TAVI
Su quali pazienti è corretto porre indicazione alla procedura

Lorenzo A. Menicanti
IRCCS POLICLINICO SAN DONATO

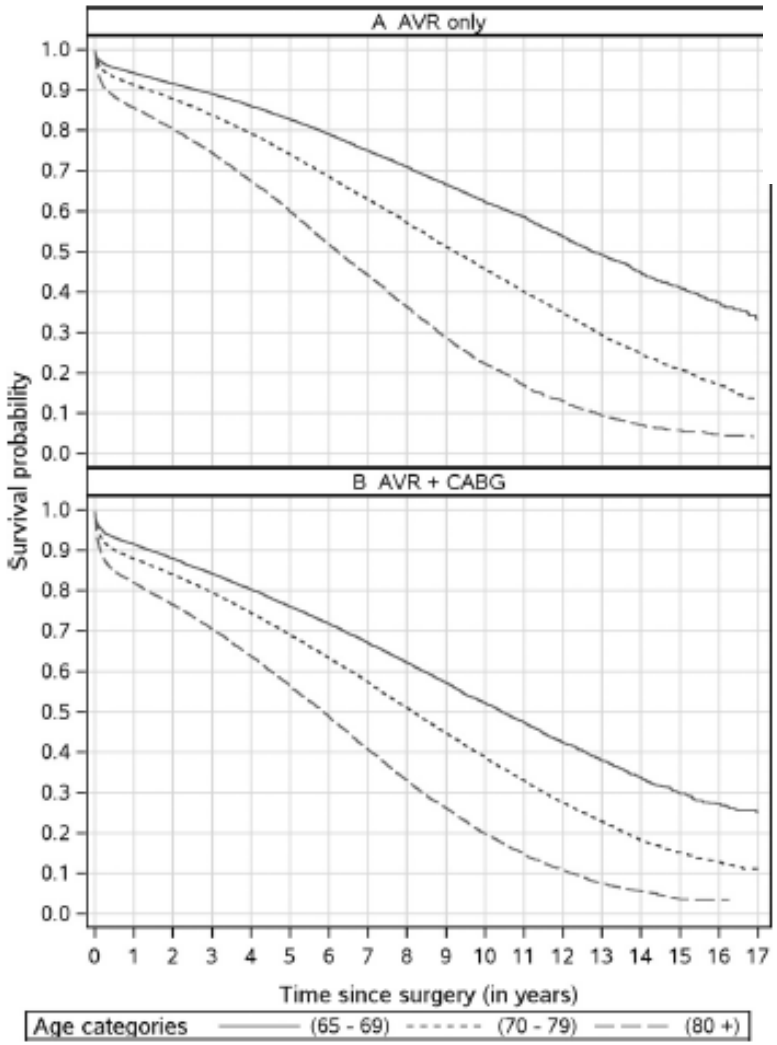


Figure 2. Long-term survival after aortic valve replacement (AVR) in elderly patients, 1991 to 2007. Long-term survival after AVR is presented by strata of patient age (65–69, 70–79, ≥80 years of age) in the overall cohort (1991–2007).

Long-Term Survival After Aortic Valve Replacement Among High-Risk Elderly Patients in the United States

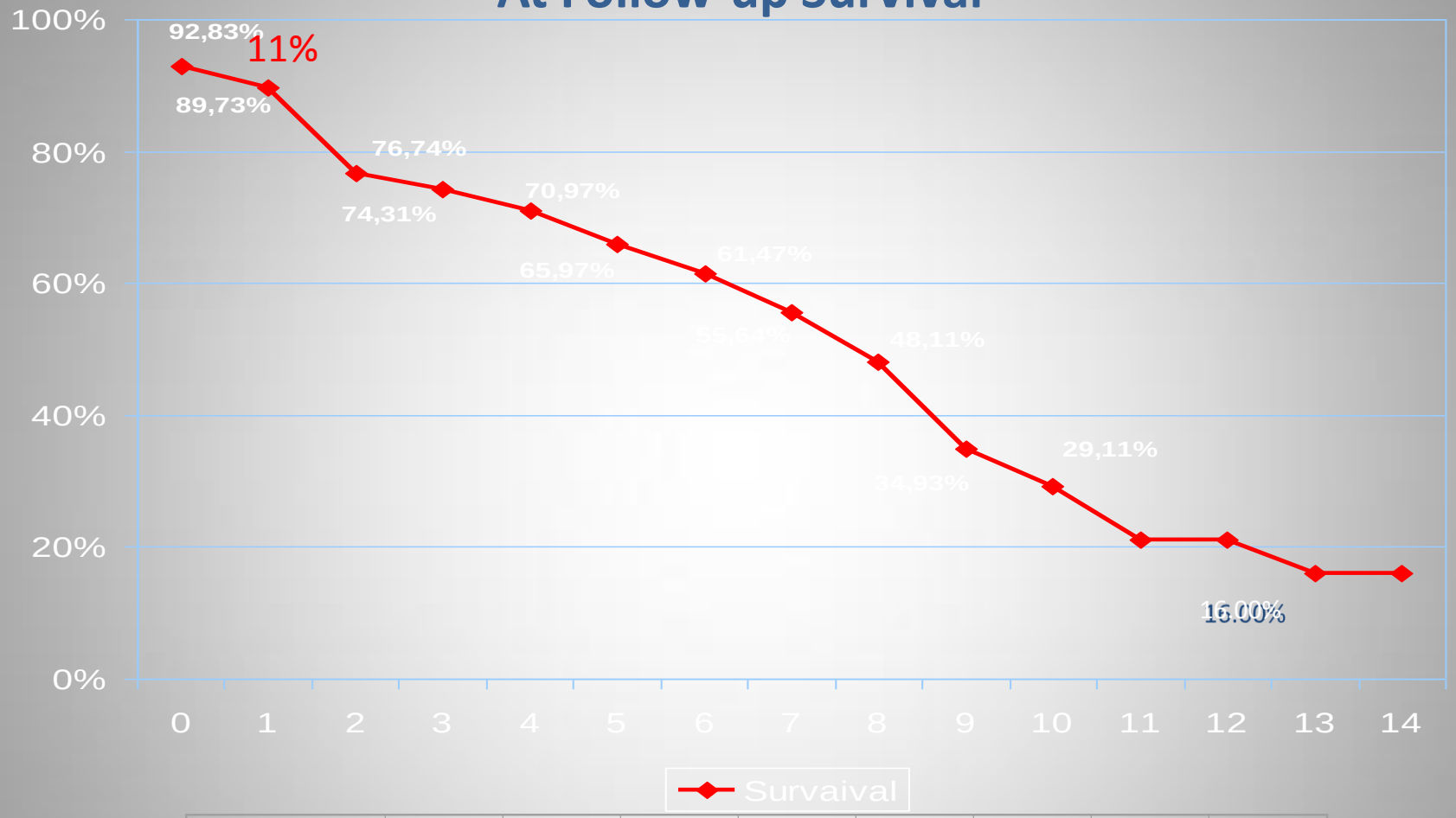
Insights From the Society of Thoracic Surgeons Adult Cardiac Surgery Database, 1991 to 2007

Methods and Results—We examined long-term survival among 145 911 AVR patients ≥65 years of age undergoing AVR at 1026 centers with participation in the Society of Thoracic Surgeons Adult Cardiac Surgery Database from 1991 to 2007. In-hospital complications and long-term survival were stratified by age, Society of Thoracic Surgeons perioperative risk of mortality, and several comorbidities. The median patient age was 76 years; 16% had chronic lung disease, 6% had preoperative renal failure, 38% had heart failure, and 12% had prior cardiac surgery. The median survival in patients 65 to 69, 70 to 79, and ≥80 years of age undergoing isolated AVR was 13, 9, and 6 years, respectively. For AVR plus coronary artery bypass graft procedures, median survival was 10, 8, and 6 years, respectively. Although only 5% of isolated AVR patients had a high Society of Thoracic Surgeons perioperative risk of mortality (≥10%), their median survival was 2.5 to 2.7 years. Severe lung disease and renal failure were each associated with a ≥50% reduction in median survival among all age groups compared with those who did not have these comorbidities, whereas left ventricular dysfunction and prior cardiac operation were associated with a 25% reduction in median survival.

(*Circulation*. 2012;126:1621-1629.)

AVR in pts of age≥80 years

At Follow-up Survival



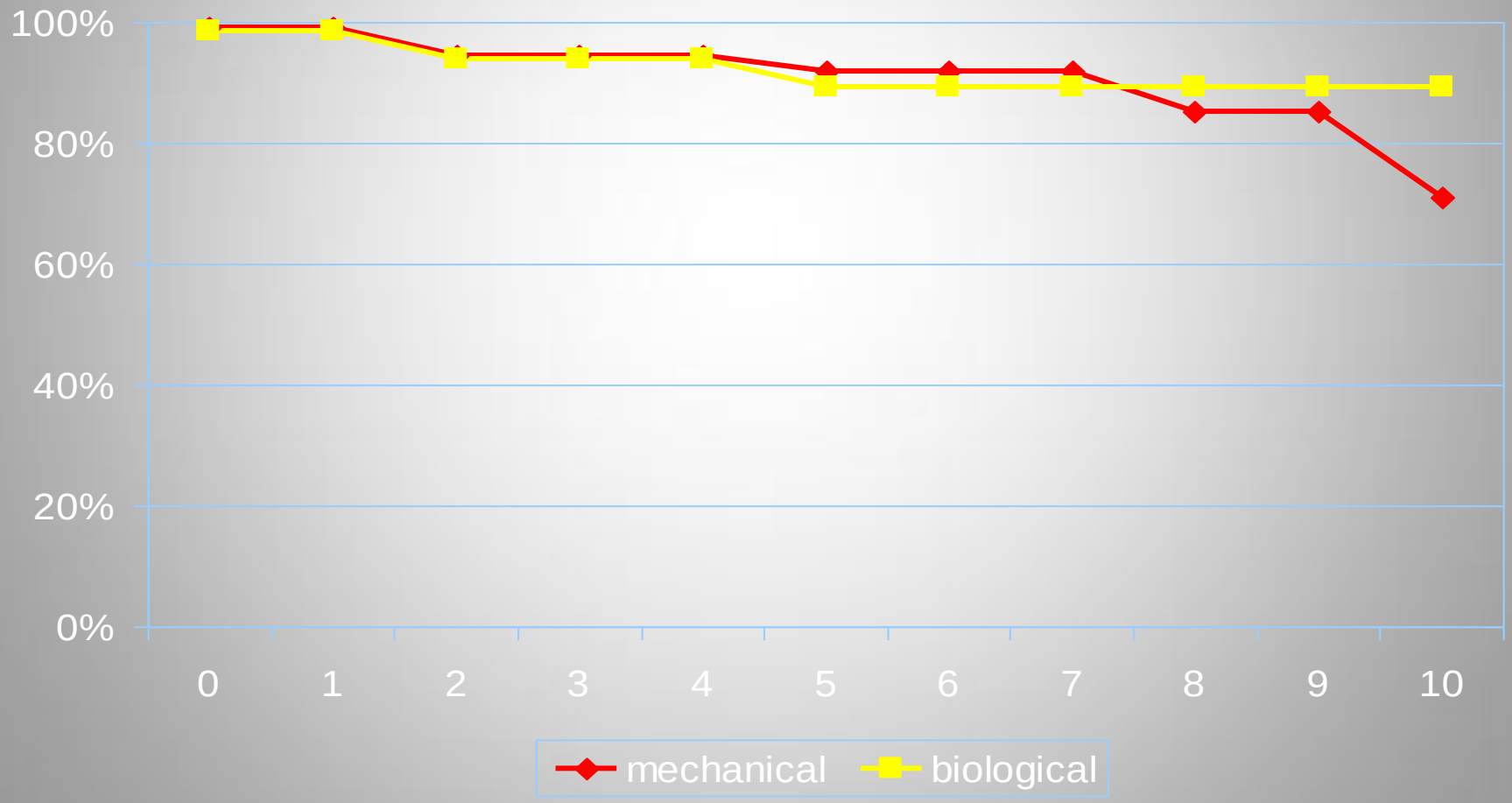
Months	0	24	48	72	96	120	144	176
Subject at risk	345	201	113	59	29	7	2	1

(Ann Thorac Surg 2008;85:1296 –302)

AVR in pts of age≥80 years

Follow up

Freedom from Cerebro-vascular events



(Ann Thorac Surg 2008;85:1296 –302)

Aortic Valve Replacement in Octogenarians: Is Biologic Valve the Unique Solution?

Carlo de Vincentiis, MD, Alessia B. Kunkl, MD, Santi Trimarchi, MD, Piervincenzo Gagliardotto, MD, Alessandro Frigiola, MD, Lorenzo Menicanti, MD, and Marisa Di Donato, MD

Cardiac Surgery Department, San Donato Hospital, Milan, and Department of Critical Care Medicine, University of Florence, Florence, Italy

- Embolic cerebral accident rate in this group of patients was 6.8%, cerebral hemoragic event rate was 2.1%. accounting for 9% at 5 years follow-up

- According to "Italian Longitudunal Study on Aging (ILSA)" (2003) cerebral accidents rate in the general pupulation older than 80 years is 10.3%

(Ann Thorac Surg 2008;85:1296 –302)

European Heart Journal (2003) 24, 1231–1243

ELSEVIER

EUROPEAN SOCIETY OF CARDIOLOGY

A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease

KEYWORDS
Valvular heart disease;
Echocardiography;
Cardiac surgery

Aims To identify the characteristics, treatment, and outcomes of contemporary patients with valvular heart disease (VHD) in Europe, and to examine adherence to guidelines.
Methods and results The Euro Heart Survey on VHD was conducted from April to July 2001 in 92 centres from 25 countries; it included prospectively 5001 adults with moderate to severe native VHD, infective endocarditis, or previous valve intervention. VHD was native in 71.9% of patients and 28.1% had had a previous intervention. Mean age was 64±14 years. Degenerative aetiologies were the most frequent in aortic VHD and mitral regurgitation while most cases of mitral stenosis were of rheumatic origin.

