SOLACI
SOCIEDAD LATINOAMERICANA DE CARDIOLOGÍA INTERVENCIONISTA

30° CONGRESO URUGUAYO DE CARDIOLOGÍA

SOCIEDAD URUGUAYA DE CARDIOLOGÍA

XXV Jornadas SOLACI
8° Región Cono Sur

TAVI:

dónde estamos y a dónde vamos

HOSPITAL ITALIANO
de Buenos Aires
Instituto de Medicina Cardiovascular

Daniel Berrocal, MD, PhD, MTSAC, FACC
Jefe de Cardiología Intervencionista
daniel.berrocal@hospitalitaliano.org.ar

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NO TENGO CONFLICTO DE INTERESES
PARA ESTA PRESENTACION

HOSPITAL ITALIANO
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TAVR a quienes? **En 2014**

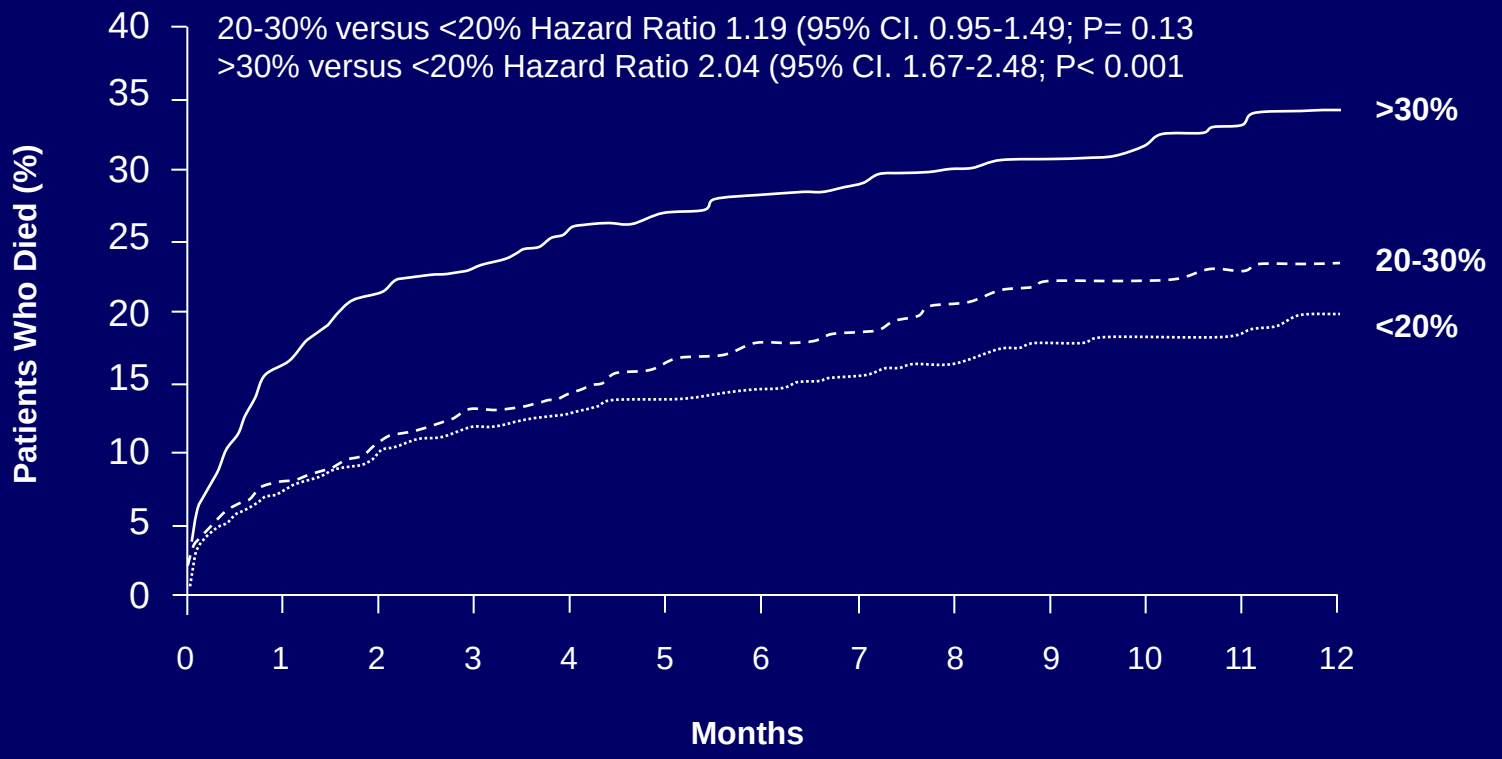
- **Estenosis Aortica severa:**
  - **AVA<0.8cm2,vel pico >4m/s o grad medio>40mmHg**
- **Sintomática**
- **Riesgo quirúrgico elevado o contraindicación quirúrgica**
  - **Scores elevados:STS,EUROSCORE**
  - **Criterio clinico-quirurgico**

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)

Muerte según EuroScore



# at Risk				
< 20%	1686	1301	636	208
20-30%	749	582	300	113
>30%	717	518	269	81

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

Que es fragilidad?

Evaluación del estado psicológico y funcional

Provee al grupo medico, el paciente y su familia,

un plan para el cuidado futuro

Ayuda a las decisiones de tratamiento

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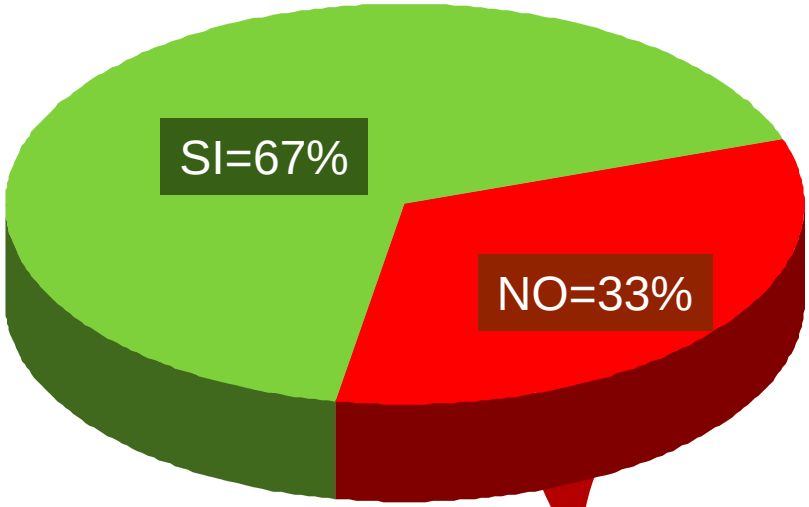

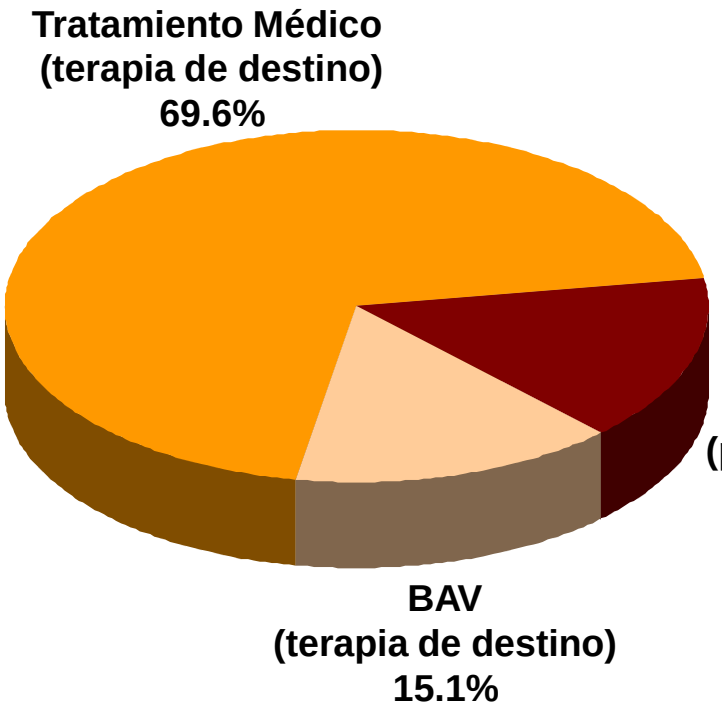

Smietniansky M et al. Abstract submitted SAM 2014

Fragilidad(AVD) y Riesgo TAVI

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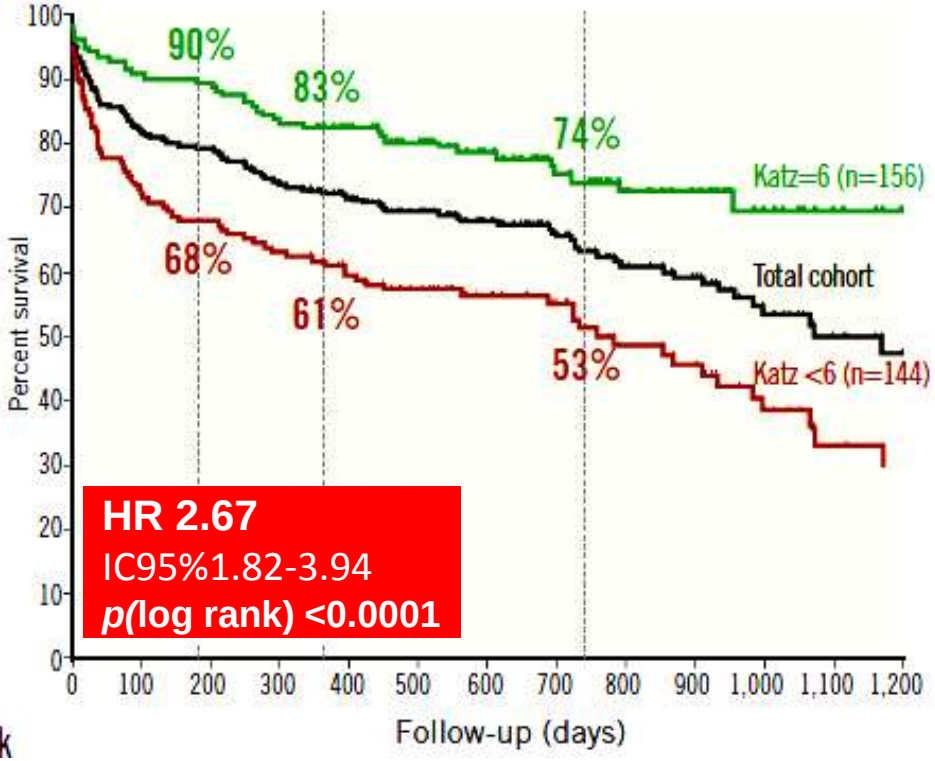
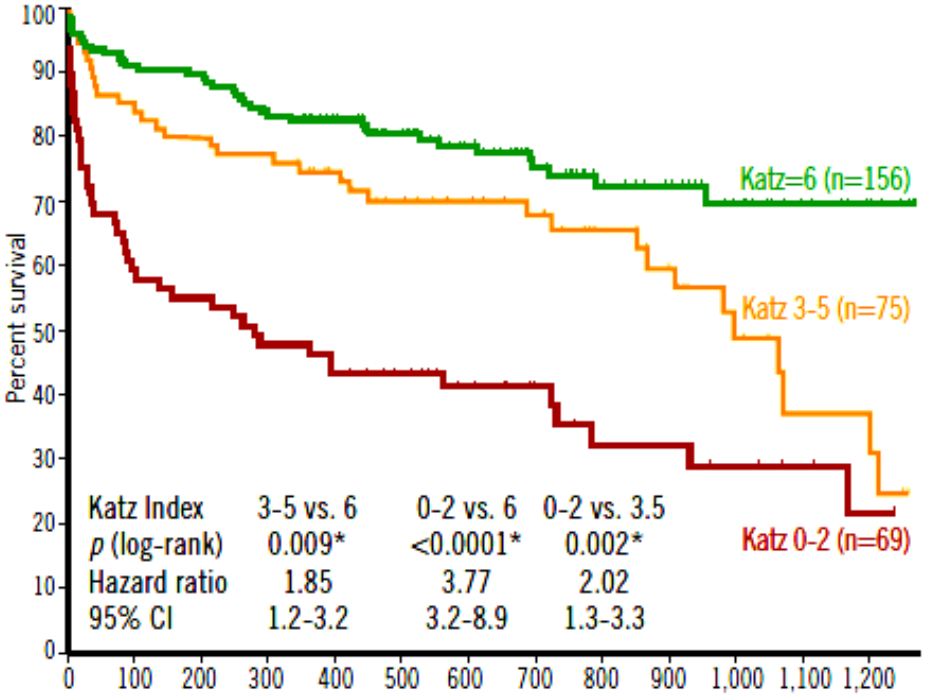
AVD Katz <6 vs. 6



