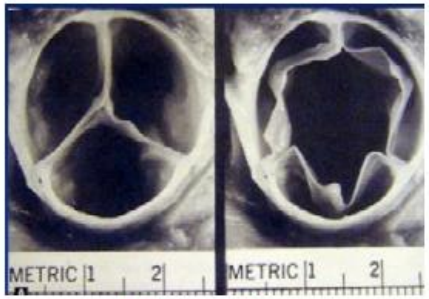
LO STATO DELL'ARTE DELLA TAVI NELLA STENOSI AORTICA

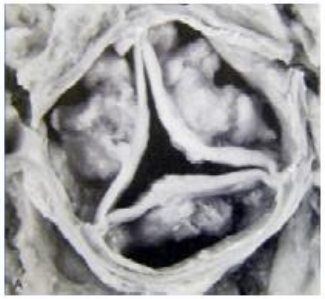
Andrea Ungar, MD, PhD, FESC

Syncope Unit, Hypertension Centre
Geriatric Cardiology and Medicine
University of Florence, Italy

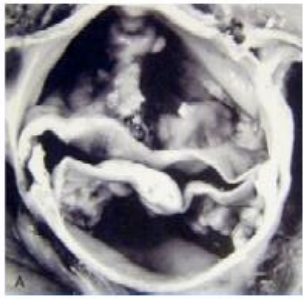
Eziologia



Normale



Degenerativo-calcifica



Bicuspide

Reumatica

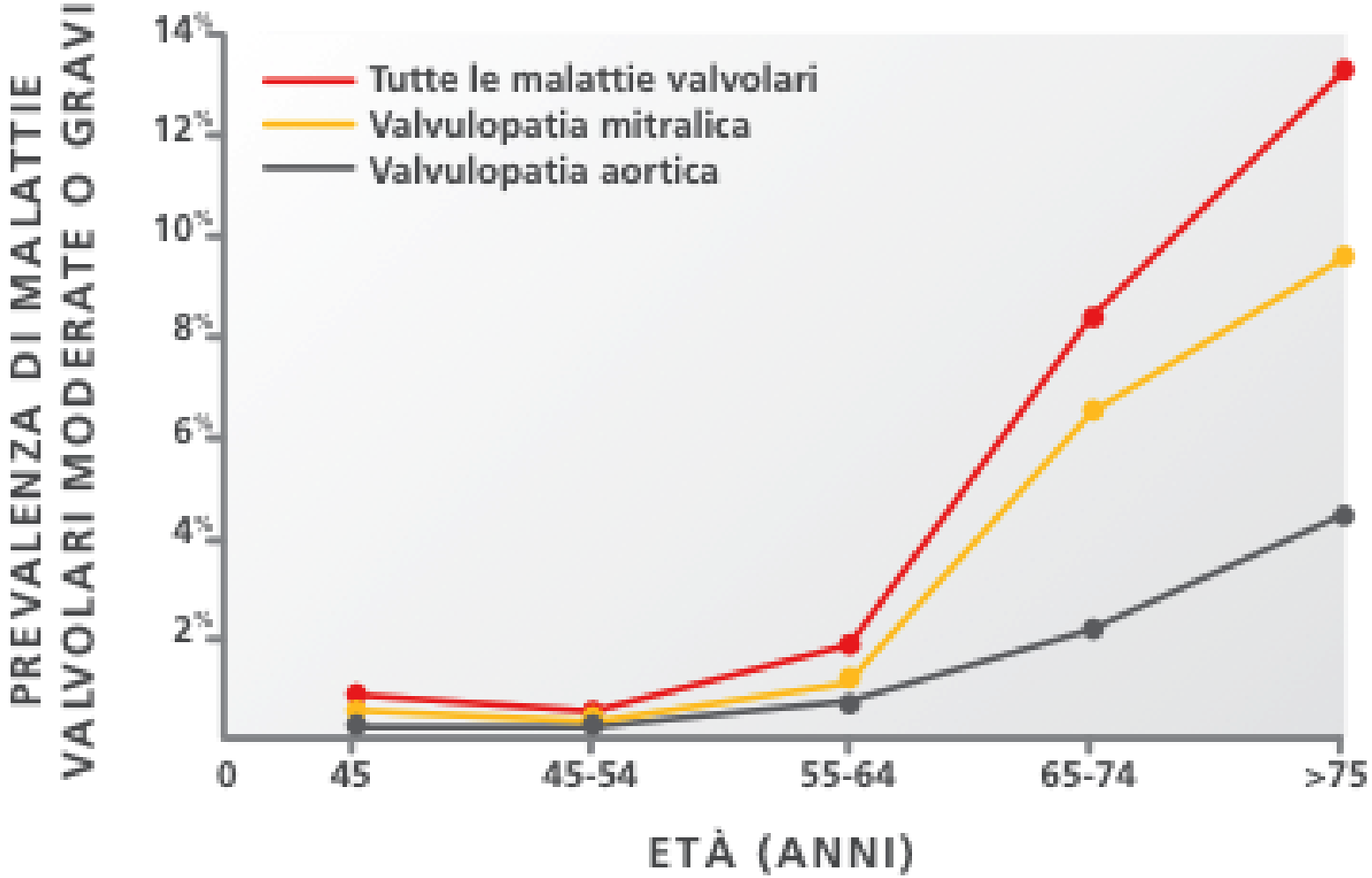
La stenosi aortica degenerativo-calcifica costituisce attualmente la causa più comune di stenosi aortica nell'anziano

DEGENERATIVA: continuum da forme di lieve ispessimento valvolare in assenza di ostruzione al flusso fino a severa calcificazione con impegno emodinamico:
SCLEROSI AORTICA (circa 25 % della popolazione > 65 anni)
STENOSI AORTICA (2-4 % della popolazione > 65 anni)

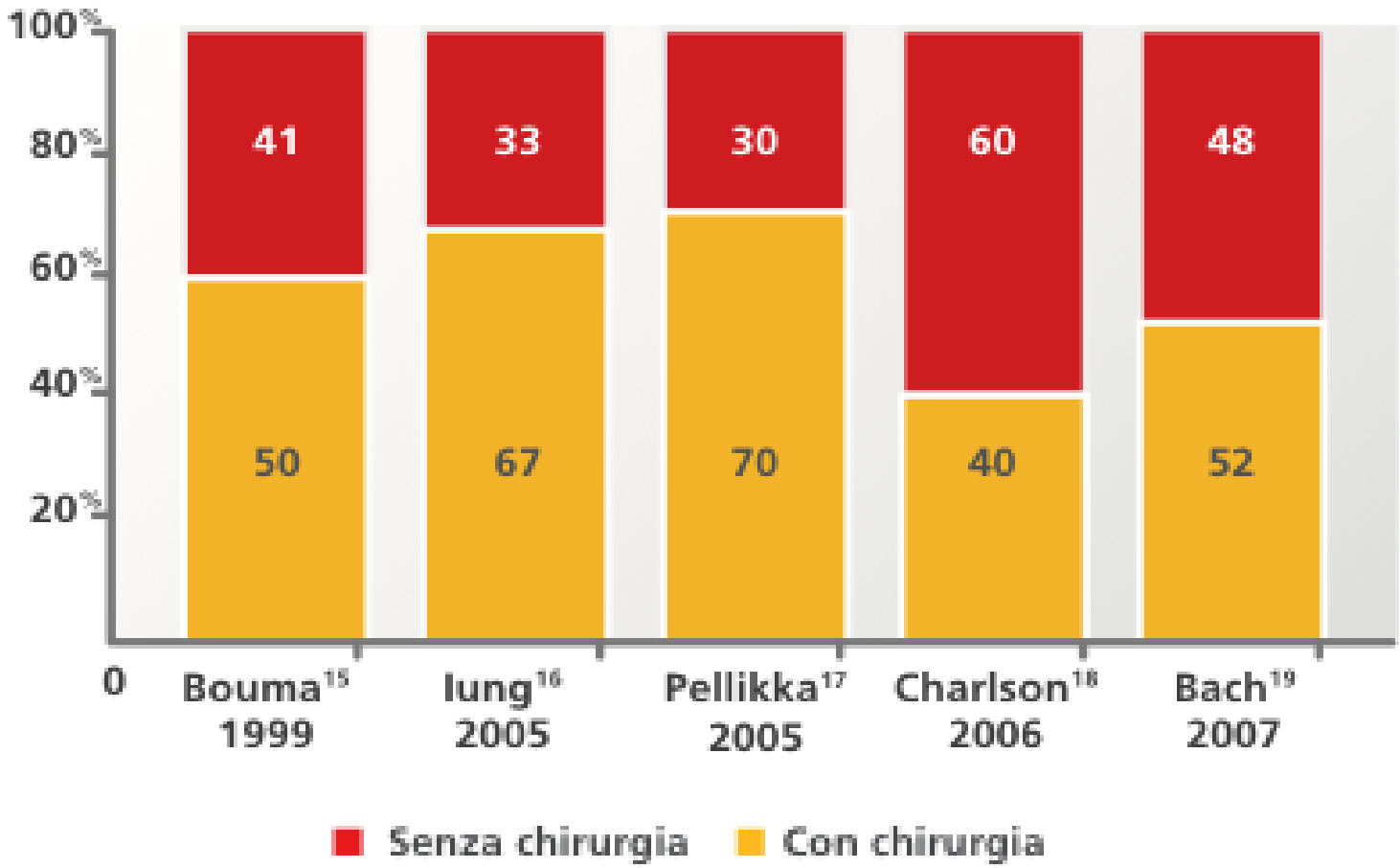
Elementi patogenetici:

- Stress meccanico
- Fenomeni infiammatori con infiltrazione di macrofagi e linfociti T
- Caratteristiche istologiche e biochimiche analoghe all'aterosclerosi simili fattori di rischio

Prevalenza delle malattie valvolari cardiache nei pazienti anziani



Molti pazienti con stenosi aortica non vengono trattati

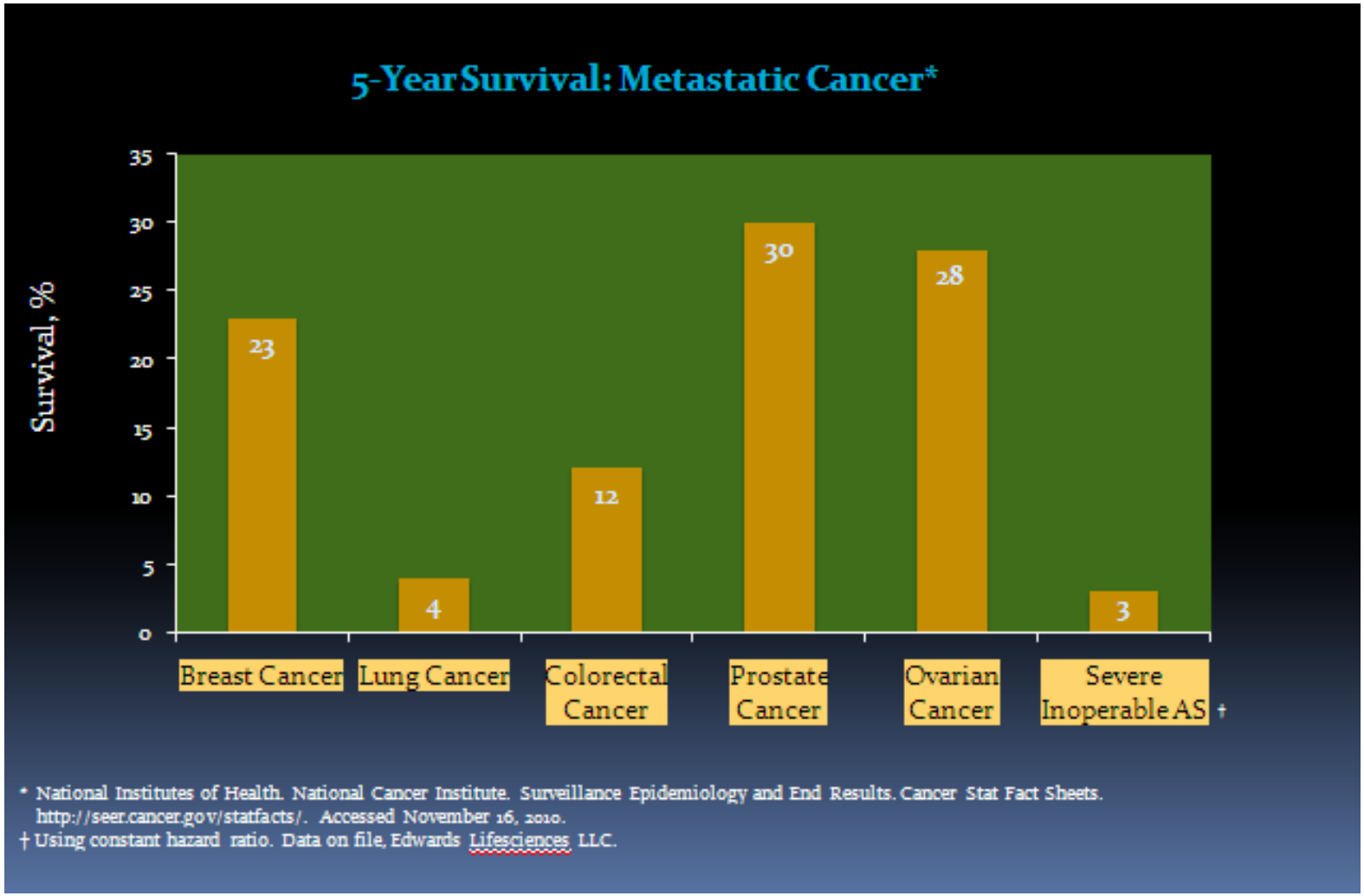


Van Geldorp MW, Eur J Cardiothorac Surg 2009;35:953-7.

