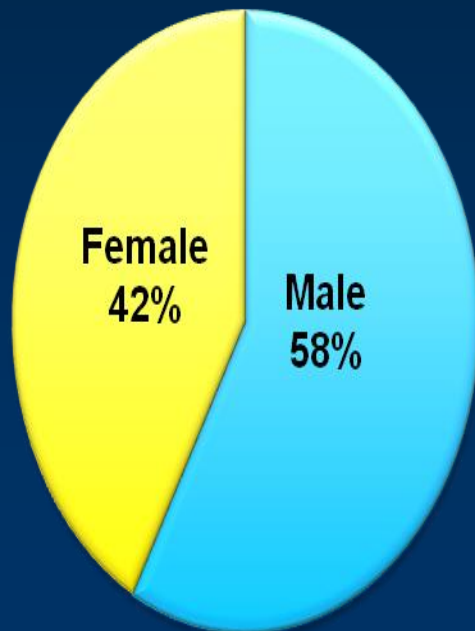
Average STS =

8.6%

(Median 8.4%)

Average Age =

82.6yrs



Baseline Patient Characteristics

S3i Patients

Average STS =

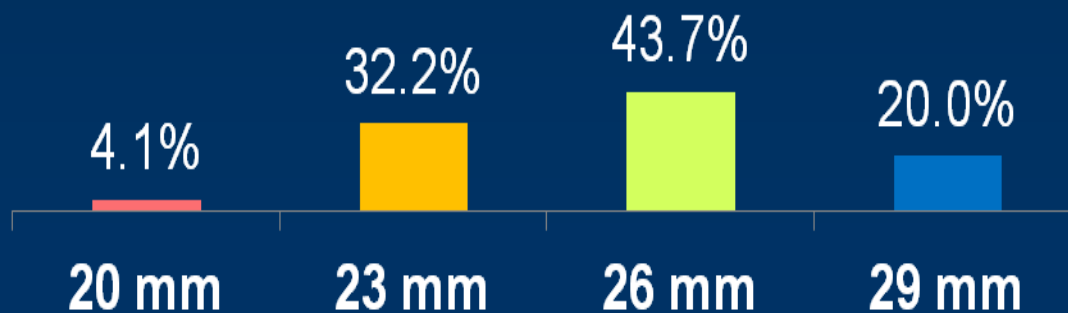
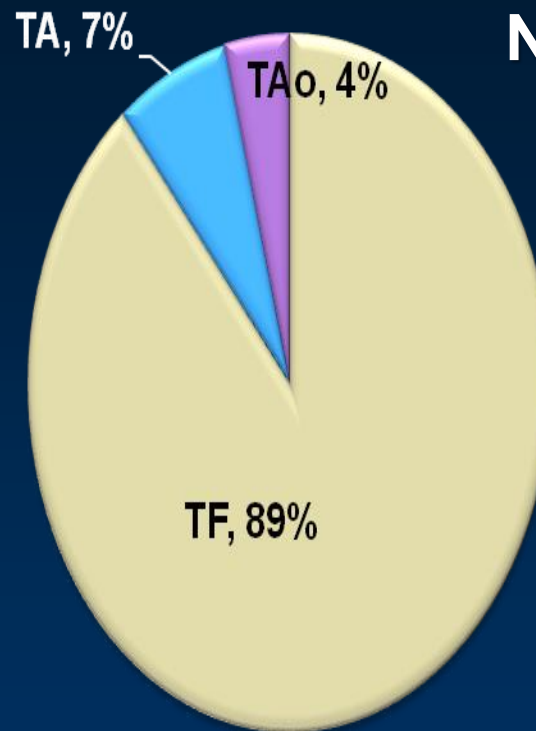
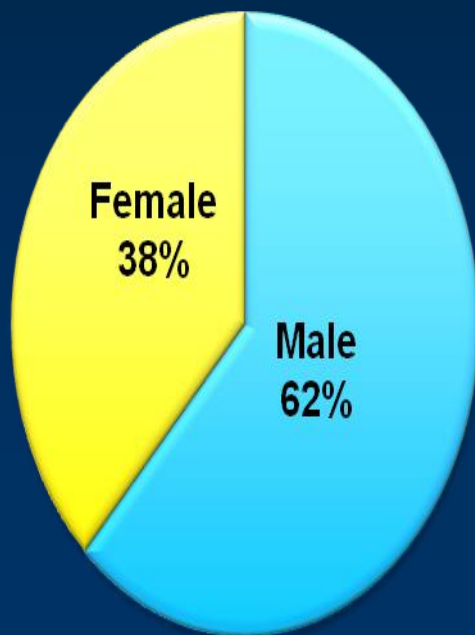
5.3%

(Median 5.2%)

Average Age =

81.9yrs

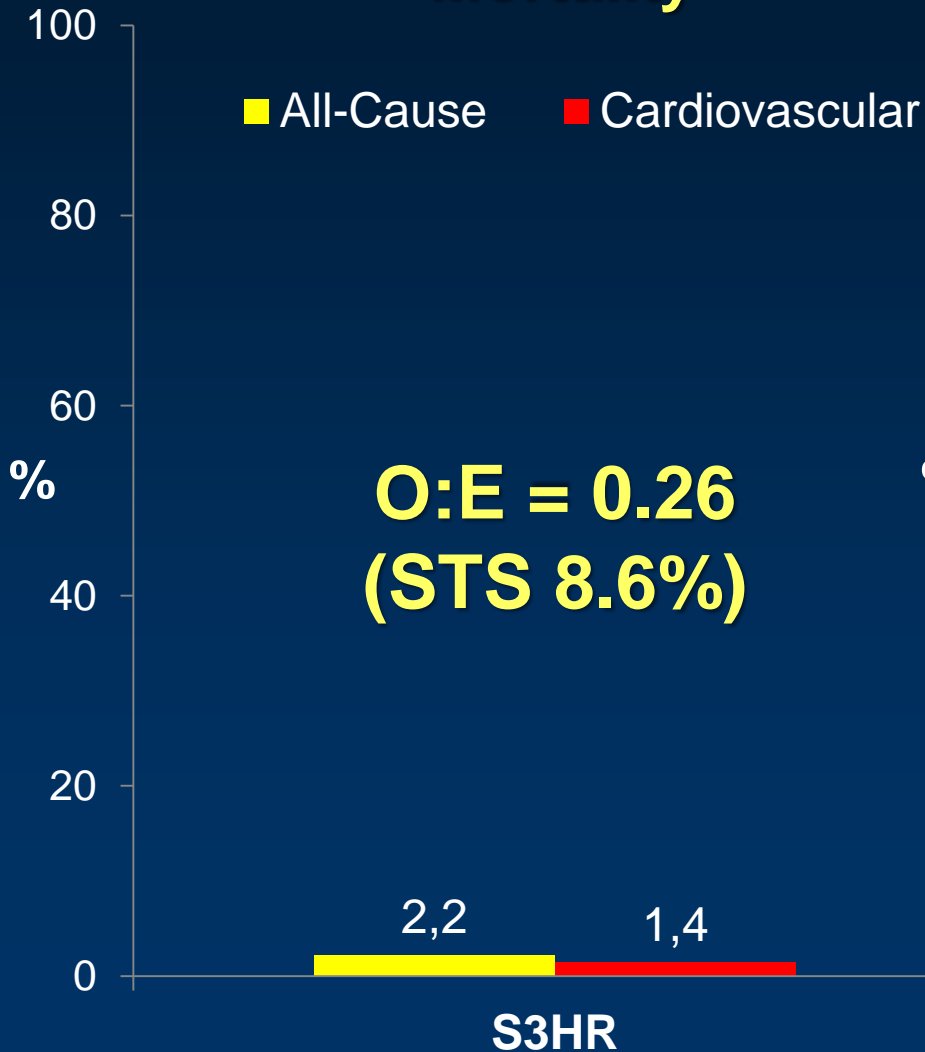
N = 1076



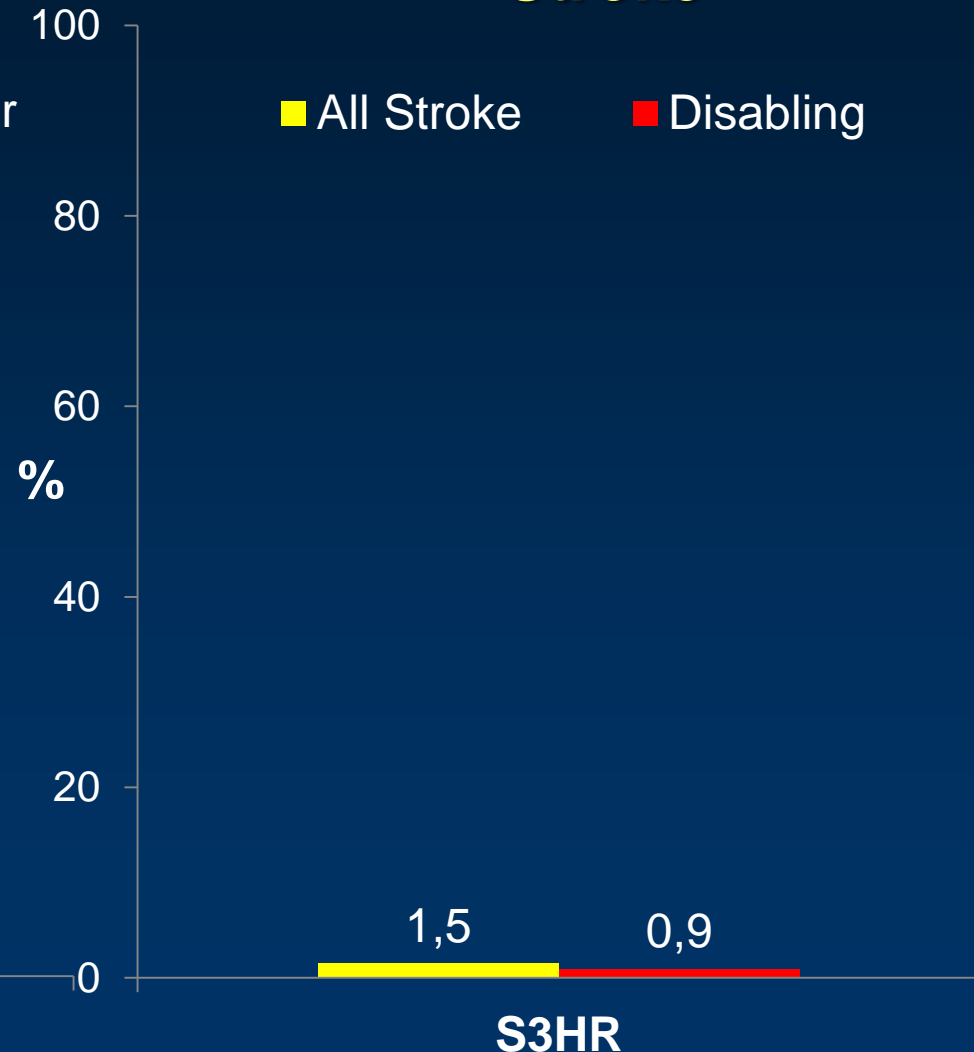
Mortality and Stroke: S3HR

At 30 Days (As Treated Patients)