Coronary angiography was used in 85.2% of patients before intervention. Of the 1269 patients who underwent intervention, prosthetic replacement was performed in 99.0%

31.8% did not undergo intervention, most frequently because of comorbidities

management of patients with VHD. Adherence to guidelines is globally satisfying as regards investigations and interventions.

- **Indications for intervention**

The reasons for not performing an intervention in the 31.8% of patients with severe single-valve disease who did not undergo intervention, while in NYHA class III or IV, were:

regression of symptoms under medical treatment (overall 39.9%, 1.8% as the sole reason), end-stage disease (18.4%), symptoms attributed to coronary artery disease (14.9%), and recent myocardial infarction (7.9%).

Besides cardiac causes, the presence of at least one extracardiac cause was considered to contraindicate surgery in 55.3% of cases. The most frequent reasons stated were:

old age (27.6%, as a sole reason in1.3%), chronic obstructive pulmonary disease (13.6%), renal failure (6.1%), and short life expectancy (19.3%).

EVALUATION OF A NEW PROCEDURE

THE PROBLEM OF ASSESSING THE RISK

UNDERESTIMATION OF RISK REPRESENT A MORE CONSERVATIVE APPROACH

WHILE

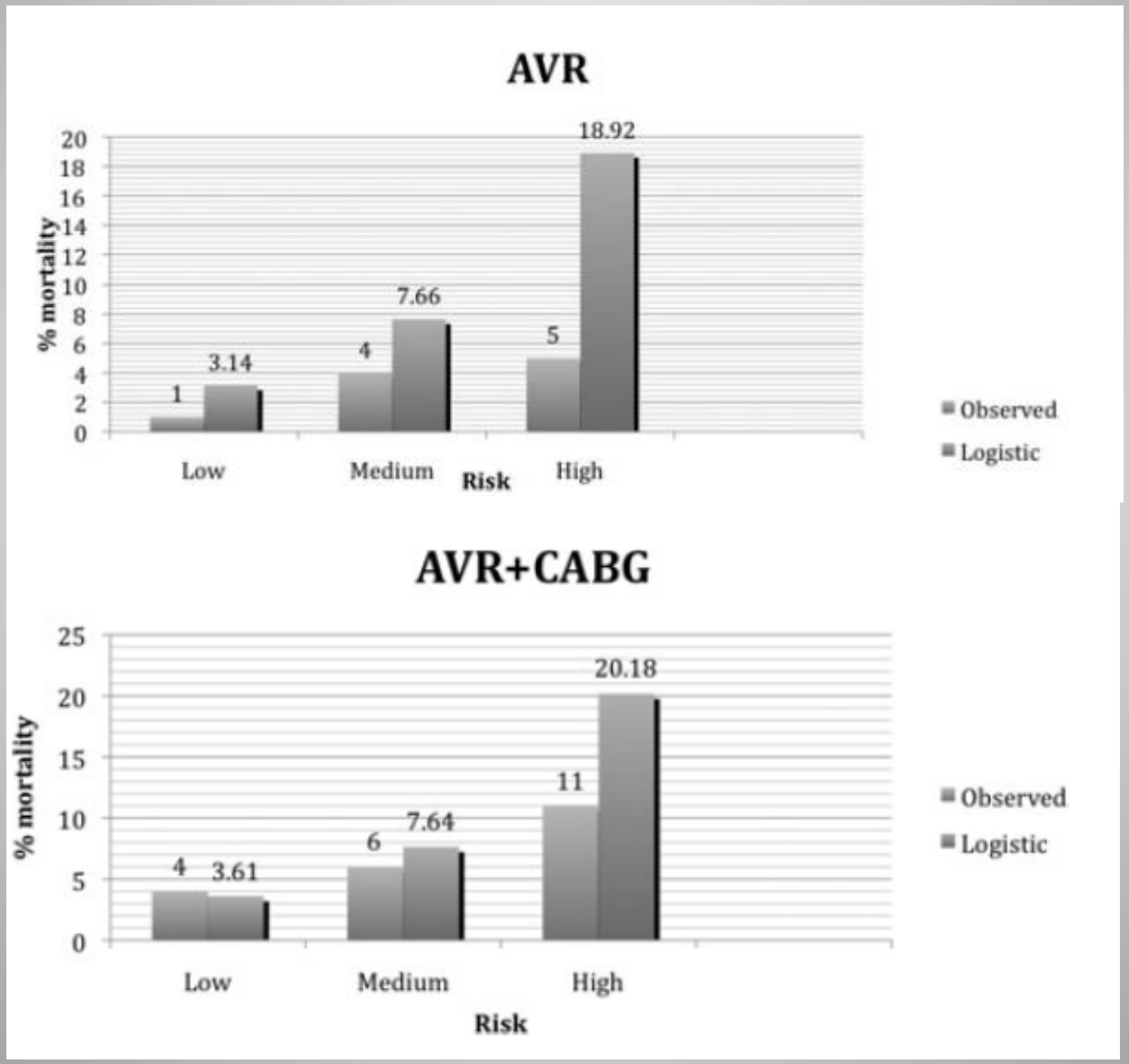
OVERESTIMATION OF RISK LEAD TO RECRUITING PATIENTS THAT MIGHT DO WELL WITH CONVENTIONAL TREATMENT

Assessment of EuroSCORE in Patients Undergoing Aortic Valve Replacement

Nathan C. Skipper, BMedSci BSc (Hons), Julian Matingal, M.D., and Vipin Zamvar, M.B.B.S.

Edinburgh University, Edinburgh Royal Infirmary, Edinburgh, United Kingdom

ABSTRACT *Aims:* The logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) is a risk stratification system used to predict the operative risk in patients undergoing surgical aortic valve replacement (AVR). The aim of this study is to investigate how accurate this system is, and how it compares to the observed risk. *Methods and results:* From January 1, 2004 through December 31, 2009, 1389 patients underwent AVR ± coronary artery bypass grafting (CABG) (865 primary isolated AVR and 524 AVR + CABG) at the New Royal Infirmary Edinburgh. The logistic EuroSCORE was calculated for each patient and summed up for expected in-hospital mortality. Expected and observed mortalities were compared. On the whole, the in-hospital mortality was 3% and was overestimated by the logistic EuroSCORE that predicted 7.2% mortality ($p = 0.05$). This discrepancy was even more pronounced in high-risk patients, where the in-hospital mortality was 8%, while the logistic EuroSCORE predicted 19.5% ($p = 0.03$). *Conclusion:* The logistic EuroSCORE overestimates the risks for AVR. Therefore, it should not be used to deny high-risk patients a surgical AVR. doi: 10.1111/j.1540-8191.2011.01201.x *(J Card Surg 2011;26:124-129)*


AVR
% mortality
20
18
16
14
12
10
8
6
4
2
0
1
3.14
4
7.66
5
18.92
Low
Medium
High
Risk
Observed
Logistic
AVR+CABG
% mortality
25
20
15
10
5
0
4
3.61
6
7.64
11
20.18
Low
Medium
High
Risk
Observed
Logistic

Alternative ways for risk assessment

A series of factor are not considered in the Scores

- Frailty
- Radiation
- Nutritional status
- Hepatic function

Surgical aortic valve replacement after percutaneous aortic valve implantation: What have we learned?

Pierre–Yves Litzler, MD,[a] Alain Cribier, MD,[b] Alan Zajarias, MD,[b] Diane Comte, MD,[a] Hélène Eltchaninoff, MD,[b] Christophe Tron, MD,[b] Catherine Haas–Hubscher, MD,[c] and Jean–Paul Bessou, MD[a]

Methods: An 87-year-old man with severe aortic stenosis **who was rejected for surgical** intervention underwent percutaneous valve implantation through a retrograde femoral approach. The procedure was complicated by **cardiogenic shock** caused by severe aortic insufficiency, leading to emergency **surgical aortic valve replacement**

Results: The operative findings revealed the presence of commissural paravalvular leaks and centrally malapposed leaflets. **Surgical replacement was uneventful**, and the patient was discharged on day 30

J Thorac Cardiovasc Surg 2008;136:697-701

Incidence and Predictors of Early and Late Mortality After Transcatheter Aortic Valve Implantation in 663 Patients With Severe Aortic Stenosis

Corrado Tamburino, MD, PhD; Davide Capodanno, MD; Angelo Ramondo, MD; Anna Sonia Petronio, MD; Federica Ettori, MD; Gennaro Santoro, MD; Silvio Klugmann, MD; Francesco Bedogni, MD; Francesco Maisano, MD; Antonio Marzocchi, MD; Arnaldo Poli, MD; David Antoniucci, MD; Massimo Napodano, MD; Marco De Carlo, MD, PhD; Claudia Fiorina, MD; Gian Paolo Ussia, MD

Background—There is a lack of information on the incidence and predictors of early mortality at 30 days and late mortality between 30 days and 1 year after transcatheter aortic valve implantation (TAVI) with the self-expanding CoreValve Revalving prosthesis.

Methods and Results—A total of 663 consecutive patients (mean age 81.0±7.3 years) underwent TAVI with the third generation 18-Fr CoreValve device in 14 centers. Procedural success and intraprocedural mortality were 98% and 0.9%, respectively. The cumulative incidences of mortality were 5.4% at 30 days, 12.2% at 6 months, and 15.0% at 1 year. The incidence density of mortality was 12.3 per 100 person-year of observation. Clinical and hemodynamic benefits observed acutely after TAVI were sustained at 1 year. Paravalvular leakages were trace to mild in the majority of cases. Conversion to open heart surgery (odds ratio [OR] 38.68), cardiac tamponade (OR 10.97), major access site complications (OR 8.47), left ventricular ejection fraction <40% (OR 3.51), prior balloon valvuloplasty (OR 2.87), and diabetes mellitus (OR 2.66) were independent predictors of mortality at 30 days, whereas prior stroke (hazard ratio [HR] 5.47), postprocedural paravalvular leak ≥2+ (HR 3.79), prior acute pulmonary edema (HR 2.70), and chronic kidney disease (HR 2.53) were independent predictors of mortality between 30 days and 1 year.

Conclusions—Benefit of TAVI with the CoreValve Revalving System is maintained over time up to 1 year, with acceptable mortality rates at various time points. Although procedural complications are strongly associated with early mortality at 30 days, comorbidities and postprocedural paravalvular aortic regurgitation ≥2+ mainly impact late outcomes between 30 days and 1 year. (*Circulation*. **2011;123:299-308.**)

Table 3. One-Year Clinical Results

End point	Cumulative Incidence
MACCE	16.6%
Death	15.0%
Myocardial infarction	1.2%
Stroke	2.5%
CHF requiring hospitalization	8.2%
Major bleeding	3.2%
Pacemaker implantation	19.1%
Prosthesis dysfunction	0.2%

MACCE indicates major adverse cardiovascular and cerebrovascular events; CHF, congestive heart failure.

Correlates and Causes of Death in Patients With Severe Symptomatic Aortic Stenosis Who Are Not Eligible to Participate in a Clinical Trial of Transcatheter Aortic Valve Implantation

Itsik Ben-Dor, MD; Augusto D. Pichard, MD; Manuel A. Gonzalez, MD; Gaby Weissman, MD; Yanlin Li, MD; Steven A. Goldstein, MD; Petros Okubagzi, MD; Asmir I. Syed, MD; Gabriel Maluenda, MD; Sara D. Collins, MD; Cedric Delhaye, MD; Kohei Wakabayashi, MD; Michael A. Gaglia, Jr, MD; Rebecca Torguson, MPH; Zhenyi Xue, MS; Lowell F. Satler, MD; William O. Suddath, MD; Kenneth M. Kent, MD, PhD; Joseph Lindsay, MD; Ron Waksman, MD

Conclusion—Patients with severe symptomatic aortic stenosis not included in transcatheter aortic valve implantation trials
do poorly and have extremely high mortality rates, especially in nonsurgical groups, and loss of quality of life in surgical groups

