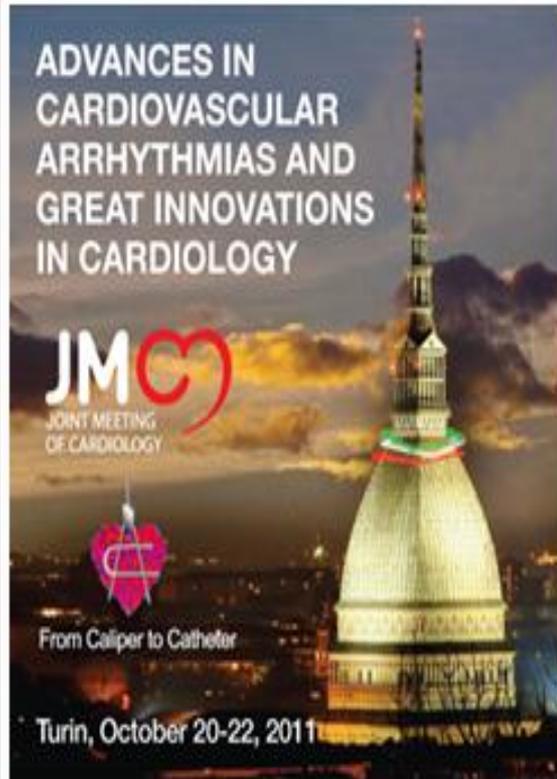




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Ospedale San Giovanni Battista - Molinette

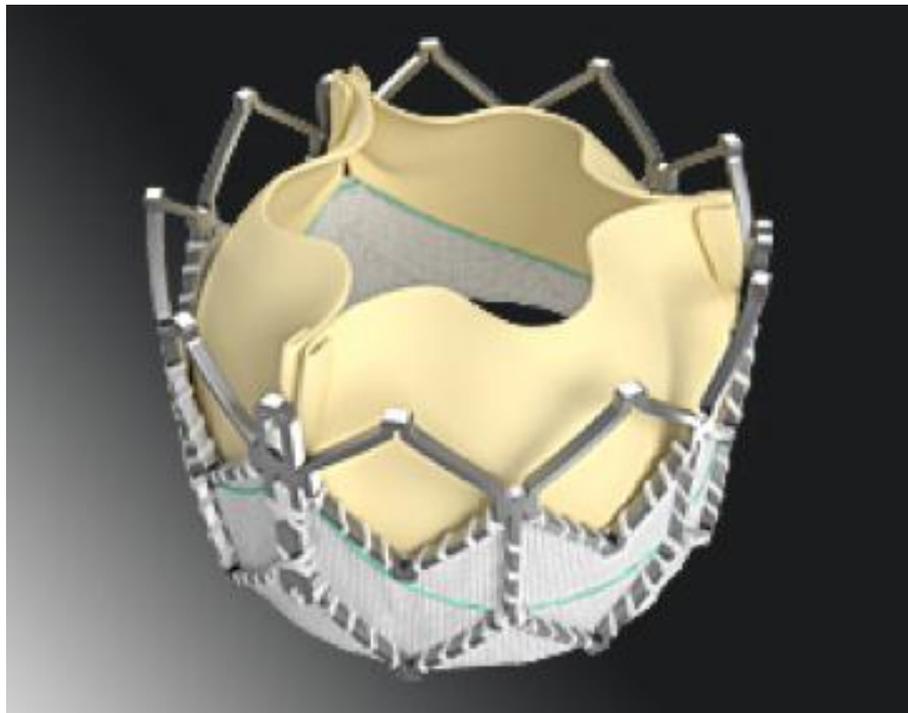


Trans-Apical Aortic valve
implantation in Italy and in Europe

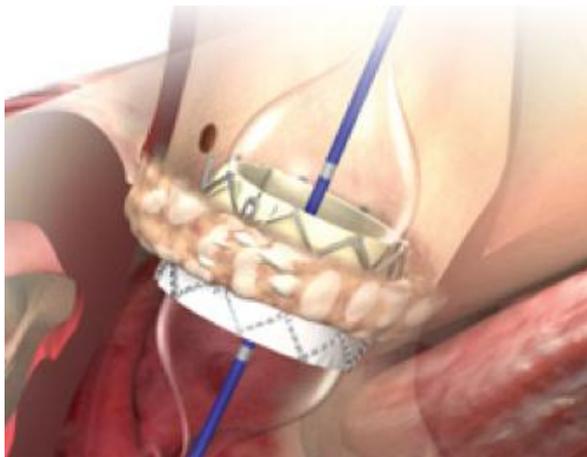
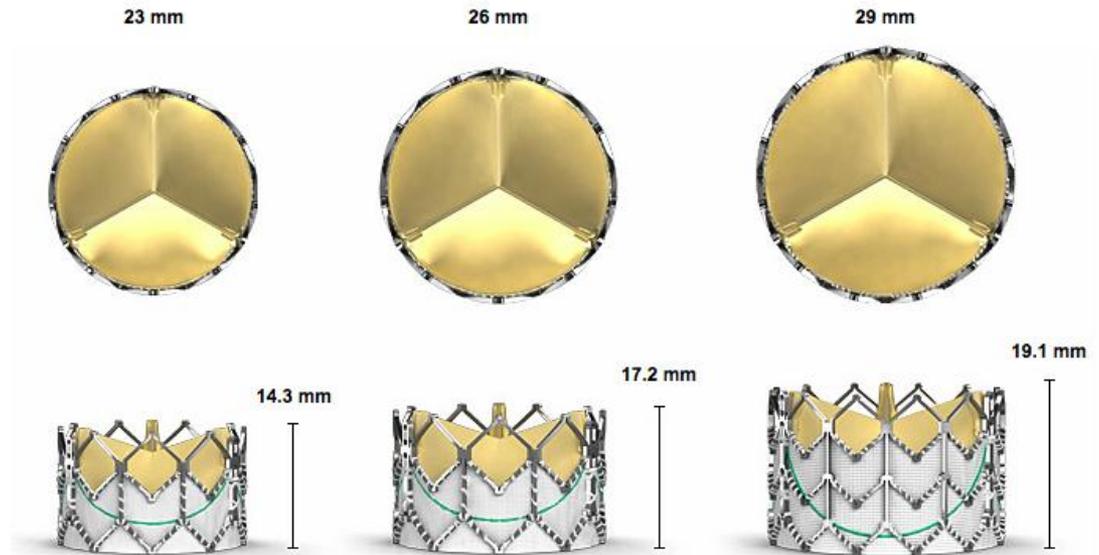
TAVI Heart Team
Prof. Mauro Rinaldi
Prof. Fiorenzo Gaita
Dott. Sebastiano Marra