Number at risk	Follow-up (days)						
Total cohort	300	240	198	135	76	42	17
Katz Index=6	156	141	118	81	42	22	8
Katz Index <6	144	99	80	54	34	20	9

AVD Katz <6

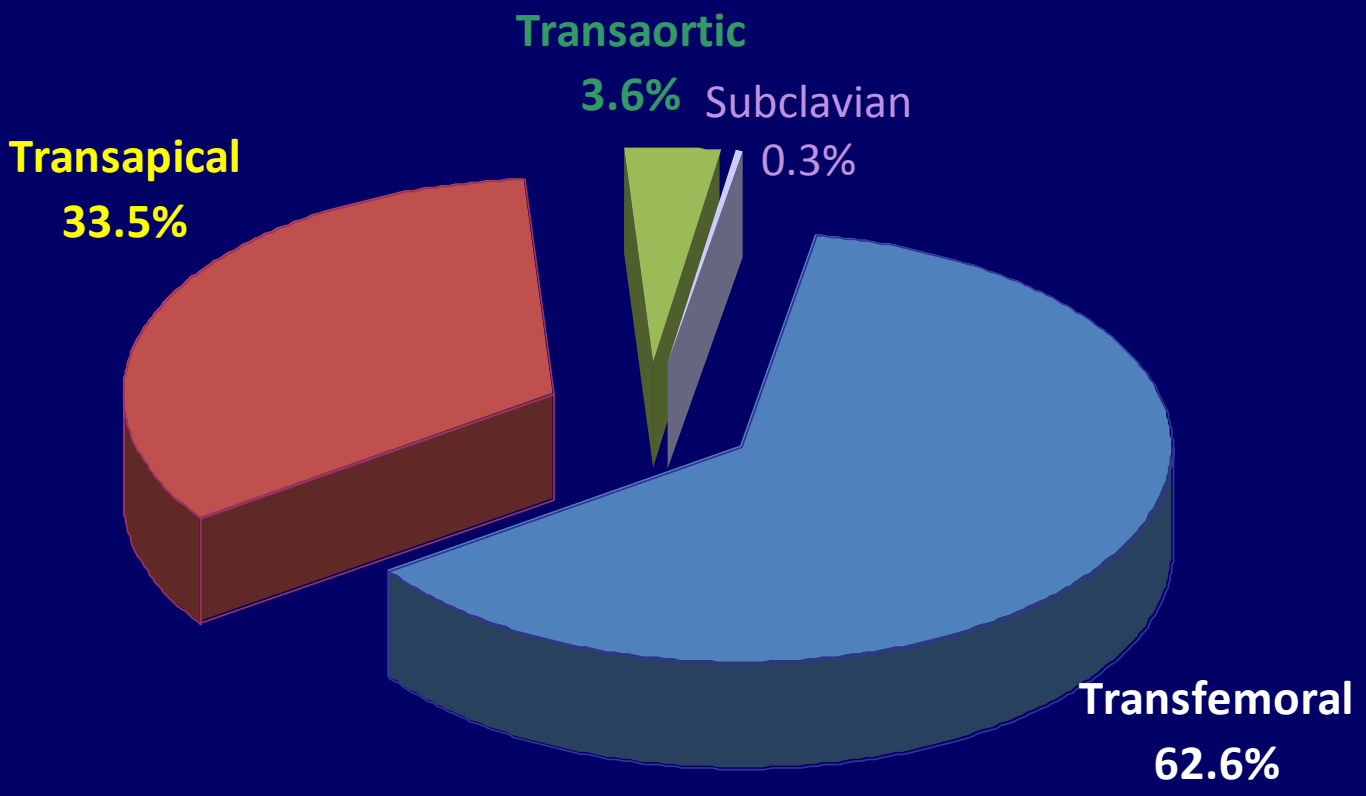


Number at risk	Follow-up (days)						
Katz Index=6	156	141	118	81	42	22	8
Katz Index 3-5	75	60	51	35	24	11	5
Katz Index 0-2	69	39	30	19	10	9	4

Impact of frailty on short- and long-term morbidity and mortality after transcatheter aortic valve implantation: risk assessment by Katz Index of activities of daily living EuroIntervention 2014;10:609-619

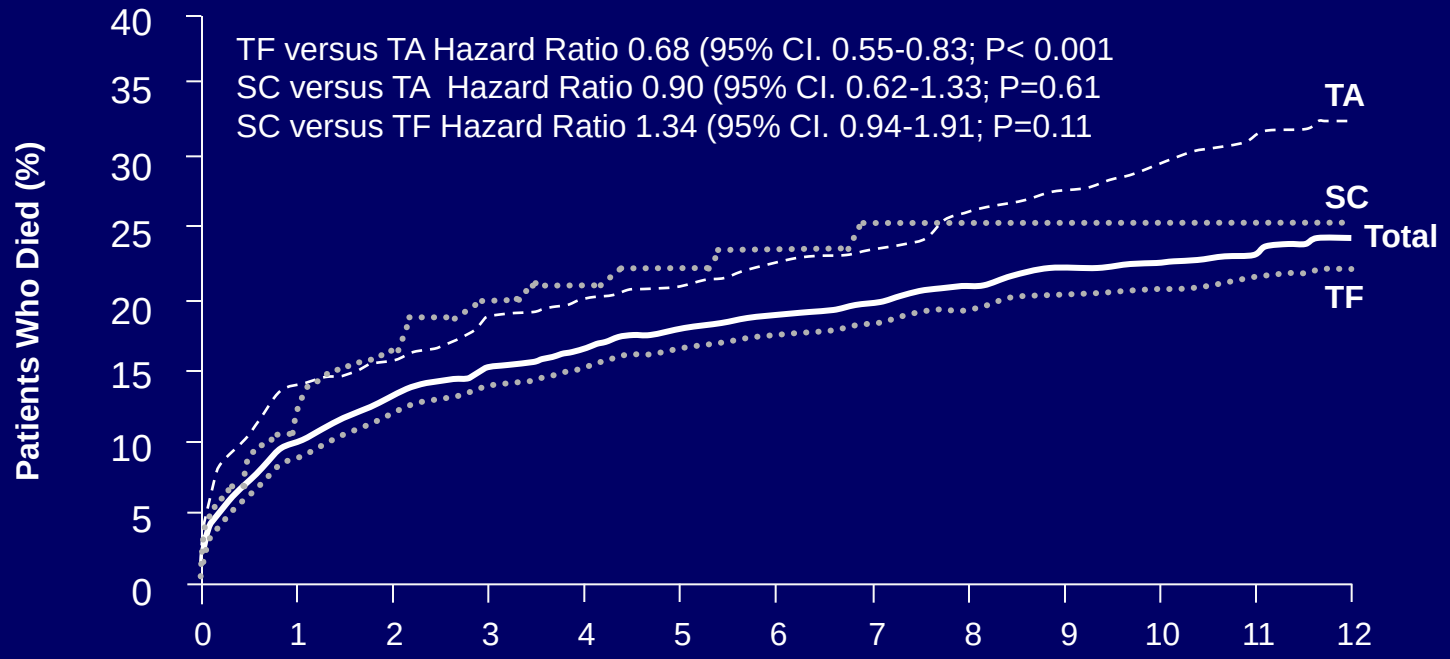
Access Routes

THE SOURCE XT REGISTRY



Olaf Wendler . PCR 2012

Vía de Acceso y Mortalidad



# at Risk				
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 patientes France 2.

Baseline Characteristics

THE SOURCE XT REGISTRY

Characteristics	Transfemoral N = 1694	Transapical N = 906	P
Age (years, mean ±SD)	**81.9 ±6.6**	**80.2 ±6.4**	**<.0001**
Female (%)	**64.5**	**45.6**	**<.0001**
Previous Stroke (%)	**7.3**	**10.6**	**0.005**
Renal Failure (%)	**24.9**	**35.2**	**<.0001**
Peripheral Vascular Disease (%)	**14.6**	**33.0**	**<.0001**
Diabetes Mellitus (%)	**26.8**	**33.7**	**0.0003**
Porcelain Aorta (%)	**4.4**	**10.7**	**<.0001**
Frail condition (mean±SD)	5.2 ±1.4	5.2 ±1.4	0.7
COPD (%)	19.6	21.9	0.2
Logistic EuroSCORE (mean±SD)	**19.9 ±12.0**	**21.8 ±13.8**	**0.0004**
STS Score (mean±SD)	8.4 ±7.0	8.7 ±7.2	0.2

Olaf Wendler . PCR 2012

THE SOURCE XT REGISTRY

Baseline Characteristics - Cardiac

Characteristic	Transfemoral N = 1694	Transapical N = 906	P
NYHA III/IV (%)	77.2	75.9	0.5
LV Ejection Fraction (mean ±SD)	**55.3 ±17.0**	**53.5 ± 12.4**	**<.0001**
Coronary Artery Disease (%)	**40.2**	**51.8**	**<.0001**
Previous MI (%)	**12.2**	**20.9**	**<.0001**
Previous PCI (%)	**27.2**	**36.7**	**<.0001**
Previous CABG (%)	**12.3**	**24.4**	**<.0001**
Atrial Fibrillation (%)	**22.8**	**29.9**	**<.0001**
Previous Pacemaker (%)	**10.0**	**12.7**	**0.03**
Previous Ao Bioprosthesis (%)	**1.8**	**4.0**	**0.001**