(***Circulation. 2010;122[suppl 1]:S37–S42.)***

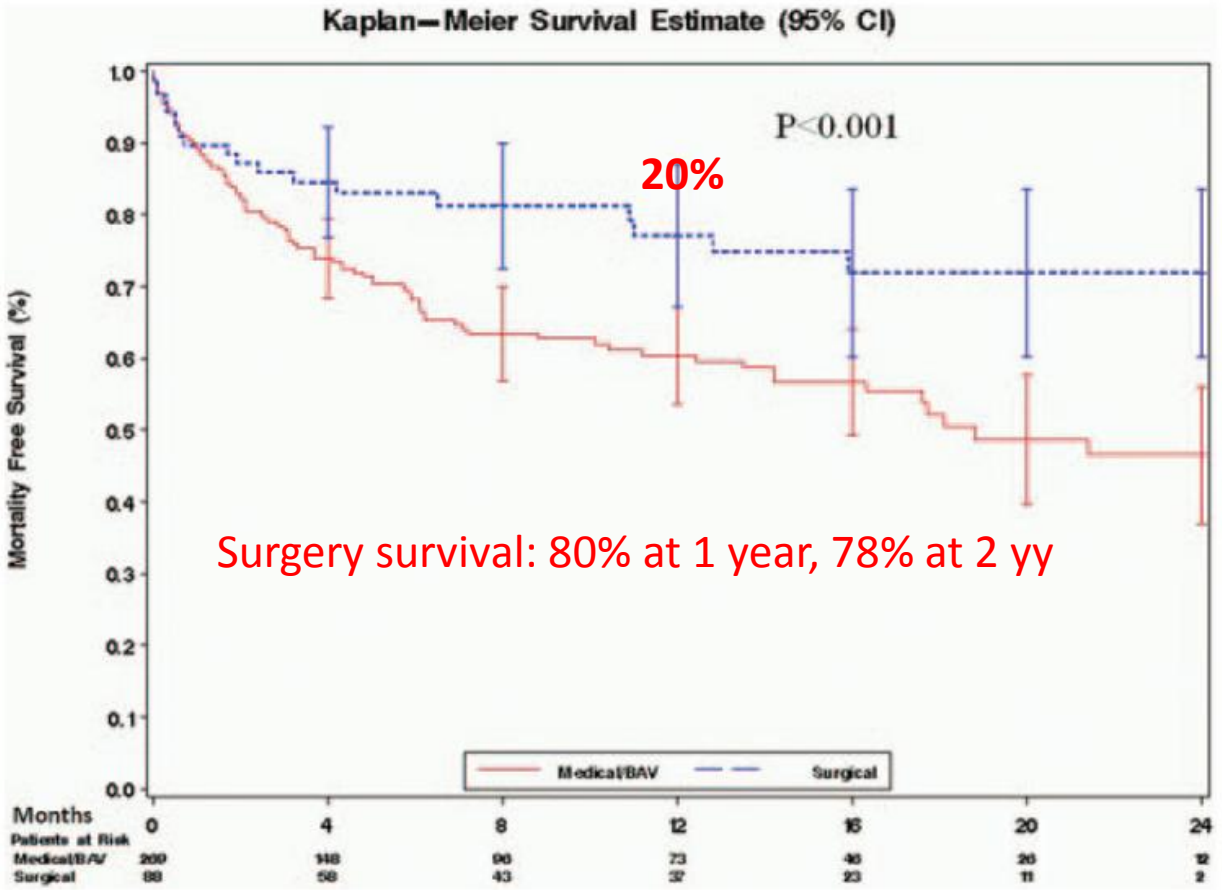


Figure 2. Kaplan–Meier survival curves of patients rejected from TAVI trials based on treatment assignment.

(*Circulation. 2010;122[suppl 1]:S37–S42.*

Permanent Pacemaker Insertion After CoreValve Transcatheter Aortic Valve Implantation

Incidence and Contributing Factors (the UK CoreValve Collaborative)

M.Z. Khawaja, MBBS; R. Rajani, MD; A. Cook, PhD; A. Khavandi, MD; A. Moynagh, MD; S. Chowdhary, MD; M.S. Spence, MD; S. Brown, BSC; S.Q. Khan, MD; N. Walker, MBChB, PhD; U. Trivedi, MBBS; N. Hutchinson, MBBS; A.J. De Belder, MD; N. Moat, MBBS; D.J. Blackman, MD; R.D. Levy, MD; G. Manoharan, MD; D. Roberts, MD; S.S. Khogali, MD; P. Crean, MD; S.J. Brecker, MD; A. Baumbach, MD; M. Mullen, MD; J.-C. Laborde, MD; D. Hildick-Smith, MD

Conclusion—One third of patients undergoing a CoreValve transcatheter aortic valve implantation procedure require a PPM within 30 days. Periprocedural atrioventricular block, balloon predilatation, use of the larger CoreValve prosthesis, increased interventricular septum diameter and prolonged QRS duration were associated with the need for PPM. (*Circulation*. 2011;123:951-960.)

New PPM Implants

Università di Pisa

Dipartimento Cardiologico A. De Gasperis
Azienda Ospedaliera Niguarda Ca' Granda - Milano

ICSA

23%

31%

15%

Sett. 2007- Ott. 2010

325 TAVI

24 %

Courtesy of F.Bedogni

Impact of residual regurgitation after aortic valve replacement†

Sandro Sponga, Jean Perron, Francois Dagenais, Siamak Mohammadi, Richard Baillot, Daniel Doyle, Chiara Nalli and Pierre Voisine*

Quebec Heart and Lung Institute, Laval University, Quebec City, Quebec, Canada

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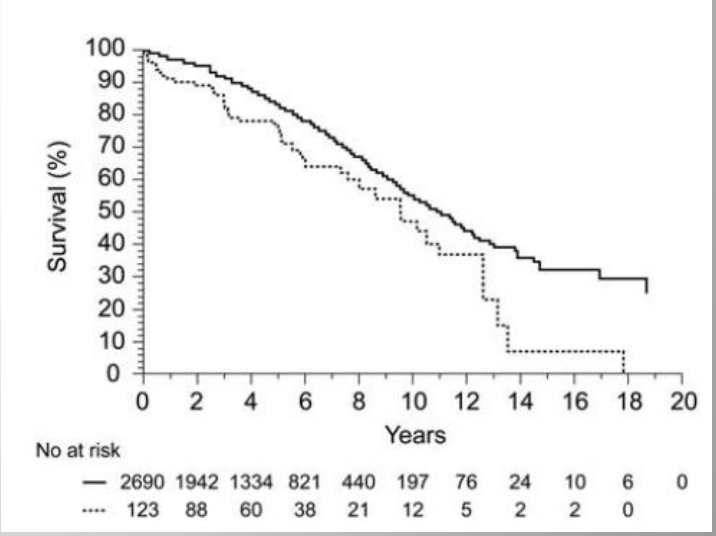
Received 2 September 2011; received in revised form 29 October 2011; accepted 6 November 2011

METHODS: Between 1992 and 2011, 3201 consecutive patients underwent isolated standard aortic valve replacement in our institution. Of these, 135 patients (4.2%) were found to have paravalvular leak >1/4. Clinical, intraoperative as well as early and late postoperative outcome variables were studied. Factors associated with residual AR and their impact on survival were assessed by multivariate analysis.



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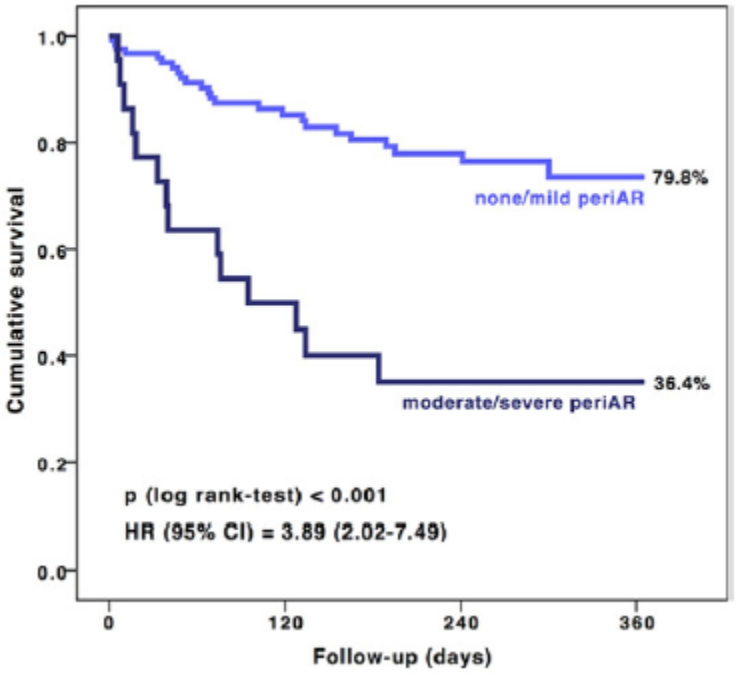
CLINICAL RESEARCH **Valvular Heart Disease**

Aortic Regurgitation Index Defines Severity of Peri-Prosthetic Regurgitation and Predicts Outcome in Patients After Transcatheter Aortic Valve Implantation

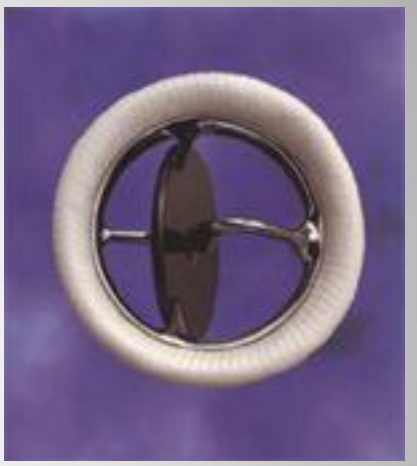
Jan-Malte Sinning, MD, Christoph Hammerstingl, MD, Mariuca Vasa-Nicotera, MD, Viktoria Adenauer, MD, Sisa Josefina Lema Cachiguango, MD, Anne-Cathérine Scheer, MD, Sven Hausen, MD, Alexander Sedaghat, MD, Alexander Ghanem, MD, Cornelius Müller, MD, Eberhard Grube, MD, Georg Nickenig, MD, Nikos Werner, MD

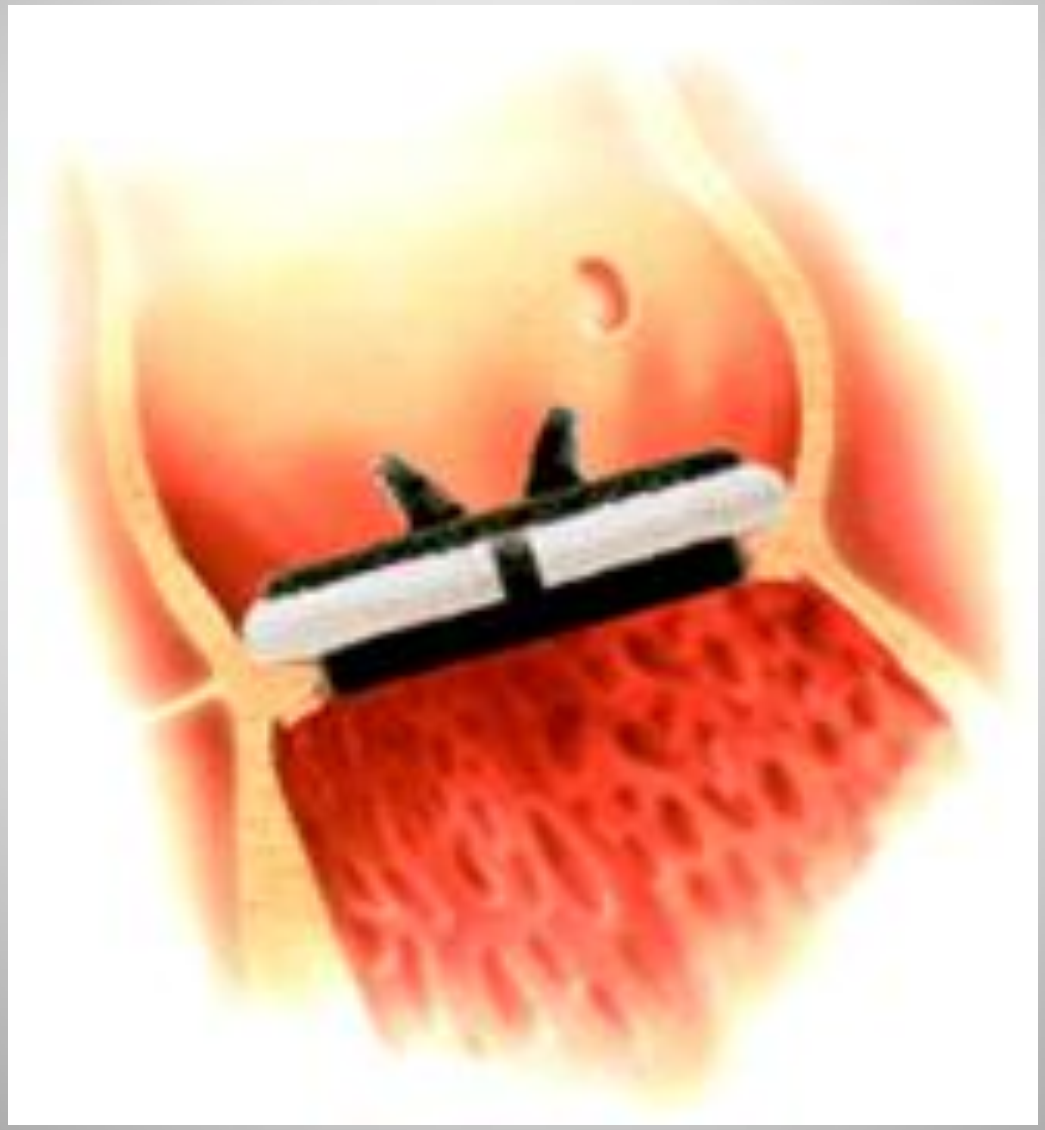
Bonn, Germany



Results After TAVI, 53 patients (36.3%) showed no signs of periAR and 71 patients (48.6%) showed only mild periAR, whereas 18 patients (12.3%) and 4 patients (2.7%) suffered from moderate and severe periAR, respectively. The AR index decreased stepwise from 31.7 ± 10.4 in patients without periAR, to 28.0 ± 8.5 with mild periAR, 19.6 ± 7.6 with moderate periAR, and 7.6 ± 2.6 with severe periAR ($p < 0.001$), respectively. Patients with AR index <25 had a significantly increased 1-year mortality risk compared with patients with AR index ≥25 (46.0% vs. 16.7%; $p < 0.001$). The AR index provided additional prognostic information beyond the echocardiographically assessed severity of periAR and independently predicted 1-year mortality (hazard ratio: 2.9, 95% confidence interval: 1.3 to 6.4; $p = 0.009$).