Trans-apical Aortic Valve 1

Edwards SAPIEN XT Transcatheter Heart Valve



Trans-apical Aortic Valve 1



- CE approval in 2007
- Ballon expandable
- Bovine pericardium
- Chrome-cobalt stent
- ThermaFix process (anticalcific treatment)

> 7.500 Implantation worldwide

Trans-apical Aortic Valve 2

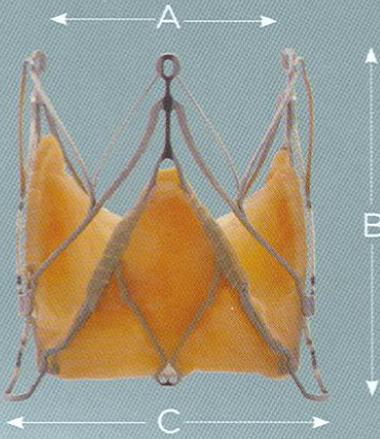
DESIGNED WITH THE PATIENT AT HEART™



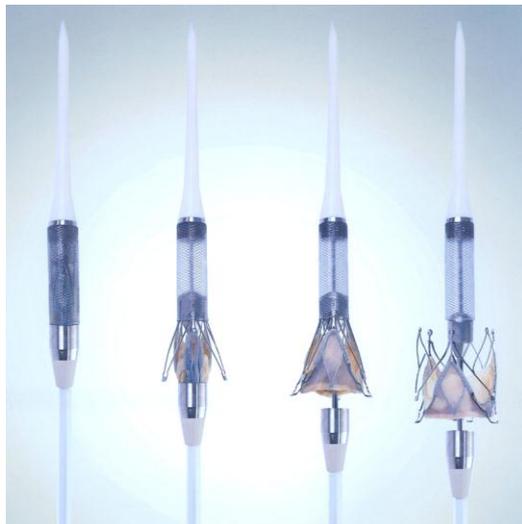
JenaValve™

Trans-apical Aortic Valve 2

THE JENAVALVE



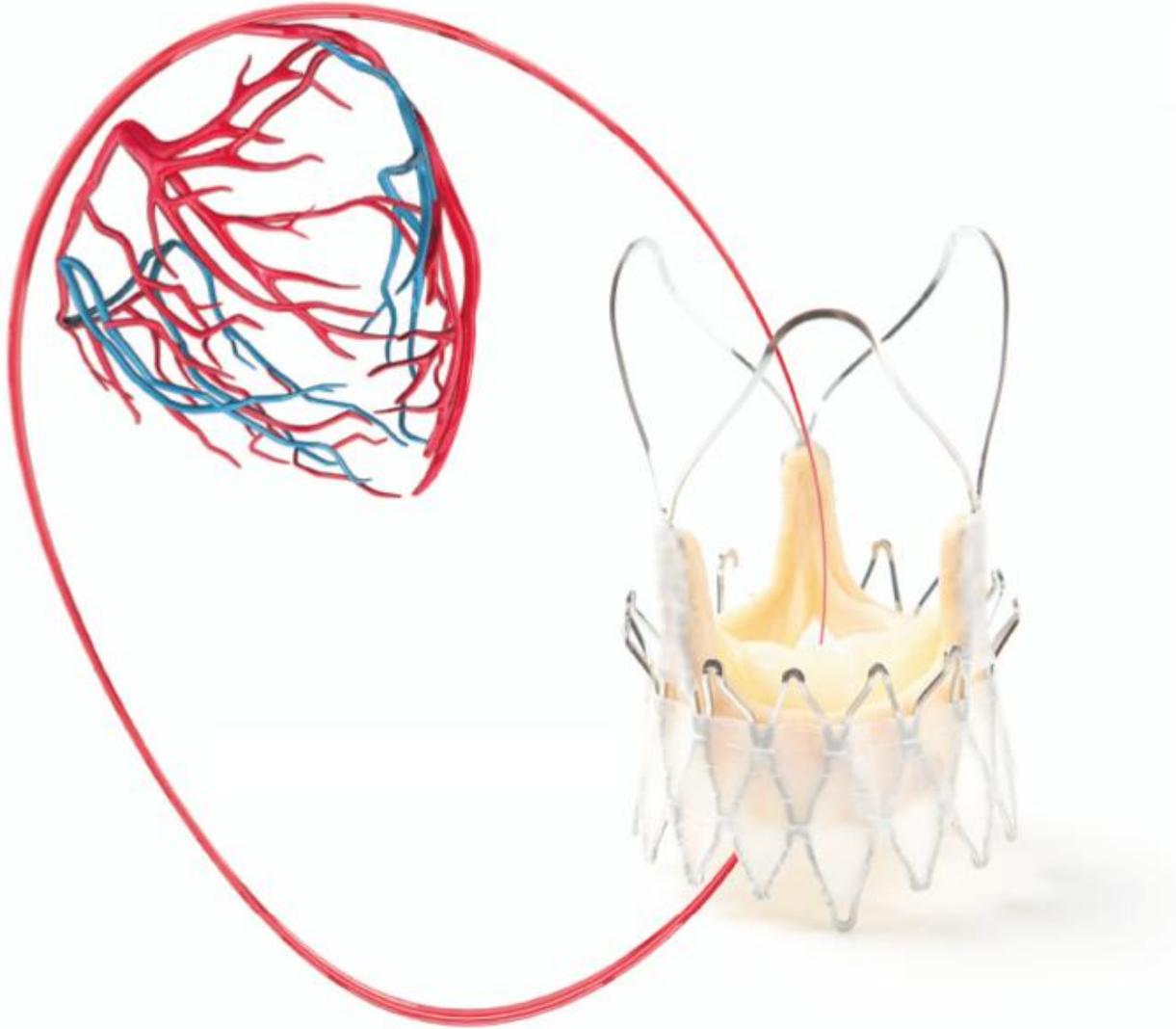
JV-1000-PX23	JV-1000-PX25	JV-1000-PX27
A = 22 mm (valve OD)	A = 24 mm (valve OD)	A = 26 mm (valve OD)
B = 30 mm	B = 32 mm	B = 31 mm
C = 28 mm (OD unrestricted stent)	C = 31 mm (OD unrestricted stent)	C = 33 mm (OD unrestricted stent)