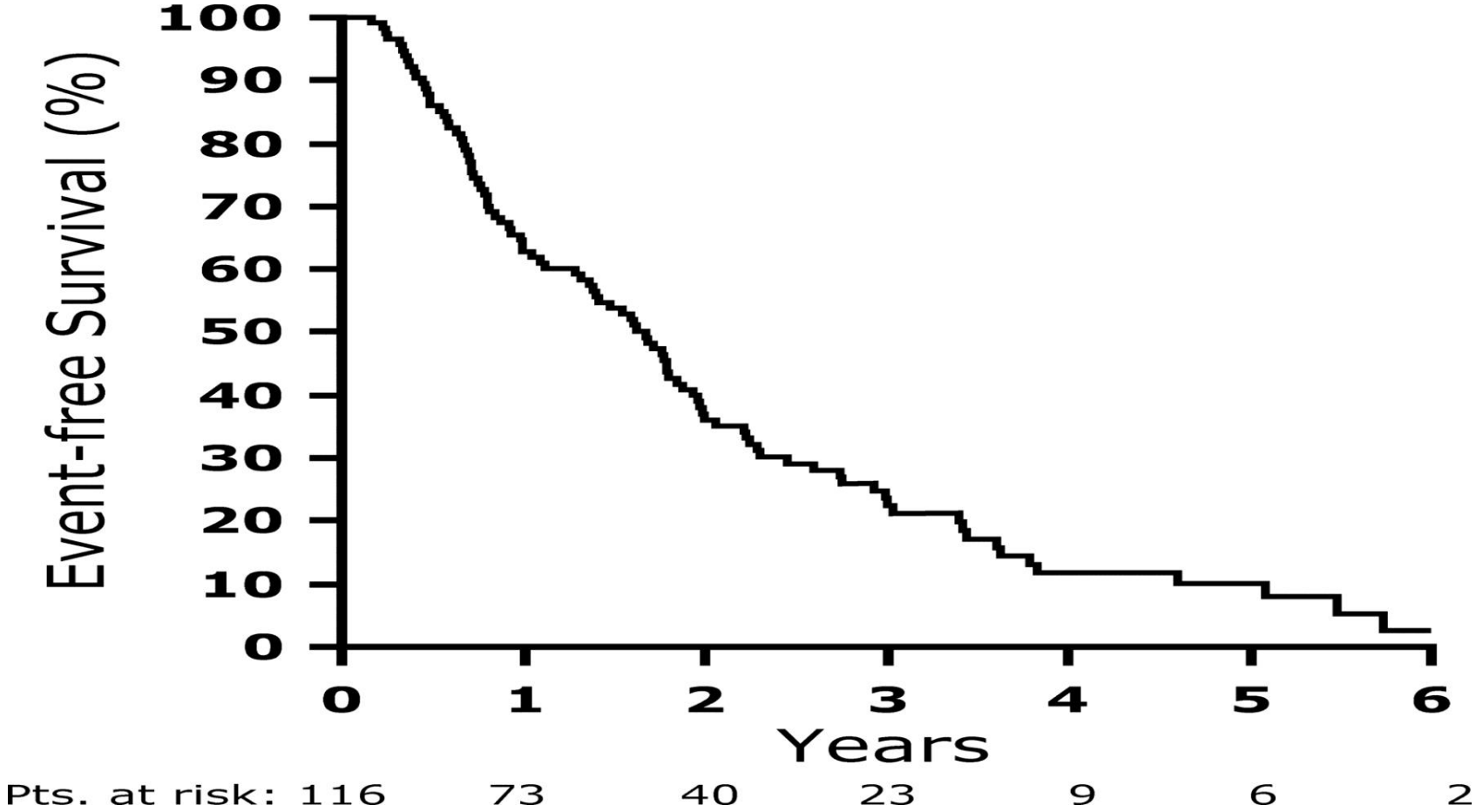
Motivi del mancato trattamento dei pazienti affetti da SA

Van Geldorp MW. Eur J Cardiothorac Surg 2009;35:953-7.

La mortalità con la terapia medica è peggiore di quella di alcuni tumori metastatici



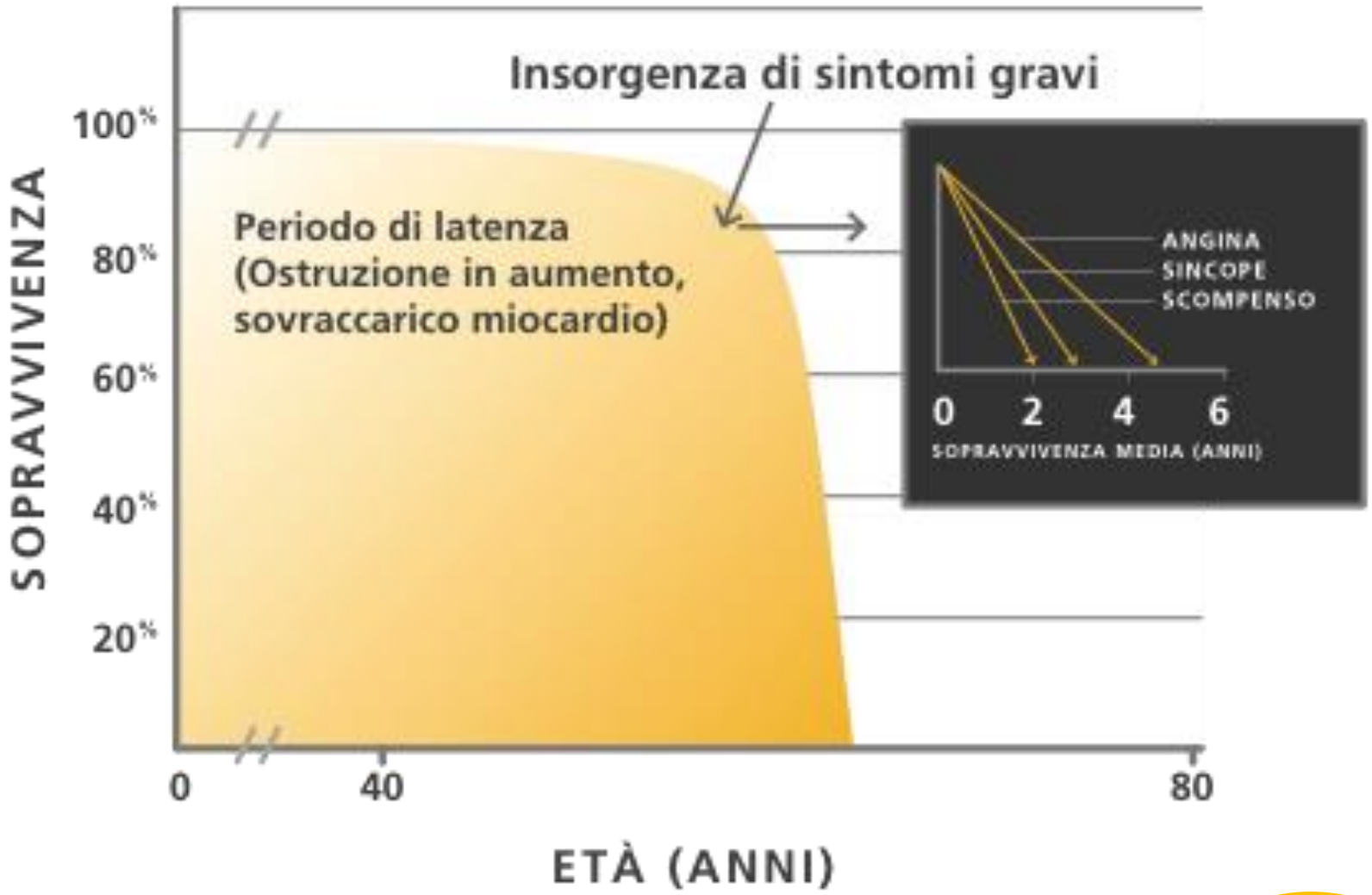
Prognosi nei pazienti con stenosi aortica severa degenerativa



American Heart Association
Learn and Live

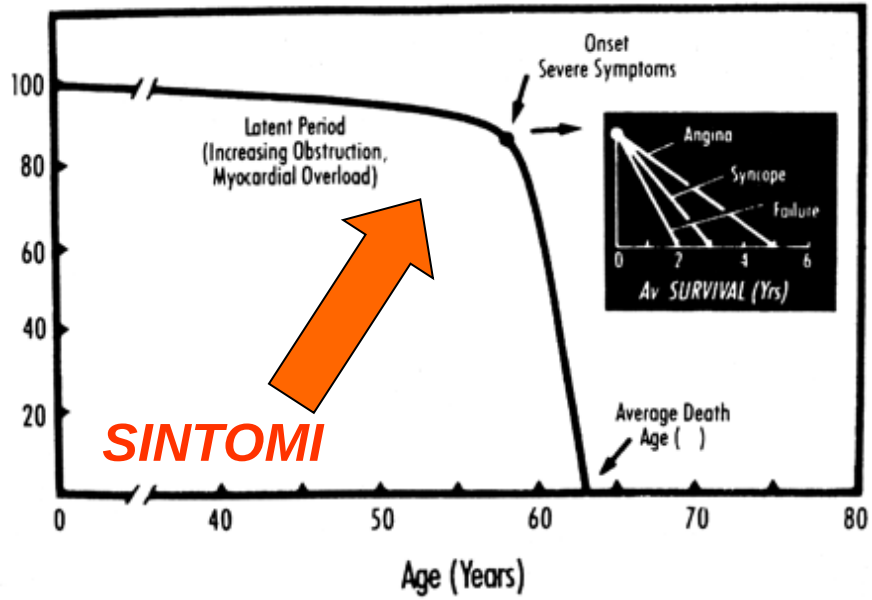
Rosenhek R et al. Circulation 2010;121:151-156

Stenosi aortica, prognosi e sintomi



Otto M, in Ross J Jr, Braunwald E. Aortic Stenosis. Circulation 1968

I Sintomi Dopo 80 Anni Di Età



Difficile definizione

- Comorbilità
- Ridotta collaborazione
- Normale riduzione della tolleranza allo sforzo

Correlati allo stile di vita

- Parte dei pazienti "asintomatici" sviluppano sintomi durante un test ergometrico

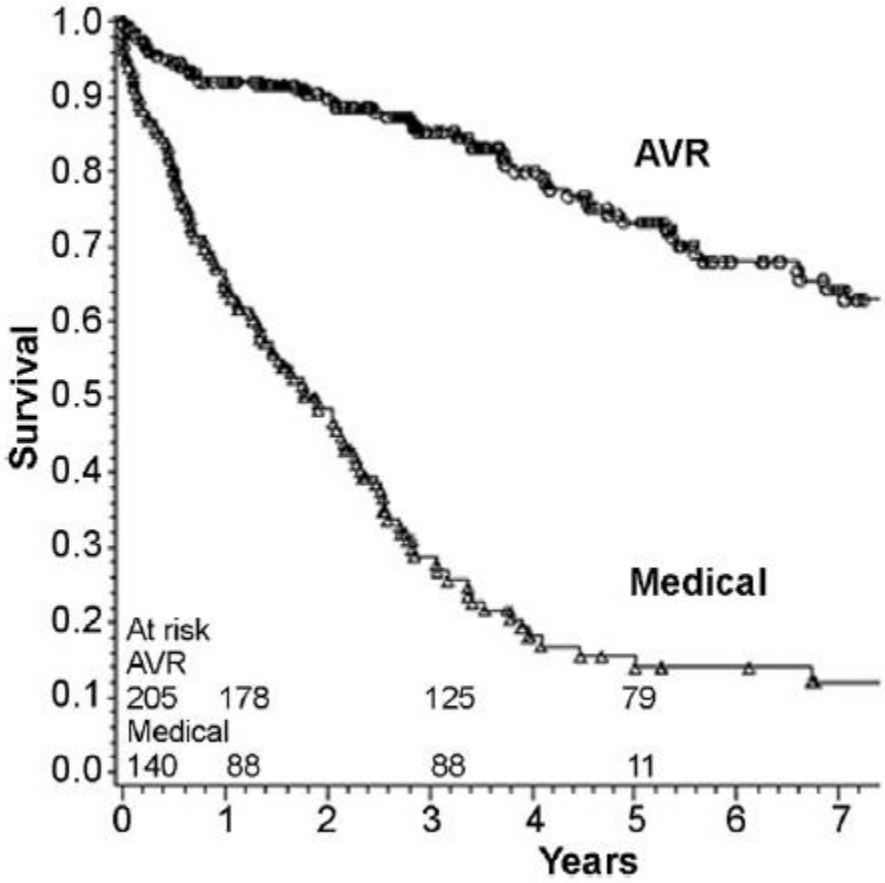
SOCIETÀ ITALIANA
DI GERONTOLOGIA
E GERIATRIA

LO STATO DELL'ARTE DELLA TAVI NELLA STENOSI AORTICA

Il trattamento

Severe Aortic Stenosis in a Veteran Population: Treatment Considerations and Survival

Faisal G. Bakaeen, MD, Danny Chu, MD, Mark Ratcliffe, MD, Raja R. Gopaldas, MD, Alvin S. Blaustein, MD, Raghunandan Venkat, MD, Joseph Huh, MD, Scott A. LeMaire, MD, Joseph S. Coselli, MD, and Blase A. Carabello, MD



(Ann Thorac Surg 2010;89:453–8)

Conventional Aortic Valve Replacement in Transcatheter Aortic Valve Implantation Candidates: A 5-Year Experience

Sreekumar Subramanian, MD, Ardawan J. Rastan, MD, PhD, David Holzhey, MD, Martin Haensig, MD, Joerg Kempfert, MD, Michael A. Borger, MD, PhD, Thomas Walther, MD, PhD, and Friedrich W. Mohr, MD, PhD

Table 1. Patient Demographics

Characteristic	Mean ± SD or No. (%) (N = 79)
Age, year	80.4 ± 3.6
Female sex	
Ejection fraction	
Resternotomy	
Diabetes mellitu	
Hypertension	
Pulmonary hype	
Smoker	
Hyperlipidemia	
COPD	
Pre-op creatinin	
Logistic EuroSCORE, %	13 ± 7
STS PROM score	4.2 ± 2.6

COPD = chronic obstructive pulmonary disease; EuroSCORE = European System for Cardiac Operative Risk Evaluation; SD = standard deviation; STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

Table 2. Hospital Outcomes

		95% CI
		–0.25 to 3.79
		−1.01 to 6.07
		0.12–10.01
		−1.25 to 3.79
		4.23–18.55
		−1.01 to 6.07
Pacemaker implantation	2 (2.5)	−1.01 to 6.07
Hospital discharge, days[a]	16.5 ± 10.0	14.29–18.80

Conclusions. Our existing patient evaluation process accurately defines an acceptable risk cohort for conventional AVR. The late mortality rate reflects the advanced age and comorbidities of this cohort. The data suggest that overzealous widening of TAVI inclusion criteria may be inappropriate.