Mortality



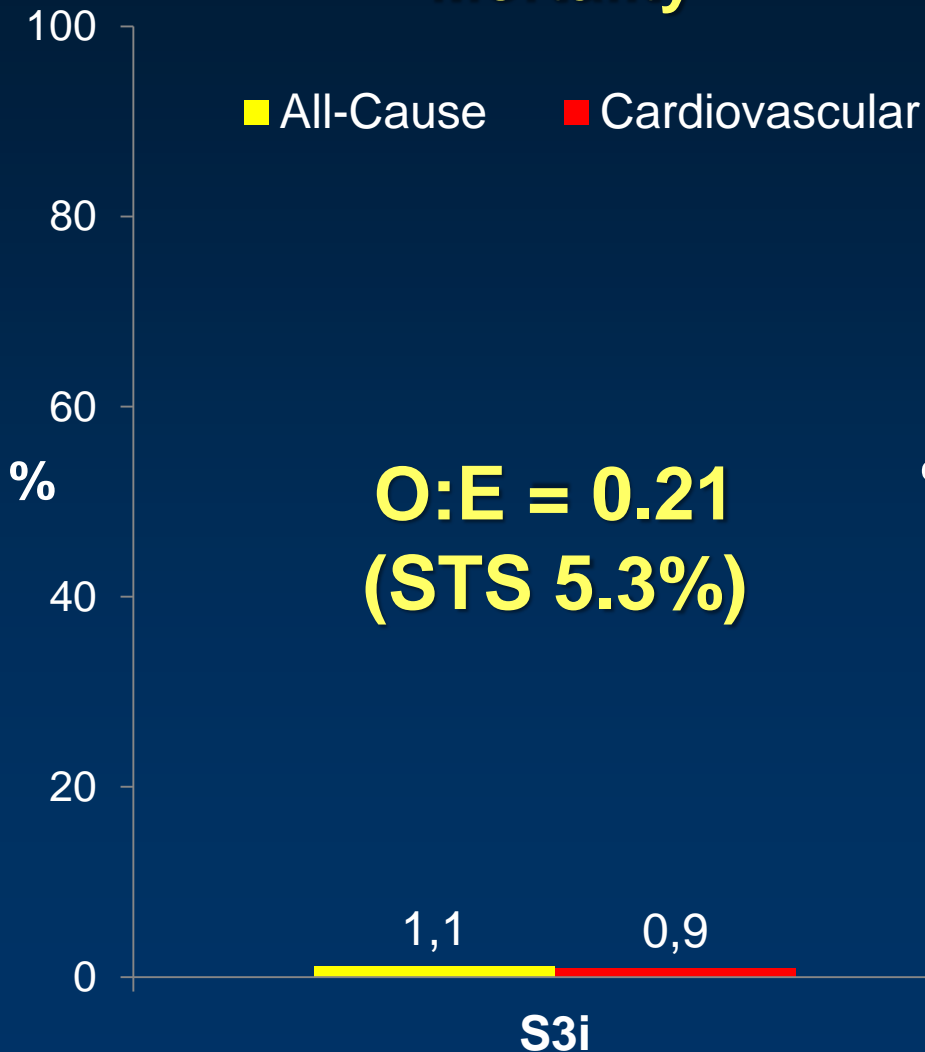
Stroke



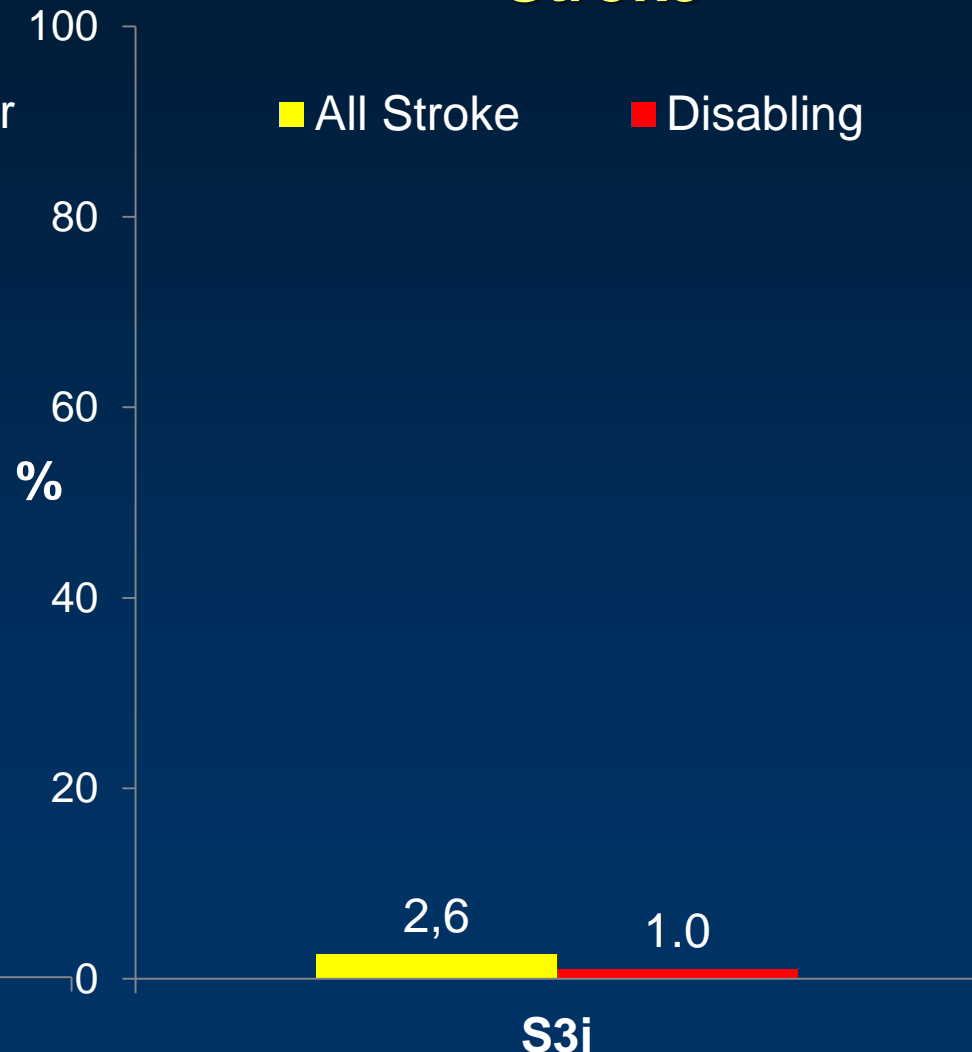
Mortality and Stroke: S3i

At 30 Days (As Treated Patients)

Mortality



Stroke

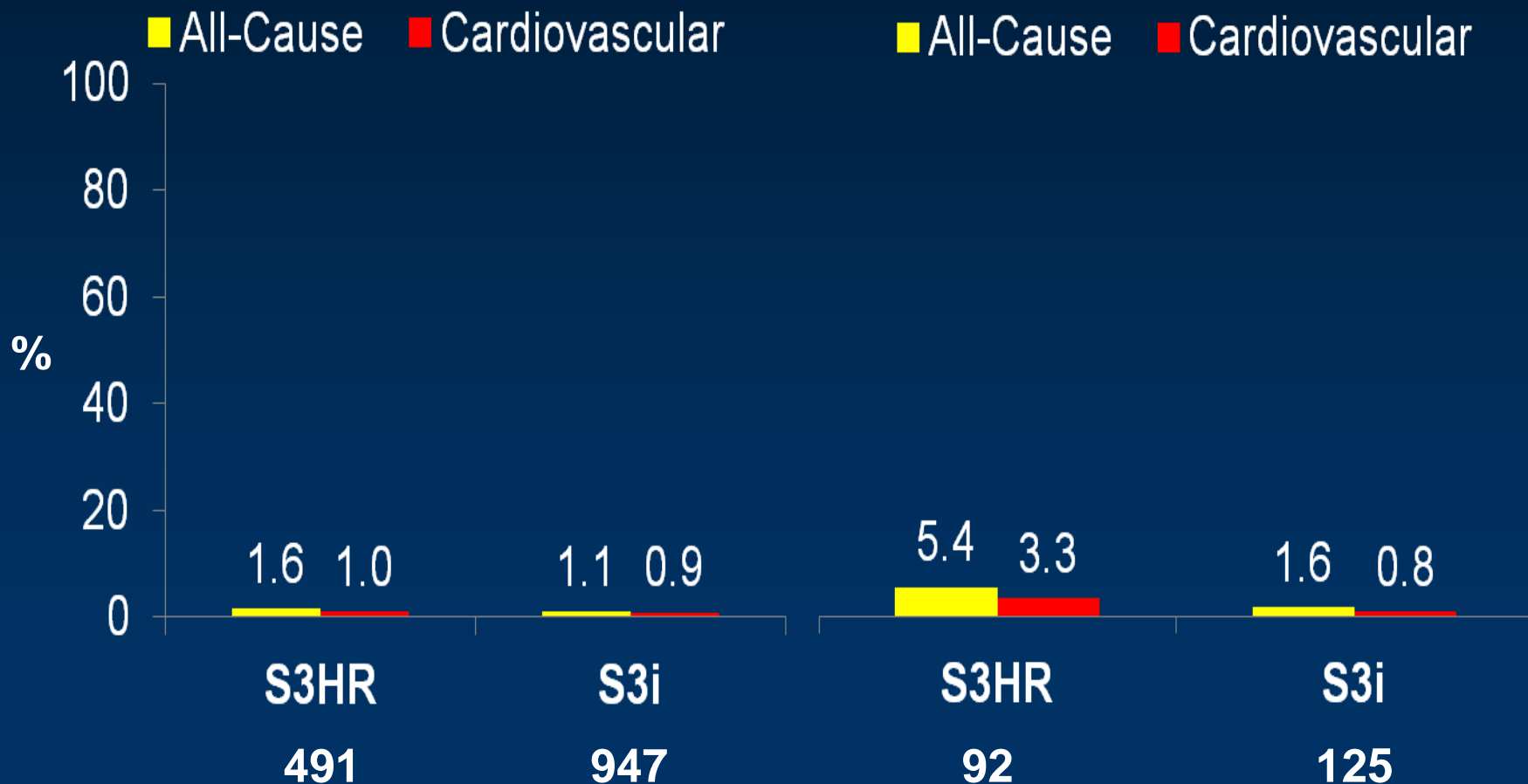


Mortality: S3HR & S3i

At 30 Days (As Treated Patients)

Transfemoral

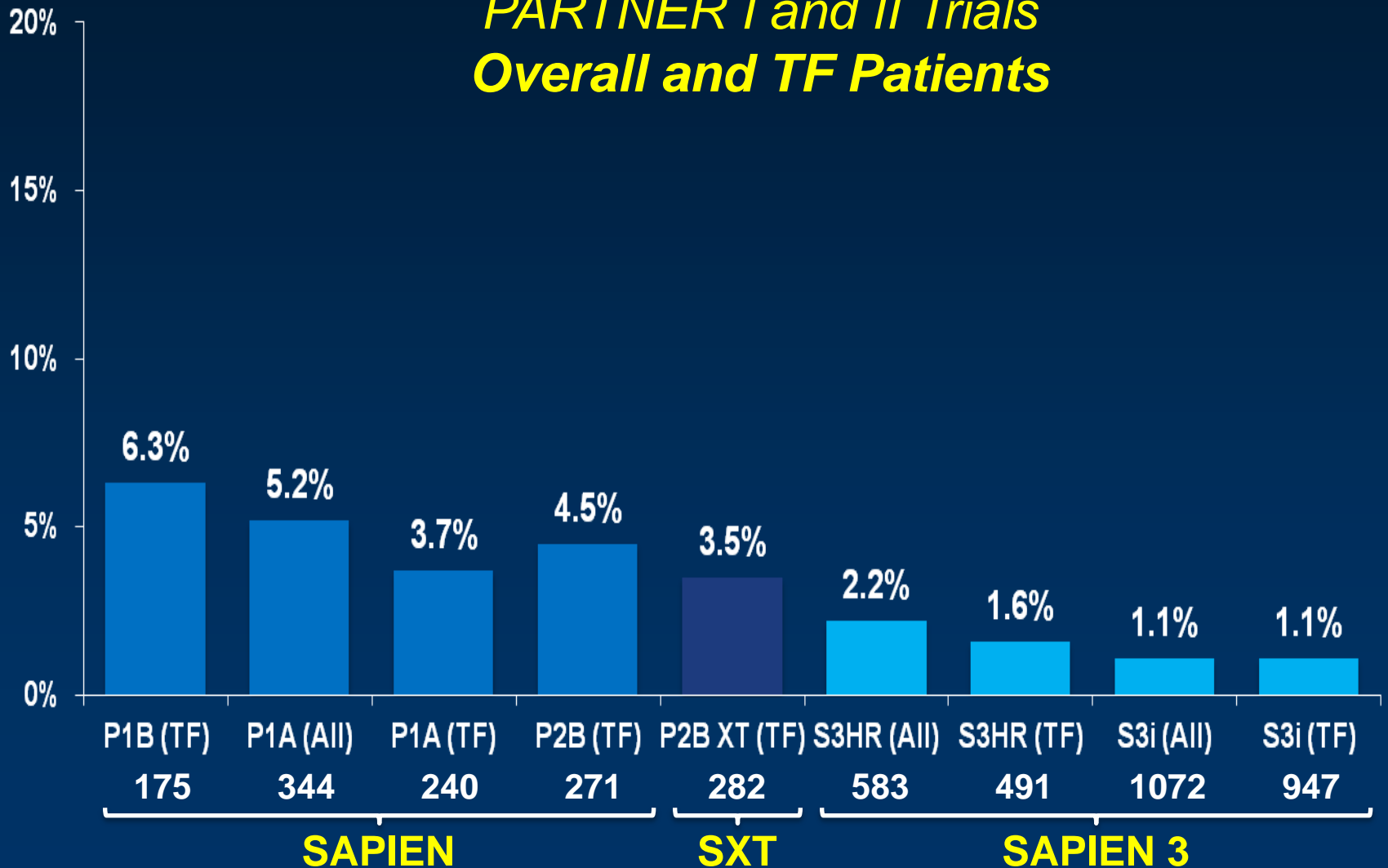
Transapical / Transaortic



All-Cause Mortality at 30 Days

Edwards SAPIEN Valves (As Treated Patients)

PARTNER I and II Trials Overall and TF Patients



Conclusiones PARTNER 2

- **En pacientes de alto riesgo o inoperables la válvula SAPIEN 3 (S3HR), muestra baja mortalidad y ACV a 30 días**
 - **Mortalidad: 2.2% (TF 1.6%, TA/TAo 5.4%)**
 - **ACV grave: 0.9%**
- **En pacientes de riesgo intermedio SAPIEN 3 se asoció a menores tasas de mortalidad y ACV a 30 días(S3i):**
 - **Mortalidad: 1.1% (TF 1.1%, TA/TAo 1.6%)**
 - **ACV grave: 1.0%**

Implications

- The rapid evolution of balloon-expandable TAVR, both procedural developments and technical enhancements, represented in the SAPIEN 3 clinical and echo results, indicates at least parity with the best surgical outcomes in comparable patients.
- ***SAPIEN 3 TAVR should now be considered as an alternative to surgery, even in lower risk patients with aortic stenosis.***

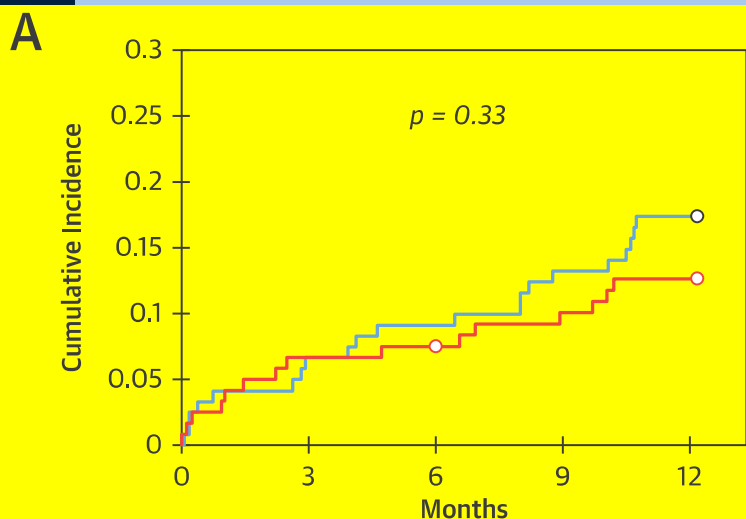
TAVI

¿Es una válvula superior a otra?