- CE approval in September 2011
- Self expandable
- Porcine Aortic Root Valve
- Nitinol Stent
- Retriavable and repositionable
- Anatomical correct feeler guided positioning
- JenaClip™ anchoring mechanism

≈ 100 Implants in Germany

Trans-apical Aortic Valve 3



ACURATE TA™
Simplicity Engineered,
Confidence Delivered.

symetis 

Trans-apical Aortic Valve 3

SIZE	S	M	L
REF	SYM-SV23-001	SYM-SV25-001	SYM-SV27-001



- CE approval in September 2011
- Self expandable
- Porcine tissue valve
- Nitinol Stent
- Stabilization arches

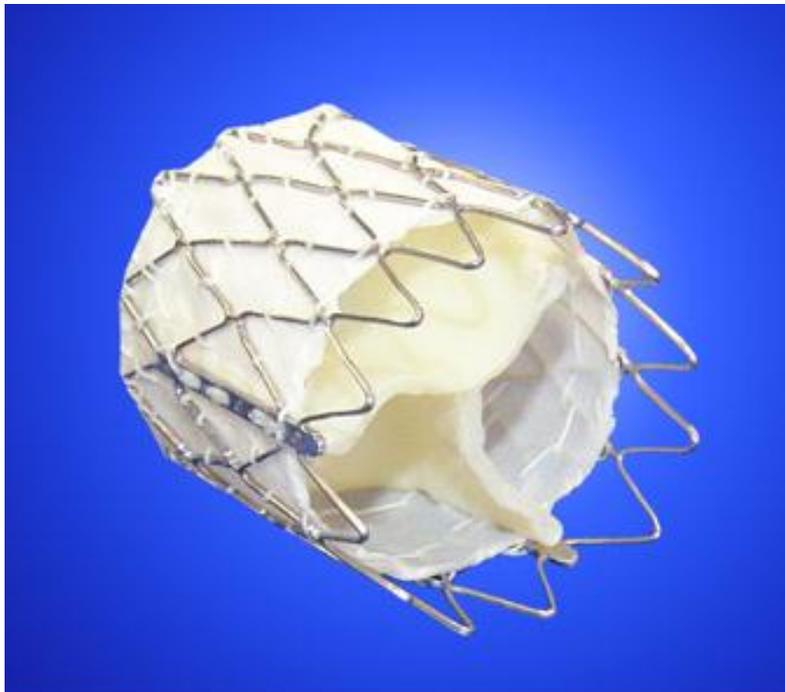
≈ 50 Implants in Germany

Trans-apical Aortic Valve 4



BRAILE
BIOMÉDICA

Tecnologia médica... de coração!



- Measures: 20-22-24-26 mm
- Commercialized in Brazil since Oct 2011
- Ballon-expandable
- Bovine pericardium
- Steel Stent

≈ 150 Implants in Brazil

Trans-Apical European Available Data

- ① UK Registry (JACC 20 Oct 2011 in press)
- ② Deutsche Herzzentrum Berlin (Ann Thorac Surg 2011;92:1315-23)
- ③ University of Leipzig (Circulation 2011;124:S124-9)
- ④ FRANCE 2 (FRrench Aortic National Corevalve and Edwards Registry)
- ⑤ Source Registry
- ⑥ Source XT Registry
- ⑦ PREVAIL-TA Study
- ⑧ I-TA (Italian Transapical Registry)
- ⑨ German Registry (690 pz → 84% Corevalve)
- ⑩ Belgian Registry (14% TA → 47 patients)

Trans-Apical Detailed Data

	UK *	Berlin	Leipzig	FRANCE2	Source	PREVAIL	I-TA
n	271	300	299	460	575	150	504
Age	82.3 ± 6.6	79.6 ± 8.1	82.1 ± 6.4	82.5 ± 7	80.7 ± 7	-	81.2 ± 6.5
Female	48 %	67.7 %	70 %	49.4 %	55.8 %	-	60.7 %
Log ES %	21.4	38.5±19.4	31 ± 15.8	22.3 ± 14	29.1 ± 16.2	4.3 – 40 (range)	26.3 ± 13.8
STS %	-	19.1±15.5	12 ± 7.7	14.7 ± 12	-	-	11 ± 4
30-days	89.3 %	95.3 %	91.3 %	88.5 %	89.7 %	91%	91.7 %
1 year surv	72.3 %	82.5±2.4	73 %	80.6% (6m)	72.1 %	-	81.4±2.2 %