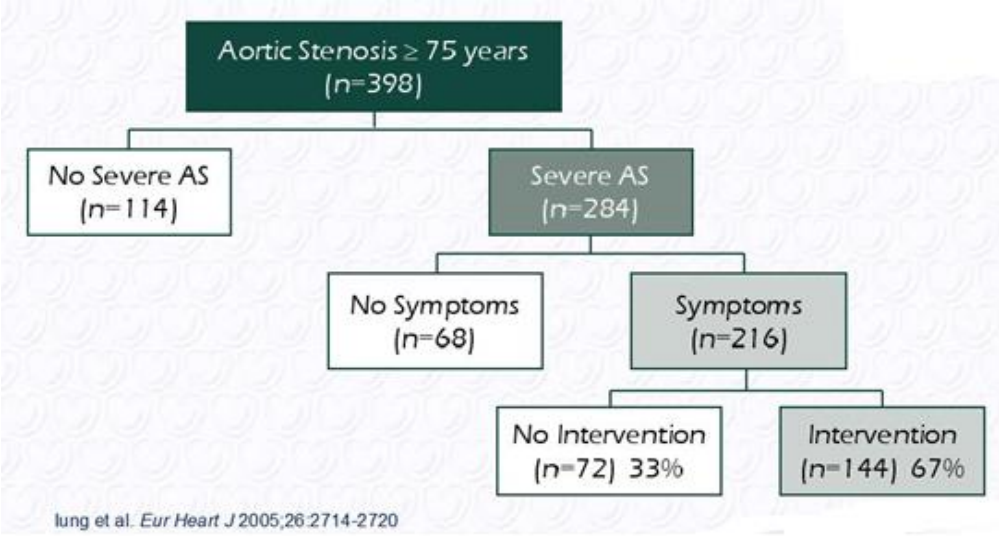
(Ann Thorac Surg 2012;94:726–30)

COME NASCE LA TAVI

- La AVR è il trattamento convenzionale di scelta per la stenosi aortica
- Elevata mortalità (7-10%) in pazienti ad alto rischio

- 30-40% dei pz anziani non vengono operati

•Pz non indirizzato alla CCH
•Pz non accettato dal CCH
•Rifiuto del pz



- Controindicazioni alla CCH

La TAVI risponde a una necessità clinica
Indicazioni per la TAVI – nuove linee guida ESC/EACTS

Guidelines on the management of valvular heart disease (version 2012)

Recommendations	Class [a]	Level [b]	Ref [c]
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C	
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B	99
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.	IIa	B	97

Partner Trial Cohort B

Partner Trial Cohort A

European Heart Journal
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian (Chairperson) (France)*, Ottavio Alfieri (Chairperson)* (Italy), Felicita Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Iung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)

ESC Committee for Practice Guidelines (CPG): Jeroen J. Bax (Chairperson) (The Netherlands), Helmut Baumgartner (Germany), Claudio Ceconi (Italy), Veronica Dean (France), Christi Deaton (UK), Robert Fagard (Belgium), Christian Funck-Brentano (France), David Hasdai (Israel), Arno Hoes (The Netherlands), Paulus Kirchhof (United Kingdom), Juhani Knuuti (Finland), Philippe Kolh (Belgium), Theresa McDonagh (UK), Cyril Moulin (France), Bogdan A. Popescu (Romania), Żeljko Reiner (Croatia), Udo Sechtem (Germany), Per Anton Sirnes (Norway), Michal Tendera (Poland), Adam Torbicki (Poland), Alec Vahanian (France), Stephan Windecker (Switzerland)

Document Reviewers:: Bogdan A. Popescu (ESC CPG Review Coordinator) (Romania), Ludwig Von Segesser (EACTS Review Coordinator) (Switzerland), Luigi P. Badano (Italy), Matjaž Bunc (Slovenia), Marc J. Claeys (Belgium), Nikša Drinkovic (Croatia), Gerasimos Filippatos (Greece), Gilbert Habib (France), A. Pieter Kappetein (The Netherlands), Roland Kassab (Lebanon), Gregory Y.H. Lip (UK), Neil Moat (UK), Georg Nickenig (Germany), Catherine M. Otto (USA), John Pepper, (UK), Nicolo Piazza (Germany), Petronella G. Pieper (The Netherlands), Raphael Rosenhek (Austria), Naltin Shuka (Albania), Ehud Schwammenthal (Israel), Juerg Schwitter (Switzerland), Pilar Tornos Mas (Spain), Pedro T. Trindade (Switzerland), Thomas Walther (Germany)

The disclosure forms of the authors and reviewers are available on the ESC website www.escardio.org/guidelines

* Corresponding authors: Alec Vahanian, Service de Cardiologie, Hopital Bichat AP-HP, 46 rue Henri-Huchard, 75018 Paris, France. Tel: +33 1 40 25 67 60; Fax: +33 1 40 25 67 32. Email: alec.vahanian@bch.aphp.fr

Ottavio Alfieri, S. Raffaele University Hospital, 20132 Milan, Italy. Tel: +39 02 26437109; Fax: +39 02 26437125. Email: ottavio.alfieri@hsr.it

[1]Other ESC entities having participated in the development of this document:
Associations: European Association of Echocardiography (EAE), European Association of Percutaneous Cardiovascular Interventions (EAPCI), Heart Failure Association (HFA)
Working Groups: Acute Cardiac Care, Cardiovascular Surgery, Valvular Heart Disease, Thrombosis, Grown-up Congenital Heart Disease
Councils: Cardiology Practice, Cardiovascular Imaging

Disclaimer. The ESC/EACTS Guidelines represent the views of the ESC and the EACTS and were arrived at after careful consideration of the available evidence at the time they were written. Health professionals are encouraged to take them fully into account when exercising their clinical judgement. The guidelines do not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patients, in consultation with that patient and, where appropriate and necessary, the patient's guardian or carer. It is also the health professional's responsibility to verify the rules and regulations applicable to drugs and devices at the time of prescription.

SOURCE: Eur Heart J 2012; doi:10.1093/eurheartj/ehs109 & Eur J Cardiothorac Surg 2012; doi;10.1093/EJCTS/EZS455

Edwards

TAVI

- La TAVI (trancatheter aortic valve implantation) è una tecnica innovativa per il trattamento della **stenosi aortica** in pazienti

AD ALTO RISCHIO CHIRURGICO

INOPERABILI

- La TAVI ha mostrato di incidere positivamente sulla storia naturale della stenosi aortica, abbattendo la mortalità e gli eventi cardiovascolari maggiori

TAVI First Implantation, Rouen, France

Alain Cribier

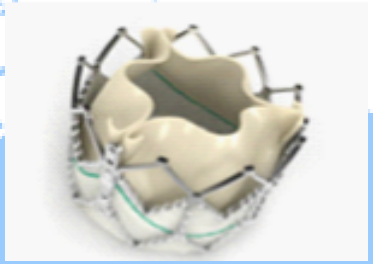
16 aprile 2002

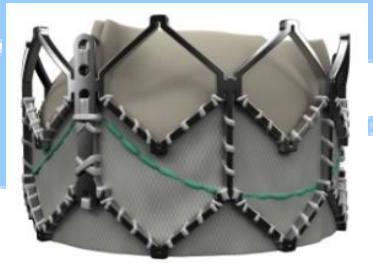
8 giorni dopo l'impianto

CoreValve Revalving® System (CRS)