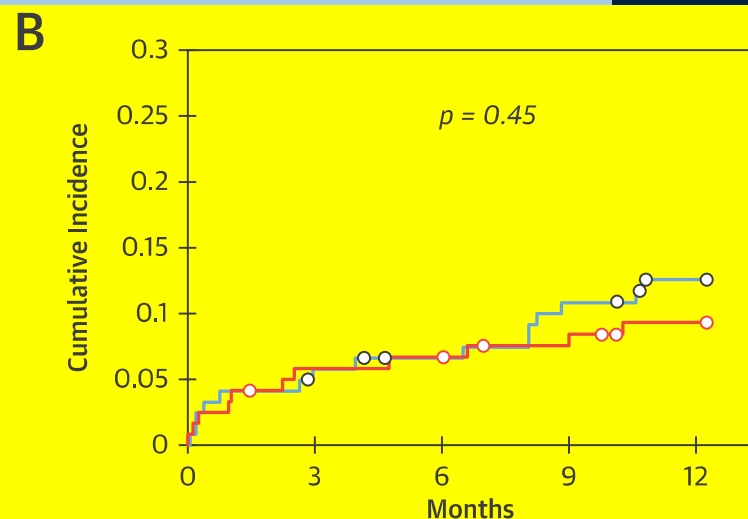
1-Year Outcomes After Transcatheter Aortic Valve Replacement With Balloon-Expandable Versus Self-Expandable Valves

Results From the CHOICE Randomized Clinical Trial

241 Transfemoral TAVR patients enrolled and randomized



No. at risk	0	3	6	9	12
Balloon-expandable	121	114	111	106	100
Self-expandable	120	113	111	106	102



No. at risk	0	3	6	9	12
Balloon-expandable	121	114	111	106	100
Self-expandable	120	113	111	106	102

— Balloon-expandable — Self-expandable

LFU = 0
Withdrawal = 0

LFU = 0
Withdrawal = 3

100% Clinical follow-up

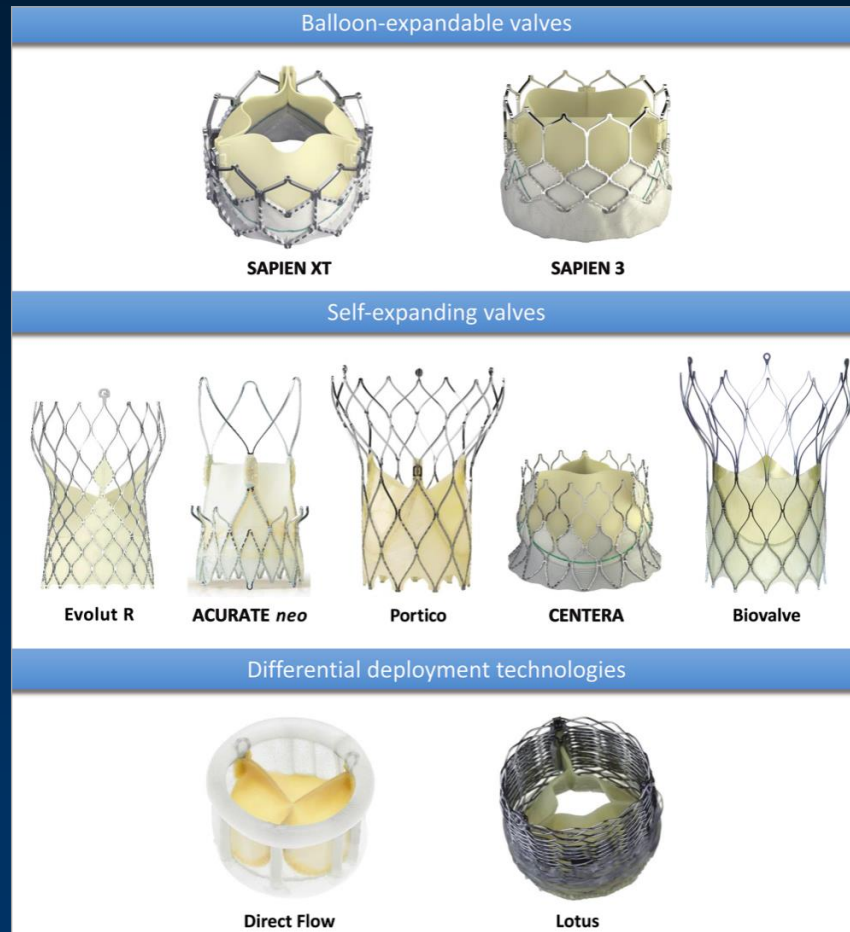
97% Clinical follow-up

TABLE 2 Clinical Outcomes		TABLE 4 Echocardiographic Follow-Up at 1 Year						
		Balloon-Expandable Valve (n = 131)	Balloon-Expandable Valve (n = 131)	Self-Expandable Valve (n = 117)	Self-Expandable Valve (n = 117)	p Value	95% CI	p Value
Death	Number of patients		69		66			
	Effective orifice area, cm ²		1.7 ± 0.4		1.8 ± 0.6	0.34		
Of any cause	Number of patients		68		66		0.73-2.50)	0.37
Of cardiovascular causes	Indexed effective orifice area, cm ² /m ²		0.9 ± 0.2		1.0 ± 0.3	0.16	0.63-2.75)	0.54
Stroke	Number of patients		79		81		0.87-8.12)	0.11
Major stroke	Mean gradient, mm Hg		9 (7-12)		8 (5-11)	0.004	0.51-5.63)	0.54
Minor stroke	Number of patients		88		91		–	0.12
Ischemic stroke	Transvalvular aortic regurgitation					0.44	0.60-6.25)	0.38
Hemorrhagic stroke	None/trace		86 (97.7)		86 (94.5)		–	0.25
	Mild		2 (2.3)		5 (5.5)			
Repeat hospitalization for heart failure	Moderate		0 (0)		0 (0)		0.26-1.27)	0.19
Myocardial infarction	Severe		0 (0)		0 (0)		0.06-15.28)	1.00
Bleeding	Number of patients		89		91			
Life threatening	Paravalvular aortic regurgitation					0.01	0.57-2.09)	0.85
Major	None/trace		52 (58.4)		44 (45.6)		0.85-2.58)	0.18
Minor	Mild		36 (40.4)		36 (39.6)		0.62-3.14)	0.50
Vascular complications	Moderate		1 (1.1)		11 (12.1)			
Major	Severe		0 (0)		0 (0)		0.48-1.94)	1.00
Minor	Number of patients		89		92		0.48-12.22)	0.45
Endocarditis	Total aortic regurgitation					0.03	0.18-20.81)	1.00
Valve thrombosis	None/trace		51 (57.3)		42 (45.6)		–	0.12
	Mild		37 (41.6)		38 (41.3)			
Repeat procedure for valve	Moderate		1 (1.1)		11 (12.0)		0.11-3.79)	0.68
New pacemaker	Severe		0 (0)		1 (1.1)		0.41-0.94)	0.02
New-onset atrial fibrillation	Left ventricular ejection fraction, %		58.9 ± 10.9		57.3 ± 11.8	0.37	0.41-2.63)	1.00
Combined efficacy endpoint	Left ventricular end-systolic dimension, mm		32.6 ± 8.8		34.6 ± 8.1	0.10	0.47-1.18)	0.22
MACCE	Left ventricular end-diastolic dimension, mm		46.1 ± 8.1		48.2 ± 7.4	0.16	0.68-3.65)	0.36
NYHA functional class improvement	Systolic pulmonary artery pressure, mm Hg		28.4 ± 10.5		32.3 ± 13.0	0.06	0.87-1.07)	0.66
Quality-of-life score	Moderate/severe mitral regurgitation		13/88 (14.8)		28/90 (31.1)	0.01	–	0.49
	Moderate/severe tricuspid regurgitation		12/85 (14.1)		20/88 (22.7)	0.14		

TAVI

¿Qué aportan las nuevas válvulas?

TAVI. Nuevos dispositivos



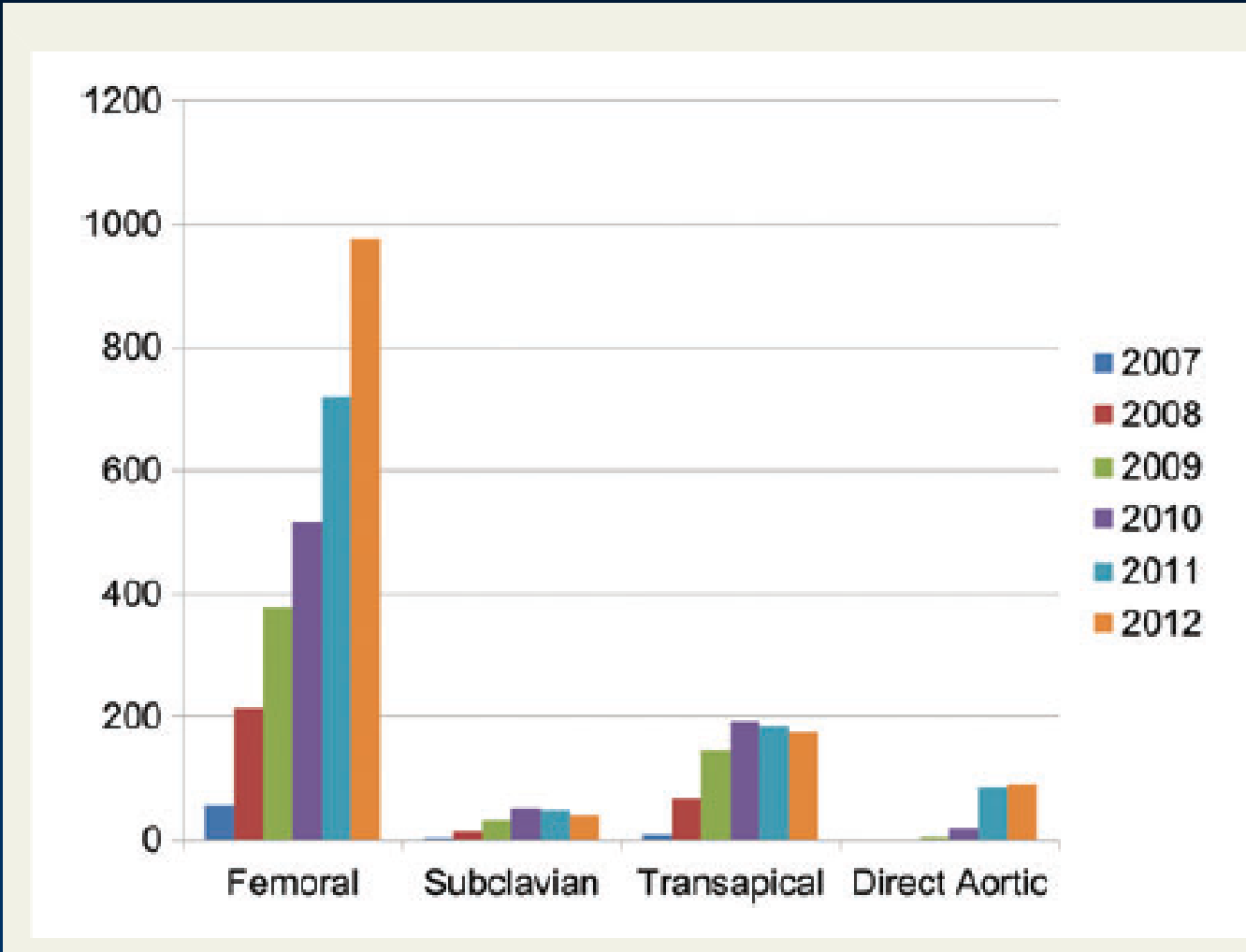
TAVI: NUEVOS DISPOSITIVOS (PCR 2014/ACC 2015)

	LOTUS	DIRECT FLOW	PORTICO	SAPIEN 3	SAPIEN 3 (APICAL)
Pacientes	120	75	83	96	54
Edad	84,4	83,1	83,8	83,6	
Euroscore	STS 7,1	23,5	16,3	19,8	24,9
Mortalidad (30 días) %	4,2	1,3	3,6	2,1	11,1
ACV (%)	5,8 (1,8)	4	3,6 (2,6)	1	5,6
MP (%)	29,4	17	10,8	12,5	14,8
IAO ≥ 2 (%)	2	2	5	2,6	5,1
IAM		1,3	1,2	2,1	
2ª Válvula	0	0		1	
Balón post	0	0		3,3	

TAVI

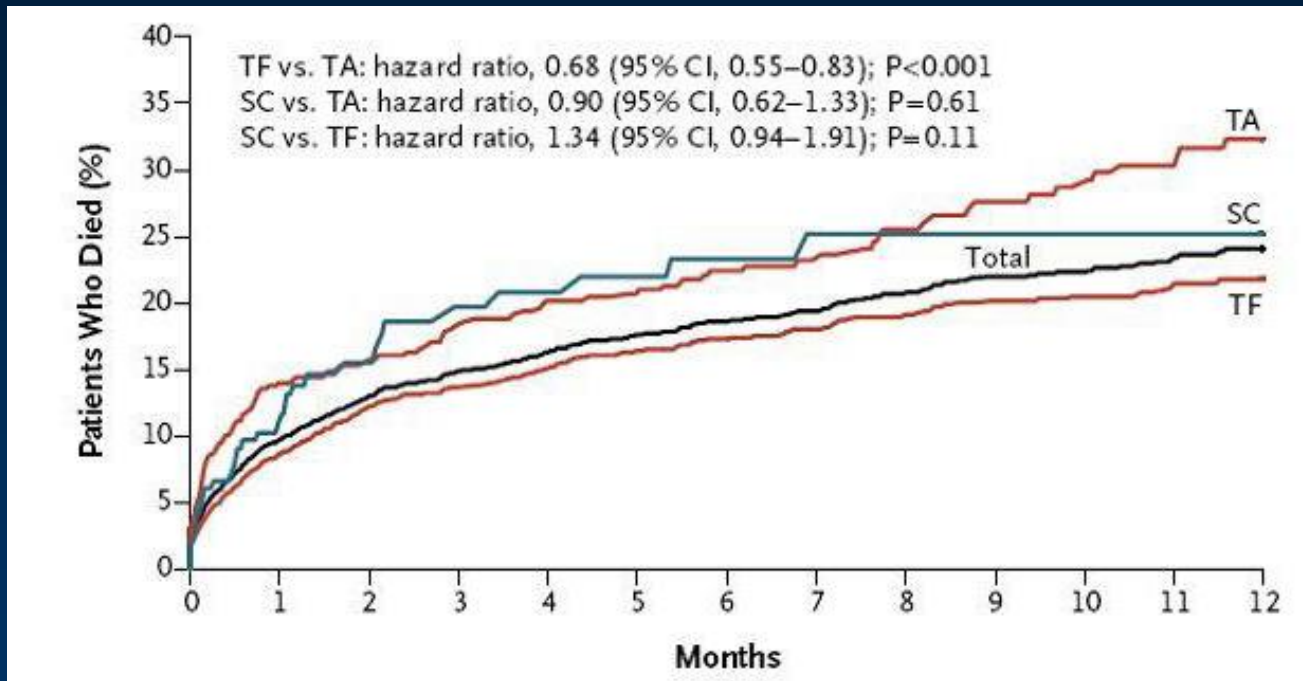
Vía de abordaje

Vía de abordaje





Mortalidad en función del tipo de acceso Registro Francés 2



N Engl J Med 2012;366:1705-15

Predictive factors of early mortality after transcatheter aortic valve implantation: individual risk assessment using a simple score

Table 3 Predictive factors of early (30-day or in-hospital) mortality after TAVI

	Adjusted OR (95% CI)	p Value	Points for score (/21)
Age (years)			
<90	1		0
≥90	1.53 (1.02 to 2.30)	0.04	1
Body mass index (kg/m ²)			
≥30	1		0
18.5–29.9	1.51 (1.01 to 2.27)	0.047	1
<18.5	2.27 (1.09 to 4.74)	0.03	3
NYHA class IV	1.79 (.26 to 2.54)	0.001	2
Pulmonary oedema (APE)			
<2 APE last year	1		0
≥2 APE last year	1.61 (1.12 to 2.30)	0.01	2
Pulmonary hypertension (systolic PAP ≥60 mm Hg)	1.45 (1.08 to 1.94)	0.01	1
Critical state*	2.39 (1.42 to 4.02)	0.001	3
Respiratory insufficiency†	1.64 (1.22 to 2.20)	0.001	2
Dialysis	2.88 (1.46 to 5.66)	0.002	4
Approach			
Transfemoral or subclavian	1		0
Transapical	2.02 (1.47 to 2.78)	<0.0001	2
Other	2.18 (1.11 to 4.28)	0.02	3