* Includes 50 Trans-subclavian access

Data from all 2419 patients including Corevalve and other access

Argument

Significant differences between Registries and Centers

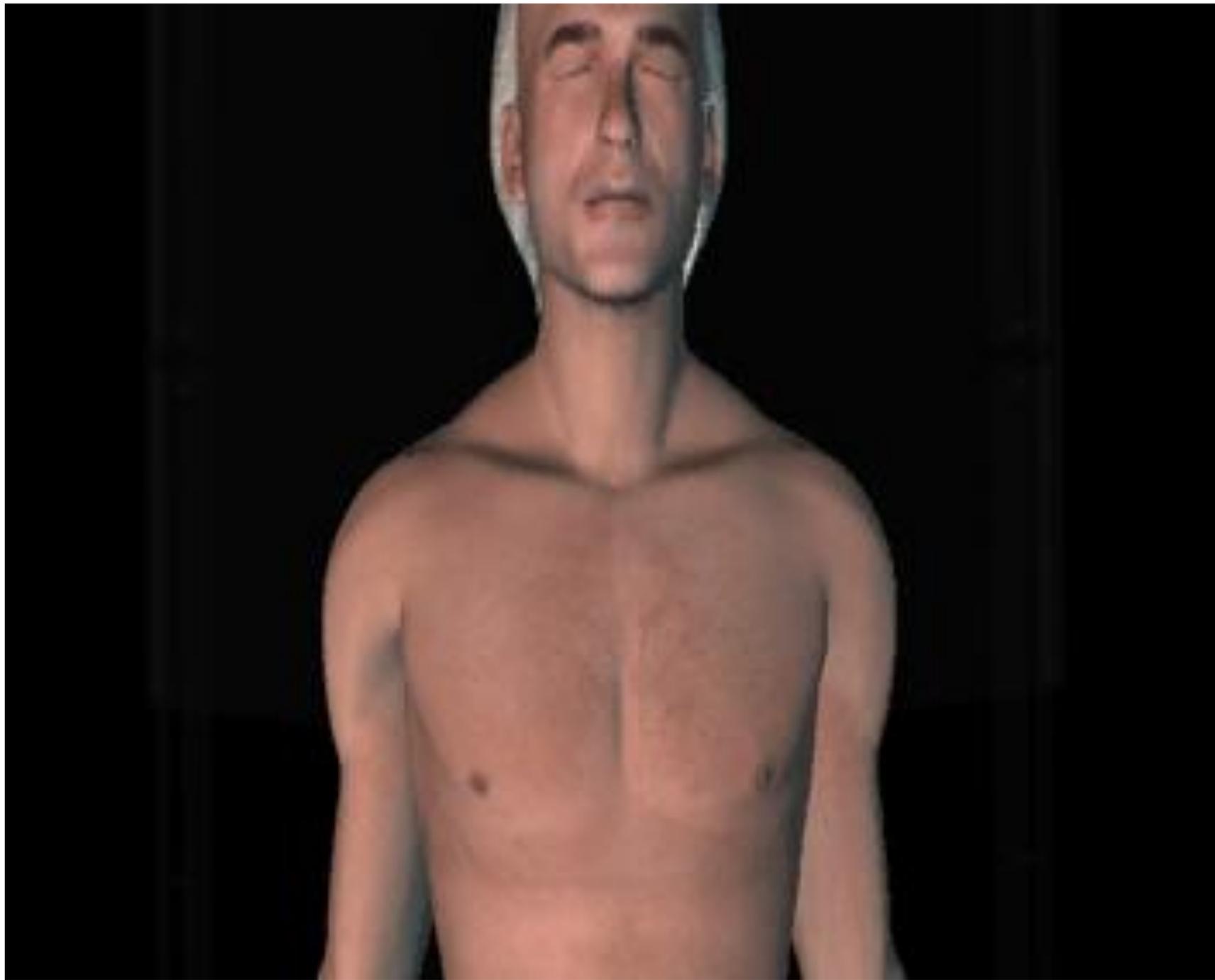
- | | |
|------------------------|-----------------|
| 1. Mean age > 80 years | 79.6 – 82.5 |
| 2. Log ES | 21.4 % - 38.5 % |
| 3. 30 days mortality | 11.5 % - 4.7 % |
| 4. 1 year survival | 72.1 % - 82.5 % |

Old population with high surgical risk, even if overestimated by LogES

30 days mortality and 1 year survival looks acceptable and superimposable to literature, considering the target population

Worrisome late mortality (between 30 days and 1 year)

Transapical
vs
Transfemoral
and
other retrograde approaches



Trans-femoral less invasive than Trans-apical?

Trans-apical technical advantages

- 1 More Precise (antegrade, direct feedback)
- 2 Short approach to target = Fast
- 3 “Zero” stored tension or slack in delivery system
- 4 No limitation in sheath diameter (new devices)
- 5 Avoidance of the Aortic Arch
- 6 Standard technique = easy and safe
- 7 Low use of contrast and less exposition radiations time
- 8 Complication rate < 1% (especially peripheral vascular events)
- 9 Potential platform for multiple valve procedures