Edwards-SAPIEN™ Aortic Bioprosthesis

CE 0050



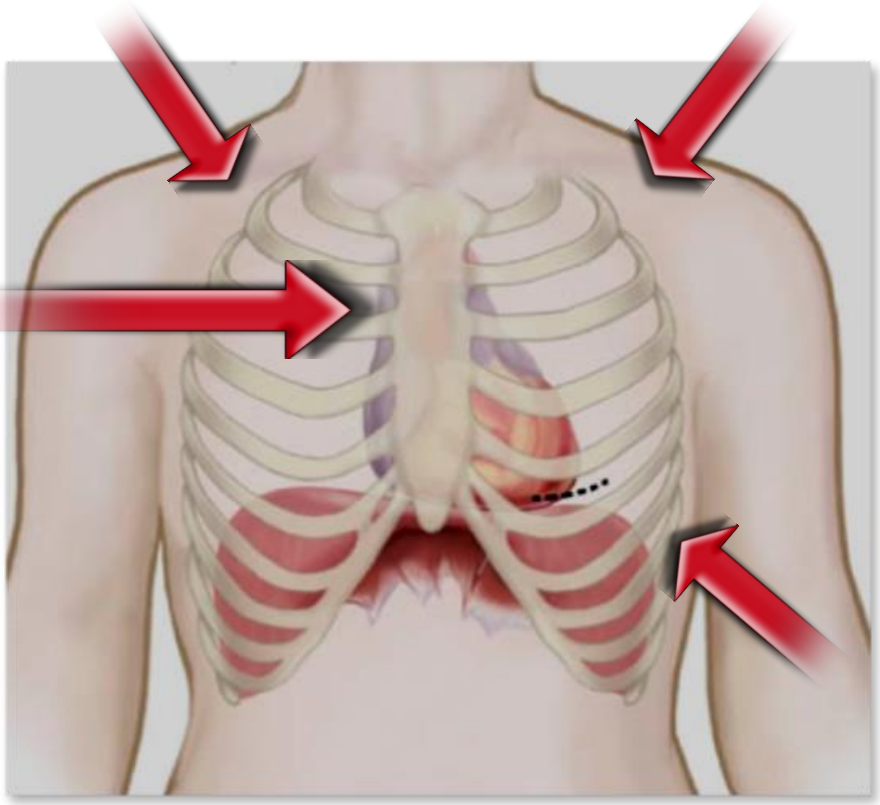


>20,000 patients

>20,000 patients

Over 40.000 implants in 40 countries

TIPI DI ACCESSO



Trans-succlavio destro

Trans-succlavio sinistro

Trans-aortico

Trans-apicale

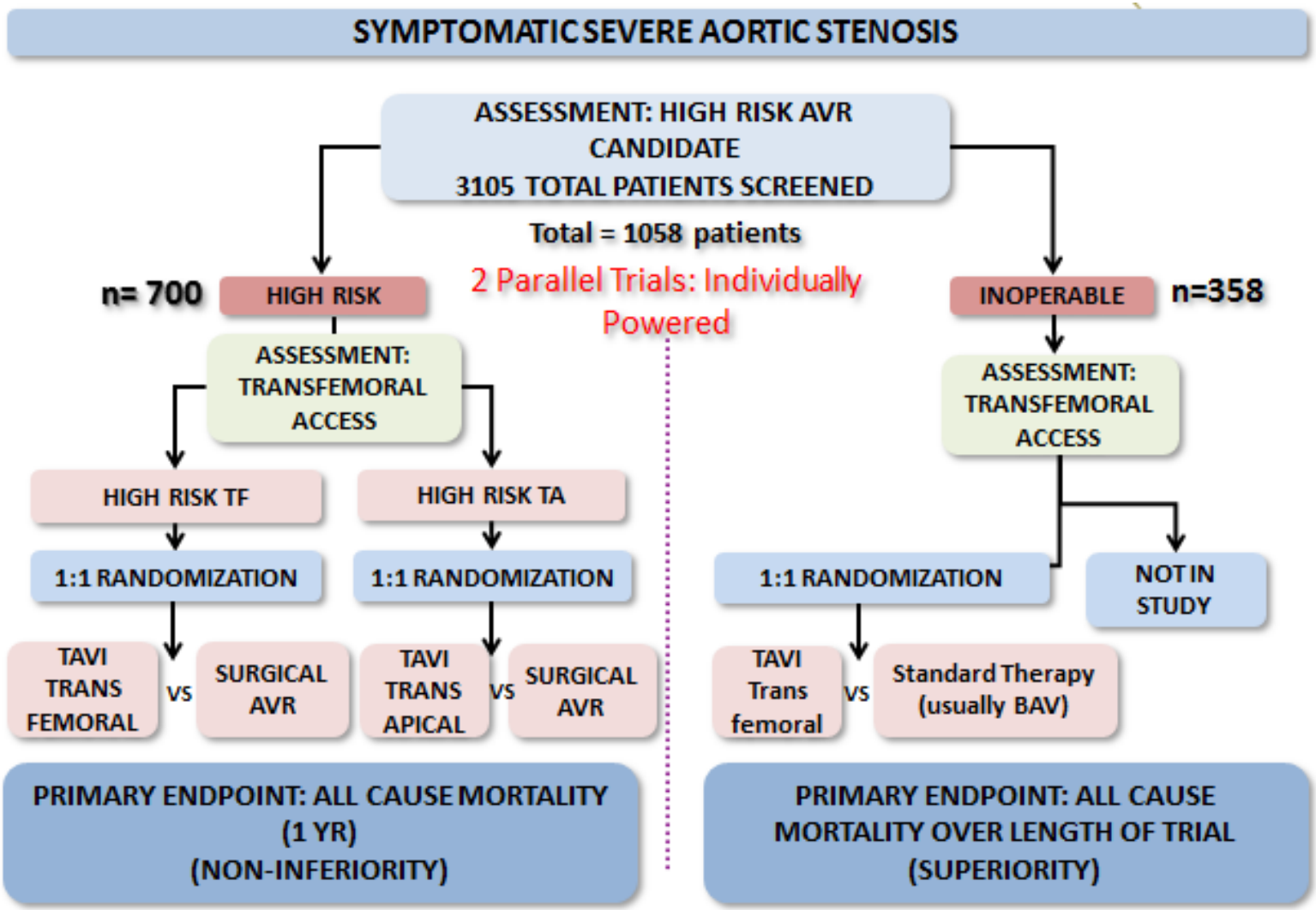
Trans-femorale destro

Trans-femorale sinistro

Valvuloplastica

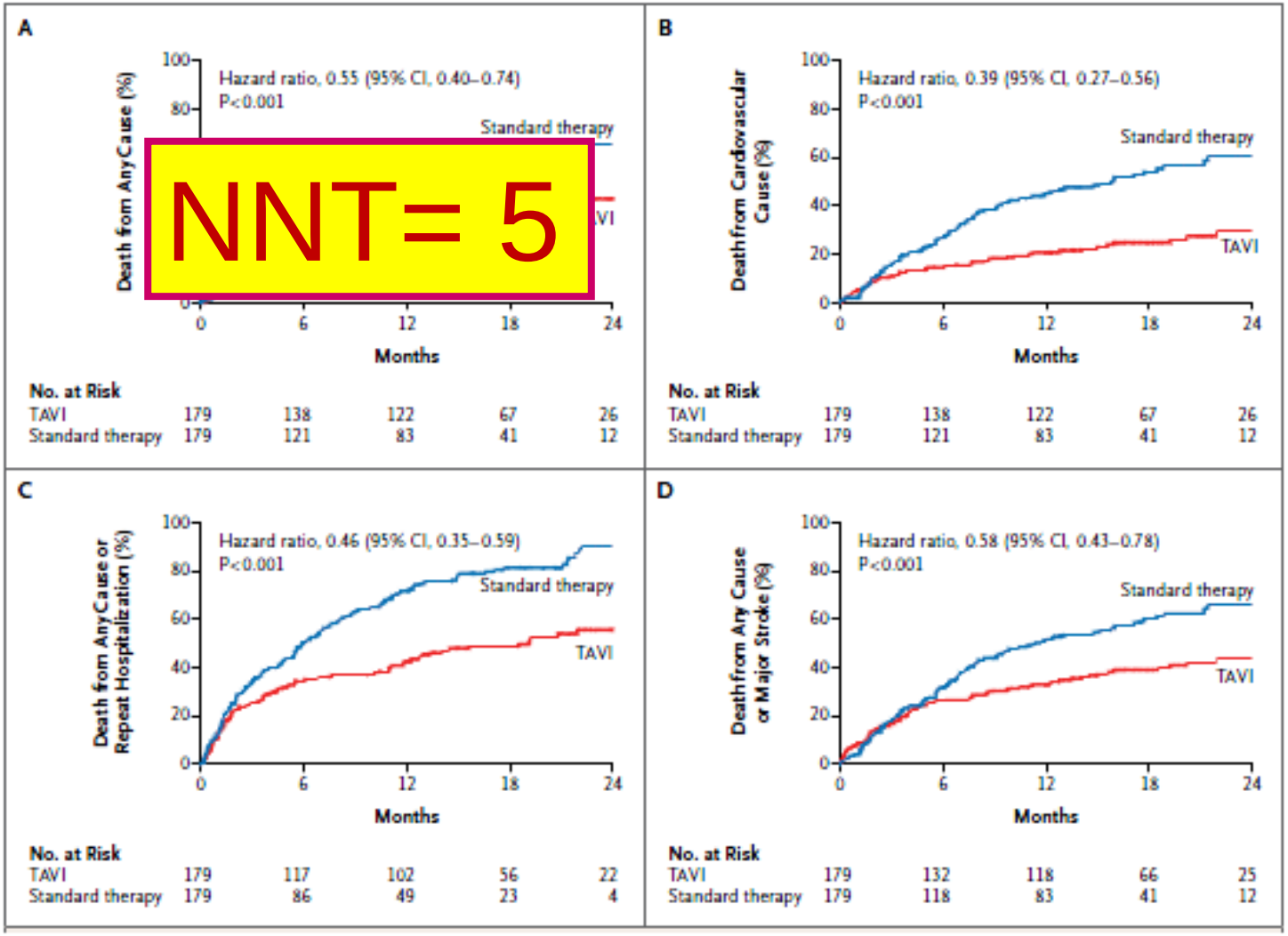
Impianto – Edwards Sapien 3

Lo studio PARTNER



Lo studio PARTNER: Cohort B

The NEW ENGLAND JOURNAL of MEDICINE



NNT= 5

n for Aortic Stenosis
rgo Surgery

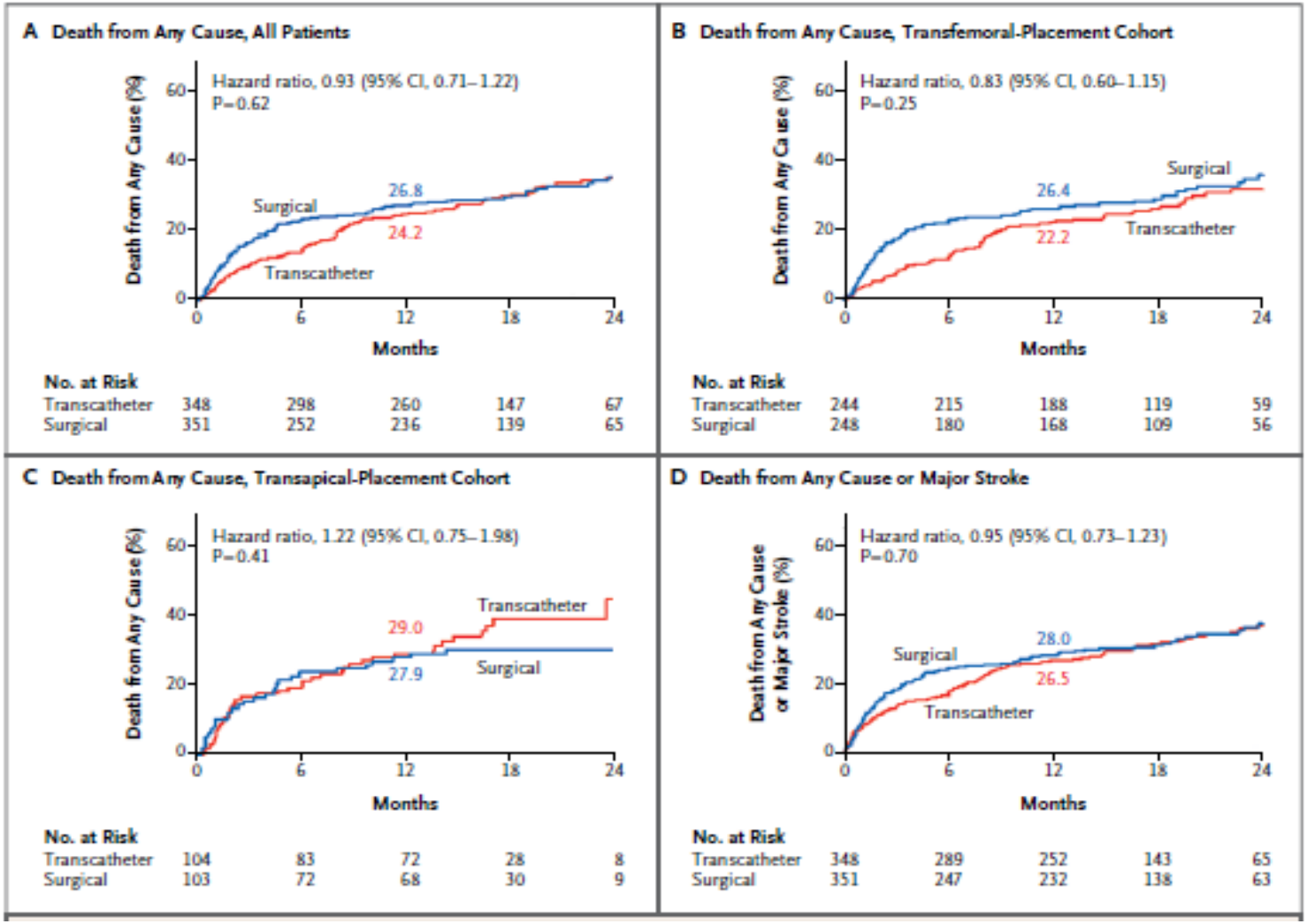
g Miller, M.D., Jeffrey W. Moses, M.D.,
, M.D., Gregory P. Fontana, M.D.,
D., Robert A. Guyton, M.D.,
nn, M.D., Pamela C. Douglas, M.D.,
, Ph.D., Duolao Wang, Ph.D.,
Investigators*

Lo studio PARTNER: Cohort A

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 JUNE 9, 2011 VOL. 364 NO. 23

eplacement

), Jeffrey W. Moses, M.D.,
ry P. Fontana, M.D.,
, Vasilis Babaliaros, M.D.,
E. Bavaria, M.D.,
olao Wang, Ph.D.,
s*



Lo studio PARTNER: Cohort A

TAVI non inferiore a AVR

TAVI

- Stroke o TIA

(5,5 vs. 2.4%, p=0.04)

- complicanze vascolari maggiori

(11.0% vs. 3.2%, p<0.001)

AVR

- sanguinamenti maggiori

(9.3% vs. 19.5%, p<0.001)

- FA

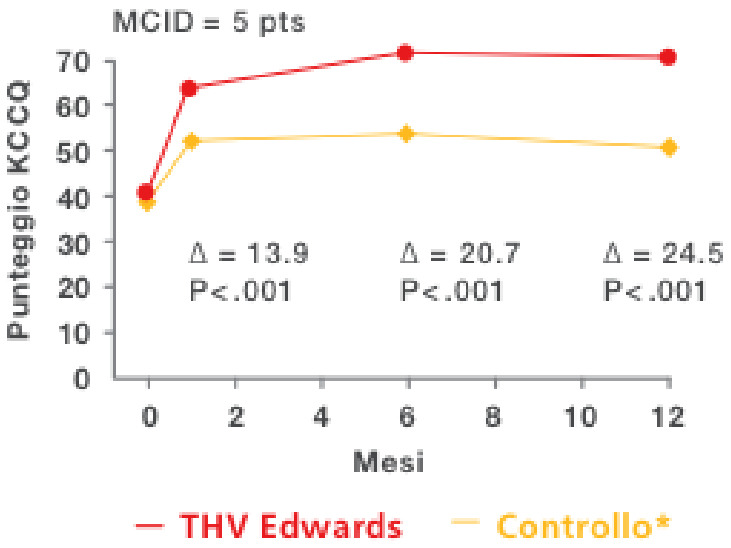
(8.6% vs. 16.0%, p<0.001)

Reperti eco: lieve beneficio della TAVI vs AVR ad 1 anno

- < mean gradient
- > rigurgito perivalvolare associato a TAVI

La TAVI migliora notevolmente sintomi e qualità della vita dei pazienti

Kansas City Cardiomyopathy Questionnaire (KCCQ) Punteggio nel tempo[1]



"L'eccezionale miglioramento dei punteggi di qualità della vita nel gruppo trattato con valvola cardiaca transcatetere (THV) Edwards SAPIEN è equivalente ad una riduzione dell'età di 10 anni."

— David J. Cohen, St Luke's Mid-America Heart and Vascular Institute, Kansas City, Missouri[2]

1. Reynolds MR et al; PARTNER Trial Investigators. Heath-Related Quality of Life After Transcatheter Aortic Valve Replacement in Inoperable Patients With Severe Aortic Stenosis. Circulation 2011;124:00-0.

2. Cohen DJ. Health related quality of life after transcatheter aortic valve implantation vs non-surgical therapy among inoperable patients with severe aortic stenosis. Results from the PARTNER trial. Presented at the American Heart Association's Scientific Sessions, Chicago, IL, November 2010.

5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial

Lancet 2015; 385: 2485–91

Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin*, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators

All cause mortality

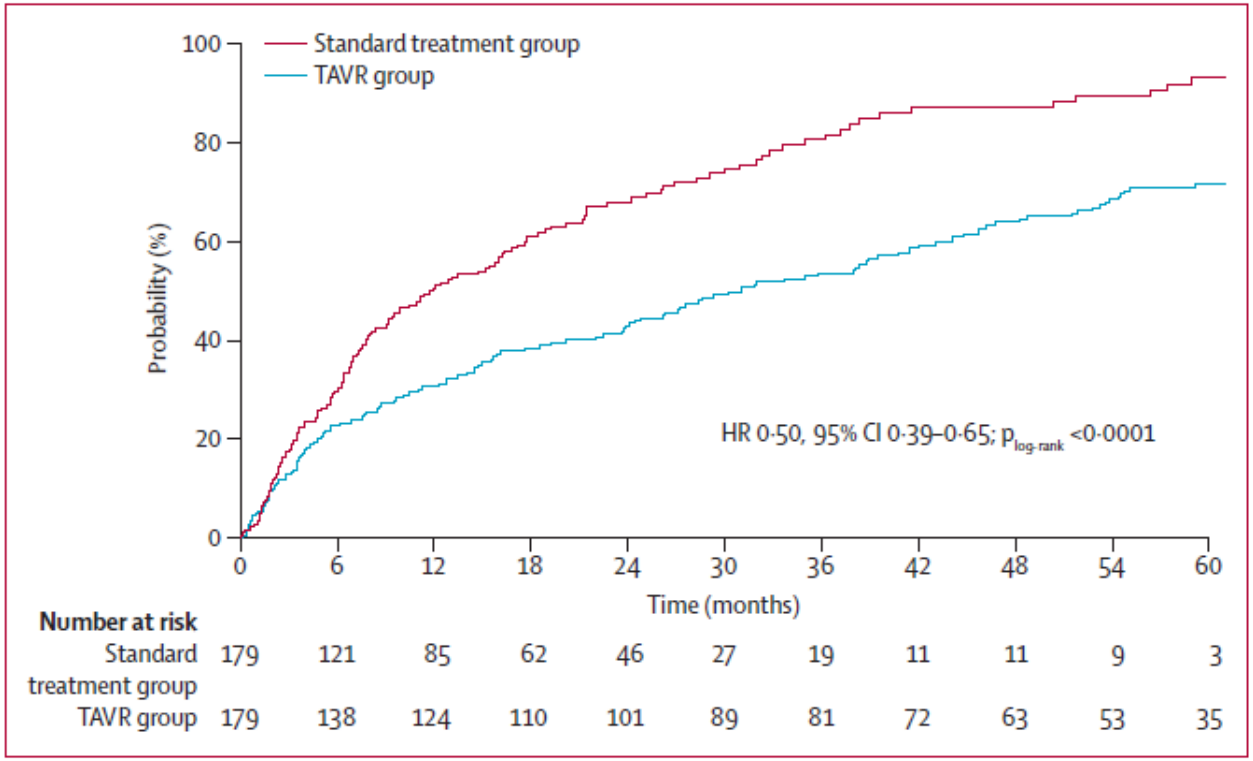


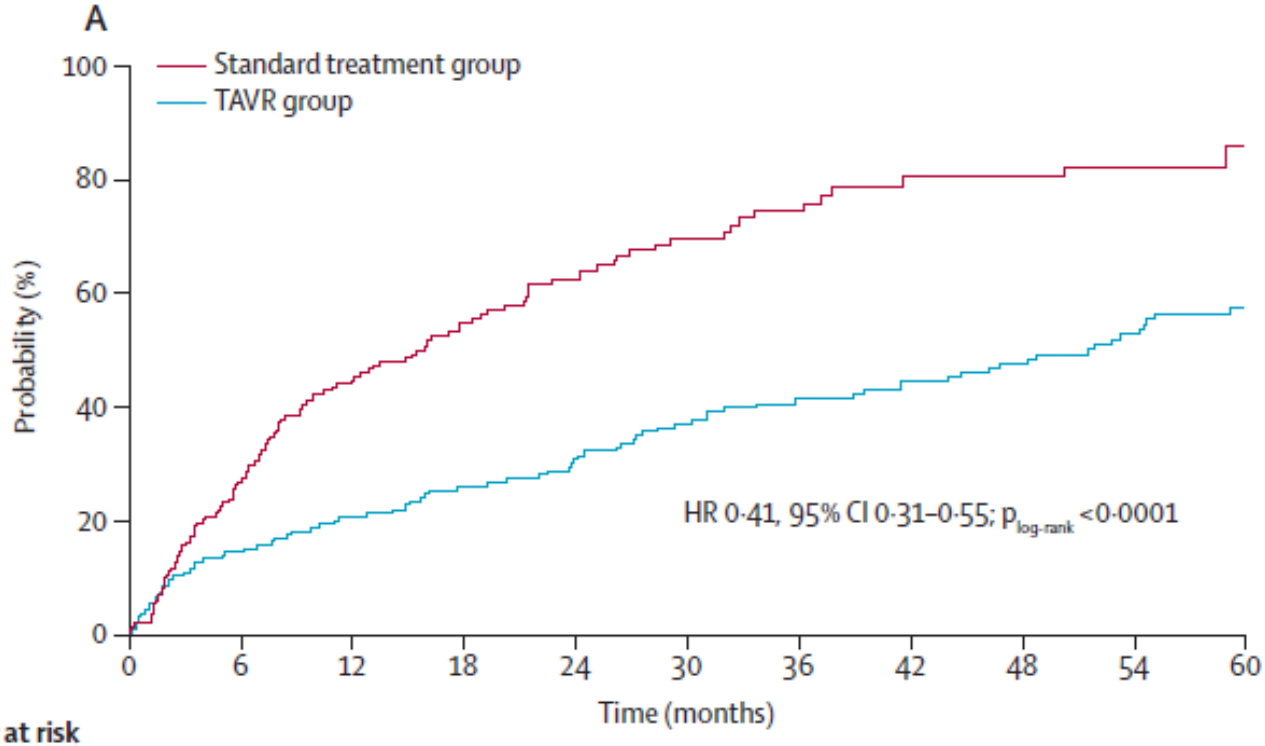
Figure 1: **Kaplan-Meier analysis of all-cause mortality for the intention-to-treat population**
TAVR=transcatheter aortic valve replacement. HR=hazard ratio.

5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial

Lancet 2015; 385: 2485–91

Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin*, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators

CV mortality



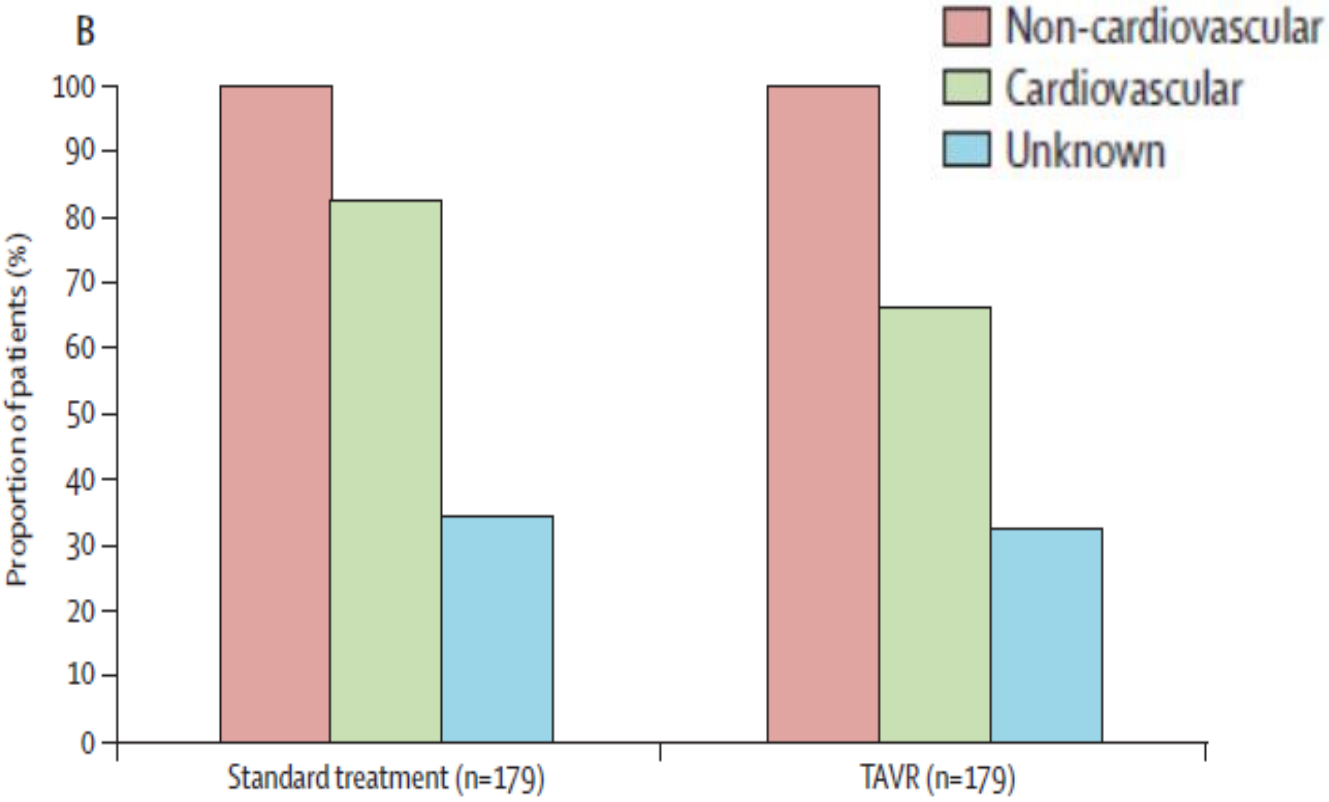
Number at risk	0	6	12	18	24	30	36	42	48	54	60
Standard treatment group	179	121	85	62	46	27	19	11	11	9	3
TAVR group	179	138	124	110	101	89	81	72	63	53	35

5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial

Lancet 2015; 385: 2485–91

Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin*, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators

CV - non CV mortality



5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial

Lancet 2015; 385: 2485–91

Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin*, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators

Stroke

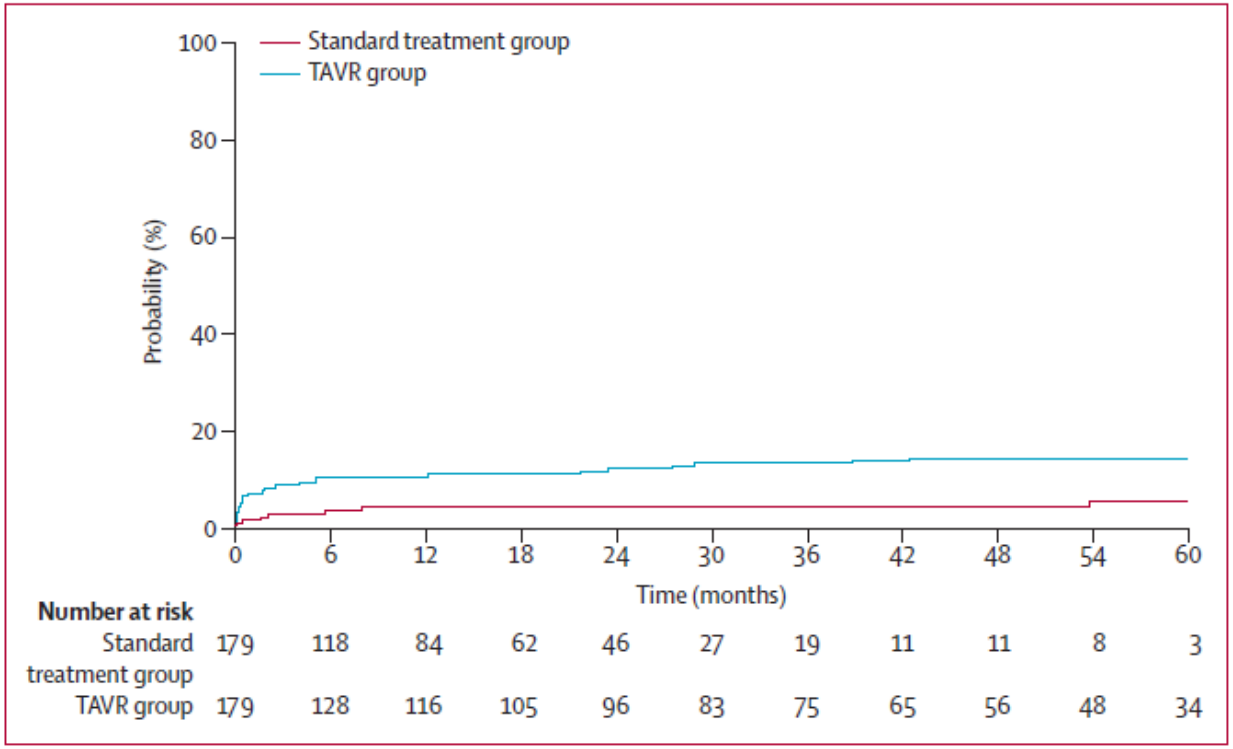
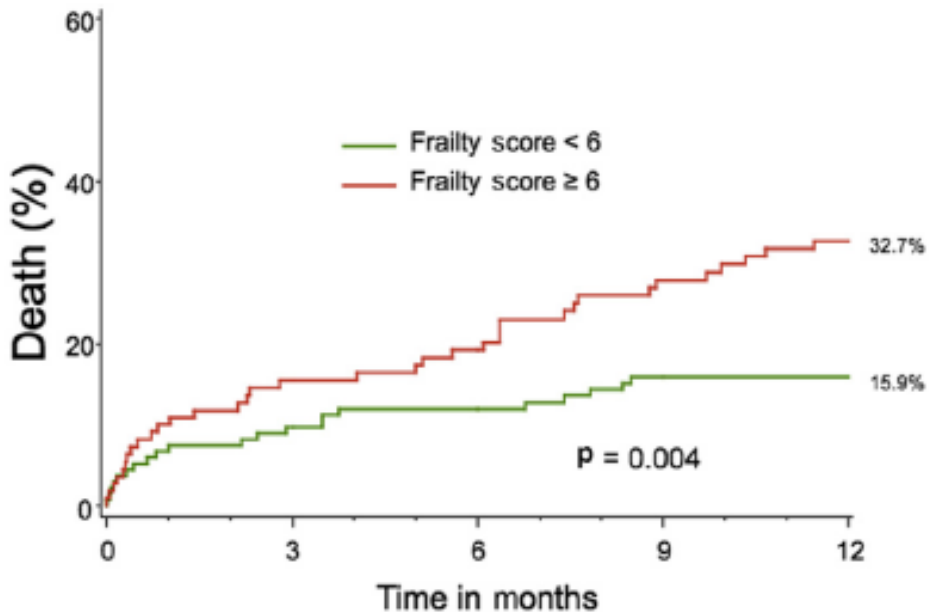


Figure 3: Risk of stroke as determined by competing risk analysis of stroke and mortality
TAVR=transcatheter aortic valve replacement.

Relation of Frailty to Outcomes After Transcatheter Aortic Valve Replacement (from the PARTNER Trial)

Philip Green, MD[a,b,*], Suzanne V. Arnold, MD, MHA[c], David J. Cohen, MD, MSc[c], Ajay J. Kirtane, MD, SM[a,b], Susheel K. Kodali, MD[a,b], David L. Brown, MD[d], Charanjit S. Rihal, MD[e], Ke Xu, PhD[a,b], Yang Lei, PhD[c], Marian C. Hawkey, RN[a,b], Rebeca J. Kim, BA[f], Maria C. Alu, MM[a,b], Martin B. Leon, MD[a,b], and Michael J. Mack, MD[f,g]



Number at risk:

Frailty score < 6	134	120	114	108	98
Frailty score >= 6	110	92	86	75	66

Figure 1. Kaplan-Meier survival estimates stratified by frailty score.

Am J Cardiol 2015;116:264–269

Relation of Frailty to Outcomes After Transcatheter Aortic Valve Replacement (from the PARTNER Trial)

Philip Green, MD[a,b,*], Suzanne V. Arnold, MD, MHA[c], David J. Cohen, MD, MSc[c], Ajay J. Kirtane, MD, SM[a,b], Susheel K. Kodali, MD[a,b], David L. Brown, MD[d], Charanjit S. Rihal, MD[e], Ke Xu, PhD[a,b], Yang Lei, PhD[c], Marian C. Hawkey, RN[a,b], Rebeca J. Kim, BA[f], Maria C. Alu, MM[a,b], Martin B. Leon, MD[a,b], and Michael J. Mack, MD[f,g]

Table 4
Univariable association of markers of frailty and frailty score with 1-year mortality after TAVR

Variable	HR (95% CI)	p-value
Gait speed (m/s)*	1.37 [0.53-3.45]	0.51
Grip strength (kg)*	1.02 [0.99-1.05]	0.28
Albumin (g/dL)*	1.25 [0.88-1.79]	0.21
Any ADL limitation	1.59 [0.93, 2.70]	0.09
Score (continuous)	1.12 [1.02, 1.22]	0.01
Score ($\geq$ 6 versus $<$ 6)	2.18 [1.27, 3.75]	0.005

ADL = activities of daily living; CI = confidence interval; HR = hazard ratio; TAVR = transcatheter aortic valve replacement.