Olaf Wendler . PCR 2012

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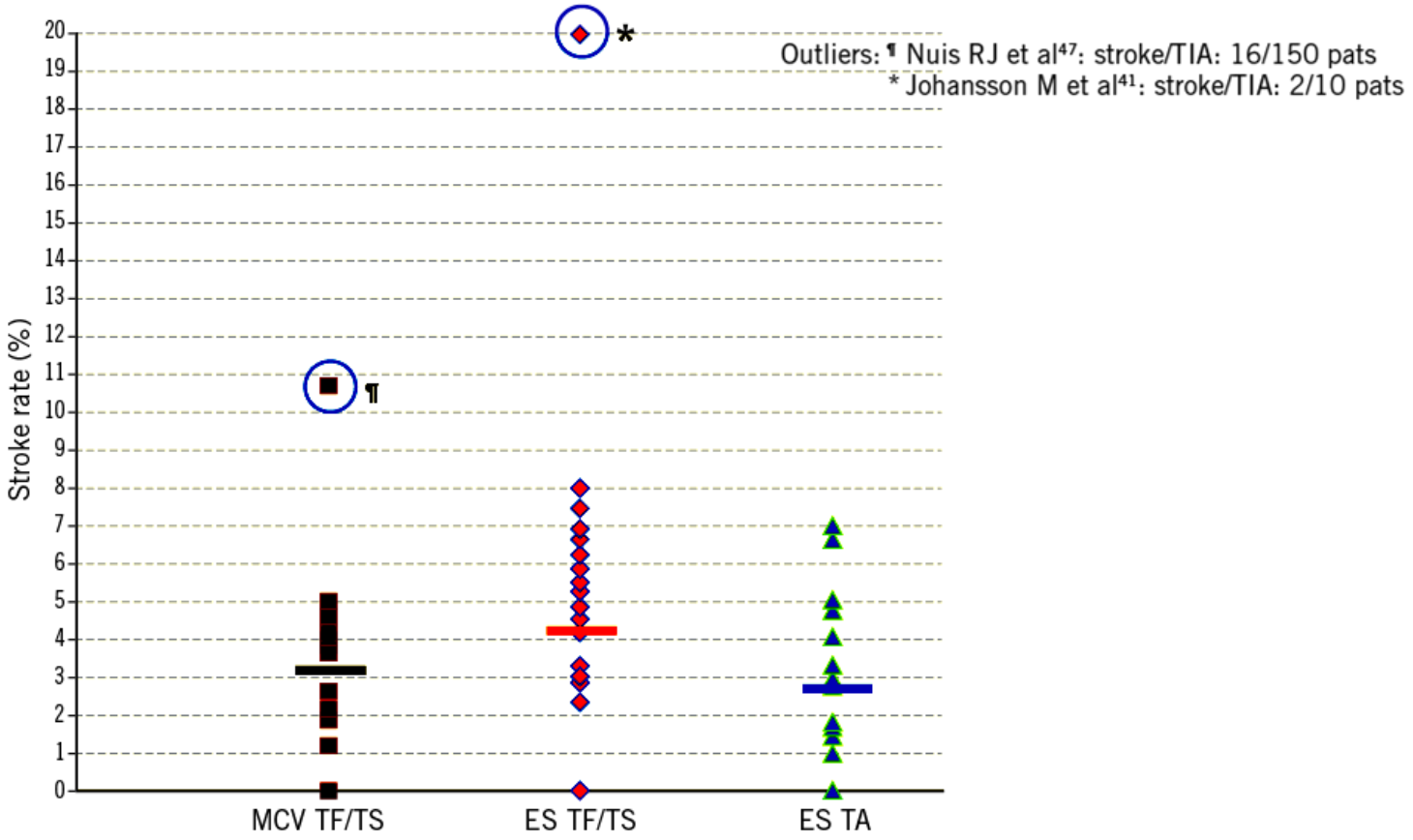
N#	60 p.		
Edad	80.75 ± 8.6 a(46-94)		
Euroscore Log.	25.6± 11		
STS	7.4 ± 4.3		
	%	**(n)**	
TF	**60**	**(36p)**	73.4% Retrógrado
TIlíaco	**5**	**(3)**	
TSubclavio	**3.3**	**(2)**	
Tao	**5**	**(3)**	
TA	**26.6**	**(16)**	26.6% Anterógrado
Mortalidad 30dias	11.6	(7)	
Mortalidad a 1 año	23.3	(24)	
MP definitivo	11.6	(7)	
Leak paravalvular >2+	16	(10)	
ACV	**1.6**	**(1)**	
Complicaciones vasculares	**0**	**(0)**	

?

Agatiello C, Berrocal D. SAC-SIAC 2013

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

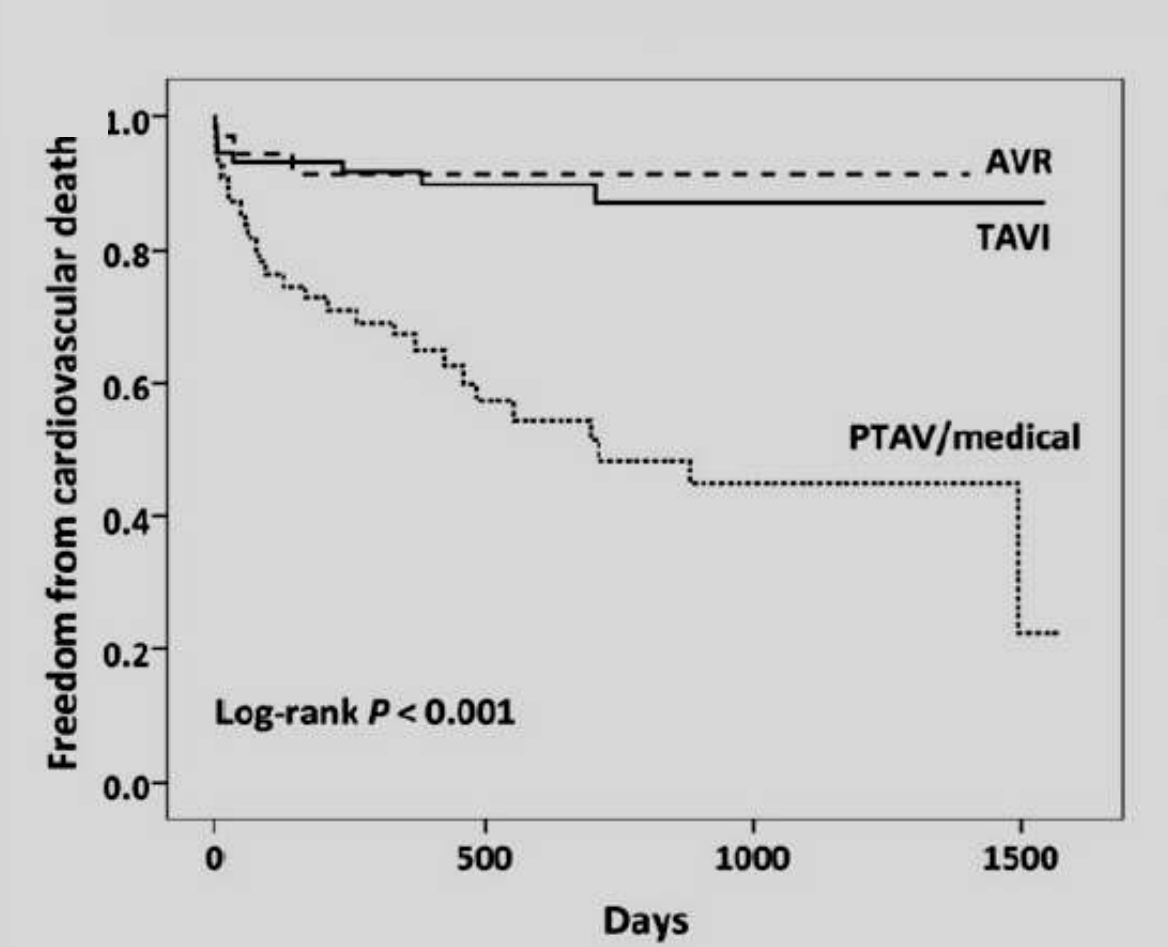


	MCV TF/TS	ES TF/TS	ES TA
# of Patients	3236	1733	2482
Log *Euroscore*	22.0±3.6	25.6±4.1	29.1±7.6

© 2012 EuroIntervention. All rights reserved.

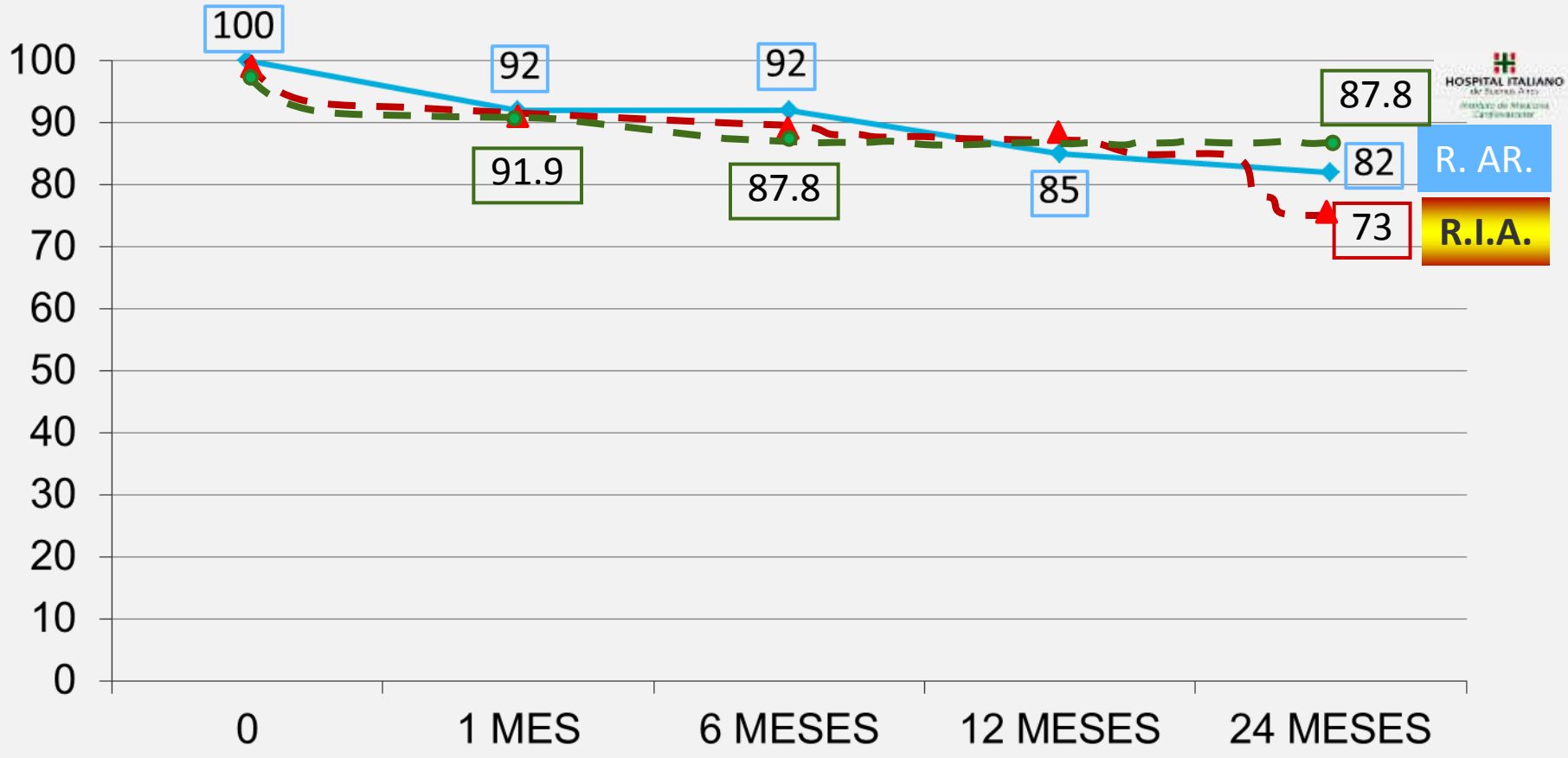
Eggebrecht H *et al.* EuroIntervention 2012;8:129-138 publish online ahead of print March 2012