- Una **guarnizione** è un dispositivo meccanico di tenuta statico che viene posto in compressione tra due oggetti, in modo da prevenire il trafilamento di liquidi o gas.





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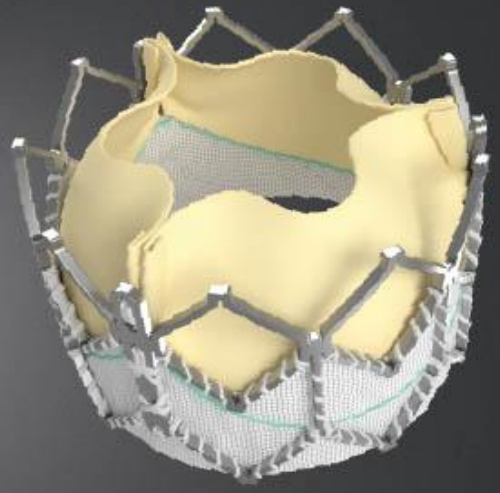

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Energy Loss Due to Paravalvular Leak With Transcatheter Aortic Valve Implantation

Ali N. Azadani, PhD, Nicolas Jaussaud, MD, Peter B. Matthews, BS, Liang Ge, PhD, T. Sloane Guy, MD, Timothy A. M. Chuter, MD, and Elaine E. Tseng, MD

Department of Surgery, University of California at San Francisco Medical Center, and San Francisco Veterans Affairs Medical Center, San Francisco, California

Background. Mild to moderate paravalvular leaks commonly occur after transcatheter aortic valve (TAV) implantation. Current TAVs match and may exceed hemodynamic performance of surgically implanted bioprostheses based on pressure gradient and effective orifice area. However, these hemodynamic criteria do not account for paravalvular leaks. We recently demonstrated that TAV implantation within 23 mm Perimount bioprostheses (Edwards Lifesciences, Irvine, CA) yields similar hemodynamics to the 23 mm Perimount valve. However, mild paravalvular leakage was seen after TAV implantation. The present study quantifies energy loss during the entire cardiac cycle to assess the impact of TAV paravalvular leaks on the ventricle.

Methods. Four TAVs designed to mimic the 23 mm SAPIEN valve (Edwards Lifesciences) were created. Transvalvular energy loss of 19, 21, and 23 mm Carpentier-Edwards bioprostheses were obtained in vitro within a pulse duplicator as a hemodynamic baseline (n = 4). The 23 mm TAVs were subsequently implanted within the 23 mm bioprostheses to assess energy loss due to paravalvular leak.

Results. The 23 mm bioprosthesis demonstrated the least energy loss (213.25 ± 31.35 mJ) compared with the 19 mm (330.00 ± 36.97 mJ, $p = 0.003$) and 21 mm bioprostheses (298.00 ± 37.25 mJ, $p = 0.008$). The TAV controls had similar energy loss (241.00 ± 30.55 mJ, $p = 0.17$) as the 23 mm bioprostheses. However, after TAV implantation, total energy loss increased to 365.33 ± 8.02 mJ significantly exceeding the energy loss of the 23 mm bioprosthesis ($p < 0.001$). Due to mild TAV paravalvular leakage, 39% of energy loss occurred during diastole.

Conclusions. Substantial energy loss during diastole occurs due to TAV paravalvular leakage. In the presence of mild paravalvular leakage, TAV implantation imposes a significantly higher workload on the left ventricle than an equivalently sized surgically implanted bioprosthesis.

(Ann Thorac Surg 2009;88:1857–63)

Conclusions. Substantial energy loss during diastole occurs due to TAV paravalvular leakage. In the presence of mild paravalvular leakage, TAV implantation imposes a significantly higher workload on the left ventricle than an equivalently sized surgically implanted bioprosthesis.

(Ann Thorac Surg 2009;88:1857–63)

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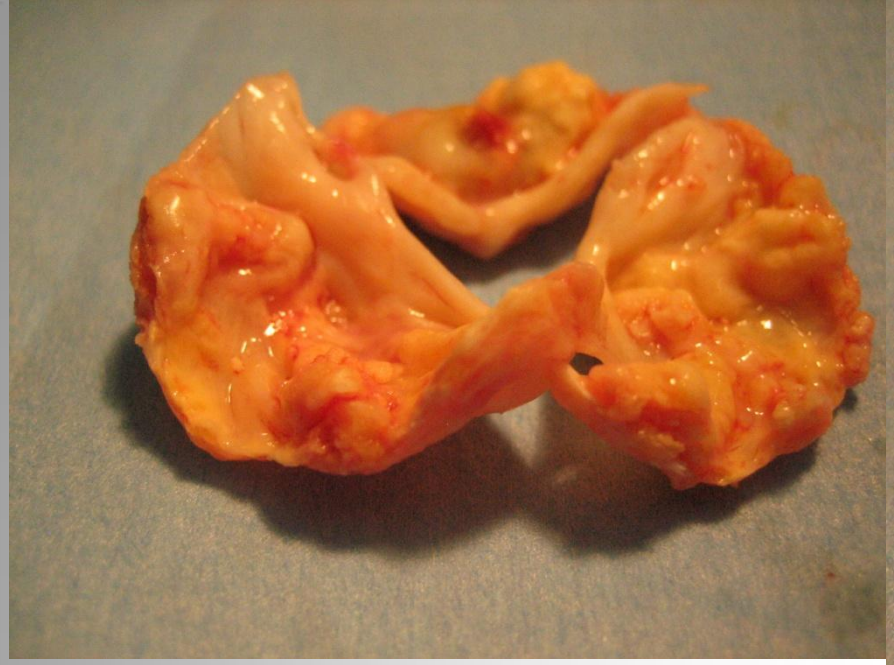
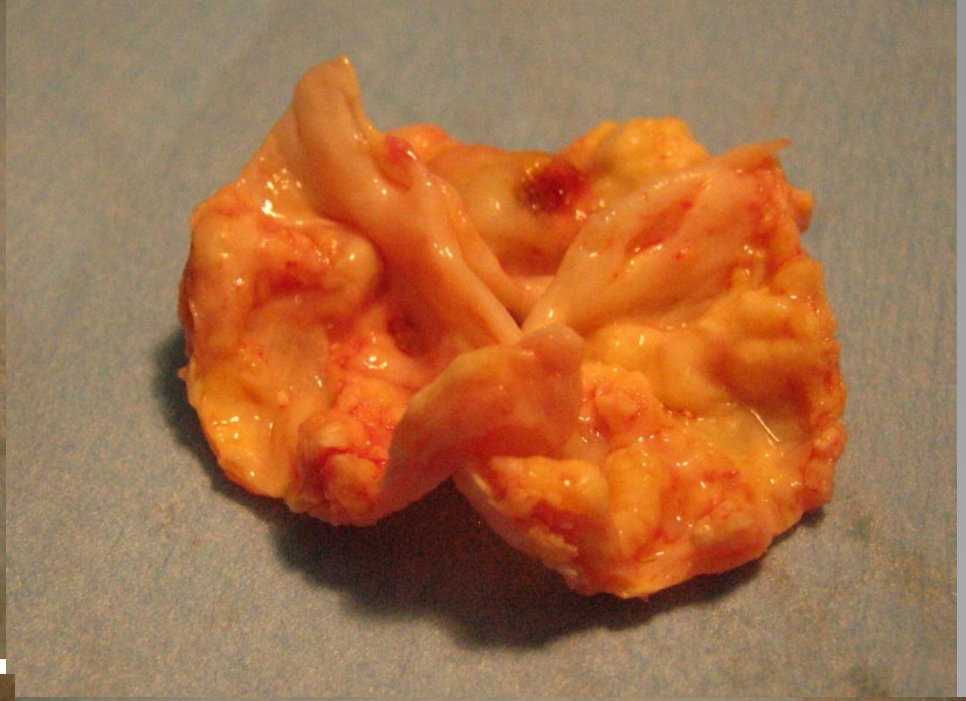
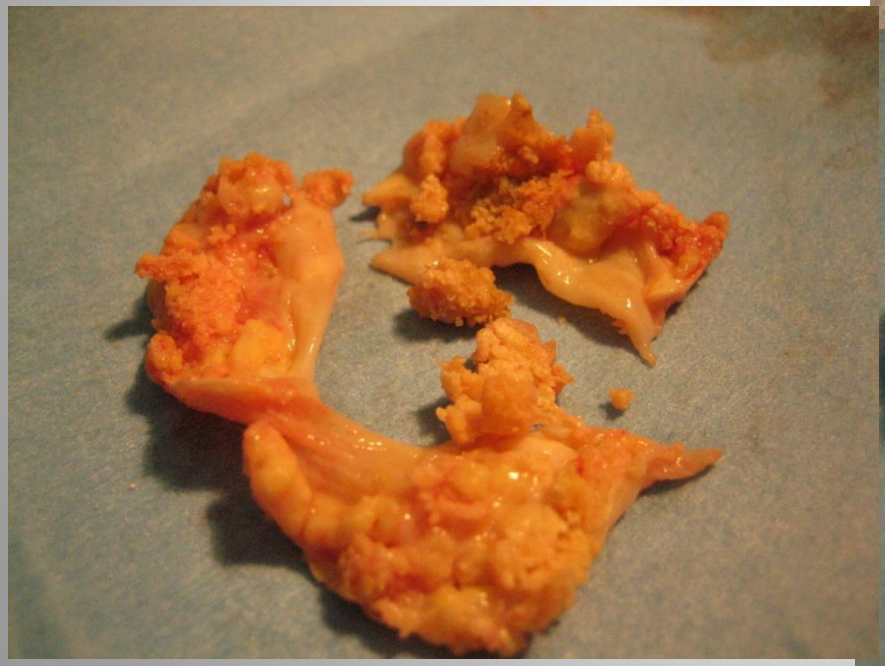
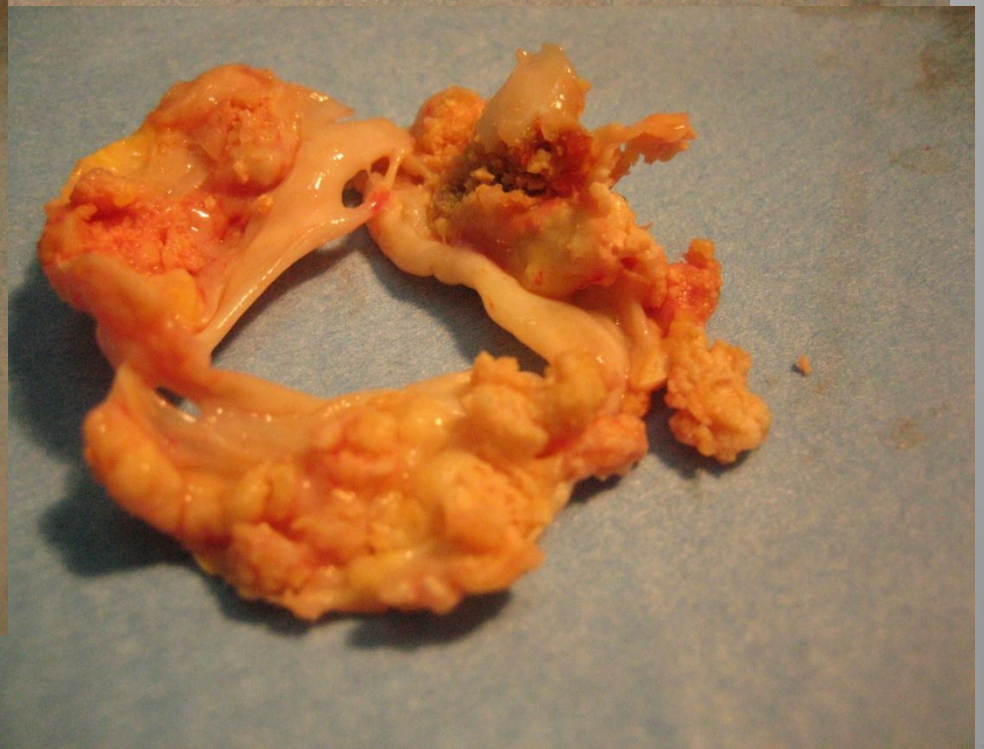