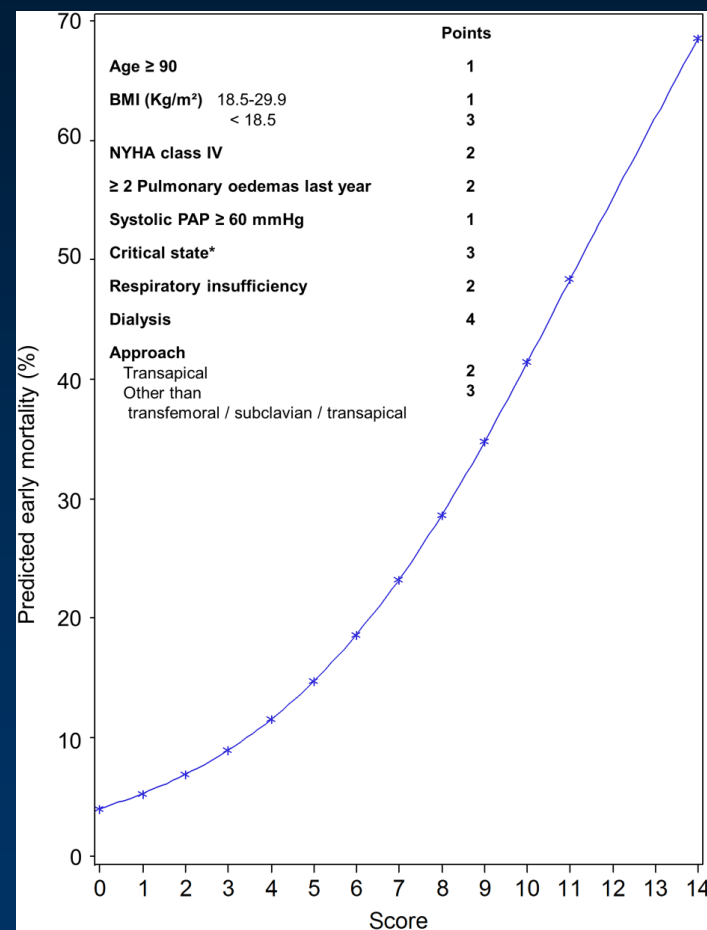
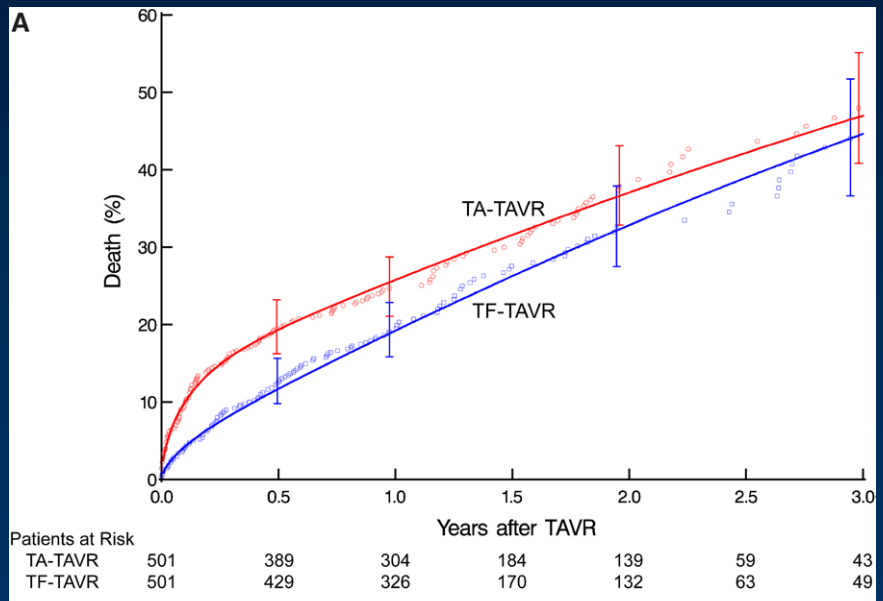
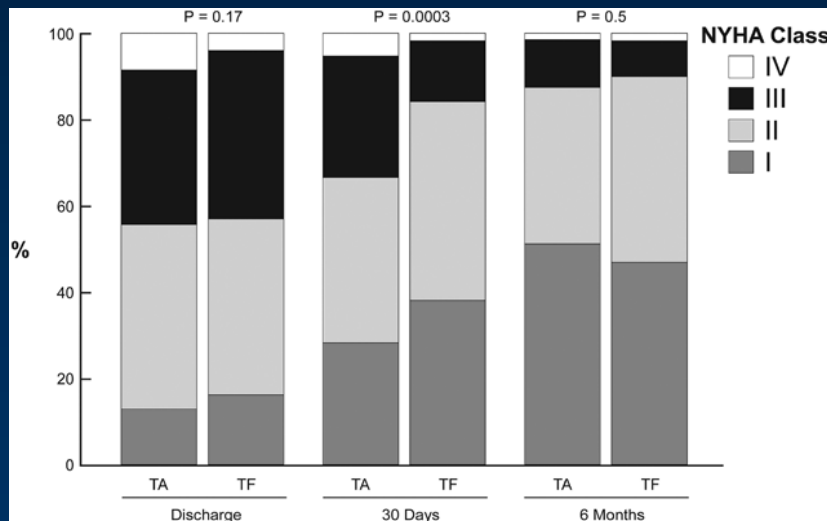


Figure 1 Relationship between the score value and predicted early mortality after transcatheter aortic valve implantation.

Propensity-Matched Comparisons of Clinical Outcomes After Transapical or Transfemoral Transcatheter Aortic Valve Replacement

A Placement of Aortic Transcatheter Valves (PARTNER)-I Trial Substudy

Eugene H. Blackstone, MD; Rakesh M. Suri, MD, DPhil; Jeevanantham Rajeswaran, PhD;
 Vasilis Babaliaros, MD; Pamela S. Douglas, MD; William F. Fearon, MD;
 D. Craig Miller, MD; Rebecca T. Hahn, MD; Samir Kapadia, MD; Ajay J. Kirtane, MD, SM;
 Susheel K. Kodali, MD; Michael Mack, MD; Wilson Y. Szeto, MD; Vinod H. Thourani, MD;
 E. Murat Tuzcu, MD; Mathew R. Williams, MD; Jodi J. Akin, MSN; Martin B. Leon, MD;
 Lars G. Svensson, MD, PhD



Mortalidad 6 meses 19% TA, 12% TF , $p < 0,001$

RESULTADOS

Hospital Universitario Virgen de la Victoria

DEMOGRAPHICS

April 2008-Septiembre 2015
N= 490 patients



Corevalve first generation
125 p (25,5%)

Accutrak
310 p (63.25%)

Evolut R
65 p (12,25%)

Mortalidad TAVI 30 días Hospital Universitario Virgen de la Victoria

	2008	2009	2010	2011	2012	2013	2014	2015	ALL
N	25	48	71	86	75	67	69	50	490
Edad	76.2±9	80.7±5	80.1±5	78.6±6	79.6±6	78.8±5	78.9±9	79.2±6	79,2±6
EuroScore	16.2±1 0	24.9±1 8	19.7±1 1	18.2±1 0	17.9±1 2	12.5±7	14.5±8	14,8±7	17.6±1
Mortalidad 30 días	4%	2.1%	5.6%	7%	4%	1.5%	1.4%	2%	3.4%

← FIRST GENERATION →

← ACCUTRAK →

← EVOLUT R →

Insuficiencia aórtica tras TAVI

4.4. IAO tras TAVI con la prótesis CoreValve

2ª Válvula	22 (5,5%)
Post-dilatación con balón	111 (27,8%)
IAO final en la aortografía (Sellers)	
- 0	157 (39,6%)
- 1	138 (34,8%)
- 2	95 (24,0%)
- 3	5 (1,3%)
- 4	1 (0,3%)
IAO en la ecocardiografía prealta	
- Ausente	186 (48,3%)
- Leve	135 (35,1%)
- Moderada	62 (16,1%)
- Severa	2 (0,5%)

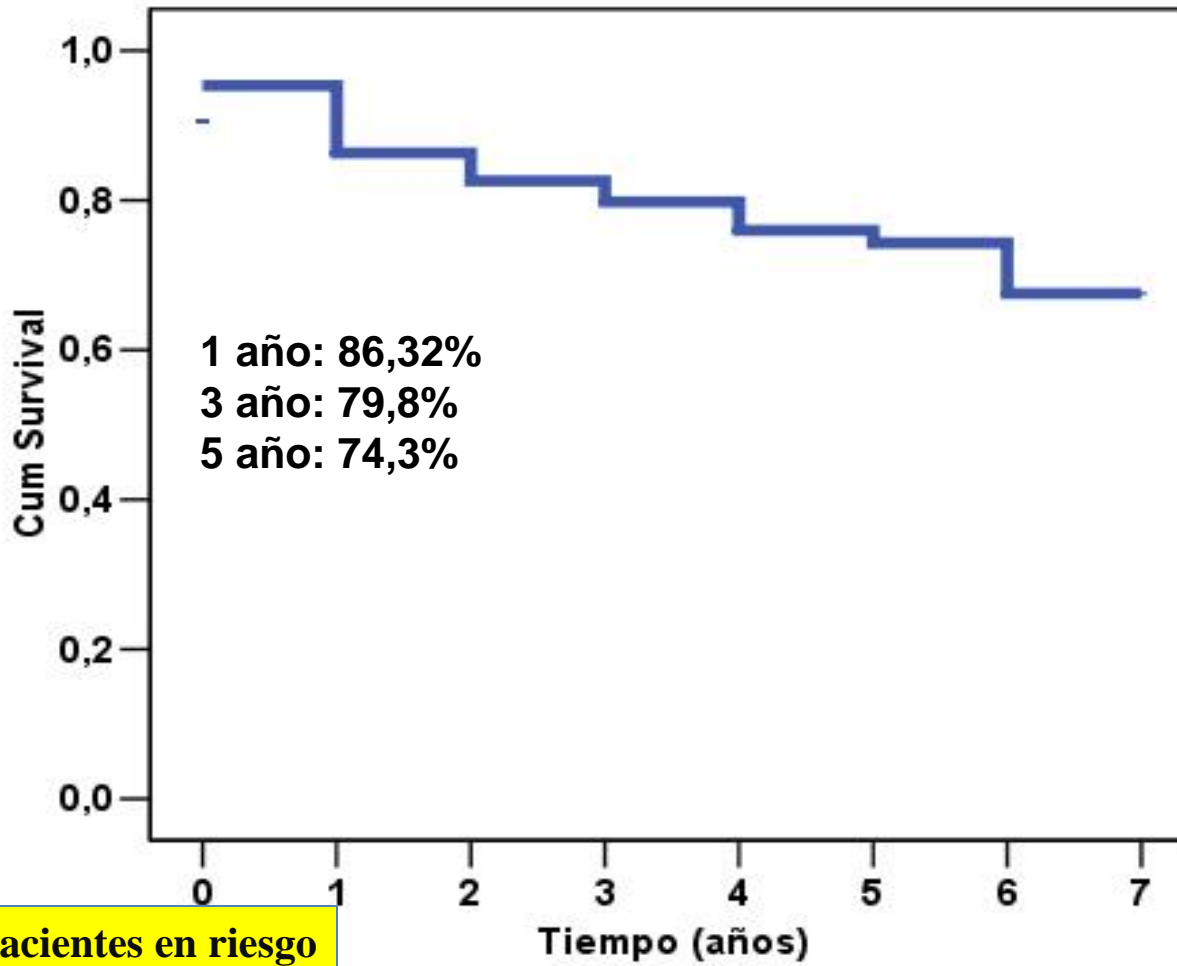
4.4. IAO tras TAVI con la prótesis CoreValve

Pacientes	1-100	101-200	201-300	301-399	
Valvuloplastia postTAVI	21%	29%	32%	29,3%	p=0,164
IAO final en aortografía					
- 0	28,6%	32%	50,5%	47,5%	
- 1	40,8%	39%	28,3%	31,3%	
- 2	30,6%	28%	19,2%	18,2%	p=0,008
- 3	0%	1%	1%	3%	
- 4	0%	0%	1%	0%	
IAO en ecocardiografía					
- Nada	32,7%	41,7%	58,3%	61,1%	
- Leve	43,9%	42,7%	29,2%	24,2%	
- Moderada	23,5%	15,6%	11,5%	13,7%	p=0,001
- Severa	0%	0%	1%	1,1%	

Seguimiento

Resultados en el Tratamiento de la Estenosis Aórtica

Abril 2008-Diciembre 2014, 441 pacientes TAVI



Nº pacientes en riesgo

441 333 254 177 105 45 11 1



Mortalidad tardía Hospital Universitario Virgen de la Victoria.