All-comer high-risk patients with aortic valve stenosis

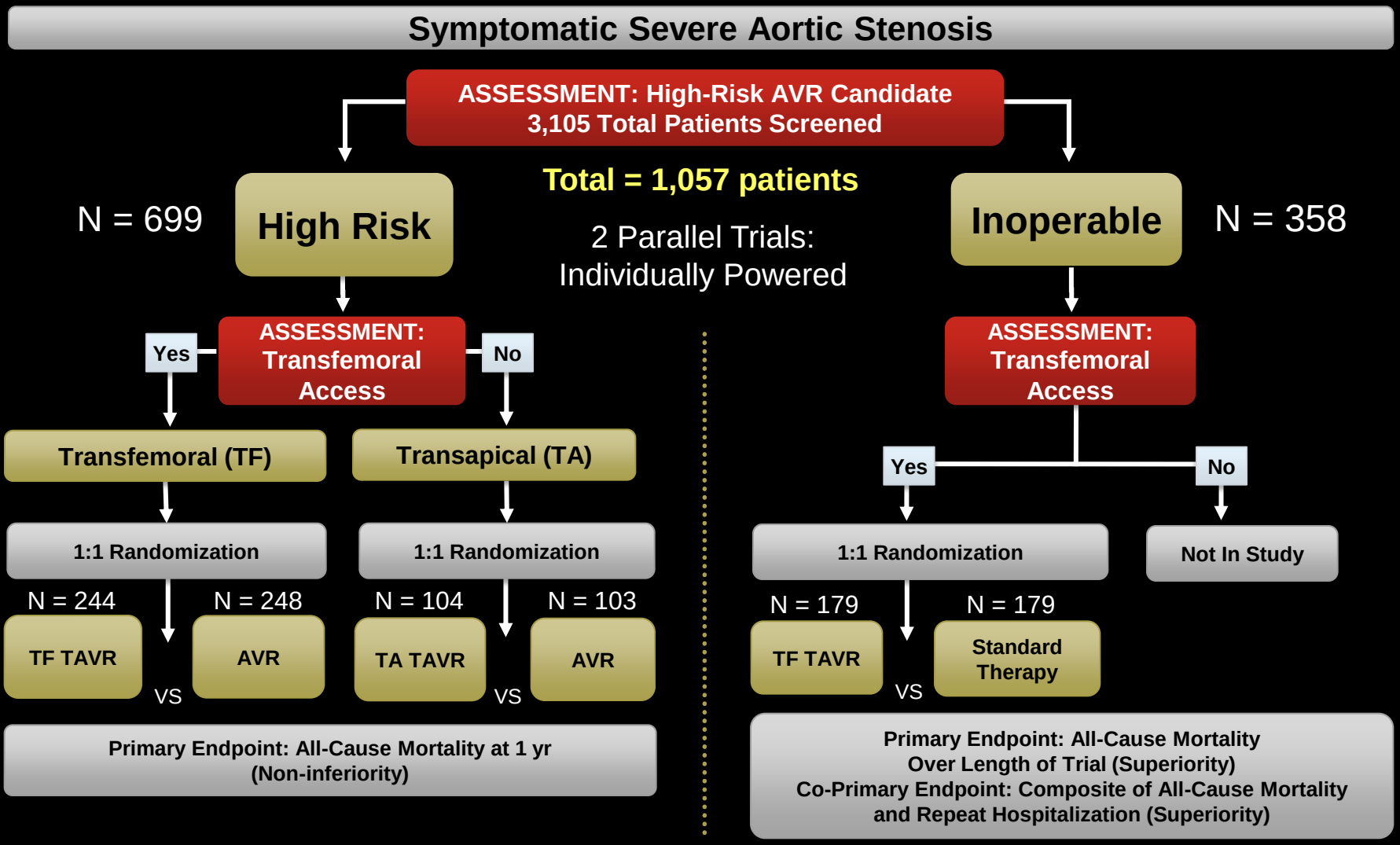


C. Dubois et al. Interactive CardioVascular and Thoracic Surgery 17 (2013) 492–500

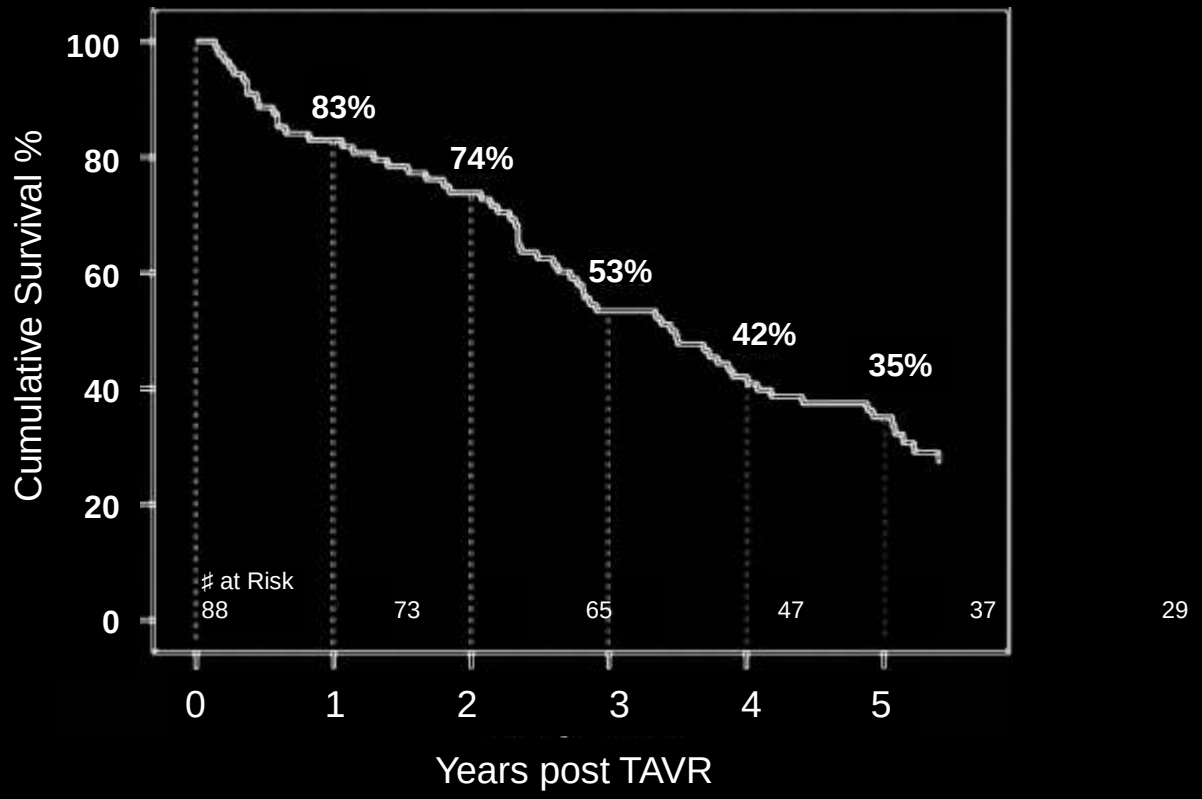
SOBREVIDA ACTUARIAL



PARTNER Study Design



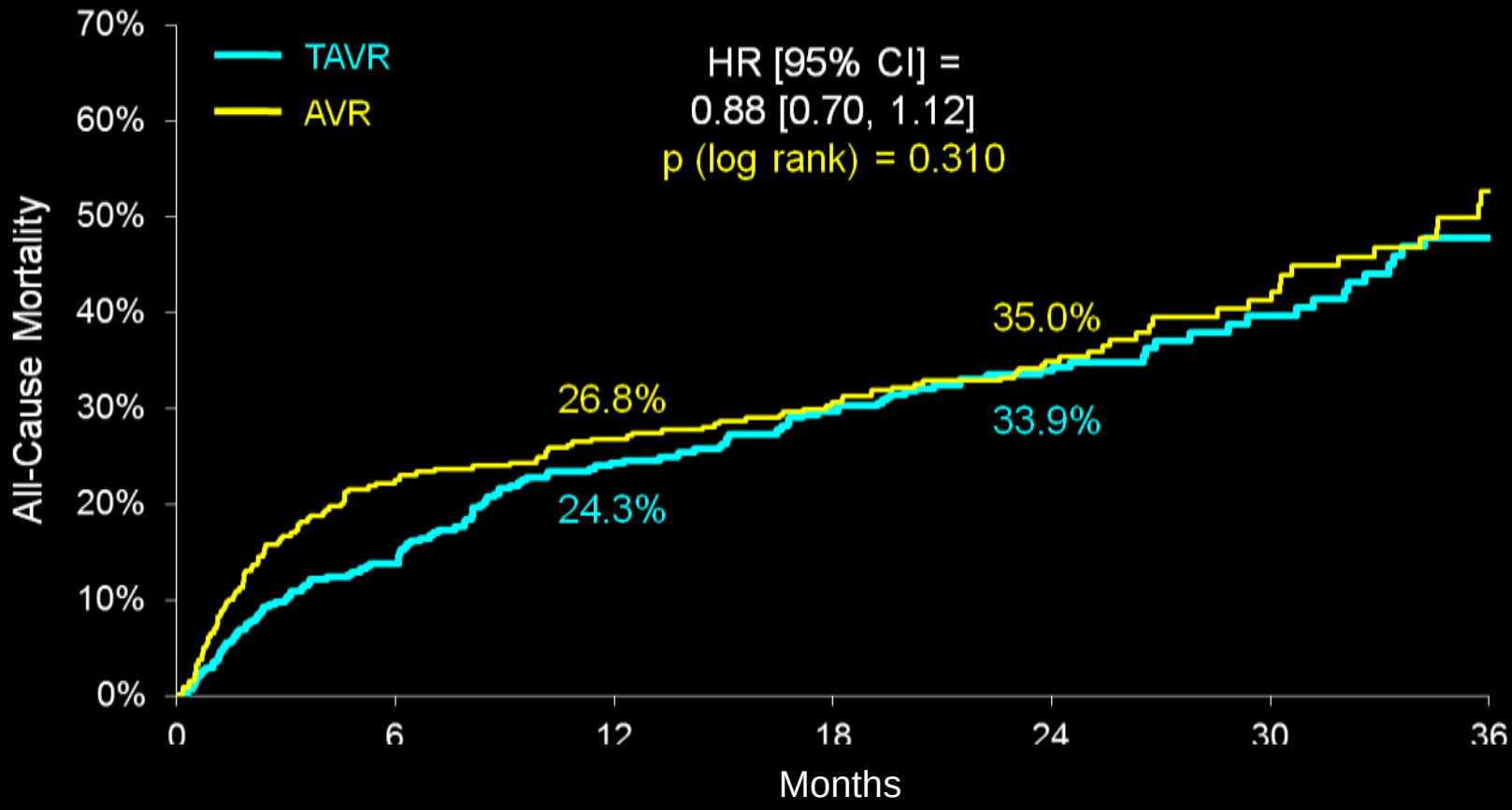
PARTNER (B): **5-Year Outcome**



Long-Term Survival After Transcatheter Aortic Valve Implantation. This represents first in human transarterial and transapical experience in nonoperative patients.