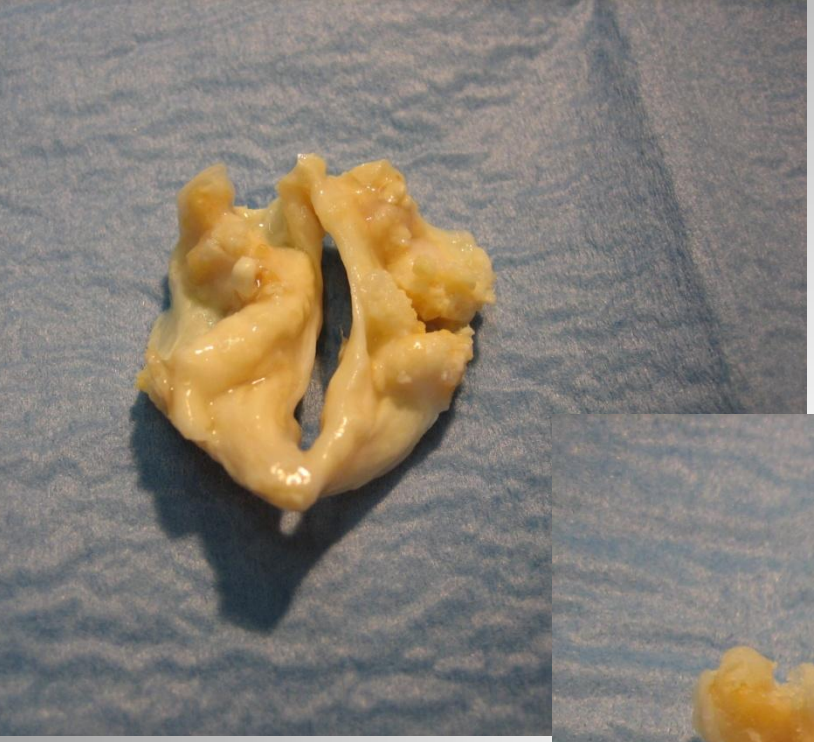

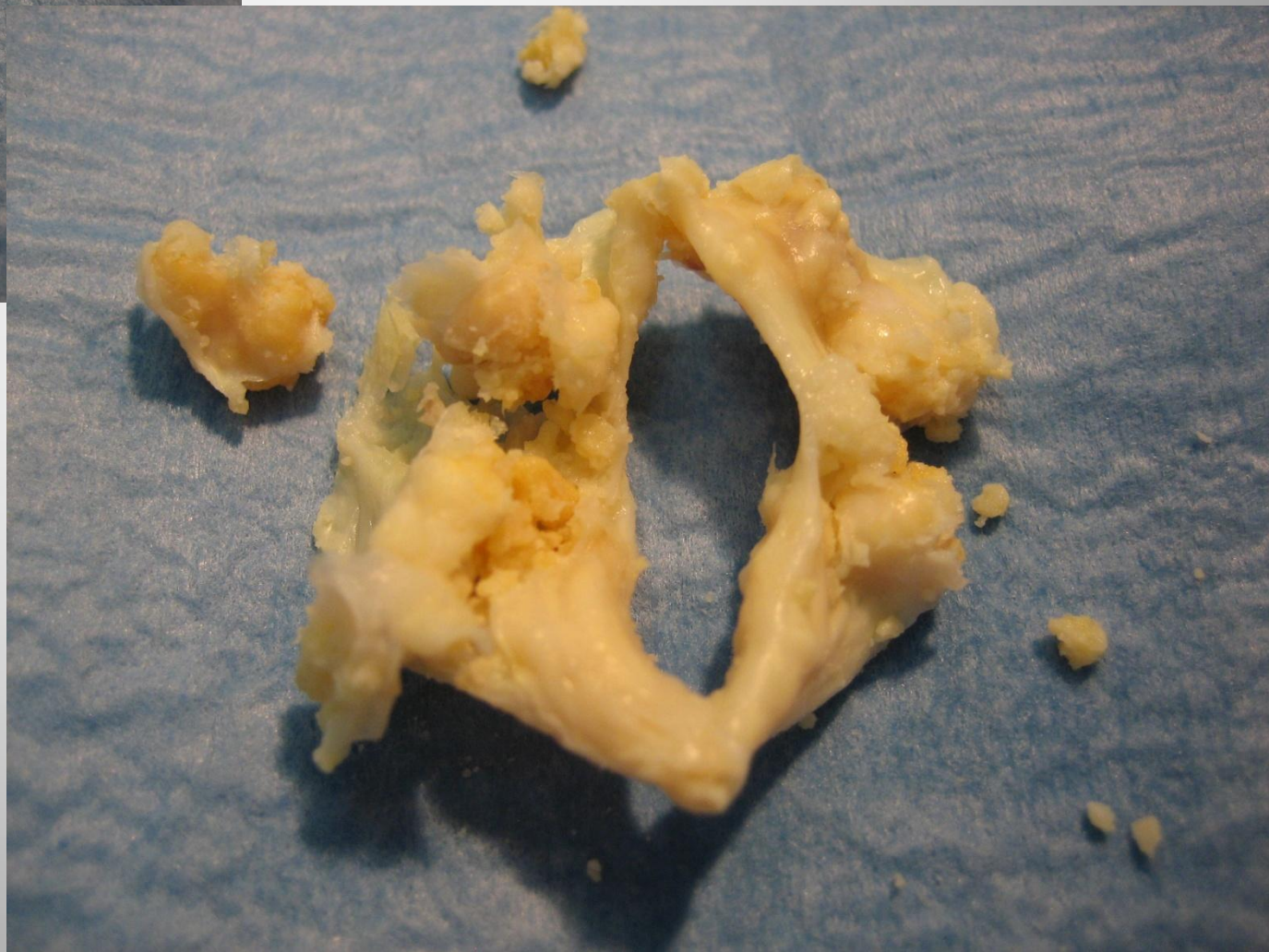

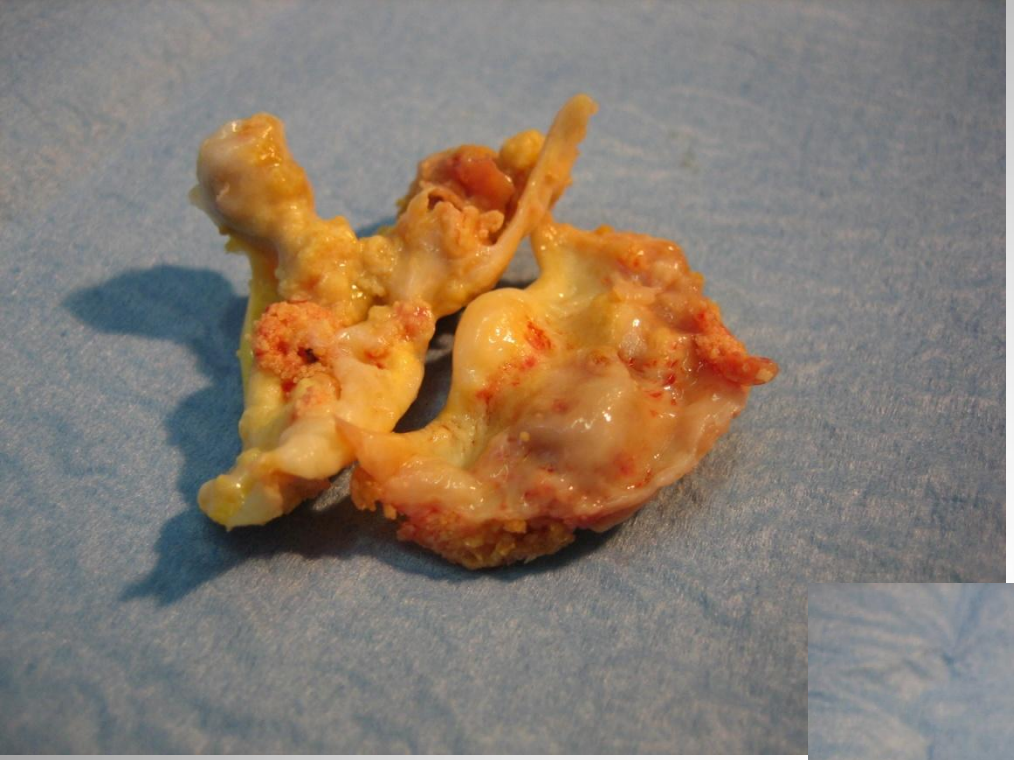

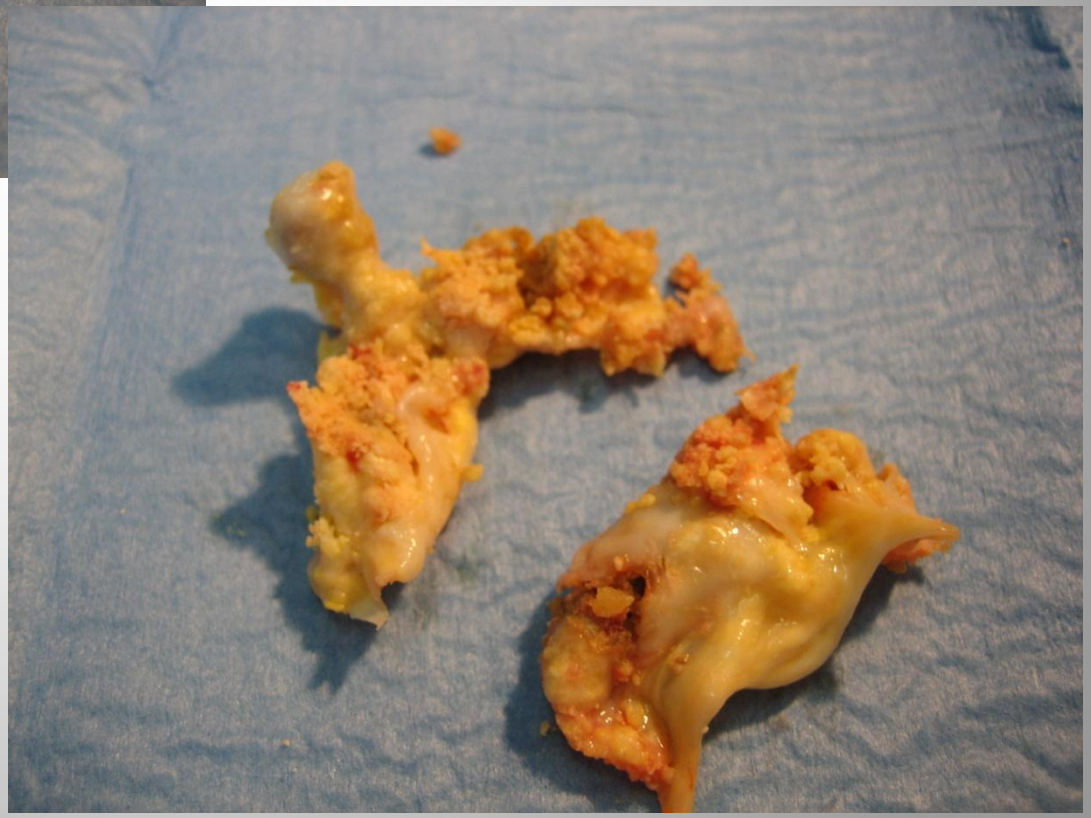

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Risk and Fate of Cerebral Embolism After Transfemoral Aortic Valve Implantation

A Prospective Pilot Study With Diffusion-Weighted Magnetic Resonance Imaging

Alexander Ghanem, MD,* Andreas Müller, MD,† Claas P. Nähle, MD,† Justine Kocurek, MD,* Nikos Werner, MD,* Christoph Hammerstingl, MD,* Hans H. Schild, MD, PHD,† Jörg O. Schwab, MD, PHD,* Fritz Mellert, MD,§ Rolf Fimmers, MD,‡ Georg Nickenig, MD, PHD,* Daniel Thomas, MD†

Bonn, Germany

Results

Thirty patients were enrolled; 22 completed the imaging protocol. Three patients (10%) had new neurological findings after TAVI, of whom only 1 (3.6%) had a permanent neurological impairment. Of the 22 TAVI patients with complete imaging data, 16 (72.7%) had 75 new cerebral lesions after TAVI presumed to be embolic. The NIHSS and NSE were not correlated with DW-MRI lesions.

Silent and Apparent Cerebral Ischemia After Percutaneous Transfemoral Aortic Valve Implantation

A Diffusion-Weighted Magnetic Resonance Imaging Study

Philipp Kahlert, MD*; Stephan C. Knipp, MD*; Marc Schlamann, MD; Matthias Thielmann, MD; Fadi Al-Rashid, MS; Marcel Weber, MD; Uwe Johansson, MD; Daniel Wendt, MD; Heinz G. Jakob, MD; Michael Forsting, MD; Stefan Sack, MD, FESC; Raimund Erbel, MD, FESC; Holger Eggebrecht, MD, FESC

Conclusions—Clinically silent new foci of restricted diffusion on cerebral magnetic resonance imaging were detected in almost all patients (84%) undergoing TAVI. Although typically multiple, these foci were not associated with apparent neurological events or measurable deterioration of neurocognitive function during 3-month follow-up. Further work needs to be directed to determine the clinical significance of these findings in a larger patient population. (*Circulation*. 2010;121:870-878.)