FRANCE 2

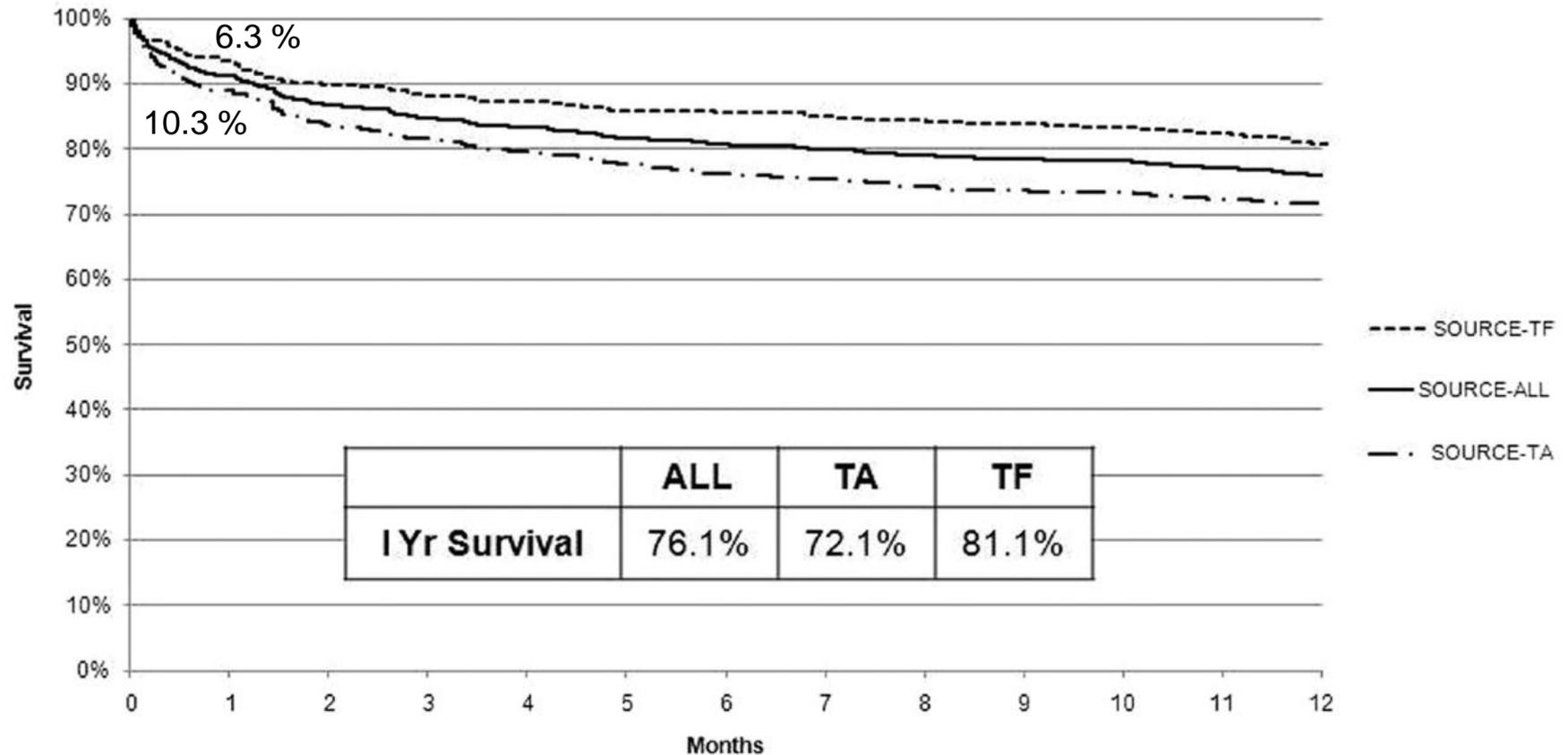
KM Mortality rate

	Mortality			
	TF Edwards n=1139	TF CoreValve n=639	TA Edwards n=465	SC CoreValve n=127
30-day	7.8%	10.3%	11.5%	11%
6-month	13.4%	14.4%	19.4%	18.7%
LogES*	25.6 ± 11.3	24.7 ± 11.2	26.8 ± 11.6	24.6 ± 14.5

* Eltchaninoff et al. FRANCE Registry (244 pts). European Heart J 2010

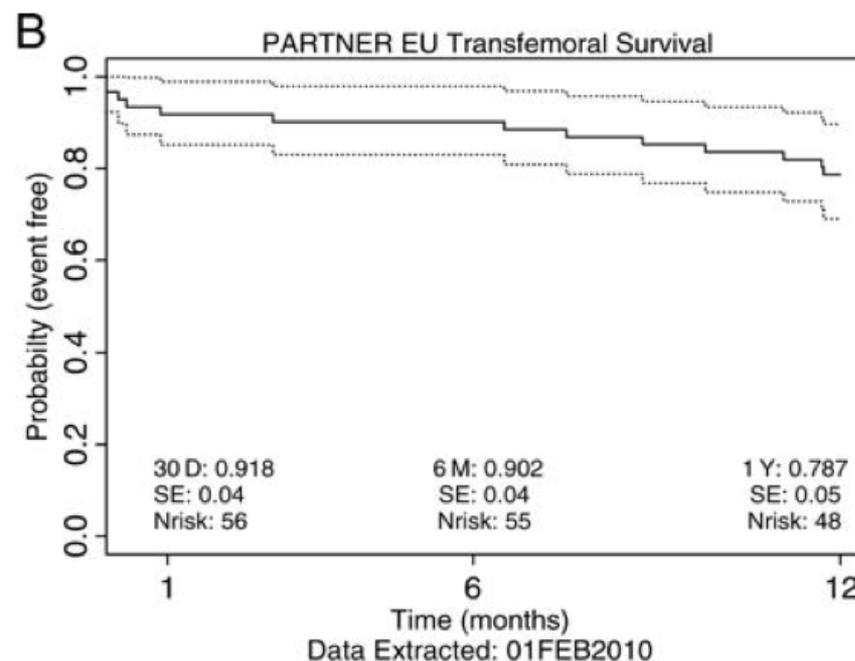
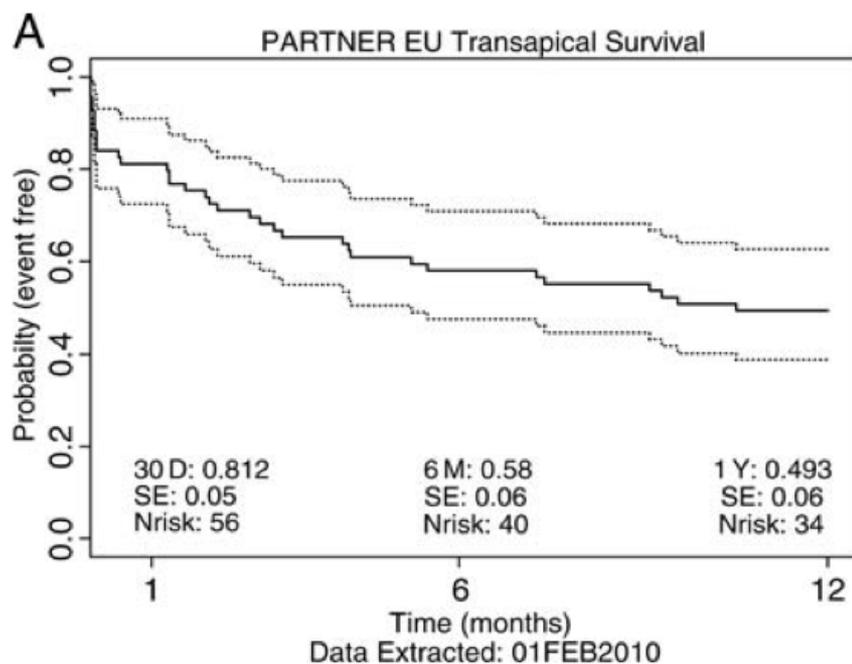
One-Year Outcomes of Cohort 1 in the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry

	TF (n=463)	TA (n=575)	<i>P</i>
Logistic EuroSCORE, mean (SD), %	25.8 (14.4)	29.1 (16.2)	0.0007



One year follow-up of the multi-centre European PARTNER transcatheter heart valve study

Characteristics	Overall (n = 130)	Transapical (n = 69)	Transfemoral (n = 61)	P-value
Logistic EuroSCORE (%)	30.0 ± 13.7 (5.1–72.1)	33.8 ± 14.4 (5.1–72.1)	25.7 ± 11.5 (6.4–65.5)	0.0005



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

JUNE 9, 2011

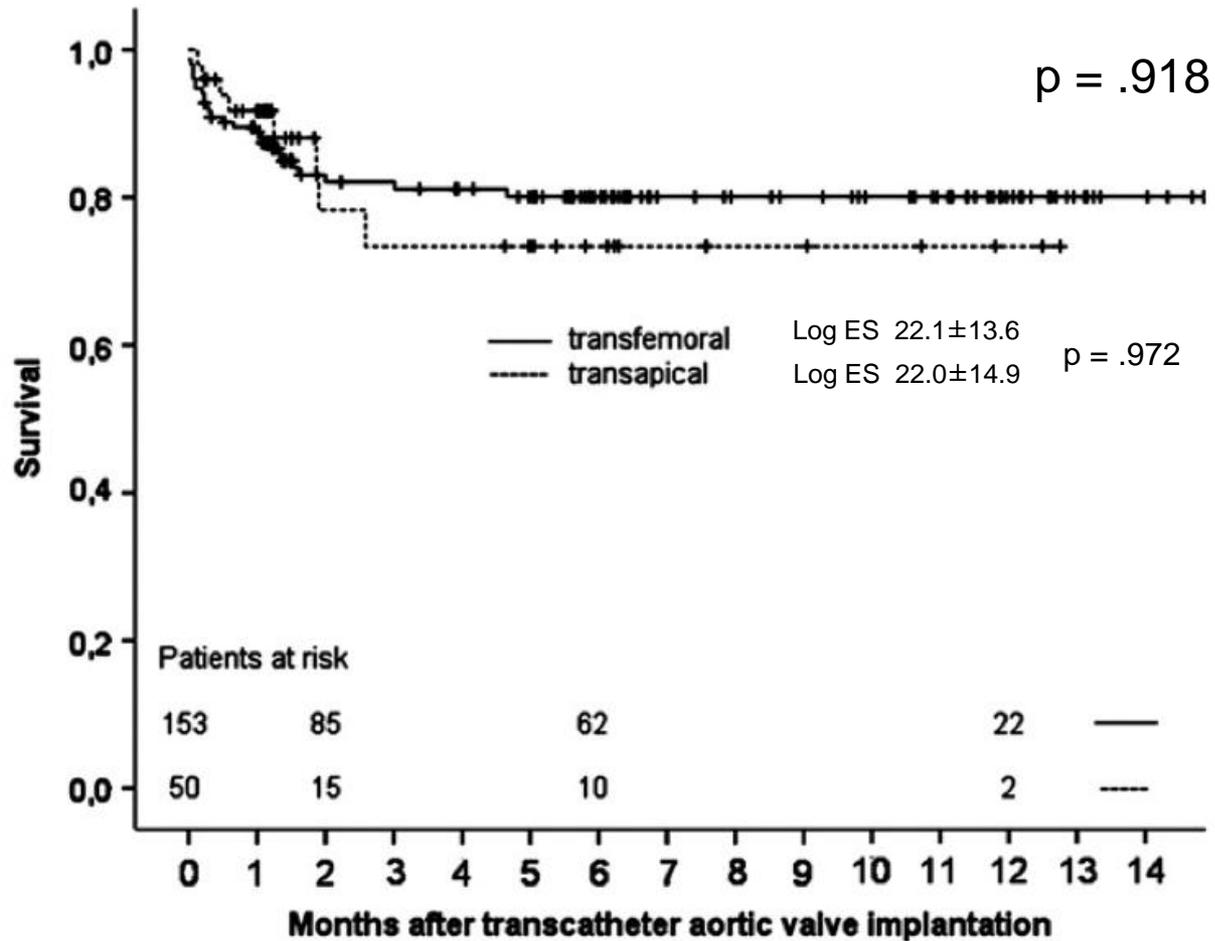
VOL. 364 NO. 23

Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

Characteristic	TF		p-value	TA		p-value
	(N = 492)			(N = 207)		
Logistic EuroSCORE	29.1 ± 16.1			29.8 ± 15.9		0.61
Outcome	30 Days			1 Year		
	TF Test (N = 244) <i>no. of patients (%)</i>	TA Test (N = 104) <i>no. of patients (%)</i>	p-value	TF Test (N = 244) <i>no. of patients (%)</i>	TA Test (N = 104) <i>no. of patients (%)</i>	p-value
All cause mortality	8 (3.3)	4 (3.8)	0.8	54 (22.2)	30 (29.0)	0.2

Survival after transapical and transfemoral aortic valve implantation: Talking about two different patient populations

Sabine Bleiziffer, MD, Hendrik Ruge, MD, Domenico Mazzitelli, MD, Andrea Hutter, MD, Anke Opitz, MD, Robert Bauernschmitt, MD, PhD, and Rüdiger Lange, MD, PhD