J Am Coll Cardiol. 2013;61(4):413-419. doi:10.1016/j.jacc.2012.11.010

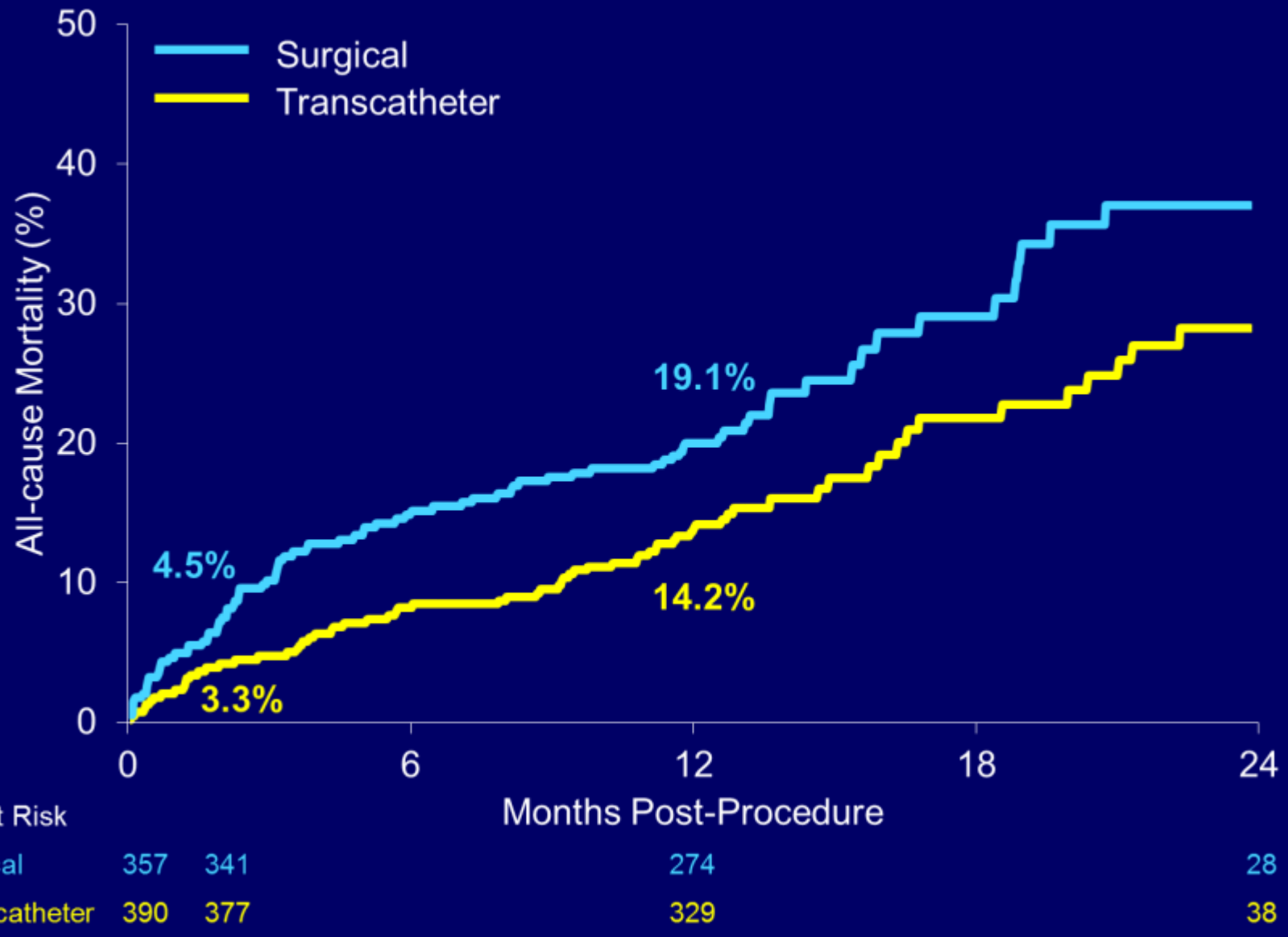
PARTNER US (A) Primary Endpoint:



Numbers at Risk

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

US CoreValve: 2-Year All-cause Mortality



No. at Risk				
Surgical	357	341	274	28
Transcatheter	390	377	329	38

Adams D on behalf of the US CoreValve Investigators. ACC 2014

PARTNER-B

Complicaciones con el TAVI vs. Tratam. Estándar

Resultados	30 dias		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)

(Leon MB y col. TAVI in pts who cannot undergo surgery. N Engl J Med 2010;363:1597-1607)

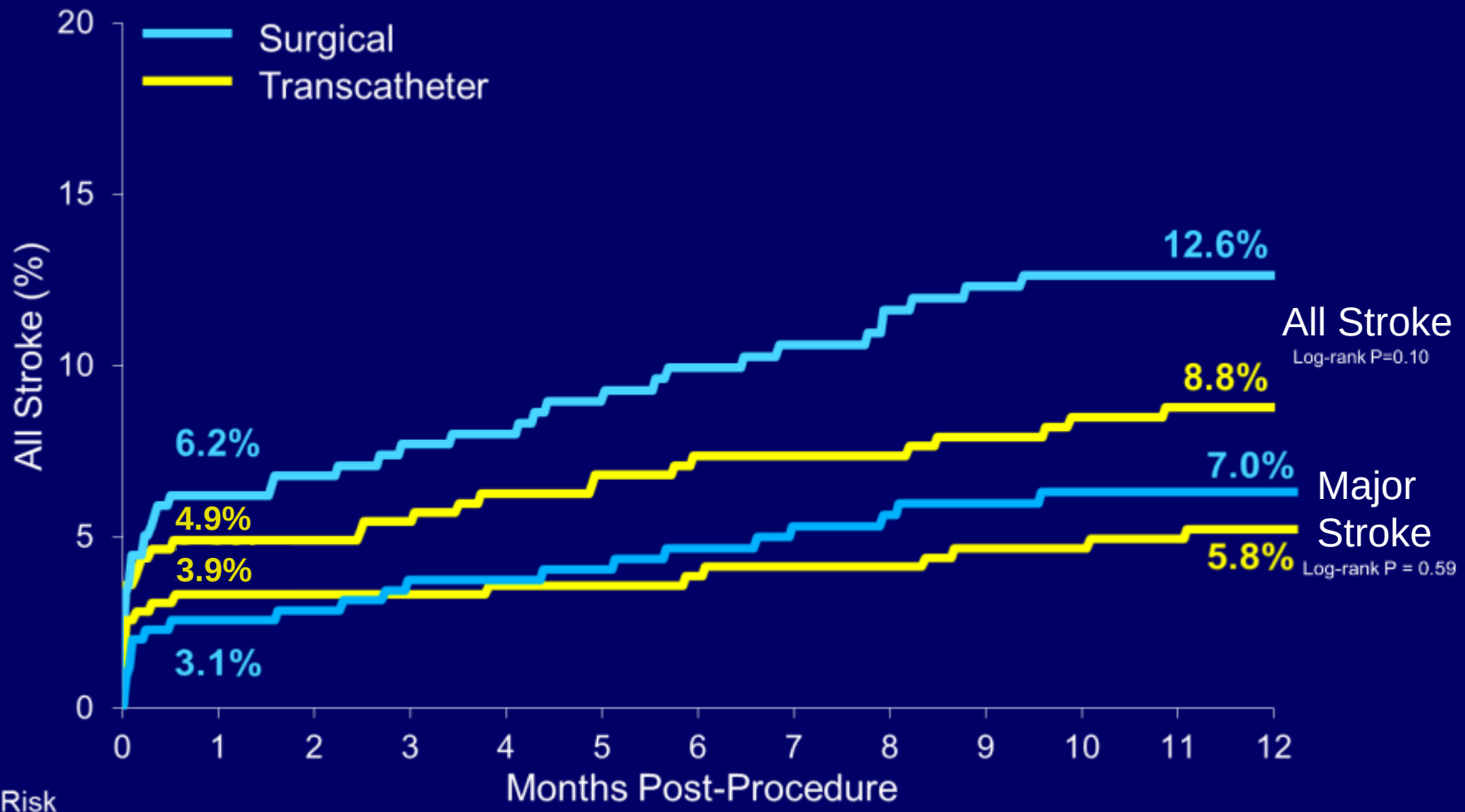
PARTNER-A – TAVI vs. Remp. VAo. en cirugía en Alto Riesgo

Complicaciones del TAVI vs. RVAo

Resultados	30 dias		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)

(Smith CR y col. TAVI vs. Surgical AVR in high risk pts.. N Engl J Med 2010;363:1597-1607)