* Hazard ratio is per unit decrease.

Am J Cardiol 2015;116:264–269

Relation of Frailty to Outcomes After Transcatheter Aortic Valve Replacement (from the PARTNER Trial)

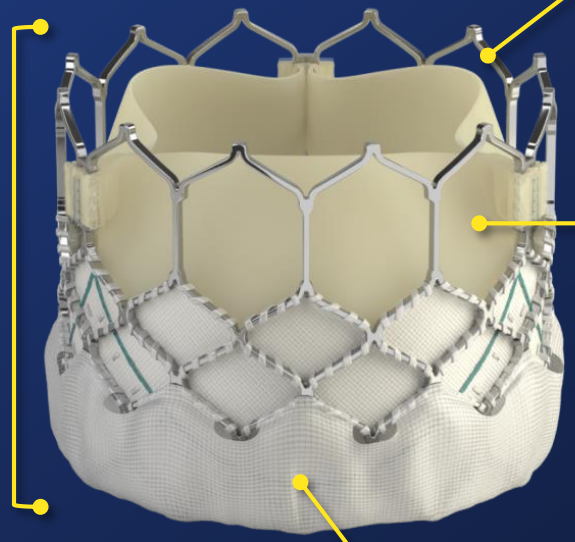
Philip Green, MD[a,b,*], Suzanne V. Arnold, MD, MHA[c], David J. Cohen, MD, MSc[c], Ajay J. Kirtane, MD, SM[a,b], Susheel K. Kodali, MD[a,b], David L. Brown, MD[d], Charanjit S. Rihal, MD[e], Ke Xu, PhD[a,b], Yang Lei, PhD[c], Marian C. Hawkey, RN[a,b], Rebeca J. Kim, BA[f], Maria C. Alu, MM[a,b], Martin B. Leon, MD[a,b], and Michael J. Mack, MD[f,g]

At 1 year, poor outcome occurred in 50.0% of the frail group and 31.5% of the non frail group (p [0.02). In conclusion, **frailty was associated with increased mortality and a higher rate of poor outcome 1 year after TAVR**

Am J Cardiol 2015;116:264–269

SAPIEN 3 Transcatheter Heart Valve

Distinguishing Features



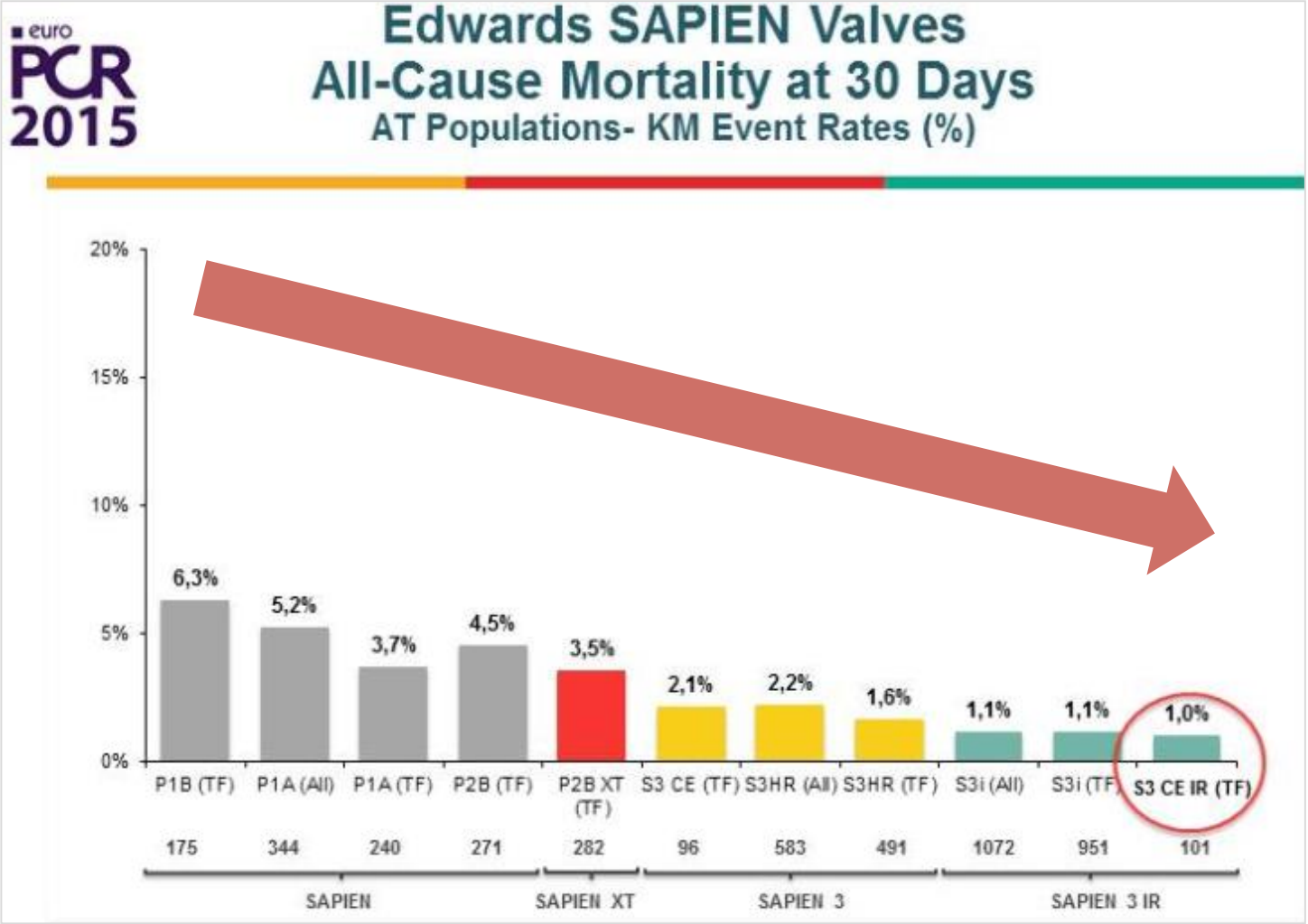
Enhanced frame geometry for low delivery profile

Bovine pericardial tissue

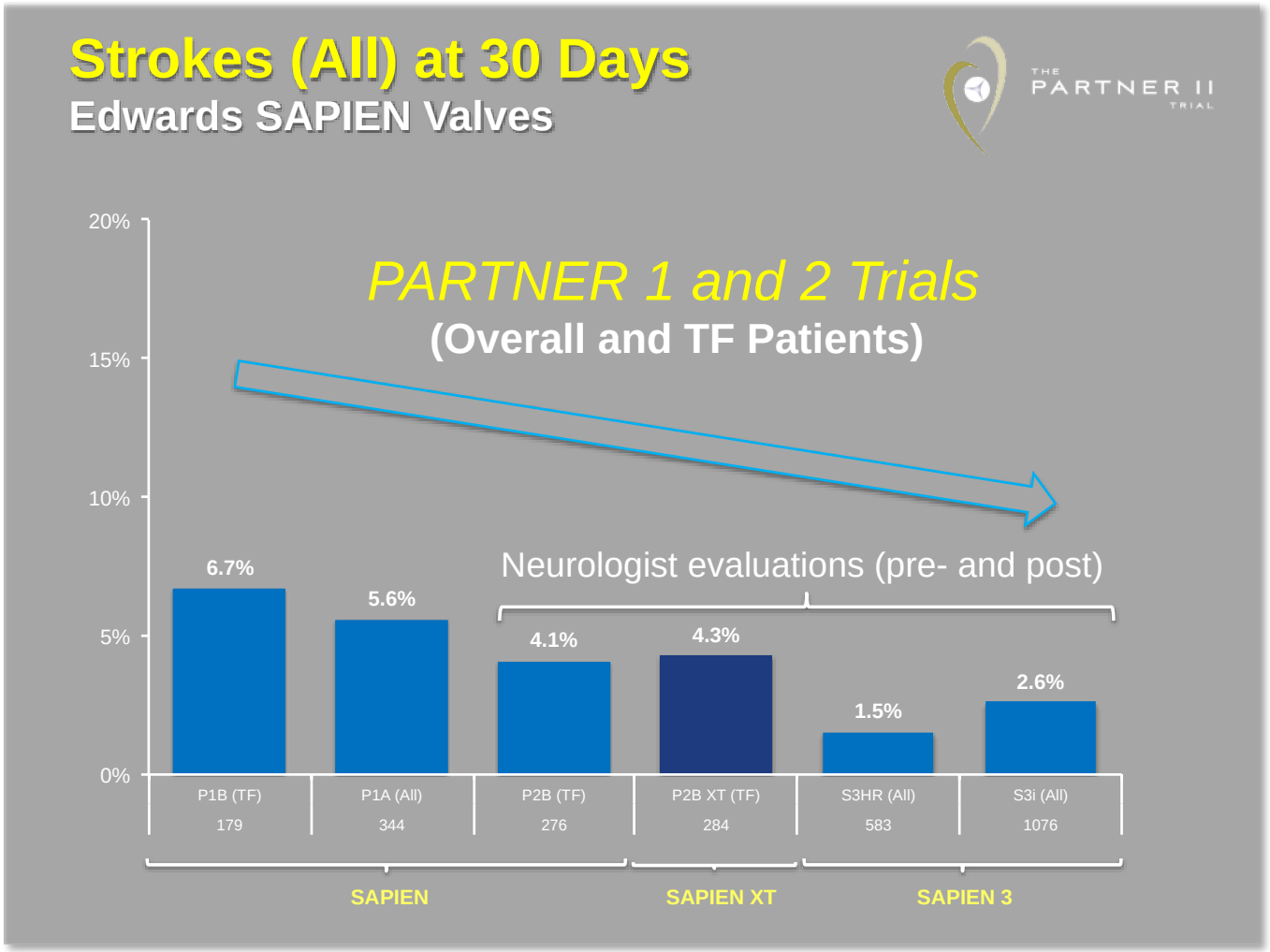
Low frame height

Outer sealing skirt to reduce PVL

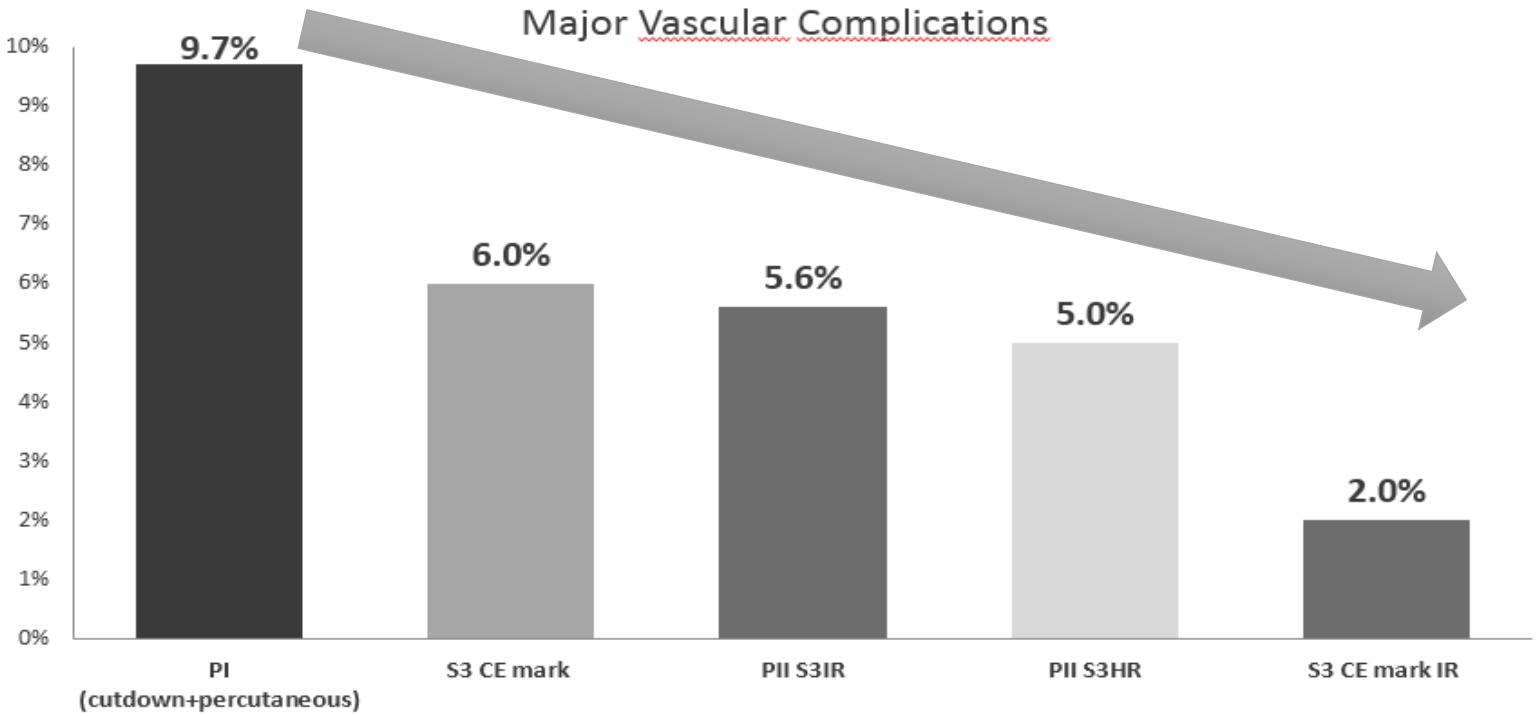
What have we learned about mortality



What have we learned about stroke



What have we learned about major vascular complications



SOCIETÀ ITALIANA
DI GERONTOLOGIA
E GERIATRIA

LO STATO DELL'ARTE DELLA TAVI NELLA STENOSI AORTICA

Il ruolo del geriatra…..