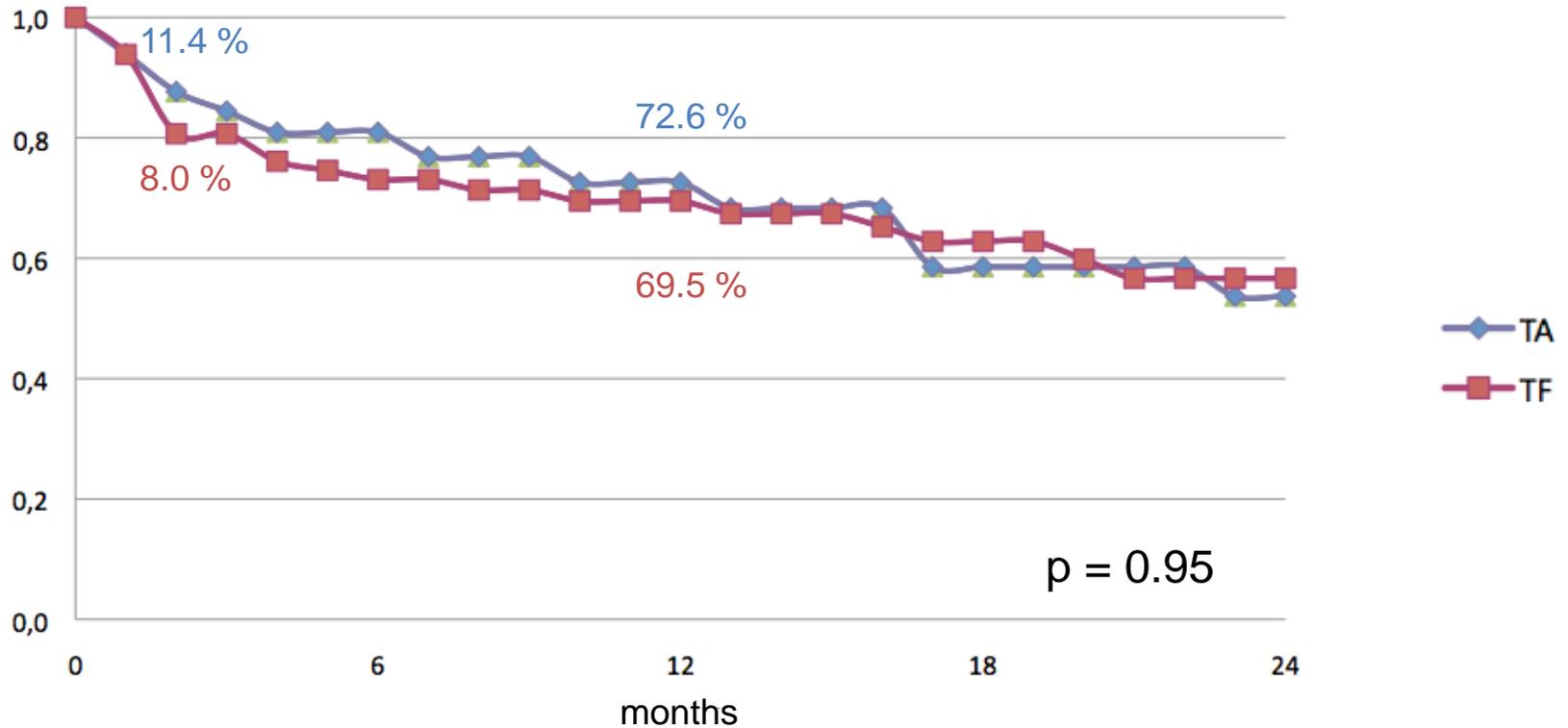


Torino Experience (110 patients)

TA LogES 24.7 ± 12.1 %

TF LogES 20.2 ± 12.0 %

$p = 0.07$



Number

35

18

11

at risk

75

34

17

1. How can we improve outcomes ?

Transapical aortic valve implantation: analysis of risk factors and learning experience in 299 patients

Kempfert J, Rastan A, Holzhey D, Linke A, Schuler G, van Linden A, Blumenstein J, Mohr FW, Walther T

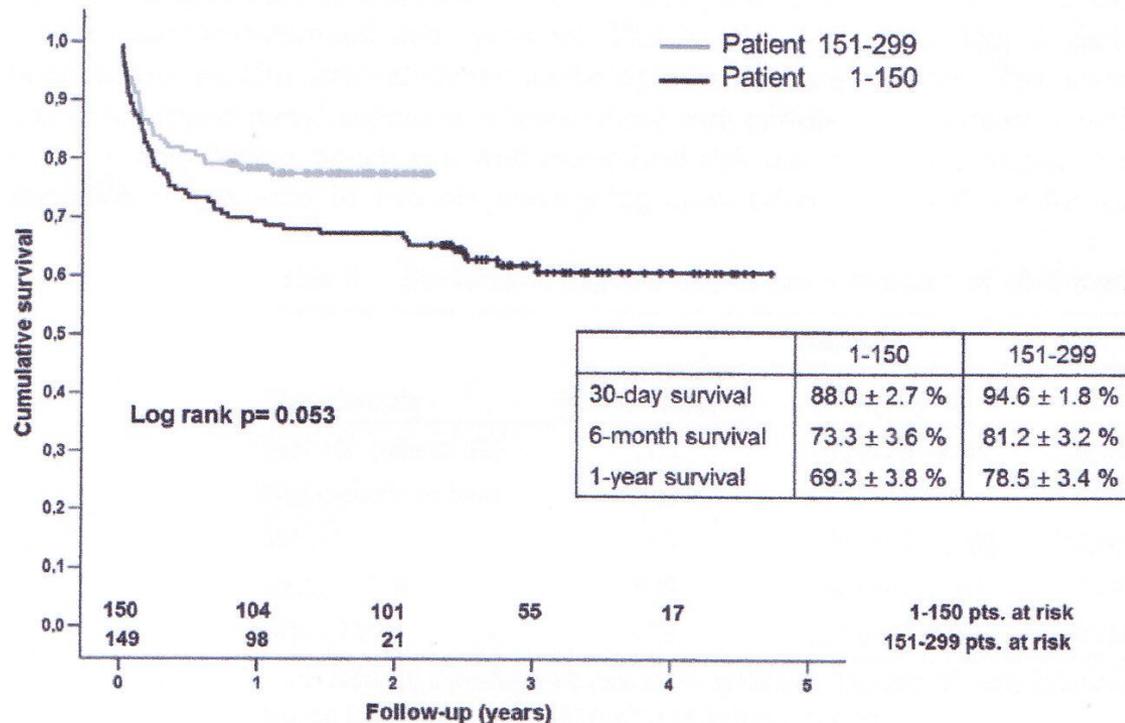


Figure. Comparative survival: early experience patients (pts) 1 to 150 (black line) vs recent experience patients 151 to 299 (gray line).