Circulation 2010;121;870-878

Risvolto economico

- Nel 2009 questa procedura ha pesato circa 20 milioni di euro sui bilanci delle regioni italiane (circa 1.000 casi) con un costo per materiale protesico analogo alla totalità degli interventi tradizionali (circa 10.000 casi)

«La mia prima scelta è Edwards»

LOMBARD ODIER

Società	Capitalizz. al 28/6/10	Eps 2010	P/e 2010	P/e 2011	P/sales 2010	Consensus di mercato
Edwards Lifesciences	6.128	1,78	30,38	25,75	4,26	Sovrappesare
Becton Dickinson*	16.137	5,13	13,48	12,32	2,12	Sovrappesare
Hologic Inc.*	3.643	1,18	11,92	10,82	2,18	Sovrappesare
Medtronic**	40.613	3,50	10,53	9,80	2,48	Sovrappesare
St Jude Medical	12.254	2,84	13,20	11,87	2,40	Sovrappesare

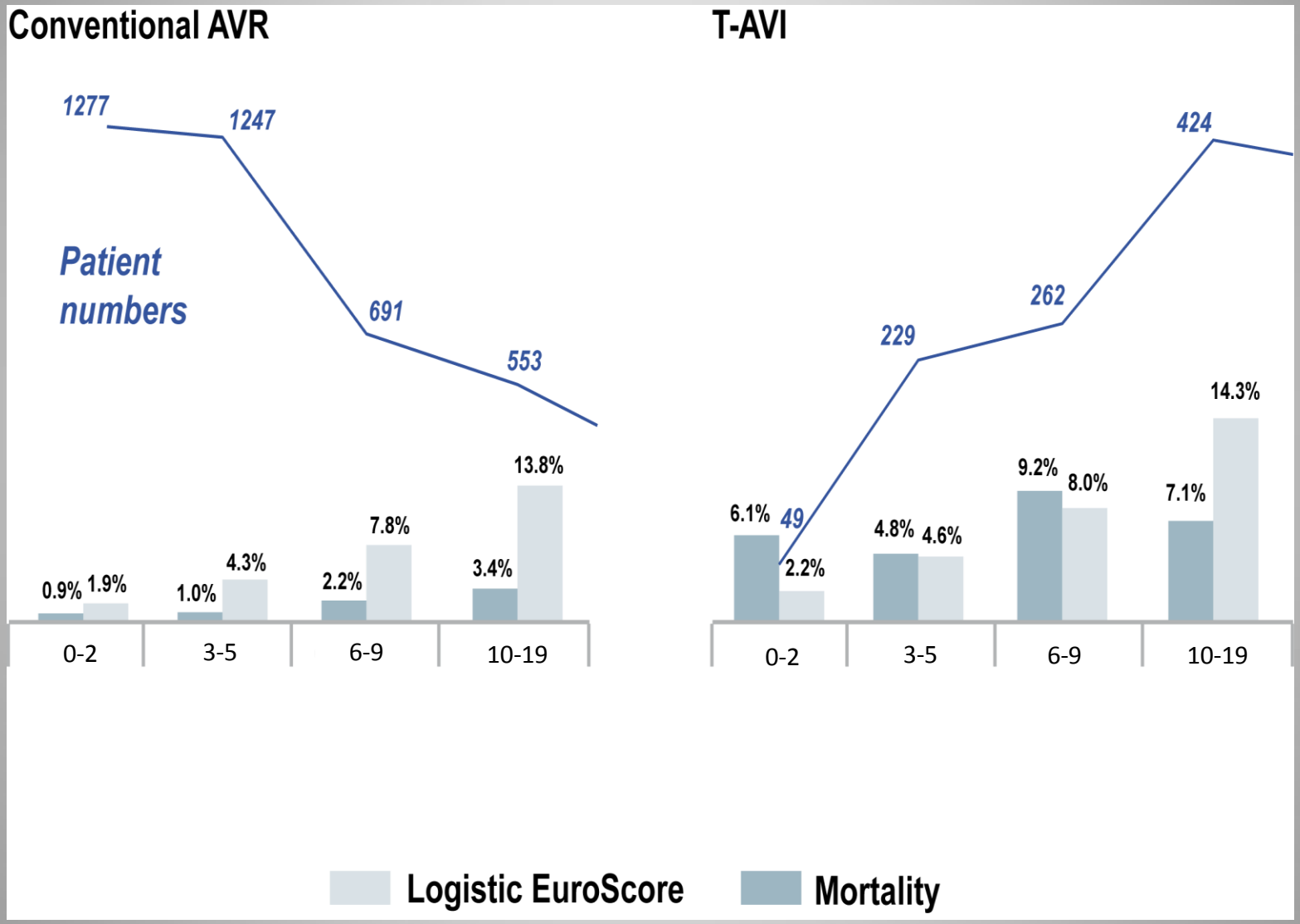
Note: in milioni di dollari; (*) chiusura esercizi: 30 settembre; (**) chiusura esercizi: 30 aprile; Eps=utile per azione; P/e=rapporto prezzo su utile; P/sales=rapporto prezzo su ricavi

Fonte: elaborazione Analisi mercati finanziari su dati Infinancials

Edwards Lifesciences

Edwards Lifesciences presenta un solido trend rialzista che si è sviluppato dai minimi del novembre 2008. I prezzi hanno da poco toccato nuovi massimi in area 56,00 prima di arretrare consolidando il recupero partito a maggio. La permanenza nel breve al di sopra di quota 50,00 appare strategica per garantire continuità al suddetto rialzo e porre i corsi nelle condizioni ideali per sferrare un nuovo attacco agli ostacoli presenti tra 55 e 56 dollari. Via libera in caso di successo su queste resistenze verso gli obiettivi a 60 e 65 dollari circa. Discese sotto quota 50 invece, amplierebbero la portata della correzione introducendo il ritorno sui citati minimi di maggio poco sotto quota 47 baluardi che dovranno scongiurare il proseguimento del ribasso in direzione di 42 dollari. A cura di Financial Trend Analysis

data from the German registry
early mortality according to the expected risk



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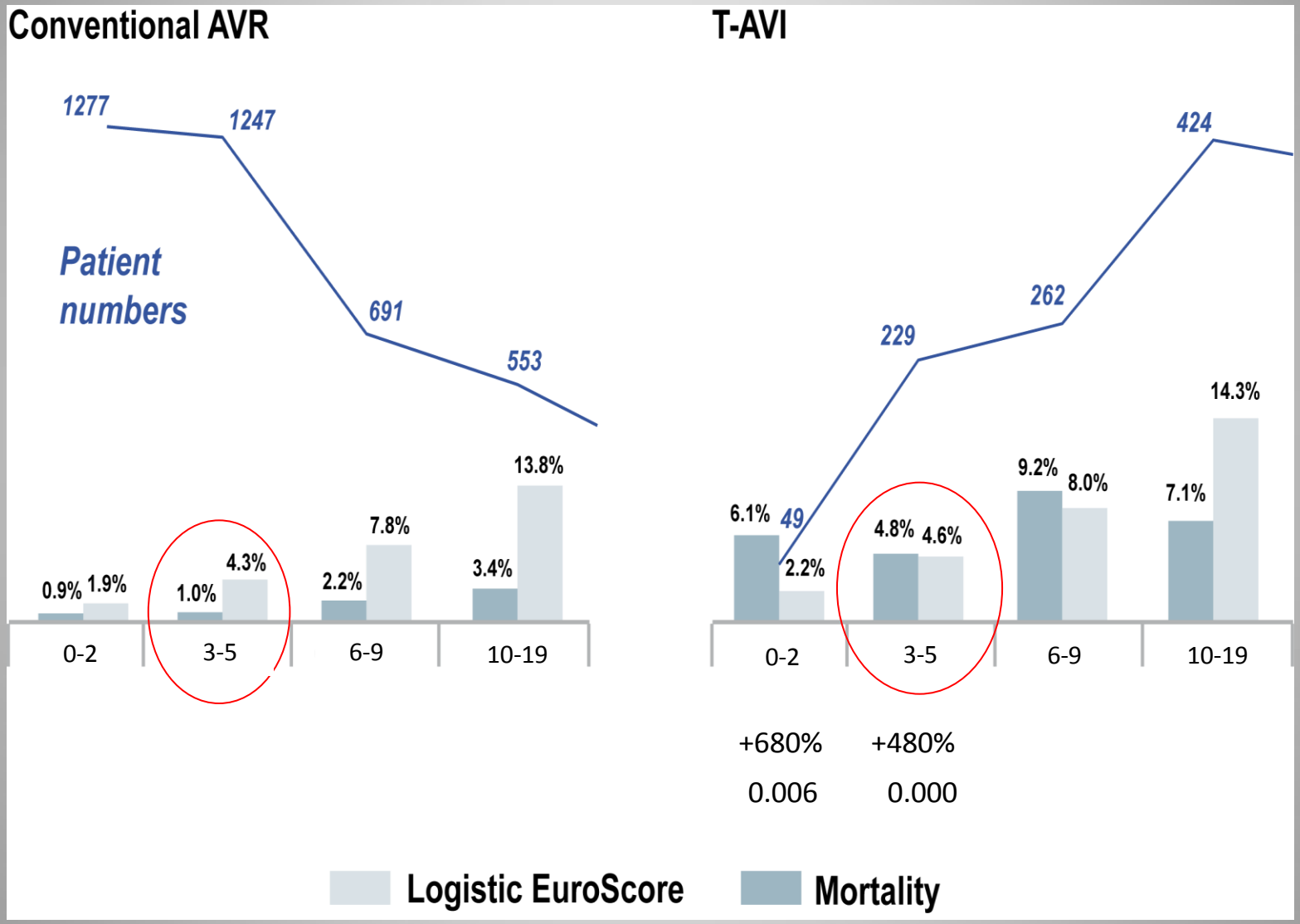

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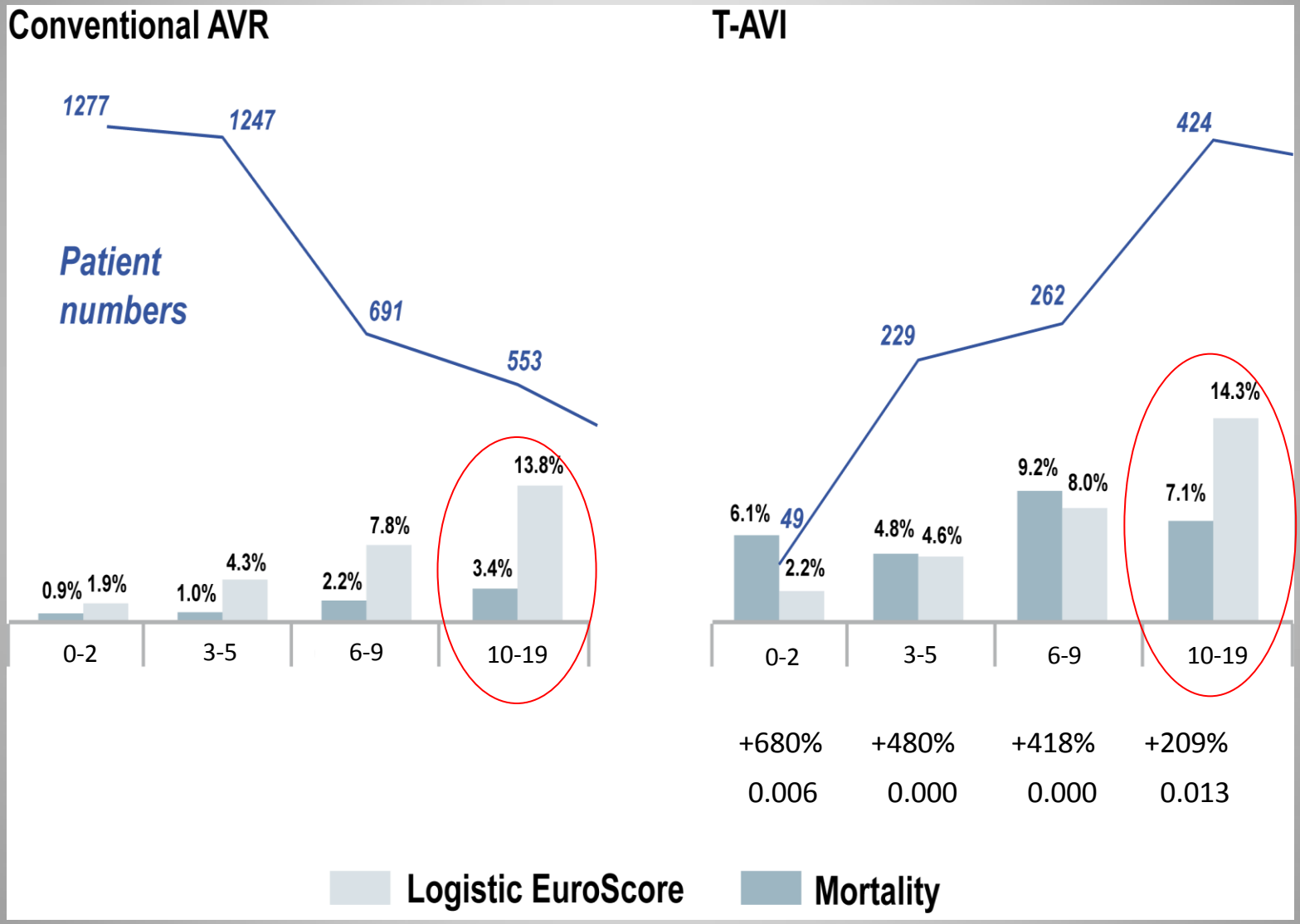


Patient Disposition and Long-Term Outcomes After Valve Surgery in Octogenarians

Linda Henry, PhD, RN, Linda Halpin, MSN, RN, Sharon Hunt, MBA, Sari D. Holmes, PhD, and Niv Ad, MD

Inova Heart and Vascular Institute, Falls Church, Virginia

Background. Valve surgery is performed routinely in octogenarians. This study explored variables affecting patient discharge disposition (home versus other facility) and whether patient disposition was related to long-term survival.

Methods. Patients 80 years or older who presented for aortic valve or mitral valve surgery from 2002 to 2010 were included. Baseline demographic, perioperative, and long-term outcomes were captured. Disposition was categorized into 2 groups; home (n = 184) or other facility (n = 123). The National Death Index and Social Security Death Index verified deaths.