European Heart Journal
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Table 11 Recommendations for the use of transcatheter aortic valve implantation

Recommendations	Class [a]	Level [b]	Ref [c]
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	

Geriatricians for Comprehensive Geriatric Assessment ??

The Association Between Geriatric Syndromes and Survival

Robe ... *in, MD,*[*†] *Kristine Talley, PhD, RN,*[‡] *and Jame*

Table 3. Dif ... Older ... Population and Individu-
als with Sele ... ric Syn

Age	Remaini Expec in the G Popul
65	18.
70	14.
75	11.
80	8.
85	6
90	4
95	2
100	0

Age	Remaining Life Expectancy in the General Population
65	18.4
70	14.9
75	11.7
80	8.9
85	6.5
90	4.6
95	2.8
100	0.4

Allostatic Load
−10.3
−8.9
−7.5
−6.0
−4.7
−3.5
−2.2
−0.4

ty type)	w ly ss ex	Allostatic Load	Disability in Activities of Daily Living
2	4	−10.3	−3.9
8	8	−8.9	−3.4
5	1	−7.5	−3.0
1	4	−6.0	−2.5
6	7	−4.7	−2.0
2	0	−3.5	−1.5
7	2	−2.2	−0.9
1	2	−0.4	−0.2

J Am Geriatr Soc 60:896–904, 2012

Predictors of functional decline in elderly patients undergoing transcatheter aortic valve implantation (TAVI)

Andreas W. Schoenenberger[1†], Stefan Stortecky[2†], Stephanie Neumann[1], André Moser[1,3], Peter Jüni[3], Thierry Carrel[4], Christoph Huber[4], Marianne Gandon[2], Seraina Bischoff[2], Christa-Maria Schoenenberger[2], Andreas E. Stuck[1], Stephan Windecker[2*], and Peter Wenaweser[2]

Table 2 Univariable associations of risk scores (EuroSCORE, STS score and frailty index) and of the frailty index compo ities of daily li

The frailty index, but not established risk scores, was predictive of functional decline. Refinement of this index might help to identify patients who potentially benefit from additional geriatric interventions after TAVI.

Predic						NR[2]
Risk sc						
Logis						
Lin						0.050
Dic						0.006
STS						
Lin						0.068
Dichotomized (≥5 vs. <5%)	1.14 (0.44–2.95)	0.78	0.001	1.83 (0.80–4.16)	0.15	0.025
Frailty index						
Linear (OR per 1 point increase)	1.57 (1.20–2.05)	0.001	0.135	1.74 (1.38–2.20)	<0.001	0.236
Dichotomized (frail vs. non-frail)	3.31 (1.21–9.03)	0.02	0.085	4.46 (1.85–10.75)	0.001	0.142

European Heart Journal (2013) **34**, 684–692

2012….

EUGMS Aortic Stenosis/TAVI Working Group was founded

Transcatheter Aortic Valve Implantation Registry with Comprehensive Geriatric Assessment

CGA-TAVI

Principal investigators

Andrea Ungar, MD
Unit of Geriatric and Medicine, University of Florence, Florence, Italy
au@cga-tavi.it

Jean-Pierre Michel, MD
Department of Rehabilitation and Geriatrics, Geneva Medical School and University Hospitals, Geneva, Switzerland
jpm@cga-tavi.ch

Advisory Board

Peter Bramlage, MD
Jana Kurucova, MD
Stefania Maggi, MD
Martin Thoenes, MD
Manuel Martinez Sellés, MD
Olivier Hanon, MD
Nikos Werner, MD

TAVI Working Group

EUGMS
European Union Geriatric Medicine Society
Fostering geriatric medicine across Europe

EUGMS AS/TAVI Working Group

The EUGMS TAVI group Survey

EUGMS
European Union Geriatric Medicine Society

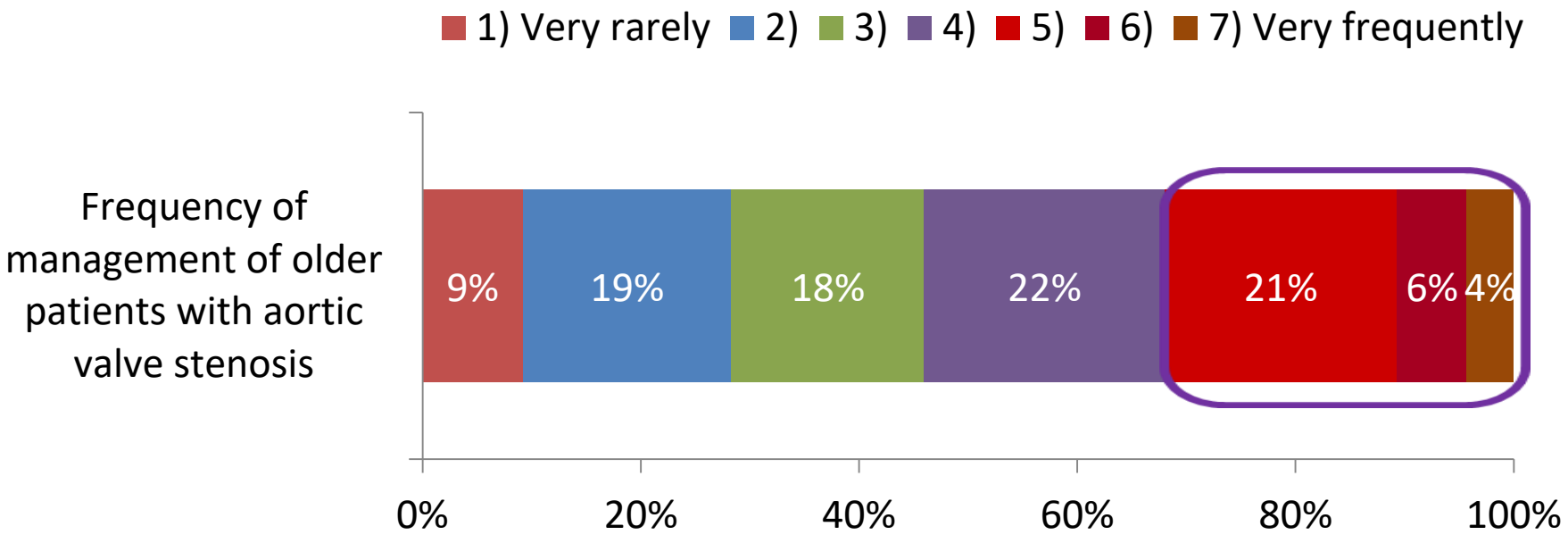
A call to action - Geriatricians' experience in treatment of aortic stenosis and involvement in transcatheter aortic valve implantation

The EUGMS TAVI group Survey

Andrea Ungar, Peter Bramlage, Martin Thoenes, Stefania Zannoni and Jean-Pierre Michel,
European Geriatric Medicine, 2013

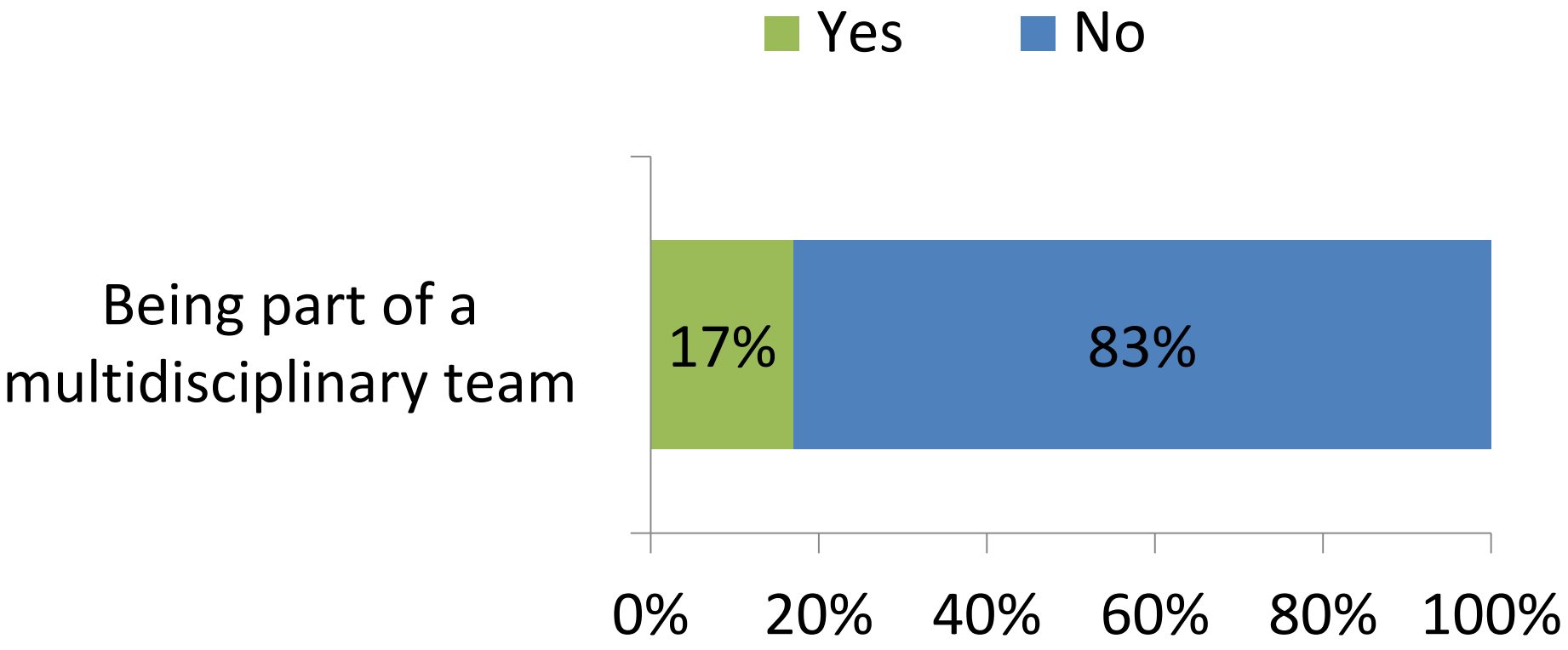
Frequency of management of patients with AS

31% of respondents (n=341) indicated that they managed patients with AS on a frequent basis.



Andrea Ungar et al, European Geriatric Medicine, 2013

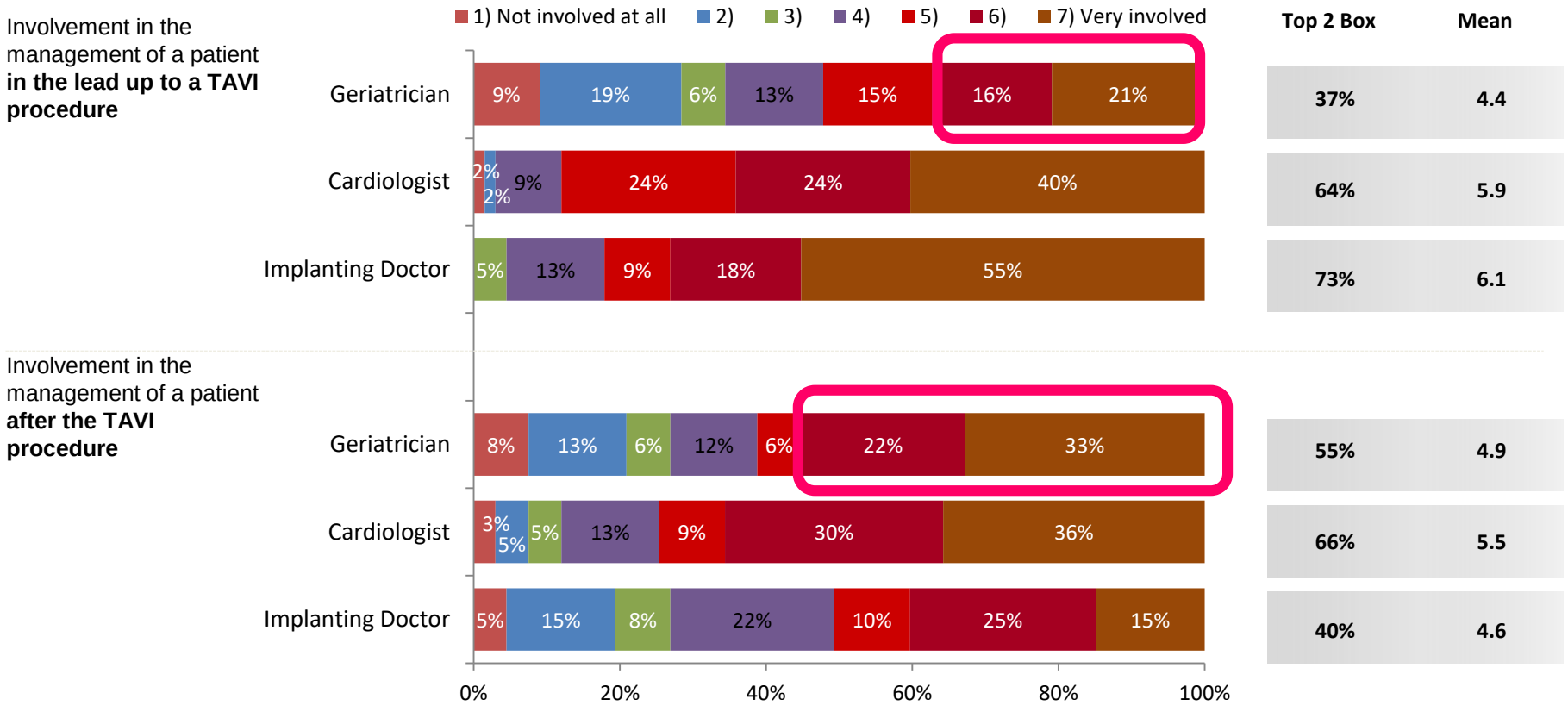
Membership in a multidisciplinary heart team



Only a **minority of respondents (17%)** who referred patients for TAVI in the past 2 years are members of a **multidisciplinary** heart team for the management of patients who are considered for TAVI.