Clinical and hemodynamic outcomes of “all-comers” undergoing transapical aortic valve implantation: Results from the Italian Registry of Trans-Apical Aortic Valve Implantation (I-TA)

Augusto D’Onofrio, MD,^a Paolo Rubino, MD,^b Melissa Fusari, MD,^c Loris Salvador, MD,^d
 Francesco Musumeci, MD,^e Mauro Rinaldi, MD,^f Ettore O. Vitali, MD,^g Mattia Glauber, MD,^h
 Roberto Di Bartolomeo, MD,ⁱ Ottavio R. Alfieri, MD,^j Elvio Polesel, MD,^k Marco Aiello, MD,^l
 Riccardo Casabona, MD,^m Ugolino Livi, MD,ⁿ Claudio Grossi, MD,^o Mauro Cassese, MD,^p
 Aniello Pappalardo, MD,^q Tiziano Gherli, MD,^r Guglielmo Stefanelli, MD,^s Giuseppe G. Faggian, MD,^t and
 Gino Gerosa, MD^a

Institution	Components of the TAVI team	Start of enrollment	Patients
Clinica Montevergine, Mercogliano	P. Rubino, L. Cota, G. Sorropago, G. Sarno, C. Moscardello, D. Catapano, V. Lucchetti, R. Mancusi, M. Agrusta	April 2008	88
Centro Cardiologico Monzino, Milan	P. Biglioli, M. Fusari, M. Agrifoglio, E. Sisillo, L. Salvi, S. Galli, G. Teruzzi	May 2008	81
San Bortolo Hospital, Vicenza	L. Salvador, P. Magagna, A. Fabbri, N. Abbiate, L. La Vecchia	October 2008	43
San Camillo Hospital, Rome	F. Musumeci, G. Luzi, R. Violini, R. Fiorilli, P. Picozzi	June 2009	39
University of Padova	G. Gerosa, R. Bianco, A. D’Onofrio, G. Isabella, G. Tarantini, M. Napolitano, C. Fracaro, V. Gaspareto, D. Pittareto	March 2009	38
University of Turin	M. Rinaldi, M. La Torre, S. Salizzoni, I. Sheiban, M. D’Amico, C. Moretti, P. Omedè, F. Conrotto, M. Lupo	February 2009	24
Humanitas Gavazzeni Hospital, Bergamo and Rozzano	E. Vitali, P. Tartara, N. Valerio, P. Sganzerla, E. Tavasci, D. Guzzon	July 2008	22
G. Pasquinucci Heart Hospital, Massa	M. Glauber, A. Cerillo, F. Chiaromonti, S. Berti, M. Mariani, P. Del Sarto	October 2008	21
University of Bologna	R. Di Bartolomeo, C. Savini, F. D. Petridis, E. Pilato, J. Pavicevic	November 2008	20
S. Raffaele Hospital, Milan	O. Alfieri, F. Maisano, M. Cioni, P. Denti, A. Zangrillo, D. Covello, A. Colombo, M. Montorfano	July 2008	18
Ospedale dell’Angelo, Venice-Mestre	E. Polesel, C. Zanchettin, A. Terrini, G. Grassi, M. Barbierato, D. Penzo	March 2009	17
University of Pavia	M. Viganò, M. Aiello, N. Vistarini, E. Bramucci, M. Ferrario, R. Veronesi, M. Maurelli	March 2009	16
Ospedale Mauriziano Umberto I, Turin	R. Casabona, S. Del Ponte, G. Punta, M. Debenedictis, I. Scrocca, C. Verdecchia, N. Lojacono	September 2009	15
S. Maria della Misericordia Hospital, Udine	U. Livi, E. Mazzaro, E. Pompei, G. Bernardi, F. Poldini	April 2009	14
S. Croce e Carle Hospital, Cuneo	C. Grossi, O. Di Gregorio, G. Steffenino, G. Baralis, A. Locatelli	June 2009	13
Clinica S. Anna, Catanzaro	M. Cassese, A. Antonazzo, G.L. Martinelli, B. Missiroli, R.M. Montesanti, A. Cuccio, P. De Fiore	February 2010	10
Ospedali Riuniti, Trieste	A. Pappalardo, E. Rauber, B. Benussi, A. Salvi, A. Percan, G. Sagrati, P. Zanei	July 2009	8
University of Parma	T. Gherli, F. Nicolini, D. Ardissino, L. Vignali, C. Grattagliano, A. Vezzani	February 2009	6
Hesperia Hospital, Modena	G. Stefanelli, D. Gabbieri, I. Ghidoni, G. Dannibale, A. Benassi, M. Mei, G. Giordano	February 2010	6
University of Verona	G. Faggian, F. Santini, F. Ribichini, G. Molinari, M. Dan	March 2010	5

University of Turin

M. Rinaldi, M. La Torre, S. Salizzoni, I. Sheiban, M. D’Amico,
C. Moretti, P. Omedè, F. Conrotto, M. Lupo

...TA-AVI in the future

UNIVERSAL ACCESS

PERCUTANEOUS ACCESS

NEW CLOSURE DEVICES



Permaseal™ is a novel transapical access device which combines soft tissue anchors with advanced biocompatible elastomers to provide spontaneous wound closure after structural heart repair procedures such as TAVI



Micro Interventional Devices, Inc.™
Taking Aim at Structural Heart Disease

Conclusions

Trans-apical AVI is by now a safe and valid alternative to AVR in patients with contraindication to surgery or considered at very high risk

Trans-apical approach seems not inferior to retrograde approaches

Outcomes will certainly improve with experience, better patient selection and new devices

Needs for randomized studies to demonstrate at least the non-inferiority of TA-AVI vs TF-AVI and other retrograde approaches

Maybe in the future it will be difficult to distinguish TA and TF-AVI approaches.....



.....Thanks