Causas de mortalidad

Causes of mortality	Patients (n = 12)	Time (m)
Cardiac failure (depressed ejection fraction)	2 (16.7%)	5 and 17
Neoplasias	3 (25%)	
Spinocellular	1	11
Pancreas	2	5 and 11
Respiratory	2 (16.7%)	3 and 5
Sudden death	1 (8.4%)	3
Stroke	1 (8.4%)	5
Multiorgan failure due to	2 (16.7%)	
Chronic renal failure	1	18
Sepsis	1	8
Gastrointestinal		
Acute biliary pancreatitis	1 (8.4%)	15

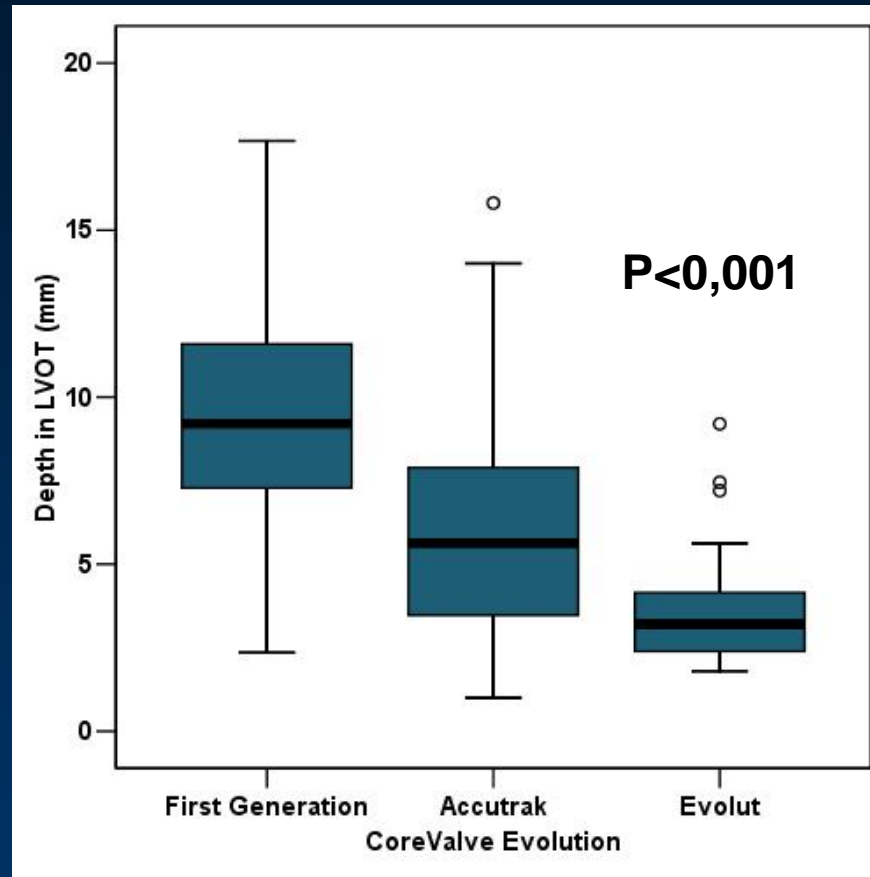
Predictores de mortalidad tardía

	Hazard ratio (95% CI)	P
Charlson index	1.439 (1.091-1.899)	<.010
Karnofsky	0.958 (0.925-0.994)	.021
Barthel post	0.978 (0.936-1.022)	.327
Barthel pre	1.030 (0.990-1.072)	.145
Depth	0.950 (0.757-1.191)	.655
Ejection fraction	1.008 (0.968-1.050)	.689
Vascular complications	5.264 (0.457-60.674)	.183
Frailty	1.022 (0.215-4.857)	.978

RESULTADOS

EVOLUT R

Depth in the left ventricular outflow (LVOT) mm



Corevalve first generation

9.5 ± 3.2 mm

Accutrak

6.36 ± 5 mm

Evolut R

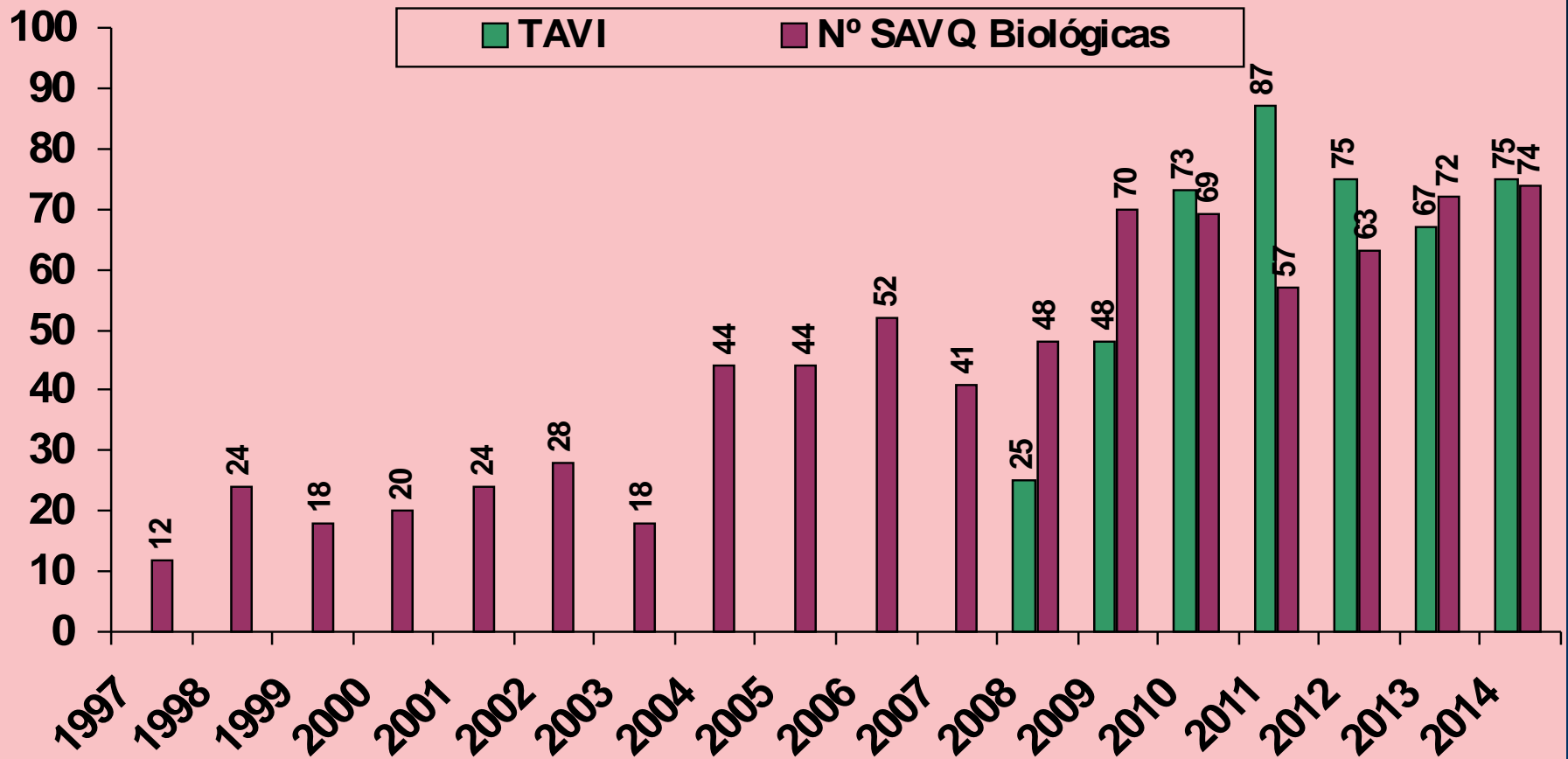
3.6 ± 1.7 mm

P<0,001

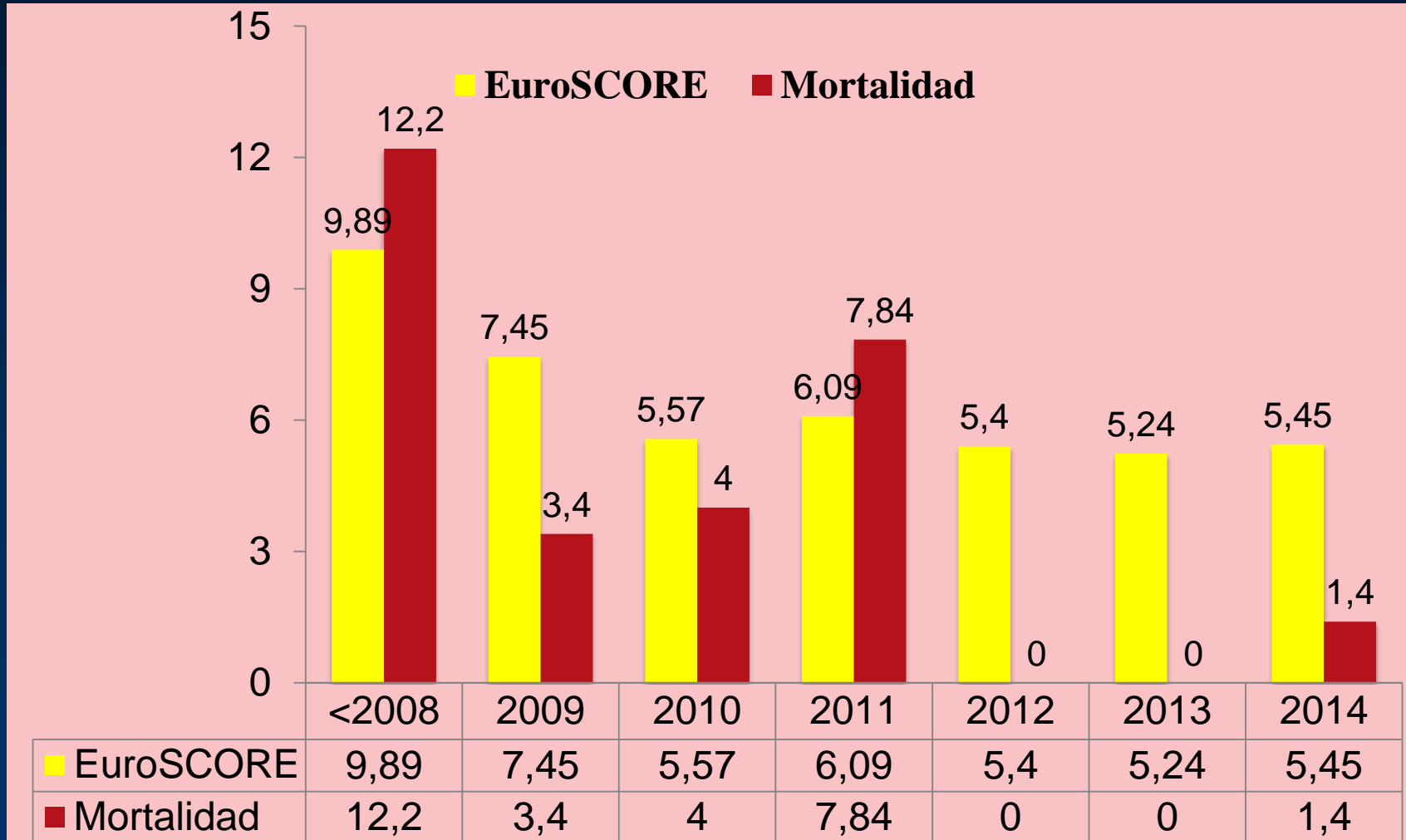
	Corevalve First (125)	Accutrak (310)	Evolut R (65)	p
AV BLOCK (procedure)	24.1%	18.2%	10.3%	0.069
VALVE IN VALVE	5 (4%)	19 (6.1%)	0%	0.938
AORTIC REGURGITATION				
0	42 (34.1%)	163 (54.7%)	39 (60,2%)	0.023
1	50 (40.7%)	95 (31.9%)	24 (36.7%)	
2	31 (25.2%)	36 (12.1%)	2 (3.1%)	
3	0	2 (0.7%)	0	
4	0	2 (0.7%)	0	
PACEMAKER	39 (33.3%)	67 (23.7%)	3 (10%)	0.005

Impacto del TAVI en la Cirugía Cardiaca

Impacto del TAVI en la Cirugía Cardíaca

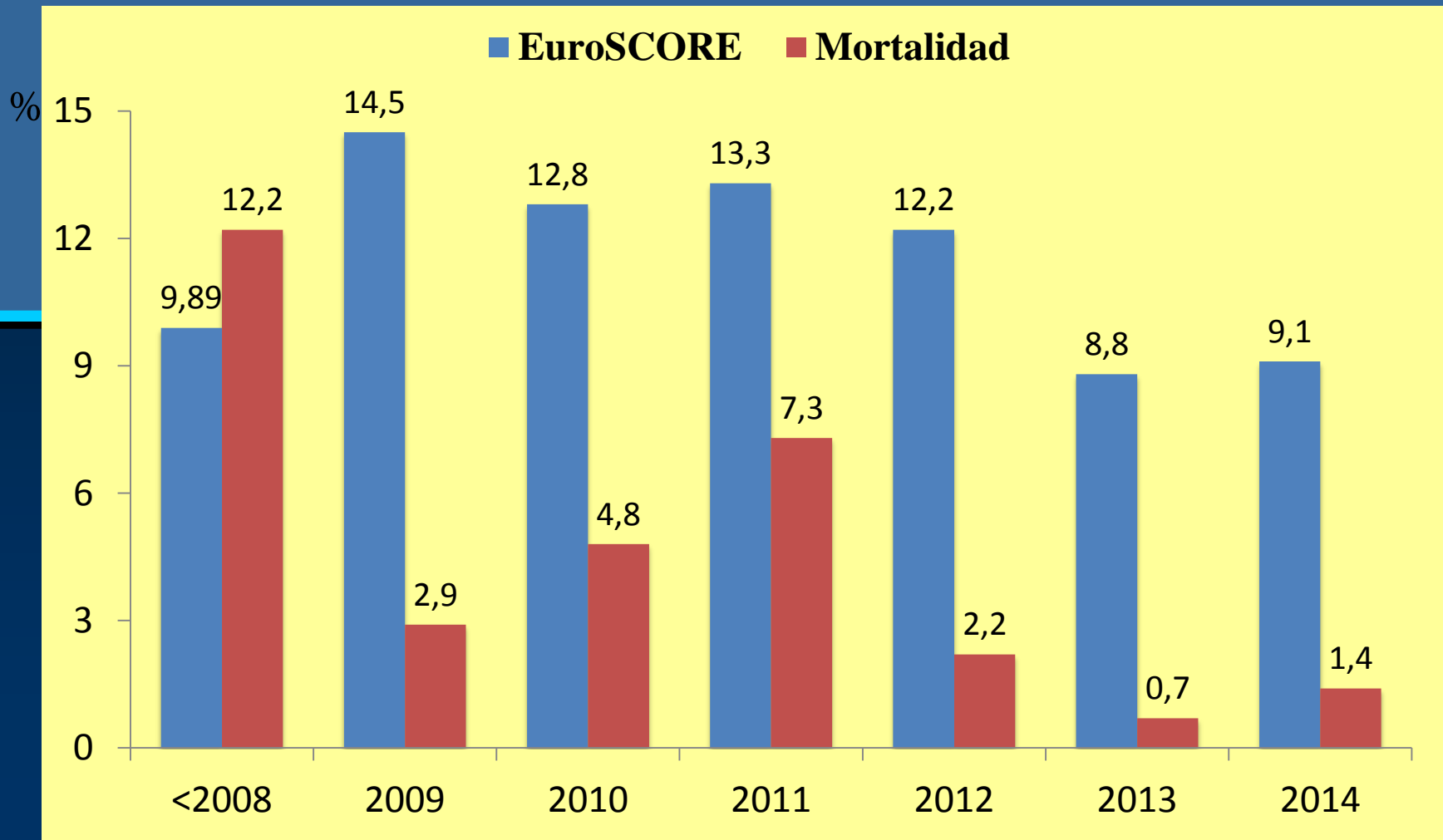


MORTALIDAD DE LA CIRUGIA CARDIACA : ESTENOSIS AÓRTICA



Impacto del TAVI en la Cirugía Cardíaca

CIRUGÍA CARDIACA + TAVI



TAVI. Cuestiones pendientes. Futuro

TAVI en pacientes de riesgo intermedio o bajo

Disminución del French y las complicaciones vasculares

Reducción del “stroke”