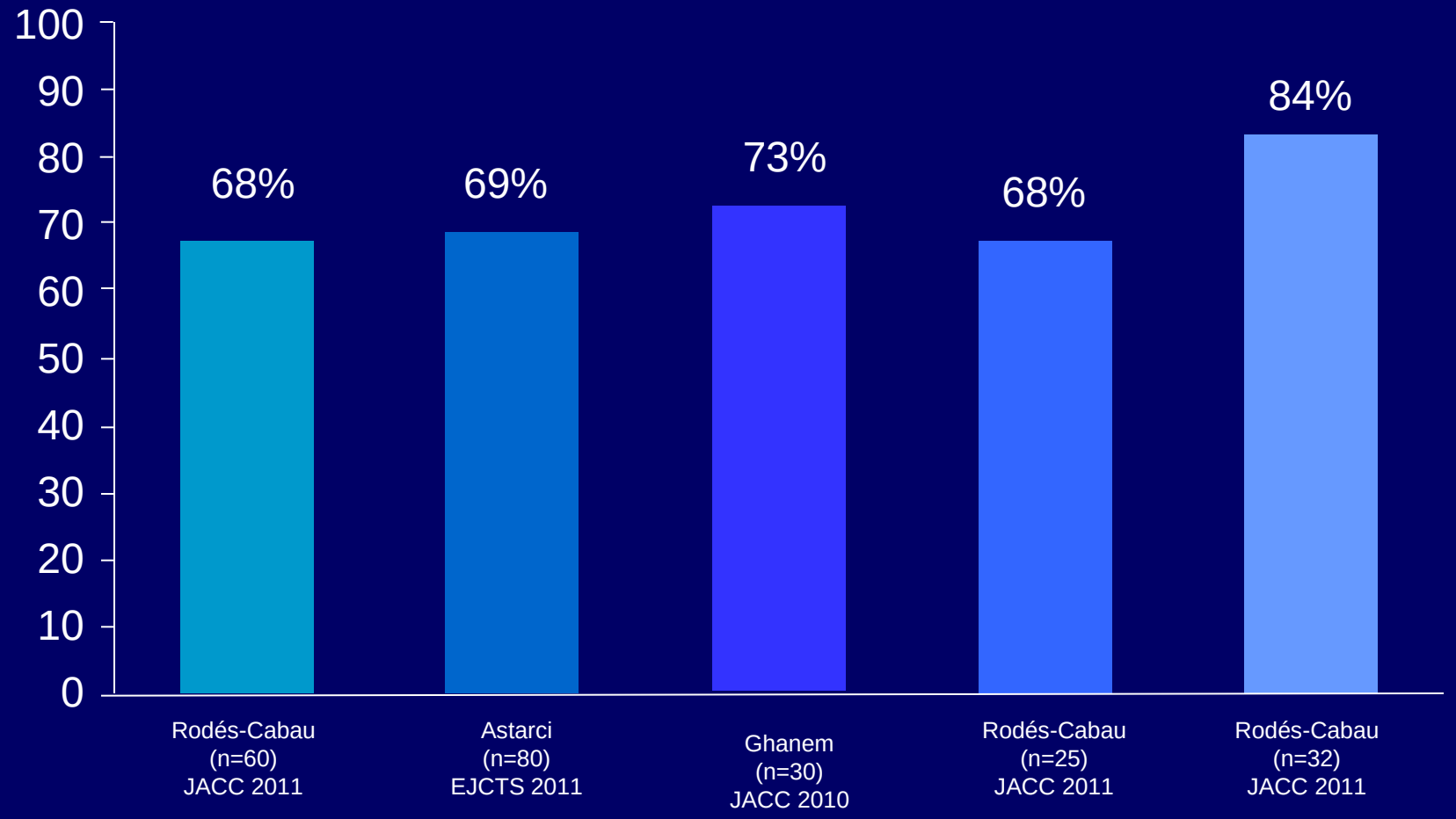
US CoreValve



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

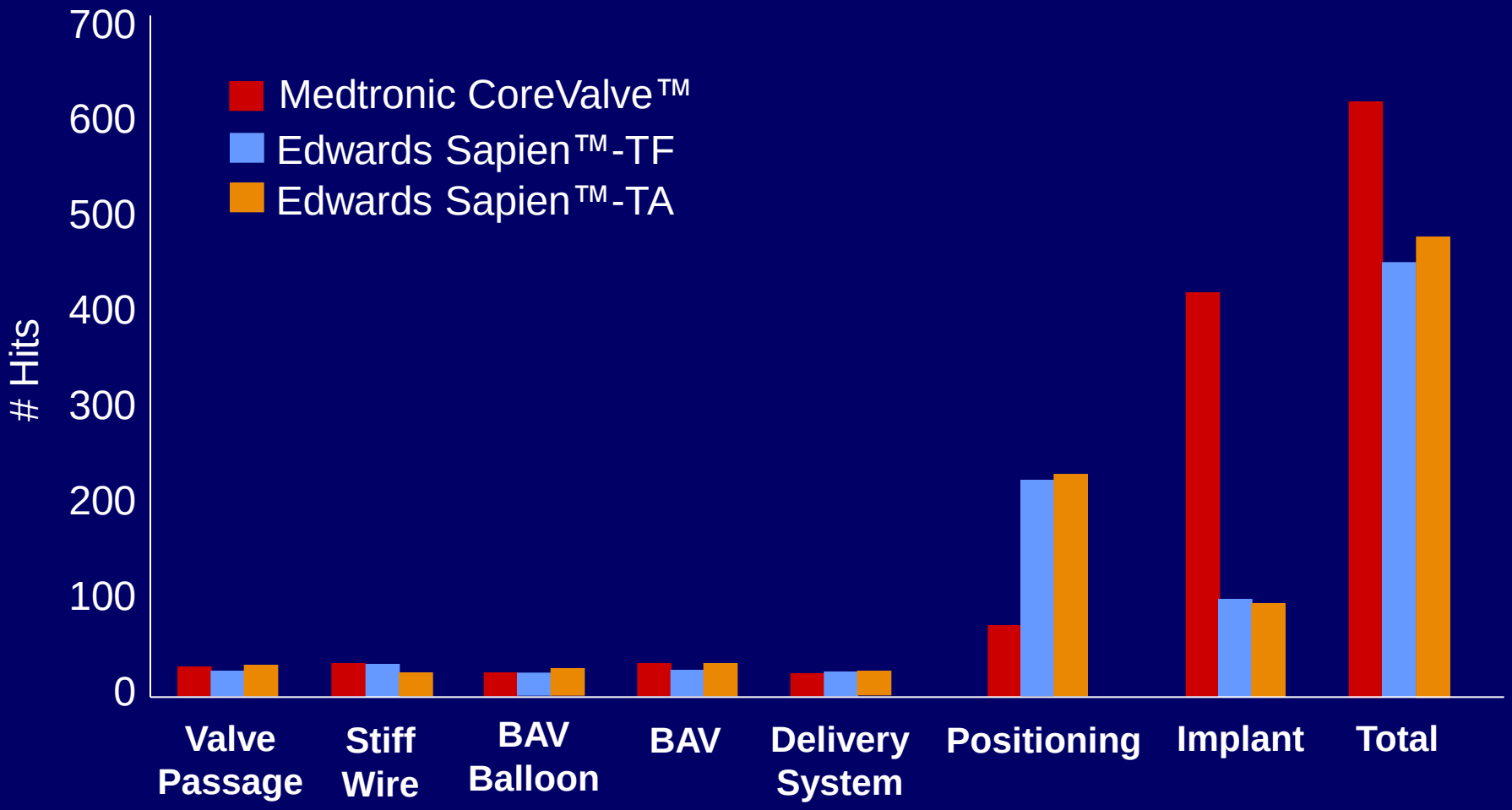
Silent Cerebral Embolism after TAVR

Difussion Weighted MRI



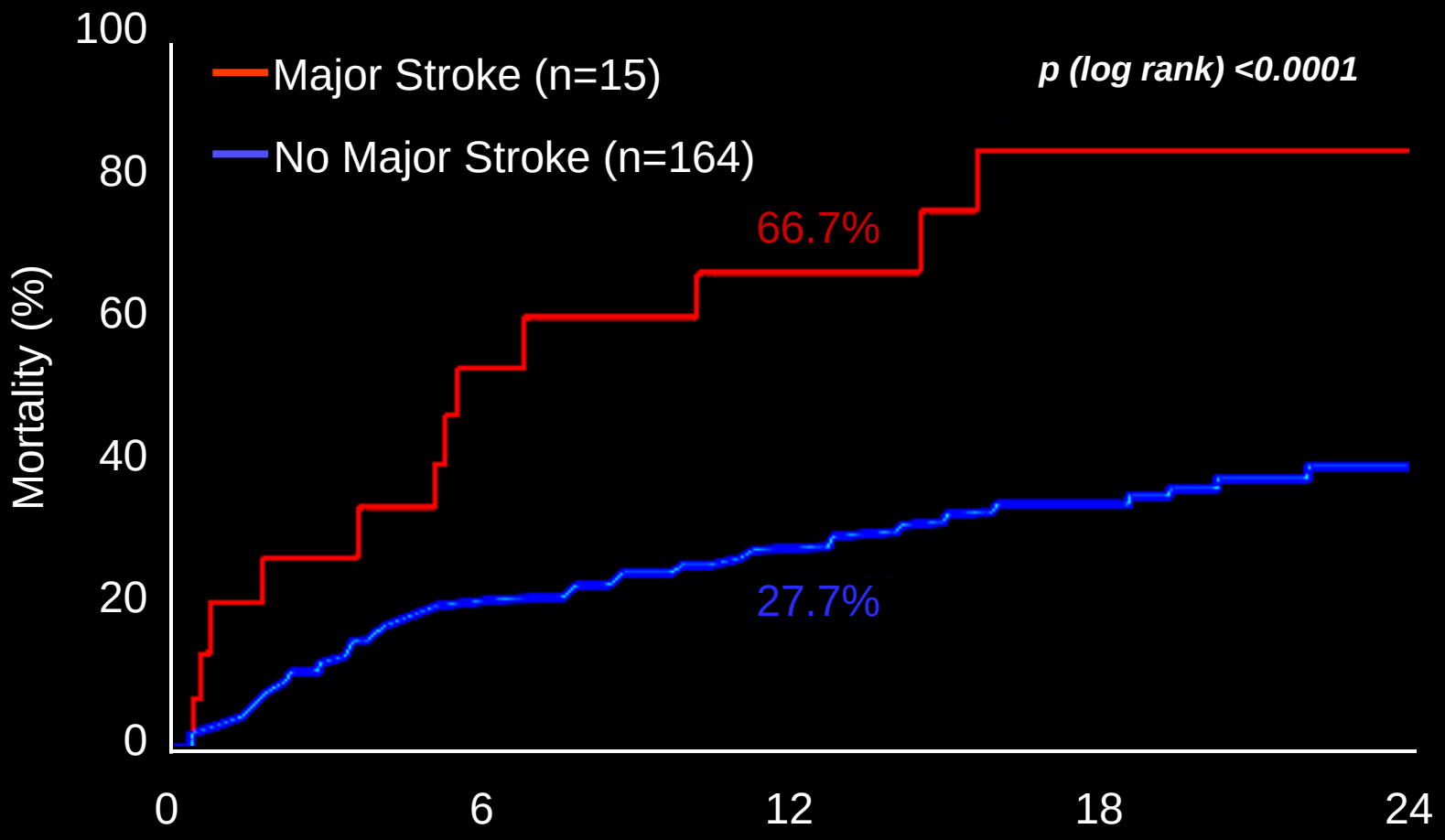
Modified from E Murat Tuzcu. TCT 2012

Timing of Emboli: Transcranial Doppler Findings

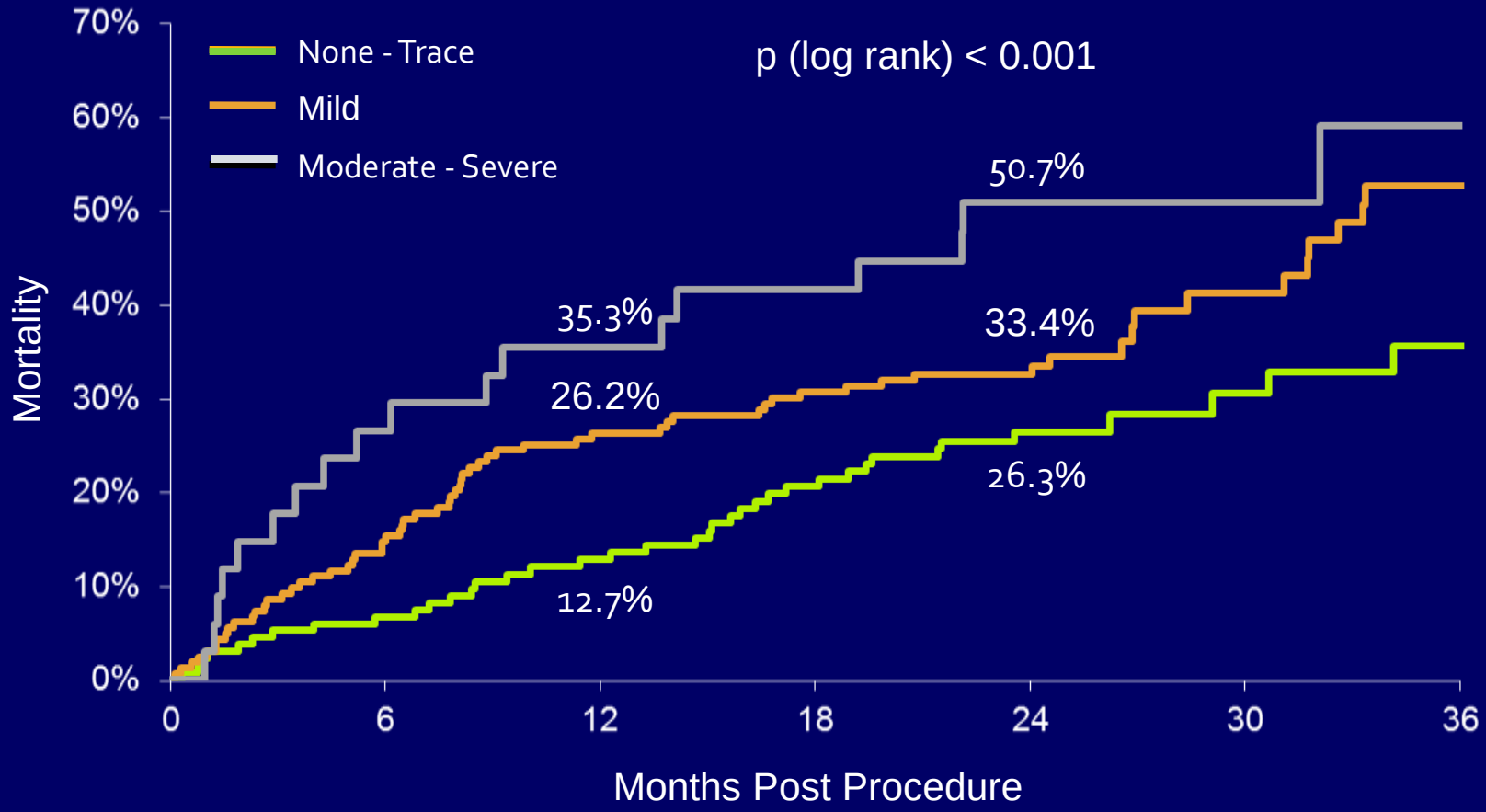


Adapted from Kahlert. AHA 2010

PARTNER-B: Impact of Major Stroke on Survival

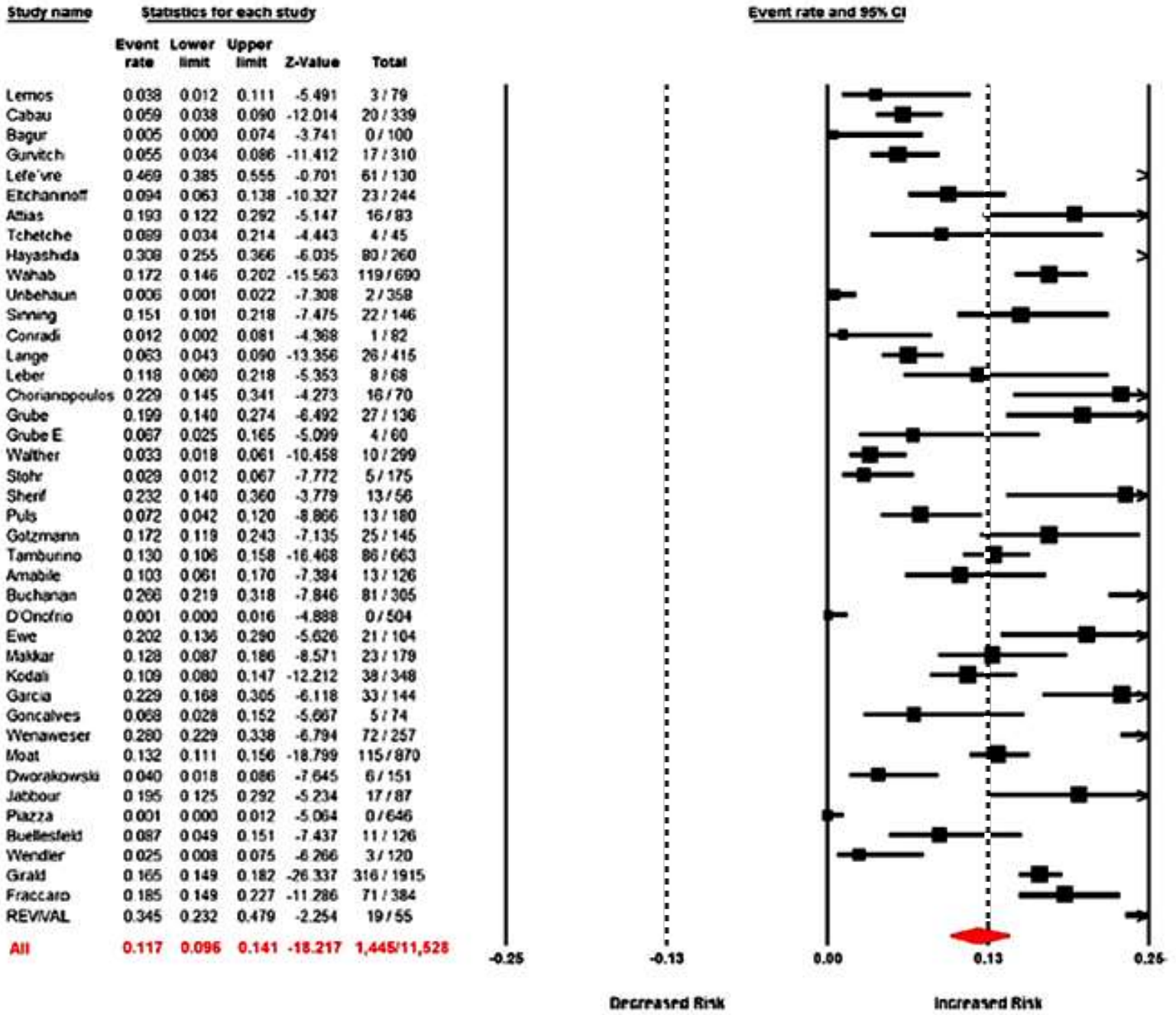


Total AR and Mortality
TAVR Patients (AT)



Numbers at Risk

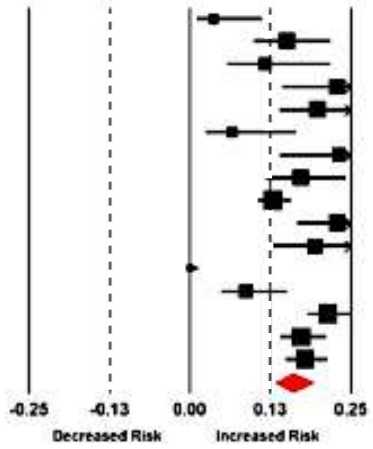
None-Tr	**135**	**125**	**115**	**101**	**68**	**31**	**11**
Mild	**165**	**139**	**121**	**111**	**71**	**33**	**16**
Mod-Sev	**34**	**25**	**22**	**19**	**15**	**6**	**2**



Ganesh Athappan et al. JACC 2013. 61:15;1585-95

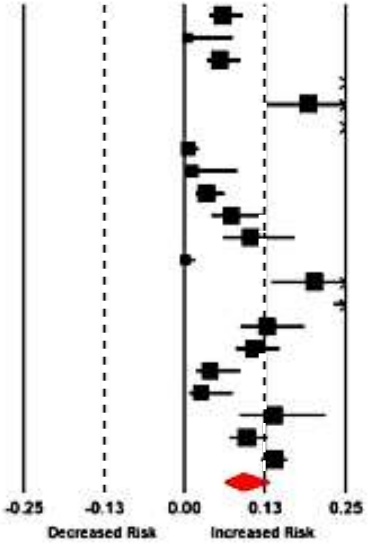
Moderate or Severe AR Post TAVR: CoreValve

Study Names	Event rate	Lower limit	Upper limit	Z-Value	p-Value	Events/Sample Size
Lemos	0.038	0.012	0.111	-5.491	0.000	3 / 79
Sinning	0.151	0.101	0.218	-7.475	0.000	22 / 146
Leber	0.118	0.060	0.218	-5.353	0.000	8 / 68
Chorianopoulos	0.229	0.145	0.341	-4.273	0.000	16 / 70
Grube	0.199	0.140	0.274	-6.492	0.000	27 / 136
Grube E	0.067	0.025	0.165	-5.099	0.000	4 / 60
Sherif	0.232	0.140	0.360	-3.779	0.000	13 / 56
Gotzmann	0.172	0.119	0.243	-7.135	0.000	25 / 145
Tamburino	0.130	0.106	0.158	-16.468	0.000	86 / 663
Garcia	0.229	0.168	0.305	-6.118	0.000	33 / 144
Jabbour	0.195	0.125	0.292	-5.234	0.000	17 / 87
Piazza	0.001	0.000	0.012	-5.064	0.000	0 / 646
Buellesfeld	0.087	0.049	0.151	-7.437	0.000	11 / 126
Girald Core	0.215	0.185	0.248	-13.482	0.000	138 / 642
Moats Core	0.173	0.141	0.211	-12.396	0.000	76 / 439
Wahab Core	0.179	0.150	0.212	-14.096	0.000	104 / 582
All	**0.160**	**0.134**	**0.190**	**-15.65**	**0.000**	**583/4089**



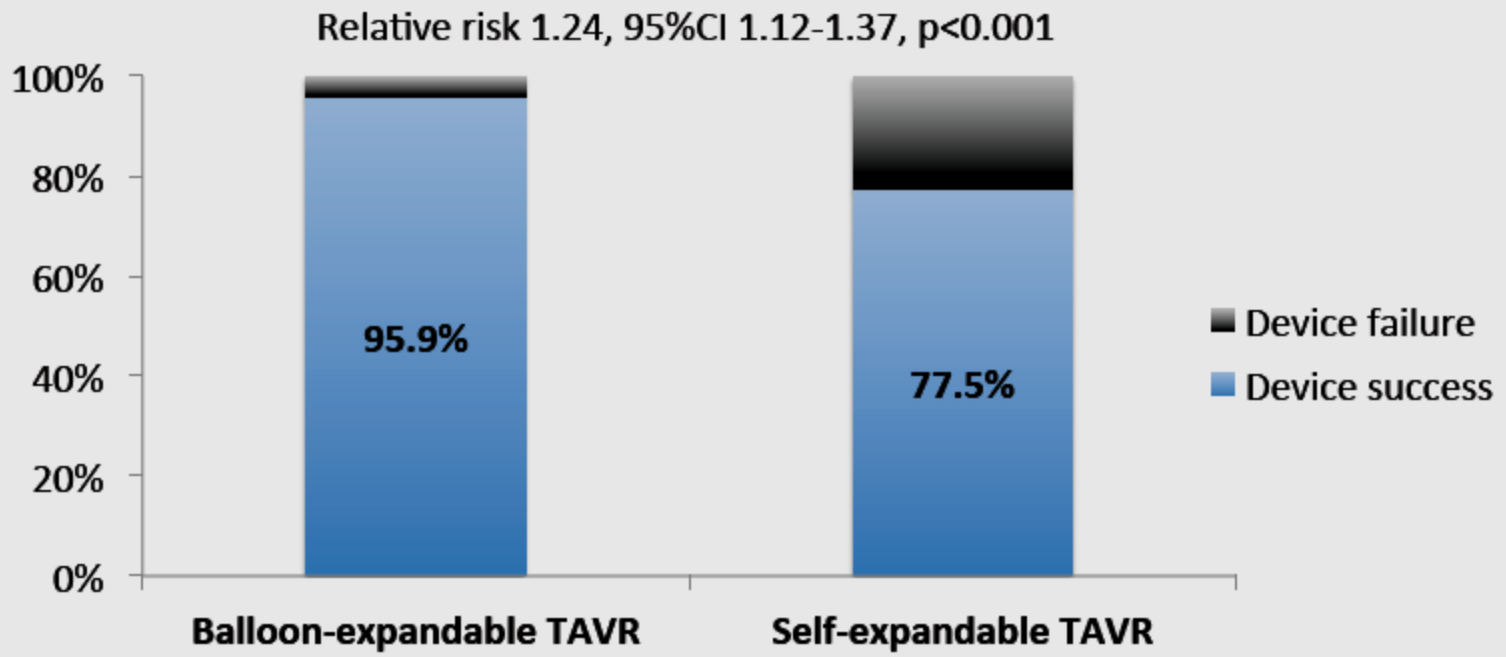