Andrea Ungar et al, European Geriatric Medicine, 2013

Level of involvement of different specialties before and after TAVI procedures



Respondents perceived that – compared to cardiologists and implanting doctors – **geriatricians are less involved** in the management of a patient in the lead up to a TAVI procedure. Their level of involvement, however, seems to increase slightly after the procedure.

CGA-TAVI

EUGMS

The value of comprehensive geriatric assessment in elderly patients with severe aortic stenosis – a **position statement** of the European Union Geriatric Medicine Society (EUGMS)

Conclusions

Inclusion of geriatricians in multidisciplinary "heart teams" and their **increased involvement** in the management of elderly patients with severe AS is **critical**. In particular, geriatricians can provide valuable CGA-related data on prognosis and risk in elderly TAVI candidates.

TAVI Working group, EGM, 2014

EUGMS AS/TAVI Working Group

The EUGMS TAVI group Study

ELSEVIER

Available online at
ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com

EUROPEAN GERIATRIC MEDICINE

Research paper

Comprehensive geriatric assessment in patients undergoing transcatheter aortic valve implantation–rationale and design of the European CGA-TAVI registry

A.W. Schoenenberger [a,*], N. Werner [b], P. Bramlage [c], M. Martinez-Selles [d], S. Maggi [e], R. Bauernschmitt [f], M. Thoenes [g,h], J. Kurucova [g], J.-P. Michel [i], A. Ungar [j]

EUGMS
European Union Geriatric Medicine Society

CGA-TAVI

Design of CGA-TAVI

- Prospective, observational, multi-center registry
- Consecutive enrolment of patients undergoing transcatheter valve implantation in participating sites
- Start: January 2013
- Follow up of this registry: 12 months
- Actual number of patients enrolled: 57 patients (August 2015)

CGA-TAVI

Design of CGA-TAVI

Primary objectives:

- Establish predictive values of CGA (MPI, SPPB, SilverCode) for mortality and/or hospitalisation in TAVI patients
- Demonstrate CGA changes within 3 months after TAVI

CGA-TAVI

Inclusion- and Exclusion Criteria

Inclusion Criteria:

- Scheduled for TAVI Compliance with the indications of the instructions for use of the respective device
- Age of at least 80 years

Exclusion Criteria:

- Presence of contraindications as to the Instructions for Use
- No possibility for a follow-up

European Geriatric Medicine 5 (2014) 8–13

CGA-TAVI

Conclusion – EUGMS, Rotterdam 2014

- In 2014 we enrolled 18 patients only in Florence…
- My conclusion was….: we need **more cooperation** between geriatricians and cardiologists and, probably, more **initiative** of the geriatrician in their Hospital to present more complete data next year in ….

1. Countries	Names
Austria	Peter Weiler
Spain	Martinez Selles
United Kindom	John Chambers
France	Alec Vahanian
United Kindom	Bernard Prendergast
Austria	Raphael Rosenhek
France	Jean Paul Emeriau
United Kindom	Daniel Bailey
Belgium	Jean-Pierre Baeyens
France	Olivier Hanon
Germany	Nikos Werner
Israel	Yitshal Berner
Italy	Andrea Ungar
Italy	Nicola Ferrara
Italy	Roberto Bernabei
Spain	Carlos Rodriguez-Pascual
Switzerland	Georg Benedikt Ehret
United Kingdom	Sinead O'Mahony

EUGMS
European Union Geriatric Medicine Society

CGA-TAVI

Patients characteristics

Florence	33 patients
Amsterdam	12 patients
Montreal	12 patients

	Mean ± SD or %	Number
Age [years]	85.5 ± 2.7	57
Female [%]	63.2	36/57
BMI [k		
Aortic		
Synco		
Dizzin		
Angina		
Cl		
Cl		
NYHA classification		
Class III [%]	68.9	31/45
Class IV [%]	11.1	5/45

We started with 20 potential centers?

Why only 3 centers enrolled????

Cardiologist ? Geriatrician ?,

Cooperation.....

CGA-TAVI

Cardiac characteristics

Cardiac baseline characteristics	%	Number
Coronary artery disease [%]	59.2	29/49
Prior myocardial infarction [%]	22.4	11/49
Prior cardiovascular intervention [%]	49.0	24/49
Prior pacemaker implantation [%]	6.1	3/49

Echocardiographic parameters	Mean ± SD	
Ejection fraction [%]	51.9 ± 12.1	46
AV peak PG [mmHg]	79.9 ± 17.0	42
AV mean PG [mmHg]	51.2 ± 13.3	45
V max [m/sec]	4.3 ± 0.5	20
Effective orifice area [cm^2]	0.9 ± 0.5	22

CGA-TAVI

Comorbidities and surgical risk

Comorbidities	%	Number
Hypertension	84.6	44/52
Diabetes	21.2	11/52
Previous Stroke/TIA	11.5	6/52
Peripheral artery disease	28.8	15/52
Pulmonary disease	19.2	10/52
Pulmonary hypertension	54.0	27/50
Creatinine > 1.5 mg/dl	13.5	7/52
Dialysis	3.8	2/52

Surcigal risk	Mean ± SD	
Logistic Euroscore I	9.7 ± 8.5	47
STS risk score	12.1 ± 10.1	35

CGA-TAVI

CGA assessment for MPI at baseline

	Mean ± SD (Range)		Number
	Total Score	Total Index Score	
Activities of daily living	5.7 ± 0.6 (4-6)	0.03 ± 0.12	52
Instrumental activities of daily living scale (IADL)	6.5 ± 1.6 (2 – 8)	0.14 ± 0.29	52
Short portable mental status questionnaire (SPMSQ)	0.96 ± 1.0 (0 – 4)	0.01 ± 0.07	52
Cumulative illness rating scale (C.I.R.S.)	24.9 ± 4.3 (15-32)	0.81 ± 0.30	52
Mini nutrional assessment (MNA) total assessment	22.7 ± 4.4 (8-28)	0.29 ± 0.33	51
Exton-Smith scale (ESS)	18.3 ± 2.7 (9-20)	0.08 ± 0.23	52
Number of medications	8.1 ± 3.3 (2-22)	0.85 ± 0.25	52
Co-habitation status		0.42 ± 0.50	52

CGA-TAVI

MPI, SPPB and Silver Code at baseline

	Mean ± SD (Range) or %	Number
Multidimensional Prognostic Index Score (MPI) – Total	0.32 ± 0.11 (0.125 – 0.625)	52
0 to 0.33	61.5	32/52
0.34 to 0.66	38.5	20/52
0.67 to 1.0	0	0/52
Silver Code	21.5 ± 8.4 (3 – 37.5)	57
Short physical performance battery (SPPB)	6.19 ± 3.30 (0 – 11)	52

CGA-TAVI

Periprocedural complications

	%	Number
Access complication	5.9	3/51
Dissection	3.9	2/51
Rupture	2.0	1/51
Uncontrolled bleeding	0	0/51
Complications	22.0	11/50
Conversion to conventional surgery	0	0/50
Complete AV block with need for permanent PM	6.0	3/50
Device malfunction	3.9	2/51
Device success (VARC2) *	95.8	46/48
Second valve used	5.8	3/52

* Absence of procedural mortality, correct positioning of a single prosthetic heart valve into proper anatomical position and intended performance of the prosthetic heart valve (no prosthetic-patient mismatch) and mean aortic valve gradient

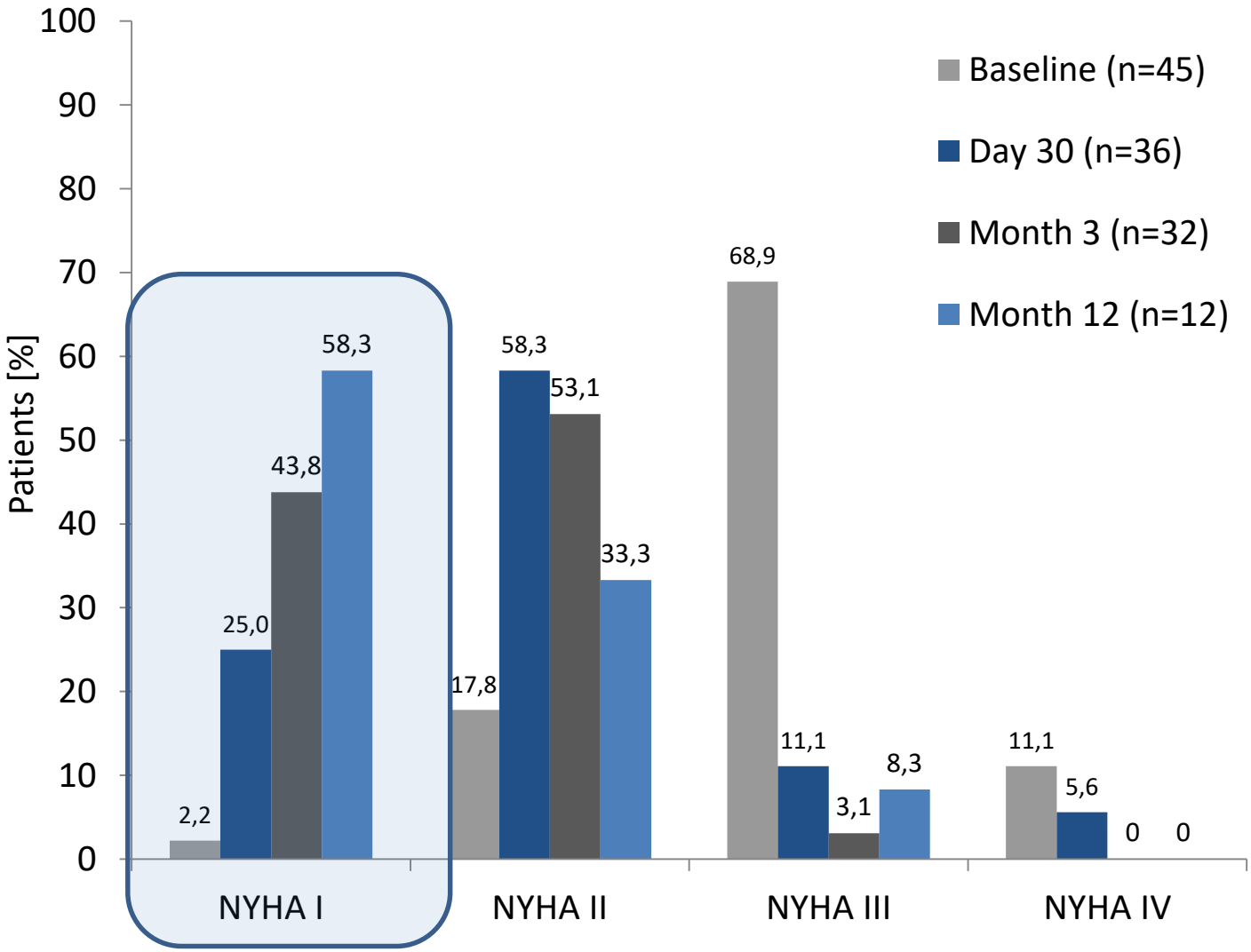
CGA-TAVI

Outcome

	n/N (%)		
	≤ Day 30	> Day 30 to ≤ 3 Months	> 3 Months to ≤ 12 Months
All-cause mortality [%]	2/36 (5.6)	3/32 (9.4)	1/13
All stroke [%]	3/36 (8.3)	0/32	0/12
Hemorrhagic stroke with death	1/36 (2.8)	0/32	0/12
Stroke minor/resolved	2/36 (5.6)	0/32	0/12
Hospitalisation for valve-related symptoms or worsening congestive heart failure [%]	2/36 (5.6)	6/31 (19.4)	0/12
Valve related dysfunction [%]	0	1/32 (3.1)	0
NYHA Class III [%]	4/36 (11.1)	1/32 (3.1)	1/12 (8.3)
NYHA Class IV [%]	2/36 (5.6)	0/32	0/12
Angina CSS Class III or IV [%]	0/36	0/31	0/12

CGA-TAVI

NYHA Classification at baseline vs. month 3-12



CGA-TAVI

MPI, SPPB and Silver Code at baseline and months 3

Baseline

	Mean ± SD (Range) or %	Number
Multidimensional Prognostic Index Score (MPI) – Total	0.32 ± 0.11 (0.125 – 0.625)	52
0 to 0.33	61.5	32/52
0.34 to 0.66	38.5	20/52
0.67 to 1.0	0	0/52
Silver Code	21.5 ± 8.4 (3 – 37.5)	57
Short physical performance b		

Month 3

	Mean ± SD (Range) or %	Number
Multidimensional Prognostic Index Score (MPI) – Total	0.31 ± 0.14 (0.125 – 0.75)	30
0.0 to 0.33	63.3	19/30
0.34 to 0.66	33.3	10/30
0.67 to 1.0	3.3	1/30
Silver Code	23.0 ± 6.8 (3 – 31)	33
	.76 1)	30

SPPB increased from 6.19 to 8.03, p=0.04

CGA-TAVI

Comparison of patients with or without death and/or stroke within 3 months after PPVI

	Without stroke or death within 3 months	With stroke or death within 3 months	p-value
Multidimensional Prognostic Index Score (MPI) – Total	0.32 ± 0.10 n = 45	0.41 ± 0.14 n = 7	0.029
Silver Code	21.3 ± 8.8 n = 50	23.4 ± 4.4 n = 7	0.319
Short physical performance battery (SPPB)	6.8 ± 3.0 n = 45	2.3 ± 4.2 n = 7	0.000

CGA-TAVI

Conclusion

- We enrolled **57 patients** in 3 different centre, characterized by old age and high comorbidity
- Proven **feasibility** of CGA-TAVI protocol
- Patients enrolled had high classical cardiovascular risk score and intermediate MPI score
- **Stroke** incidence was 5.9%
- **Mortality** rate was 13% at 3 months
- NYHA class and SPPB score **improved** during follow-up
- Low SPPB score seems to be the best **predictor** of mortality or stroke after TAVI

G.B, 94 years old
Procchio, Elba Island