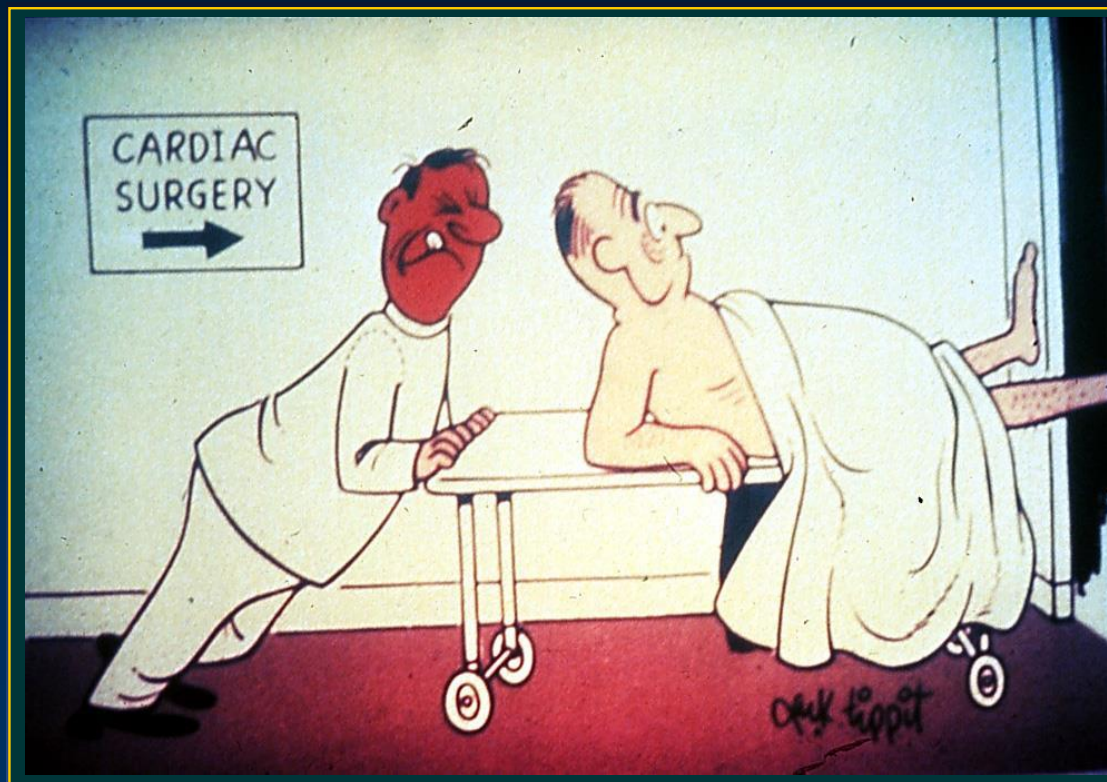
Disminución de los “leaks” paravalvulares

Integración de nuevas tecnologías

***TAVI en otras indicaciones: válvula bicúspide,
Regurgitación aórtica, “valve in valve”***

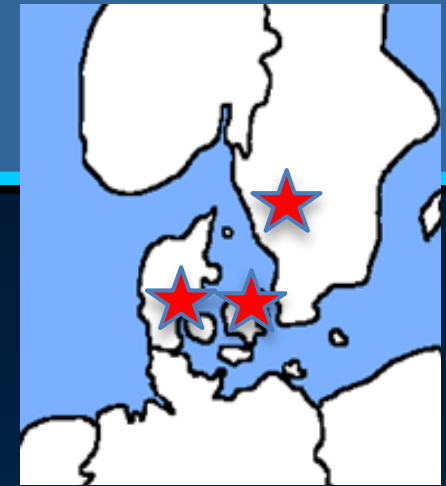
TAVI “ad hoc” en el mismo procedimiento diagnóstico

TAVI EN PACIENTES CON RIESGO INTERMEDIO O BAJO



The NOTION Trial

An All-comers Randomized Clinical Trial Comparing Transcatheter with Surgical Aortic Valve Replacement in Patients with Aortic Valve Stenosis



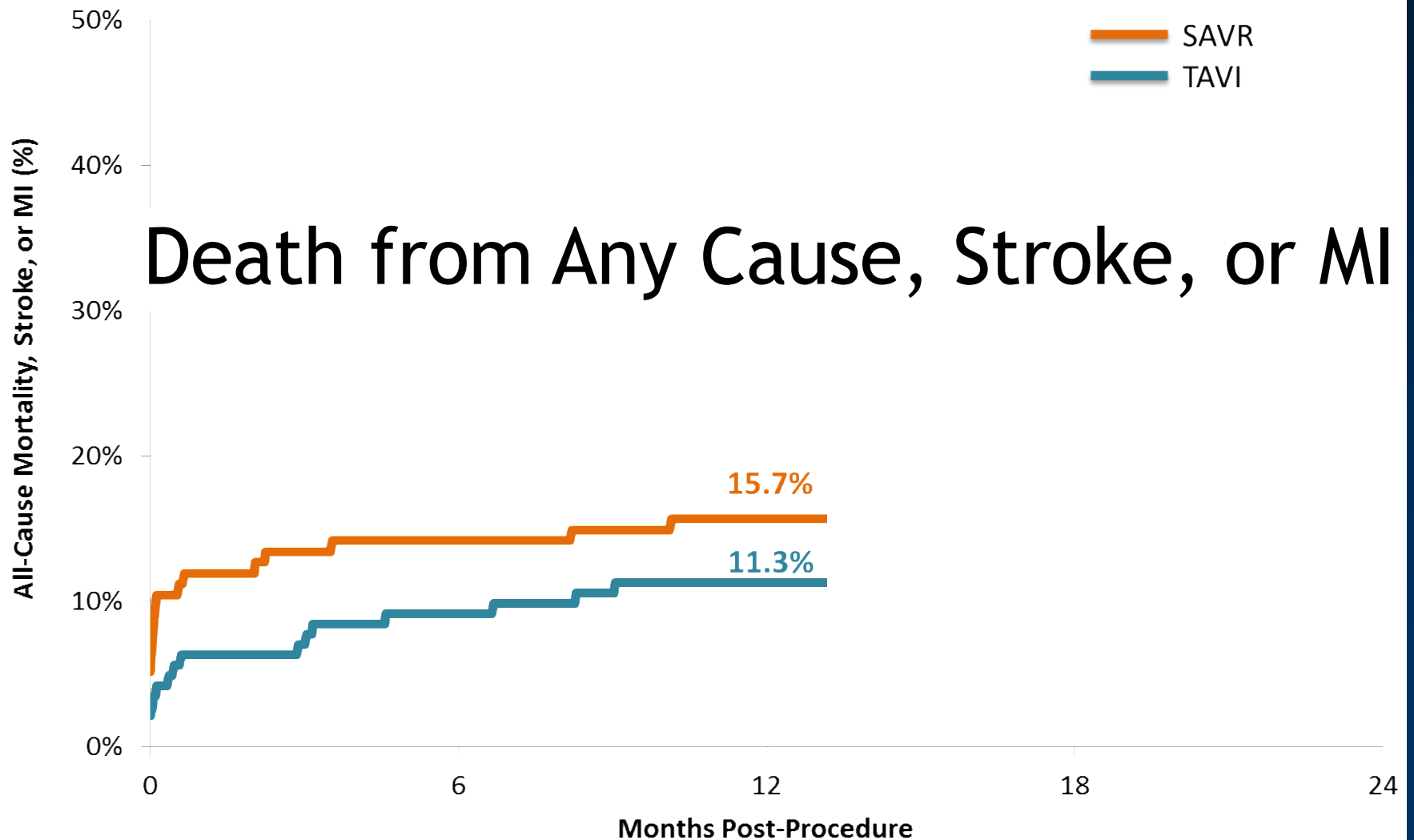
Main inclusion criteria

CR
015 Severe AS



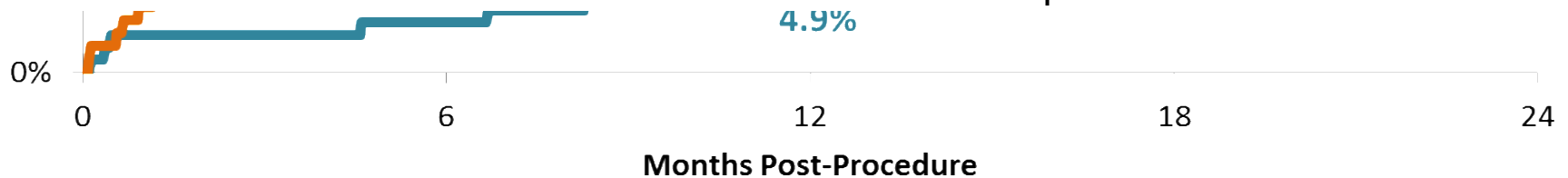
Characteristic, % or mean \pm SD	TAVI n=145	SAVR n=135	p-value
Age (yrs)	79.2 \pm 4.9	79.0 \pm 4.7	0.71
Male	53.8	52.6	0.84
STS Score	2.9 \pm 1.6	3.1 \pm 1.7	0.30
STS Score < 4%	83.4	80.0	0.46
Logistic EuroSCORE I	8.4 \pm 4.0	8.9 \pm 5.5	0.38

The NOTION Trial



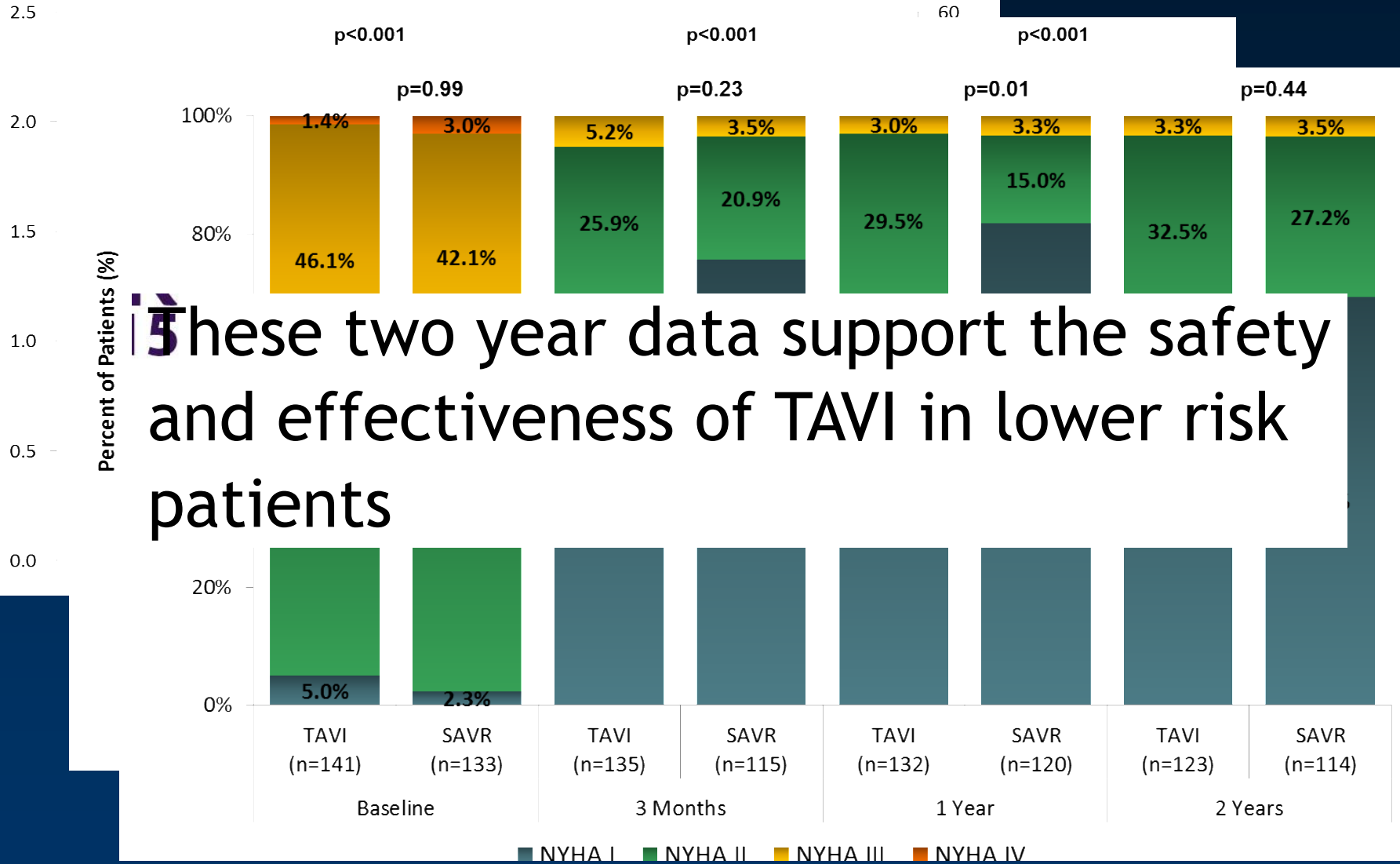
The NOTION Trial

Outcome, %	1 Year			2 Years		
	TAVI	SAVR	p-value	TAVI	SAVR	p-value
Death, any cause	4.9	7.5	0.38	8.0	9.8	0.54
Death, cardiovascular	4.3	7.5	0.25	6.5	9.1	0.40
Stroke	2.9	4.6	0.44	3.6	5.4	0.46
TIA	2.1	1.6	0.71	6.0	3.3	0.30
Myocardial infarction	3.5	6.0	0.33	5.1	6.0	0.69
Atrial fibrillation	21.2	59.4	<0.001	22.7	60.2	<0.001
Pacemaker	38.0	2.4	<0.001	41.3	4.2	<0.001
Aortic valve re-intervention	0.0	0.0	na	0.0	0.0	na