Results. Mean age was 82.9 ± 2.5; 46% (140 of 307) were female. Discharge location logistic regression, adjusted for gender (odds ratio [OR] = 1.45, $p = 0.17$) and European System for Cardiac Operative Risk Evaluation score (OR = 1.09, $p = 0.10$), predicted that older (OR = 1.18, $p < 0.001$), unmarried (OR = 2.07, $p = 0.006$) patients with at least 1 major complication (OR = 3.86, $p < 0.001$) were more likely to be not discharged home. Kaplan-Meier analysis found significantly lower 1- and 2-year (85.8% vs 94.6%, $p = 0.009$; 80.1% vs 90.3%, respectively, $p = 0.01$) cumulative survival in patients not discharged home. A multivariate Cox proportional hazards model demonstrated poorer 1- and 2-year survival (hazard ratio [HR] = 2.56, $p = 0.04$; HR = 2.06, $p = 0.05$, respectively). Predictors of follow-up mortality for patients not discharged home were length of stay (OR = 1.06, $p = 0.03$) and any major complication (OR = 6.90, $p = 0.002$); lower body mass index was marginally significant (OR = 1.12, $p = 0.06$). The significant predictor for patients discharged home was length of stay (OR = 1.17, $p = 0.002$).

Conclusions. Octogenarians can expect excellent survival after valve surgery. Those not discharged home had poorer long-term survival. Therefore, adequate resources should be secured so sicker patients receive the appropriate level of care.

(Ann Thorac Surg 2012;94:744–50)

Table 1. Baseline Patient Characteristics Comparing Patients Discharged Home Versus Those Discharged to a Skilled Facility

Variable	Home (n = 184)	Skilled Facility (n = 123)	*p* Value
Age, years[a]	82 [3]	83 [4]	<0.001
Female	74 (40)	66 (54)	0.02
Married	117 (64)	52 (42)	<0.001
Ejection fraction	0.57 ± 0.12	0.56 ± 0.13	0.34
Congestive heart failure	69 (38)	71 (58)	<0.001
NYHA class I	8 (12)	0	
NYHA class II	24 (35)	18 (25)	
NYHA class III	29 (42)	35 (49)	
NYHA class IV	8 (12)	18 (25)	
Chronic pulmonary disease	18 (10)	33 (27)	<0.001
Diabetes	36 (20)	31 (25)	0.24
Renal failure with dialysis	3 (2)	3 (2)	0.69
Hypertension	148 (80)	98 (80)	0.87
Creatinine > 2 mg (%)	5 (3)	6 (5)	0.36
Previous cerebrovascular accident	15 (8)	10 (8)	1.00
Additive EuroSCORE	9.80 ± 2.28	10.38 ± 2.51	0.04
Logistic EuroSCORE	17.6 ± 12.8	21.4 ± 16.0	0.03
STS risk score (%)	6.6 ± 3.9	10.0 ± 9.6	0.001
Concomitant CABG	87 (47)	71 (58)	0.07
Concomitant Cox-maze	14 (8)	12 (10)	0.54
Cardiopulmonary bypass time	134.7 ± 52.0	138.4 ± 51.1	0.55

[a] Median [IQR], evaluated with the Mann-Whitney test.

(Ann Thorac Surg 2012;94:744–50)

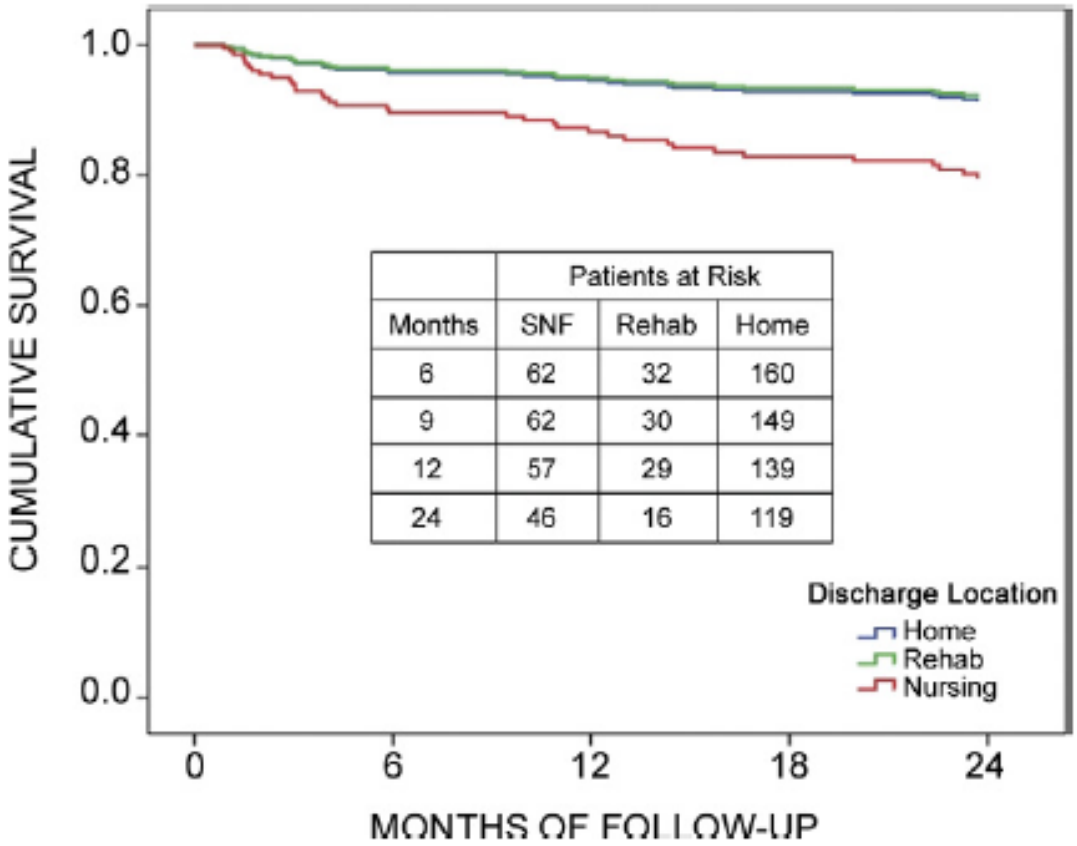


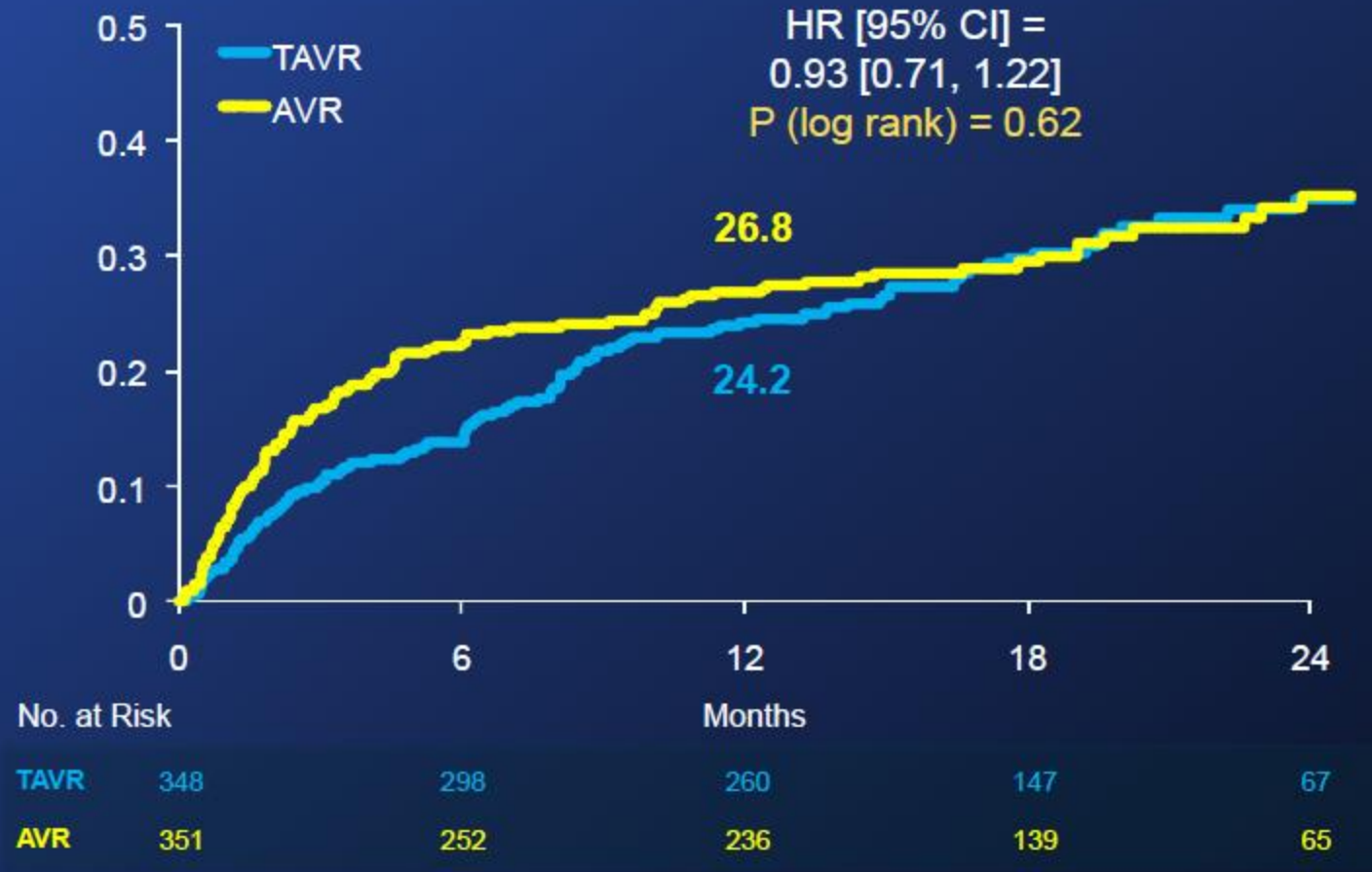
Fig 2. Comparison of 2-year survival among 3 discharge location groups, using Cox regression analysis. (SNF = skilled nursing facility.)

(Ann Thorac Surg 2012;94:744–50)

TAVI: Current Status

- TAVI provides a treatment option to patients that are at high risk or prohibitive risk for standard AVR.
- Randomized trial results will show if TAVI is merely an addition to the armamentarium or a fundamental change.
- Safety of the procedure needs to be further improved.
- There are a number of technical issues that need to be addressed.
- Expansion of the technique to lower risk patients would be premature without further data

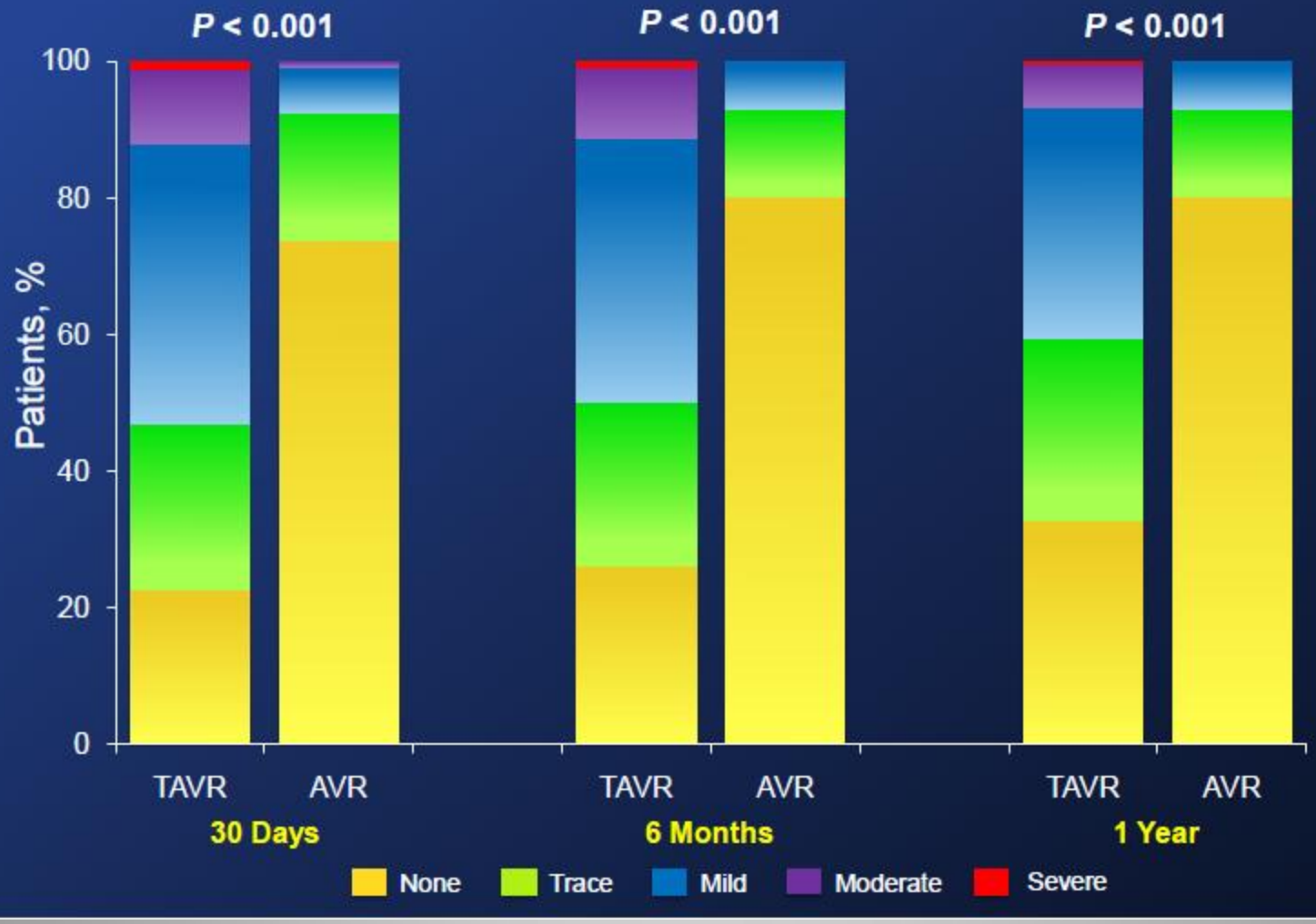
Primary Endpoint:
All-Cause Mortality at 1 Year



Neurological Events at 30 Days and 1 Year
All Patients (N=699)

Outcome	30 Days			1 Year		
	TAVR (N = 348)	AVR (N = 351)	p-value	TAVR (N = 348)	AVR (N = 351)	p-value
All Stroke or TIA – no. (%)	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
TIA – no. (%)	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
All Stroke – no. (%)	16 (4.6)	8 (2.4)	0.12	20 (6.0)	10 (3.2)	0.08
Major Stroke – no. (%)	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07
Minor Stroke – no. (%)	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84
Death/maj stroke – no. (%)	24 (6.9)	28 (8.2)	0.52	92 (26.5)	93 (28.0)	0.68

Paravalvular Aortic Regurgitation



Prothèses : la loi de la jungle

Par Anne Jouan - le 04/01/2012

Le scandale des implants PIP a levé le voile sur certaines pratiques. Enquête sur un monde où les contrôles sont quasi inexistants et la pression de l'industrie très forte.