Moderate or Severe AR Post TAVR: Edward Valve

Study Names	Event rate	Lower limit	Upper limit	Z-Value	p-Value	Events/Sample Size
Cabau	0.059	0.038	0.090	-12.014	0.000	20 / 339
Bagur	0.005	0.000	0.074	-3.741	0.000	0 / 100
Gurvitch	0.055	0.034	0.086	-11.412	0.000	17 / 310
Lefe'vre	0.469	0.385	0.555	-0.701	0.483	61 / 130
Attias	0.193	0.122	0.292	-5.147	0.000	16 / 83
Hayashida	0.308	0.255	0.366	-6.035	0.000	80 / 260
Unbehaun	0.006	0.001	0.022	-7.308	0.000	2 / 358
Conradi	0.012	0.002	0.081	-4.368	0.000	1 / 82
Walther	0.033	0.018	0.061	-10.458	0.000	10 / 299
Puls	0.072	0.042	0.120	-8.866	0.000	13 / 180
Amabile	0.103	0.061	0.170	-7.384	0.000	13 / 126
D'Onofrio	0.001	0.000	0.016	-4.888	0.000	0 / 504
Ewe	0.202	0.136	0.290	-5.626	0.000	21 / 104
REVIVAL	0.345	0.232	0.479	-2.254	0.024	19 / 55
Makkar	0.128	0.087	0.186	-8.571	0.000	23 / 179
Kodali	0.109	0.080	0.147	-12.212	0.000	38 / 348
Dworakowski	0.040	0.018	0.086	-7.645	0.000	6 / 151
Wendler	0.025	0.008	0.075	-6.266	0.000	3 / 120
Wahab Edw	0.139	0.085	0.218	-6.557	0.000	15 / 108
Moats Edw	0.096	0.071	0.129	-13.293	0.000	39 / 405
Girald Edw	0.139	0.121	0.159	-22.375	0.000	174 / 1256
All	**0.091**	**0.062**	**0.131**	**-11.03**	**0.000**	**571/5497**



Ganesh Athappan et al. JACC 2013. 61:15;1585-95

Primary Endpoint – Device Success



Causes of device failure	Balloon-expandable (n=121)	Self-expandable (n=120)
Unsuccessful vascular access, delivery and deployment	0/121 (0)	0/120 (0)
Incorrect position with implantation of more than one valve	1/121 (0.8)	7/120 (5.8)
Inadequate performance of the prosthetic heart valve		
- Aortic valve area < 1.2 cm^2 or mean aortic valve gradient > 20 mmHg	0/121 (0)	0/120 (0)
- Moderate or severe prosthetic valve regurgitation	5/121 (4.1)	22/120 (18.3)
Total (hierarchical)	5/121 (4.1)	27/120 (22.5)

Wahab M-A on behalf of the CHOICE investigators. ACC 2014

Clinical Outcome at 30 Days (I)