The NOTION Trial

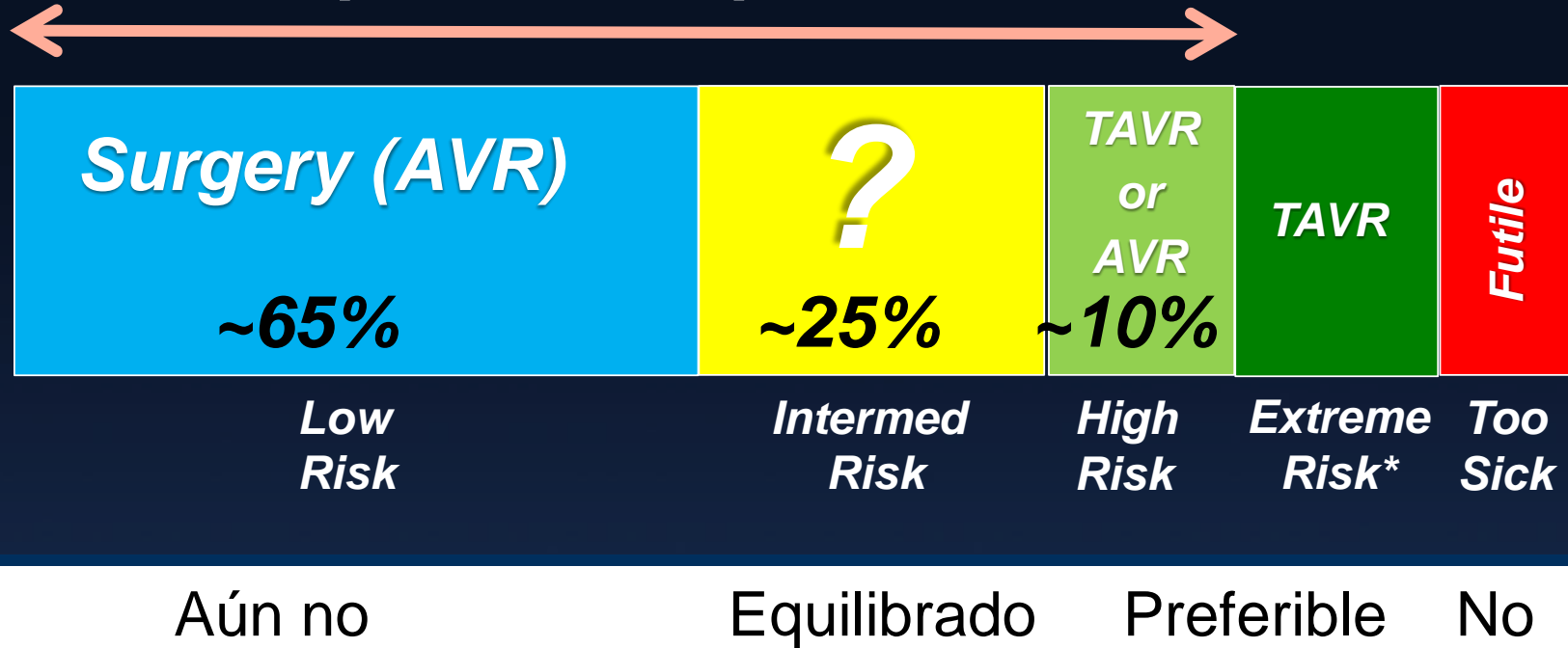
p<0.001 TAVI vs. SAVR, for both EOA and Mean Gradient at all follow-up timepoints



These two year data support the safety and effectiveness of TAVI in lower risk patients

TAVI Y CIRUGIA EN 2015

Operable AS patients



Large Vessel Closure Landscape

Category

Emerging Suture
Based Technologies

Emerging
Patch or Plug
Technologies

Strategic
Players

Company

Interventional
Therapies

MediGlobe

SpiRx

Vivasure

ePacing

Sealing Solutions

Vascular Closure
Systems

Apica Cardiovascular

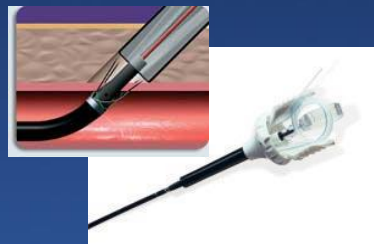
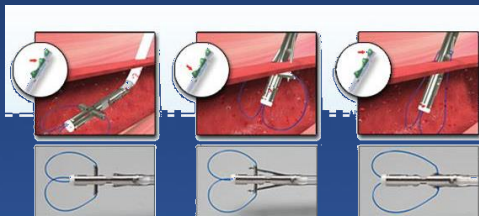
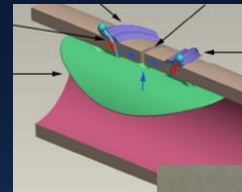
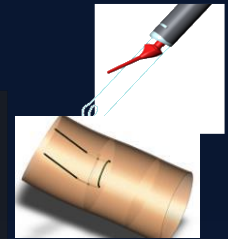
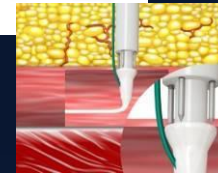
Medtronic, Inc.

Abbott Vascular

St. Jude Medical

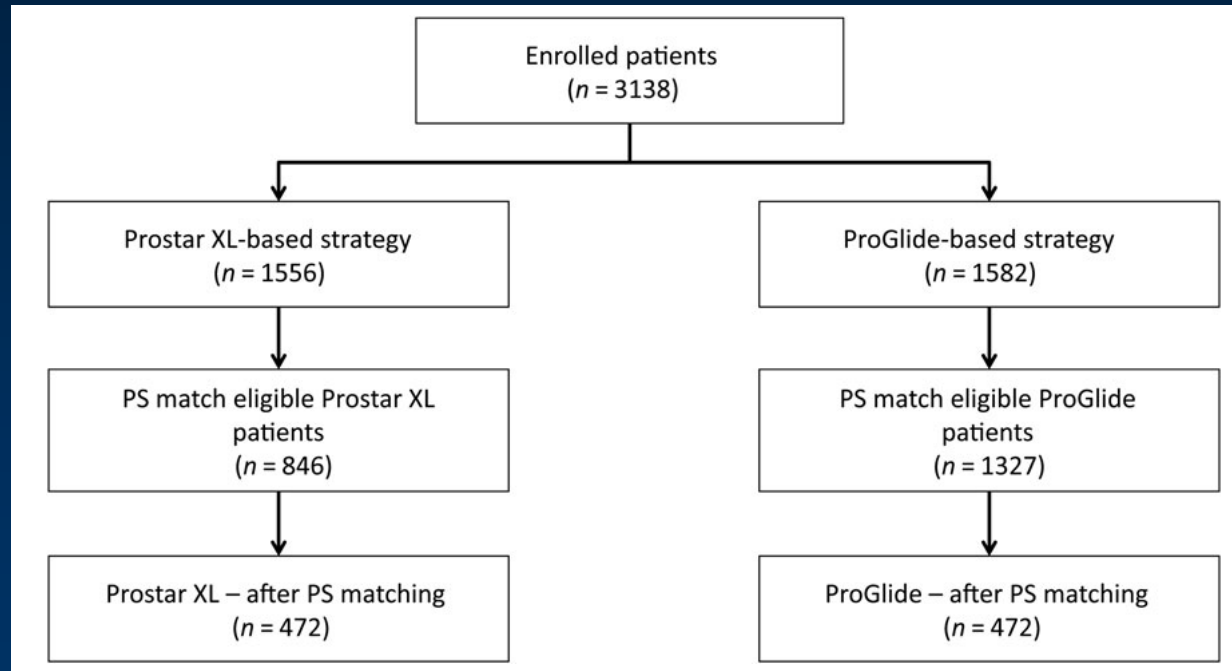
Cook/Cardica

Technology

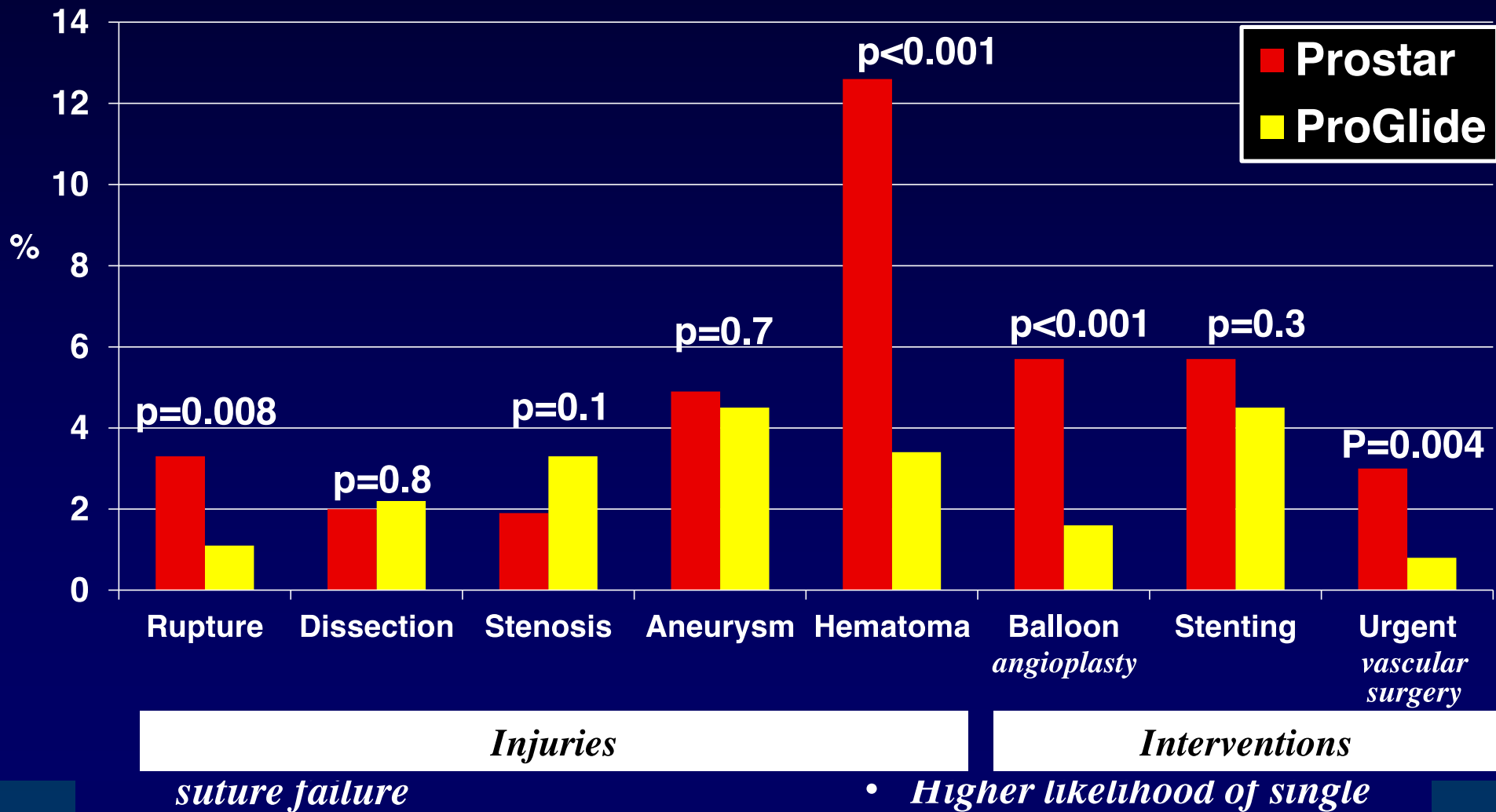


Comparison of vascular closure devices for access site closure after transfemoral aortic valve implantation

To compare the efficacy of a Prostar XL- vs. Perclose ProGlide-based vascular closure strategy.
The CLOsure device iN TRansfemoral aOrtic vaLve implantation (CONTROL) multi-center study



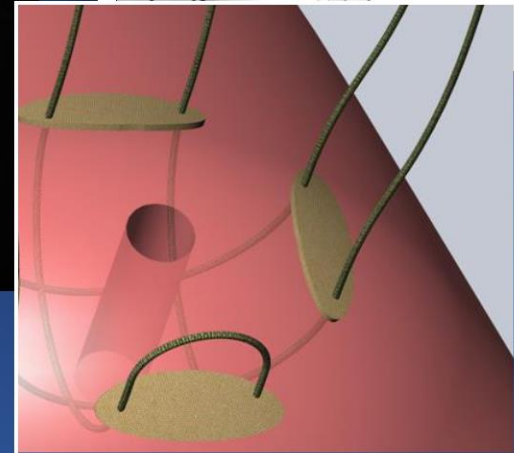
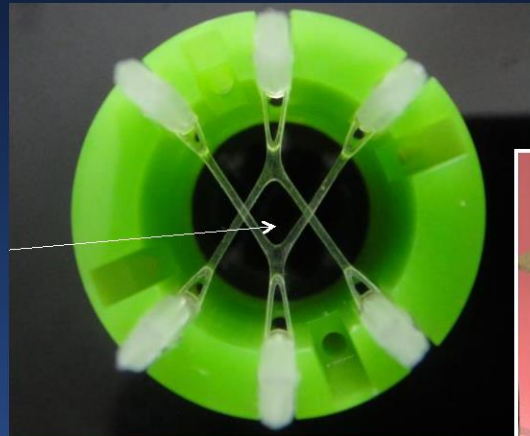
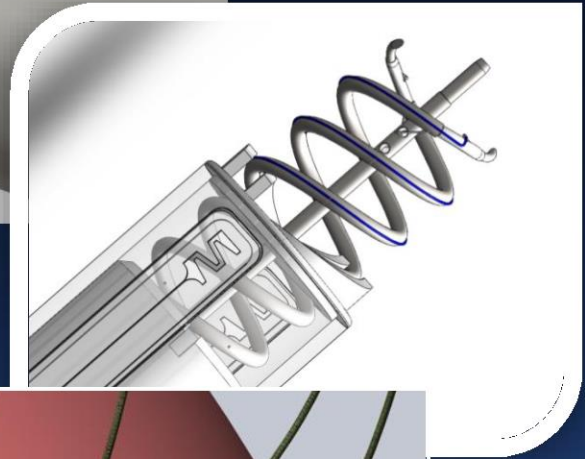
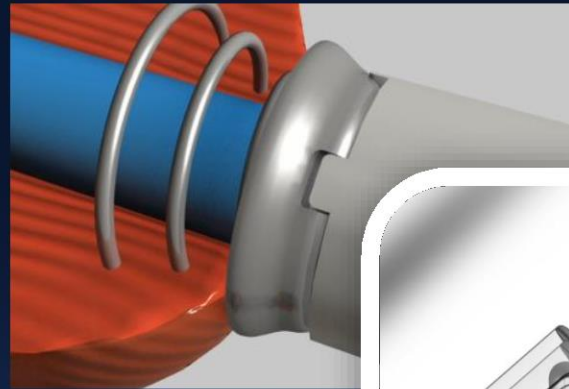
DISPOSITIVOS DE CIERRE VASCULAR