Selon nos informations, les implants mammaires de PIP ne seraient que la face émergée de l'iceberg dans le monde des «dispositifs médicaux», appellation qui regroupe tous les produits de type prothèses, pacemaker, ou respirateurs artificiels.

L'exemple des valves cardiaques percutanées

Le Dr Rachid Zegdi, chirurgien cardiaque à l'hôpital européen Georges Pompidou (Paris) explique que «très peu d'études comparent les valves entre elles. Le choix n'est donc pas scientifique, ce qui est ennuyeux». Et de donner l'exemple des valves percutanées du géant américain Edwards dont la première a été posée en 2002. Ces dernières permettent d'éviter une opération lourde puisque la valve est installée de la même façon qu'un stent, en passant par une artère. Ce type d'intervention était à l'origine réservée aux patients «inopérables», or de plus en plus demandent à bénéficier de ces valves, y compris des malades parfaitement opérables. «Il y a une énorme pression de la part de l'industrie pour poser cette prothèse plutôt que les valves traditionnelles. Alors que nous n'avons pour l'instant aucun recul et qu'il va très vraisemblablement y avoir des problèmes avec elles», note le Dr Zedgi.

Approval processes

Given the enthusiasm with which the procedure has been adopted, we might expect the evidence for its efficacy to be solid. But a health technology assessment we carried out, commissioned by the Belgian government, concluded that the Belgian health authorities should pay for TAVI in only a minority of patients (10%) of those currently considered for treatment—those who are deemed inoperable for technical reasons such as a series of previous operations or irradiation of the chest wall

BMJ

BMJ 2012;345:e4710 doi: 10.1136/bmj.e4710 (Published 31 July 2012)

ANALYSIS

Transcatheter aortic valve implantation (TAVI): risky and costly

Many of the 40 000 transcatheter procedures so far carried out cannot be justified on medical or cost effectiveness grounds. **Hans Van Brabandt**, **Mattias Neyt**, and **Frank Hulstaert** examine why practice has gone beyond the evidence

Hans Van Brabandt *researcher*[1 2], Mattias Neyt *researcher*[1], Frank Hulstaert *researcher*[1]

Our rigorous analysis of all the available data, in combination with a study of real world TAVI practice in Europe, led us to conclude that the arguments supporting the widespread use of TAVI do not stand up to scrutiny. In addition, the PARTNER trial seems to have important problems, the most relevant being publication bias and lack of data transparency, unbalanced patient characteristics, and incompletely declared conflicts of interest.

Taken together, these results suggest that TAVI can be justified for inoperable patients on clinical grounds, though cost effectiveness calculations are more equivocal. But even this conclusion is thrown into doubt by a follow-up study authorised by the FDA, in which 41 inoperable patients were randomised to TAVI and 49 to standard therapy. This study remains unpublished, and our attempts to gain access to further details have been rebuffed by the FDA and the study sponsor. But the data presented at an FDA meeting on 20 July 2011 showed that the TAVI patients fared worse than those given standard therapy (one year mortality 34.3% *v* 21.6%).[15]

Given our failure to make progress with the FDA or the sponsor, we approached the *NEJM* which had published the PARTNER trial. We put our objections to the *NEJM*, which passed them on to the investigators. Their response convinced the *NEJM* editors that "while each of the points we raised deserved a thoughtful review, they did not, either individually or together, fundamentally place the findings of the PARTNER trial in serious doubt." Asked what the responses of the investigators had been, *NEJM* responded that it had not requested permission from them to pass them on, since they were intended for its own confidential evaluation. We were recommended to request this information directly from the study sponsor, which we did, to no avail.

Our concerns about the PARTNER trial go further than this, however. Published data on the inoperable patients, who had the most convincing results, show that the treatment and control groups are unbalanced in a way that would favour TAVI. The control group contained more patients with comorbidities, more who had had a previous heart attack, and more who were classified as frail than the TAVI group. There were fewer patients with an extensively calcified aorta. All these differences could have arisen from a flawed randomisation or by chance; but since they favour TAVI, an analysis that adjusted for prognosis at baseline would have produced a more realistic estimate of the effect size.

Percutaneous Valve Technologies, for $125m in 2004.[18] The *NEJM* paper article acknowledges under Leon´s conflicts of interest "2004—payment for equity holdings as company was sold to Edwards Lifesciences." But it does not mention that he was to receive three further payments on the achievement of three milestones: successful treatment of 50 patients, regulatory approval in Europe, and limited approval in the US.[18] In an interview with *Businessweek*, Leon said that he had donated his milestone payments to a Manhattan school.[18]

Concerns about transapical TAVI were heightened by the early termination of a Danish trial called STACCATO,[23] which compared transapical TAVI against conventional surgery. Five of 34 TAVI patients and only one of 36 surgically treated patients had either died or had a major stroke or renal failure within 30 days, prompting the data safety monitoring board to call a halt. This discouraging result was reported at the 2011 transcatheter cardiovascular therapeutics conference in San Francisco and drew criticism from Michael Mack, of the University of Texas at Dallas, who said the study was poorly designed and poorly executed.[24] Mack, an investigator in the PARTNER trial, said: "I think there is some misinformation here, based on an invalid trial design, that is likely to hurt the field."

Based on current evidence, and considering efficient use of limited resources, it is difficult to see how healthcare payers can justify reimbursing TAVI for patients suitable for surgery, given that the risk of stroke is twice as high after TAVI. In addition, TAVI is much more expensive, on average about €20 000 more per patient in our analysis of Belgian data. Based on observational data, the costs during the initial hospital admission, inclusive of an Edwards Sapien valve of €18 000, are on average €43 600 for TAVI versus €23 700 for surgical valve

Conclusions: It is inappropriate to consider reimbursement of TAVI for high-risk operable patients. Reimbursing TAVI in inoperable patients in essence is a political decision. From an economic perspective, it would be prudent to first target patients that are inoperable because of anatomical prohibitive conditions. **In the search for evidence, the authors identified non-published negative results from a randomised controlled TAVI trial**.

The study sponsor
should be more willing to share this information to allow balanced evaluations and policy recommendations. Payers should require these data before taking reimbursement decisions

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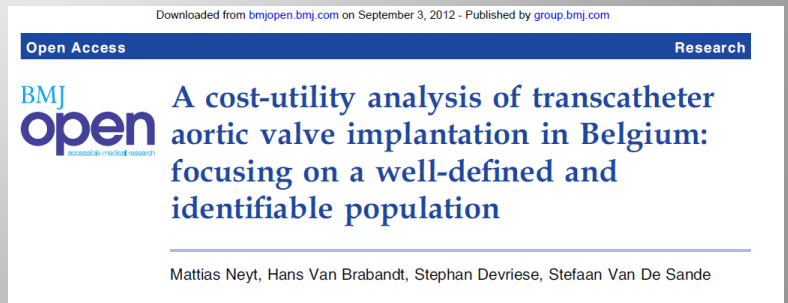


Open Access Research

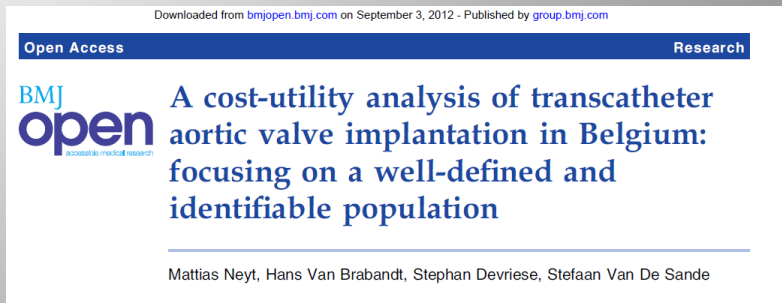
BMJ open

A cost-utility analysis of transcatheter aortic valve implantation in Belgium: focusing on a well-defined and identifiable population

Mattias Neyt, Hans Van Brabandt, Stephan Devriese, Stefaan Van De Sande

- **Key messages**

In high-risk operable patients, surgical aortic valve replacement and TAVI are associated with similar mortality rates at 1 year. However, there is a twice as high rate of stroke after TAVI. From an economic point of view, the less invasive nature of the TAVI procedure does not weigh against the extra costs of about €20 000 per patient



Open Access Research

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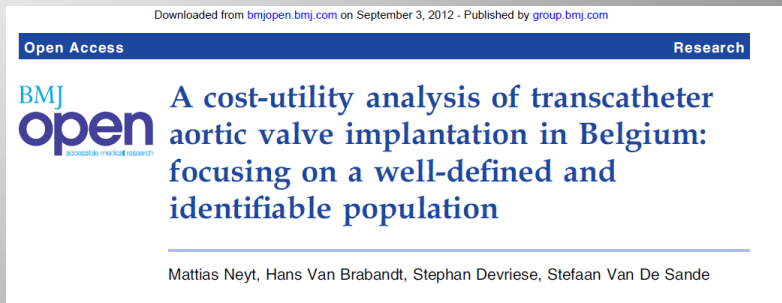
A cost-utility analysis of transcatheter aortic valve implantation in Belgium: focusing on a well-defined and identifiable population

Mattias Neyt, Hans Van Brabandt, Stephan Devriese, Stefaan Van De Sande

In inoperable patients, TAVI significantly reduces the rate of death from any cause as compared with a non-surgical approach. The ICER is about €45 000 per QALY gained. Nevertheless, a distinction should be made between inoperability for anatomic versus medical reasons. TAVI offers more value for money in the former patient group with ICERs decreasing more than €10 000 per QALY



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A cost-utility analysis of transcatheter aortic valve implantation in Belgium: focusing on a well-defined and identifiable population

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Conclusions (1)
PARTNER B

- The primary endpoint of the trial was met:
  - In patients with aortic stenosis at high risk for operation, TAVR was non-inferior to AVR for all-cause mortality at 1 year (24.2% vs. 26.8%, p=0.001 for non inferiority)
  - Transfemoral TAVR subgroup was also non-inferior to AVR (p=0.002 for non-inferiority)
- Death at 30 days was lower than expected in both arms of the trial:
  - TAVR mortality (3.4%) was the lowest reported in any series, despite an early generation device and limited previous operator experience
  - AVR mortality (6.5%) was lower than the expected operative mortality (11.8%)

Conclusions (2)
PARTNER B

- Both TAVR and AVR were associated with important but different peri-procedural hazards:
  - Major strokes at 30 days (3.8 vs. 2.1%, p=0.20) and one year (5.1% vs. 2.4%, p=0.07) and major vascular complications were more frequent with TAVR (11.0% vs. 3.2%, p<0.001)
  - Major bleeding (9.3% vs. 19.5%, p<0.001) and new onset atrial fibrillation (8.6% vs. 16.0%, p<0.001) were more frequent with AVR
- TAVR and AVR are both acceptable therapies in these high-risk patients; differing peri-procedural hazards should influence case-based decision-making

Conclusions (3)
PARTNER B

- Symptom improvement (NYHA class and 6-min walk distance) favored TAVR at 30 days and was similar to AVR at one year
- Echo findings indicate:
  - Small hemodynamic benefit with TAVR vs. AVR at 1 year (mean gradient p=0.008, AVA p=0.002)
  - Increased para-valvular regurgitation associated with TAVR ($p<0.001$)
- Preliminary subgroup analyses should be interpreted cautiously:
  - Possible TAVR benefit in women and patients without prior CABG

- A **gasket** is a **mechanical seal** that fills the space between two mating surfaces, generally to prevent leakage from or into the joined objects while under compression. Gaskets allow *"less-than-perfect"* mating surfaces on machine parts where they can fill irregularities. Gaskets are commonly produced by cutting from sheet materials, such as gasket paper, rubber, silicone, metal, cork, felt, neoprene, nitrile rubber, fiberglass, or a plastic polymer (such as polychlorotrifluoroethylene)