	Balloon-expandable (n=121)	Self-expandable (n=117)	p-value
Death			
From any cause	5/121 (4.1%)	6/117 (5.1%)	0.77
From CV causes	5/121 (4.1%)	5/117 (4.3%)	0.99
Stroke	7/121 (5.8%)	3/117 (2.6%)	0.33
Major	3/121 (2.5%)	3/117 (2.6%)	0.99
Minor	4/121 (3.3%)	0/117 (0.0%)	0.12
Myocardial infarction	1/121 (0.8%)	0/117 (0.0%)	0.99
Bleeding			
Life threatening	10/121 (8.3%)	14/117 (12.0%)	0.35
Major	23/121 (19.0%)	17/117 (14.5%)	0.36
Minor	11/121 (9.1%)	9/117 (7.7%)	0.70
Major or minor	34/121 (28.1%)	26/117 (22.2%)	0.30
Vascular complications			
All	17/121 (14.0%)	15/117 (12.8%)	0.78
Major	12/121 (9.9%)	13/117 (11.1%)	0.76
Minor	5/121 (4.1%)	2/117 (1.7%)	0.28

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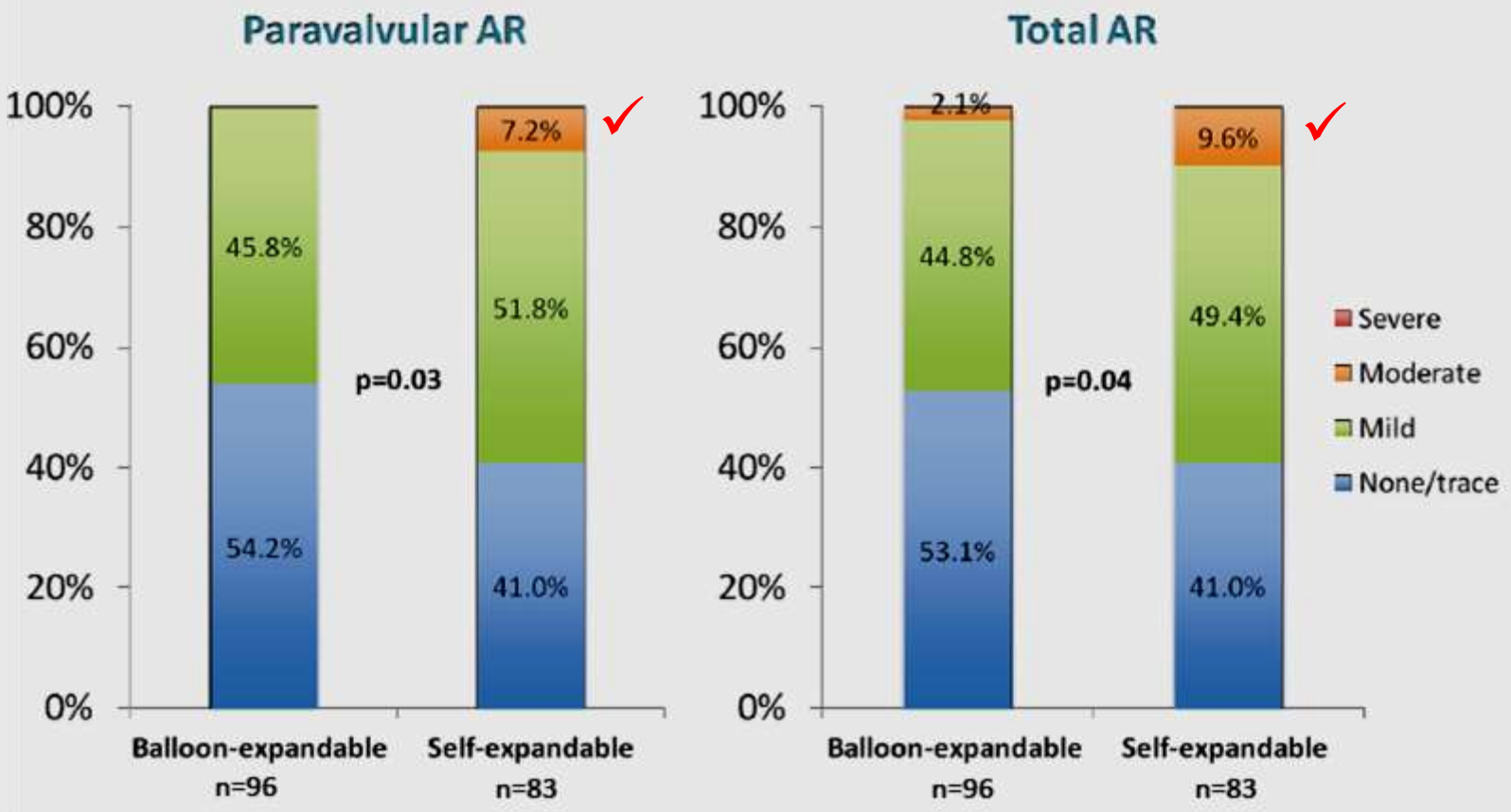
Echocardiographic Findings

Aortic Regurgitation at 30 Days



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Selección de dispositivo

RETROGRADAS

- **Trans Femoral/Iliaca**

Corevalve

- **Vía Tran Subclavia**

Corevalve

- **Vía Trans Aortico**

Corevalve

ANTEROGRADA

- **Vía Transapical**

Acurate TA

Jenavalve TA

Robin Williams reveals huge scars on chest eight weeks after heart surgery

By DAILY MAIL REPORTER
UPDATED: 12:52 GMT, 14 May 2009

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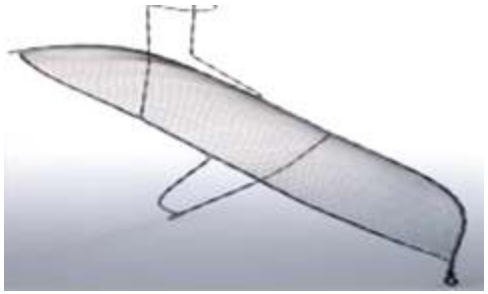
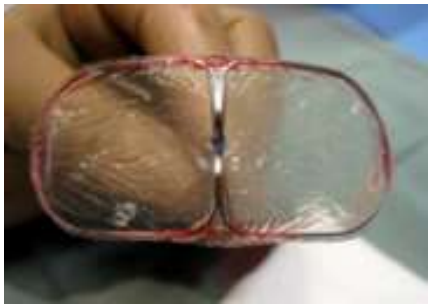
Robin Williams has revealed a picture of the scars running down his chest and stomach eight weeks after having heart surgery.

In his first interview since his operation to replace an aortic valve, the actor told the David Letterman show in the U.S. that he was feeling much better - but older.

The 57-year-old Good Will Hunting star bounded on to the set of the show wearing a T-shirt emblazoned with a large heart.

Bouncing back: Robin Williams revealed a picture of the scars left eight weeks after having heart surgery to replace an aortic valve

TriGuard™ Cerebral	Embrella™	Claret Montage 2™
Deflector	**Deflector**	**Filter**
3 Vessels Covered	**2 Vessel Coverage**	**2 Vessel Coverage**
Groin Access	**Radial Access**	**Radial Access**
Nitinol® Mesh	**Polymer based Mesh**	**Polymer based Filter**
EU Feasibility	**CE approved**	**CE approved**
9F Sheath (7F Delivery)	**6F Shuttle Sheath**	**6F Radial Sheath**
		

Evolución de las bioprótesis

Sadra MEDICAL

Boston Scientific

JENAVALVE TF

ACURATE neo/TF™

SYMETIS

DIRECT FLOW MEDICAL, INC.

Medtronic

ENGAGER

SAPIEN3™

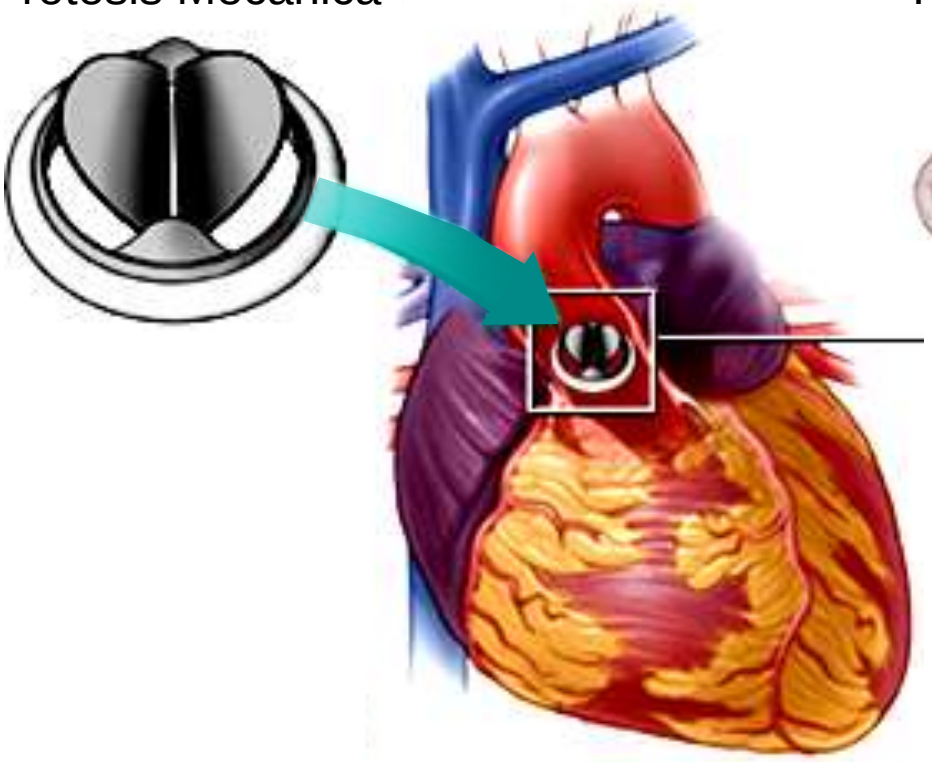
Edwards

Descalcificación Percutánea?

McBride LR *et al.* J Thorac Cardiovasc Surg. 1990 Jul;100(1):36-42

Correcta elección de prótesis quirúrgica

Prótesis Mecánica



Prótesis Biológica

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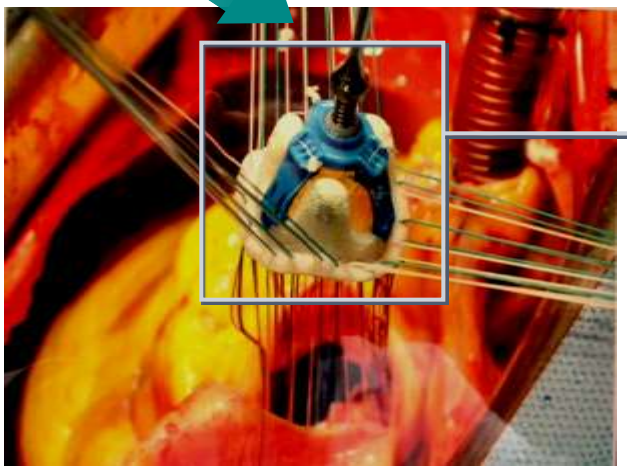
de Buenos Aires
Instituto de Medicina Cardiovascular



- ✓ **Alto Riesgo quirúrgico con razonable expectativa de sobrevida y calidad funcional**
- ✓ Las válvulas NO son todas iguales y cada vez menos
- ✓ Resultados comparables con Cirugía y mejores que el Tx Mx
- ✓ Durabilidad, por ahora, hasta 5 años
- ✓ Mayor ACV
- ✓ Complicaciones vasculares
- ✓ El “leak” es un problema prevalente y aumenta la mortalidad

HOSPITAL ITALIANO de Buenos Aires
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Daniel Berrocal, MD, PhD, MTSAC, FACC
Jefe de Cardiología Intervencionista
daniel.berrocal@hospitalitaliano.org.ar

- ✓ Se extenderá a la mayoría de los pacientes quirúrgicos hasta hoy
- ✓ Los sistemas de protección reducirán el ACV
- ✓ Nuevas válvulas reducirán el “leak” y las complicaciones vasculares
- ✓ Mejor preparación de la válvula nativa (ultrasonido)
- ✓ Las válvulas quirúrgicas serán todas biológicas pensando en futuro TAVR

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NOTHING IS AS STRONG
AS TEAM SPIRIT