European Heart Journal
doi:10.1093/eurheartj/ehw417

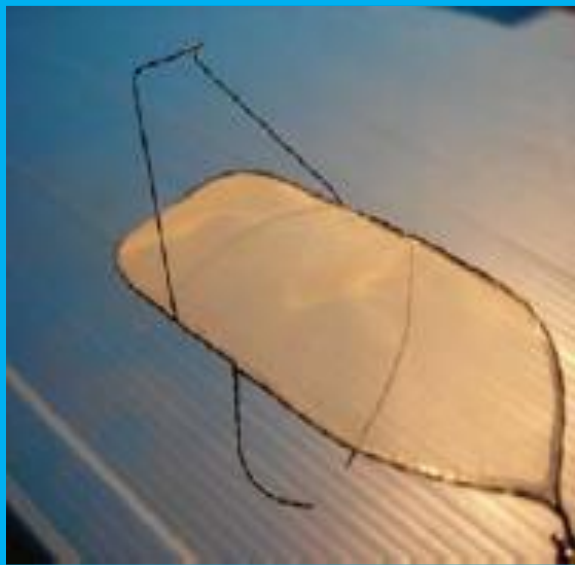
Transcutaneous Ventricular Access and Closure (TVAC)

- *Apica*
- *Entourage CardioClose*
- *MID Permaseal*
- *Novogate*
- *SpiRx*
- *Cardiapex*

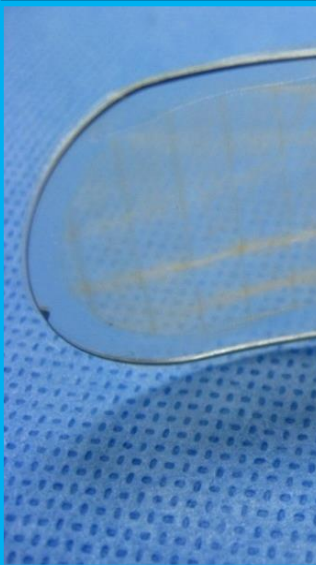


ACCIDENTE CEREBROVASCULAR “STROKE”

Cerebral Embolic Protection Devices *Deflectors and Filters*



Keystone



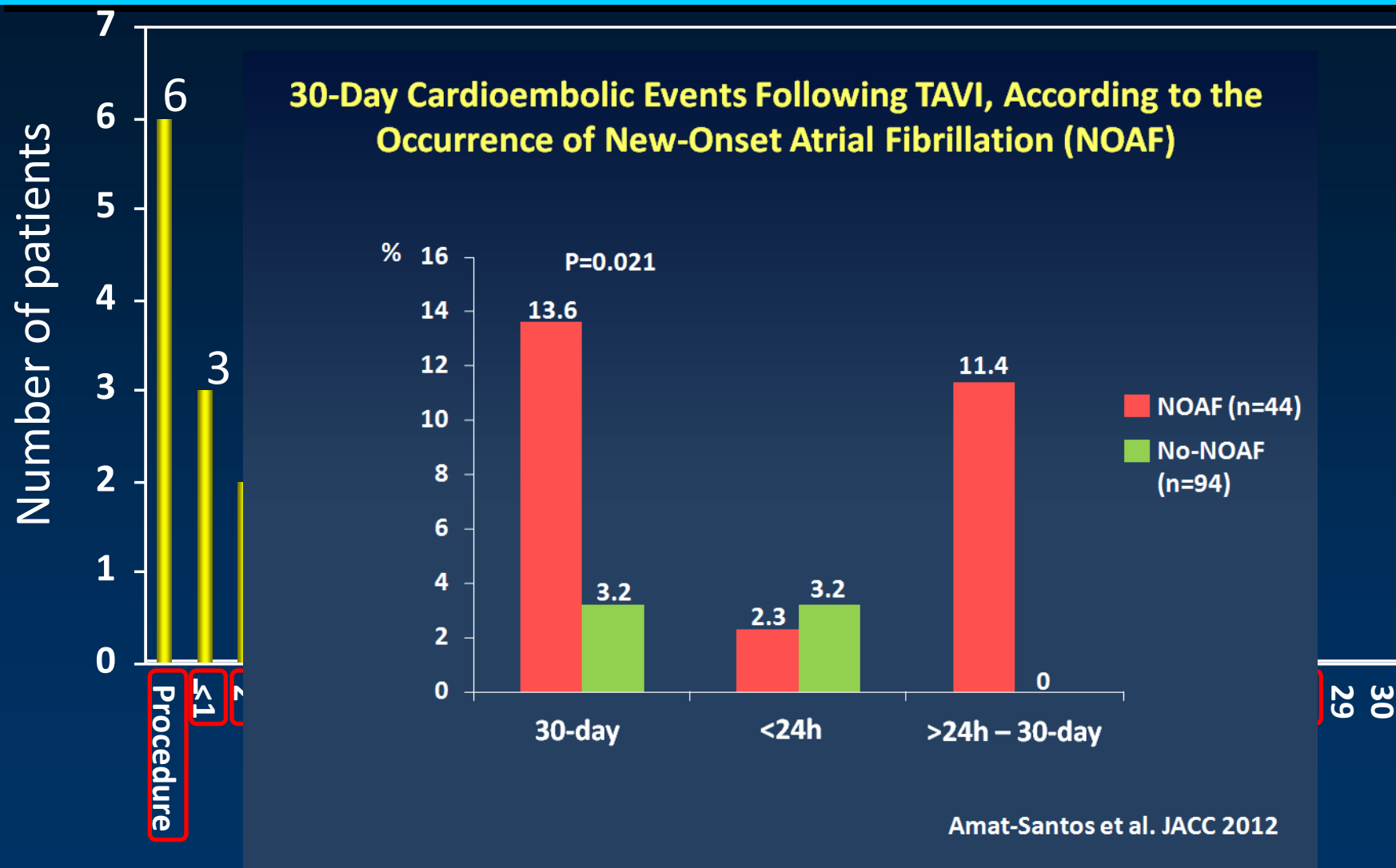
Embrella



Claret

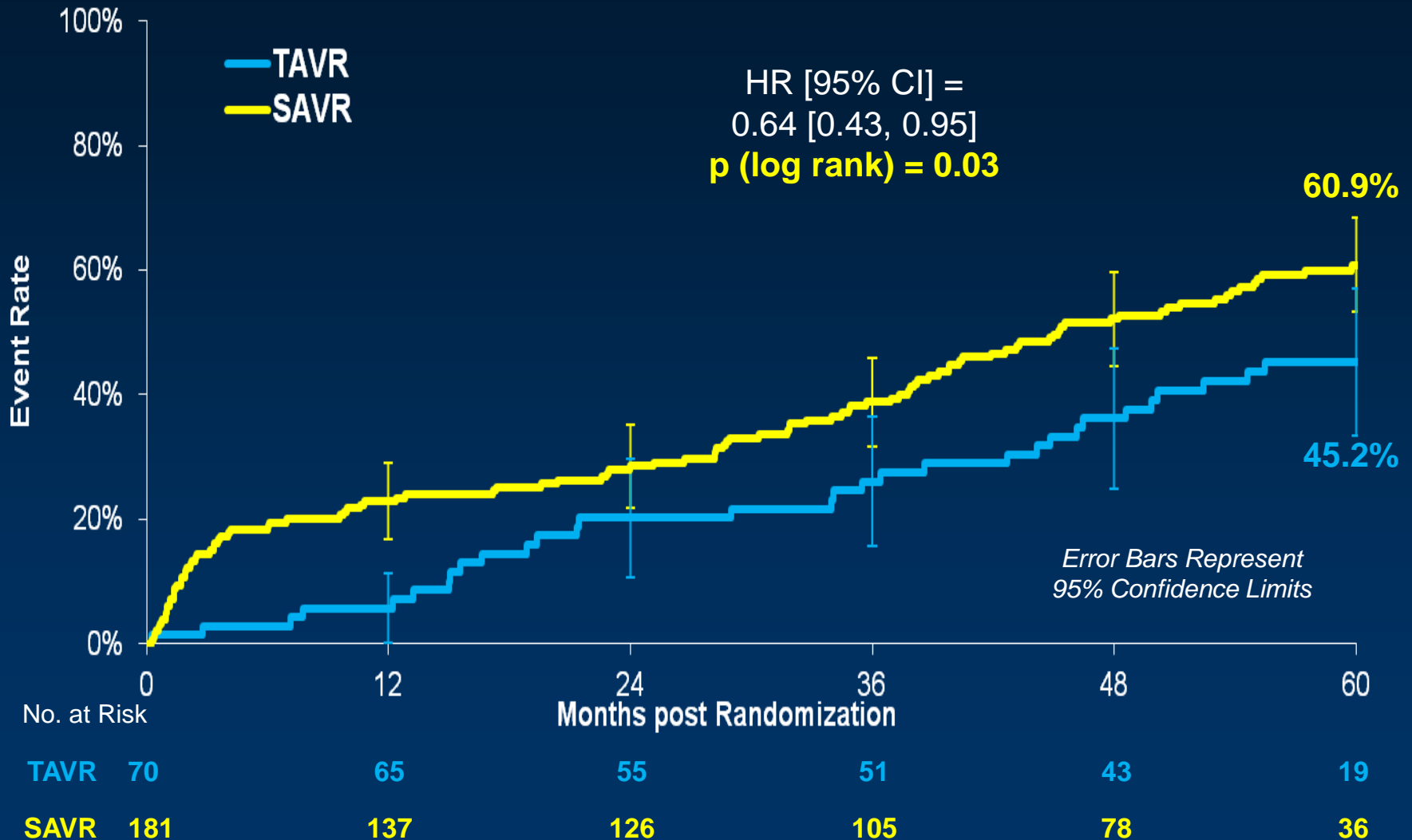
Stroke post-TAVI (30 days)

Canadian Experience and PARTNER cohort B (22 patients)



*1 patient with hemorrhagic stroke

Mortality and None-Trace Total AR Transfemoral Patients



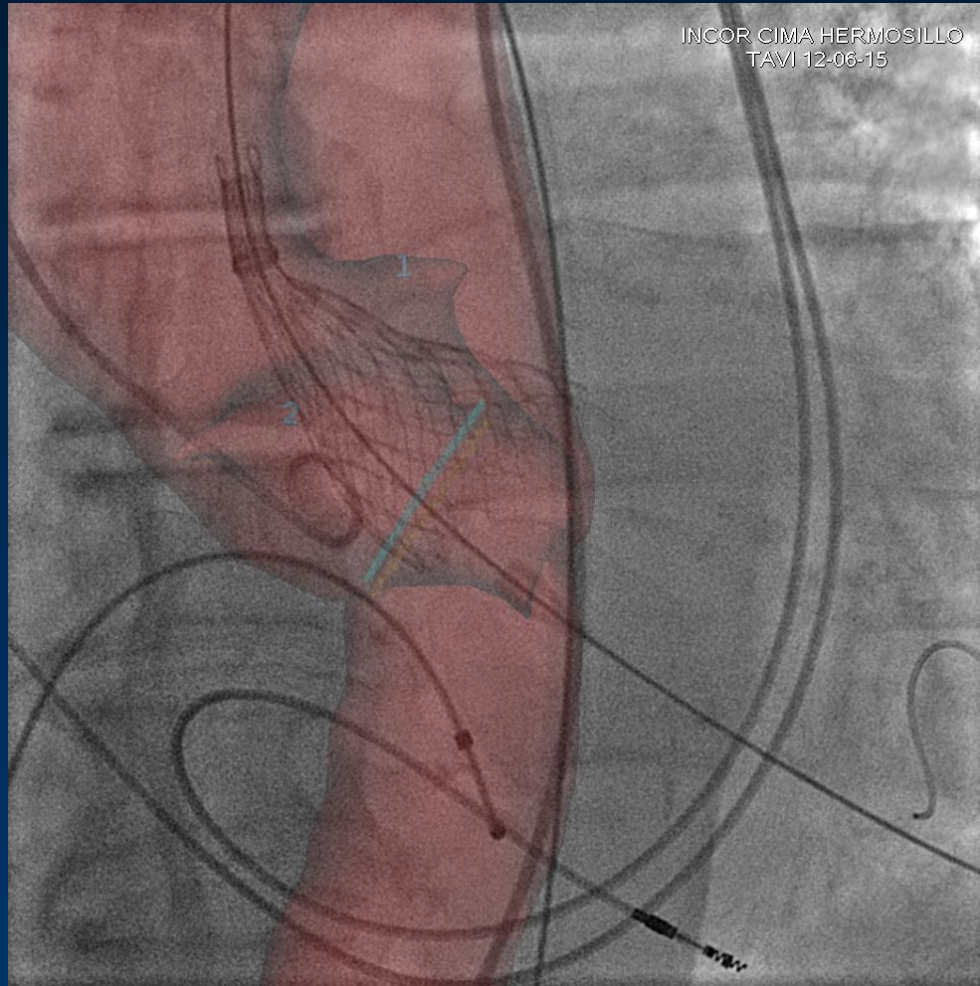
TAVI: NUEVOS DISPOSITIVOS (PCR 2015/ACC 2015)

	LOTUS	DIRECT FLOW	PORTICO	SAPIEN 3	EVOLUT - R
Pacientes	120	75	83	96	100
Edad	84,4	83,1	83,8	83,6	81
Euroscore	STS 7,1	23,5	16,3	19,8	16,7
Mortalidad (30 días) %	4,2	1,3	3,6	2,1	0
ACV (%)	5,8 (1,8)	4	3,6 (2,6)	1	0
MP (%)	29,4	17	10,8	12,5	11,7
IAO ≥ 2 (%)	2	2	5	2,6	3,7
IAM		1,3	1,2	2,1	0
2ª Válvula	0	0		1	
Balón post	0	0		3,3	

INTEGRACIÓN DE NUEVAS TECNOLOGÍAS



INTEGRACIÓN DE NUEVAS TECNOLOGÍAS



CONCLUSIONES: ESTADO ACTUAL

La mortalidad del implante percutáneo de una válvula aórtica ha disminuido con la experiencia y la mejora en los dispositivos

Hay datos que sugieren que puede expandirse la técnica a pacientes de menor riesgo

La incidencia de insuficiencia aórtica y marcapasos disminuye con la experiencia y con los nuevos dispositivos

Hay datos consistentes de la durabilidad a cinco años, con áreas valvulares mayores y gradientes menores por el menor “mismatch”

La incidencia de ACV es igual o menor que con la cirugía

La introducción de un programa TAVI mejora los resultados de la cirugía, al derivar a TAVI los de mayor riesgo quirúrgico, sin disminuir el número de intervenciones

Evolution

6:00
Universal Time

Surgery is

Surge

S
ii

