

THE "OLD SURGERY" IN THE TAVI ERA: WAS IT REALLY SO BAD?

THE EMILIA ROMAGNA EXPERIENCE

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Giovanni Andrea⁵, Pignini Florio⁴, Zussa Claudio³, Ghidoni Italo¹, Pacini
Davide²**

XXVI NATIONAL
CONGRESS

Rome, November 10-13, 2012



- ¹ Hesperia Hospital Modena
- ² Policlinico S. Orsola-Malpighi Bologna
- ³ Gruppo Villa Maria
- ⁴ Villa Torri Bologna
- ⁵ Azienda Ospedaliero-Universitaria Parma
- ⁶ Agenzia Sanitaria e Sociale Emilia Romagna

Aim of the study

review the Emilia Romagna experience

(30-day mortality, in-hospital mortality, six-year survival)

with regional patients eligible for TAVI

but undergoing the “OLD” isolated AVR

Inclusion criteria

n Inclusion criteria:

- Age > 75 and LogEuroSCORE >20% (FIC-SICCH) *Group 1***
- Age > 85 and LogEuroSCORE >10% (FIC-SICCH) *Group 2***
- LogEuroSCORE >20% (ESC-EACTS-EAPCI) *Group 3***

n Emilia Romagna cardiac surgery 2003-2011

n *Isolated AVReplacement* in pts. with severe AV stenosis (active IE and isolated AR excluded)

n *Only regional patients (100% follow-up)*

HOME > GOVERNO CLINICO > VALUTAZIONE DELLA QUALITÀ DELL'ASSISTENZA NELLE AZIENDE SANITARIE: DATABASE E INDICATORI

DATABASE REGIONALE DEGLI INTERVENTI DI CARDIOCHIRURGIA (RERIC)

REFERENTE: Daniela Fortuna
e-mail: d.fortuna@regione.emilia-romagna.it

Dal 2002 è stato avviato in Emilia-Romagna il Sistema di Monitoraggio dell'Attività CardioChirurgica (SMACCh) con l'obiettivo di valutare la qualità dell'assistenza in tale ambito e di determinare l'impatto sulla pratica clinica di nuove metodiche, come a suo tempo è stato possibile per l'introduzione di tecniche meno invasive di rivascolarizzazione coronarica (Stent a rilascio di farmaco).

HOME > GOVERNO CLINICO > VALUTAZIONE DELLA QUALITÀ DELL'ASSISTENZA NELLE AZIENDE SANITARIE: DATABASE E INDICATORI > DATABASE REGIONALE DEGLI INTERVENTI DI CARDIOCHIRURGIA (RERIC)

COLLABORATORI E CENTRI PARTECIPANTI

Collaboratori:

Laura Belotti - ASR

Centri partecipanti-referenti:

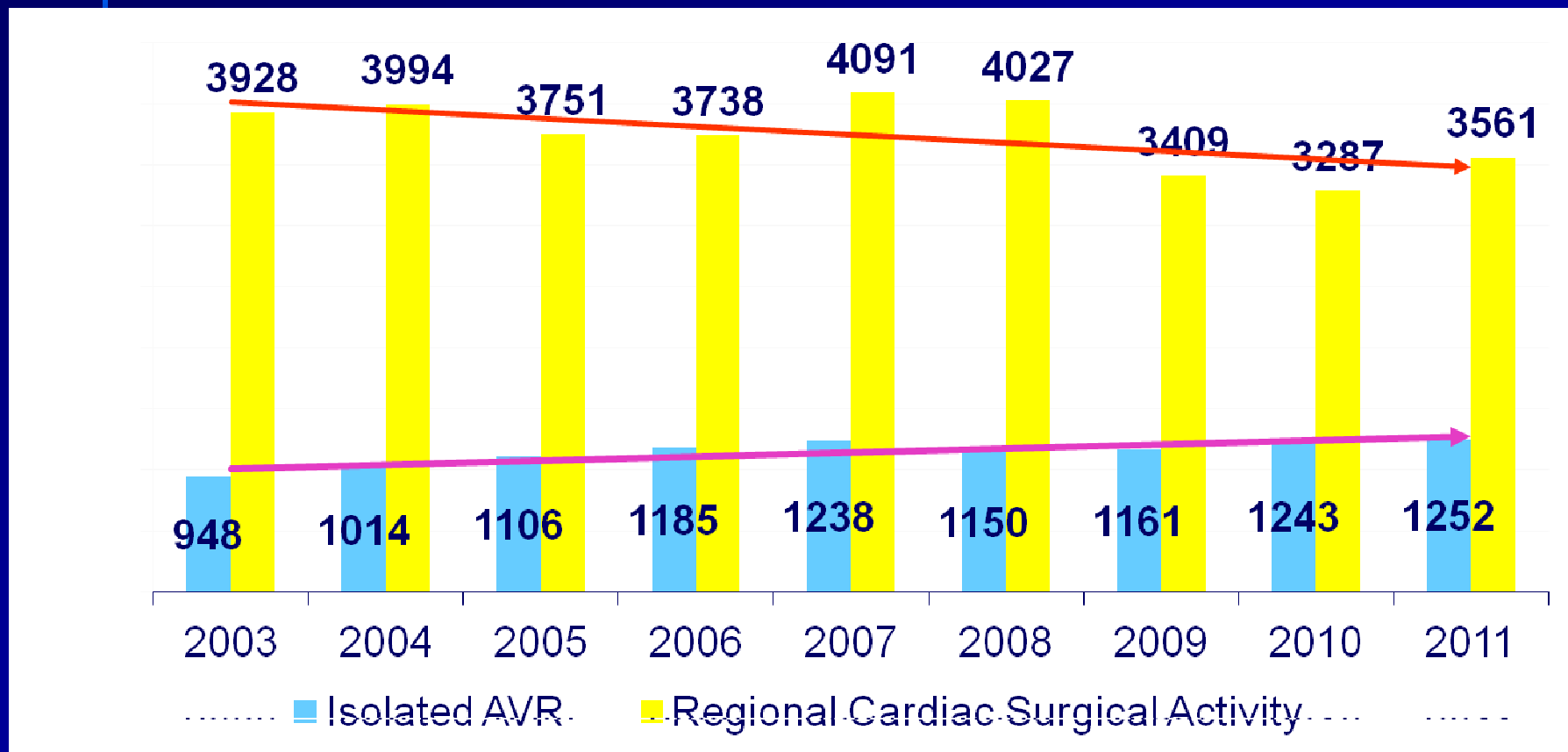
Salus Hospital di Reggio Emilia - Claudio Zussa e Maria C
Hesperia Hospital di Modena - Italo Ghidoni e Davide Gabbieri
Villa Torri di Bologna - Florio Pigni
Villa Maria Cecilia di Cotignola - Claudio Zussa e Maria Cristina Barattoni
Azienda Ospedaliera Universitaria di Parma - Andrea Contini
Azienda Ospedaliera Universitaria di Bologna - Davide Pacini



RERIC registry

Jan. 2003 – Dec. 2011

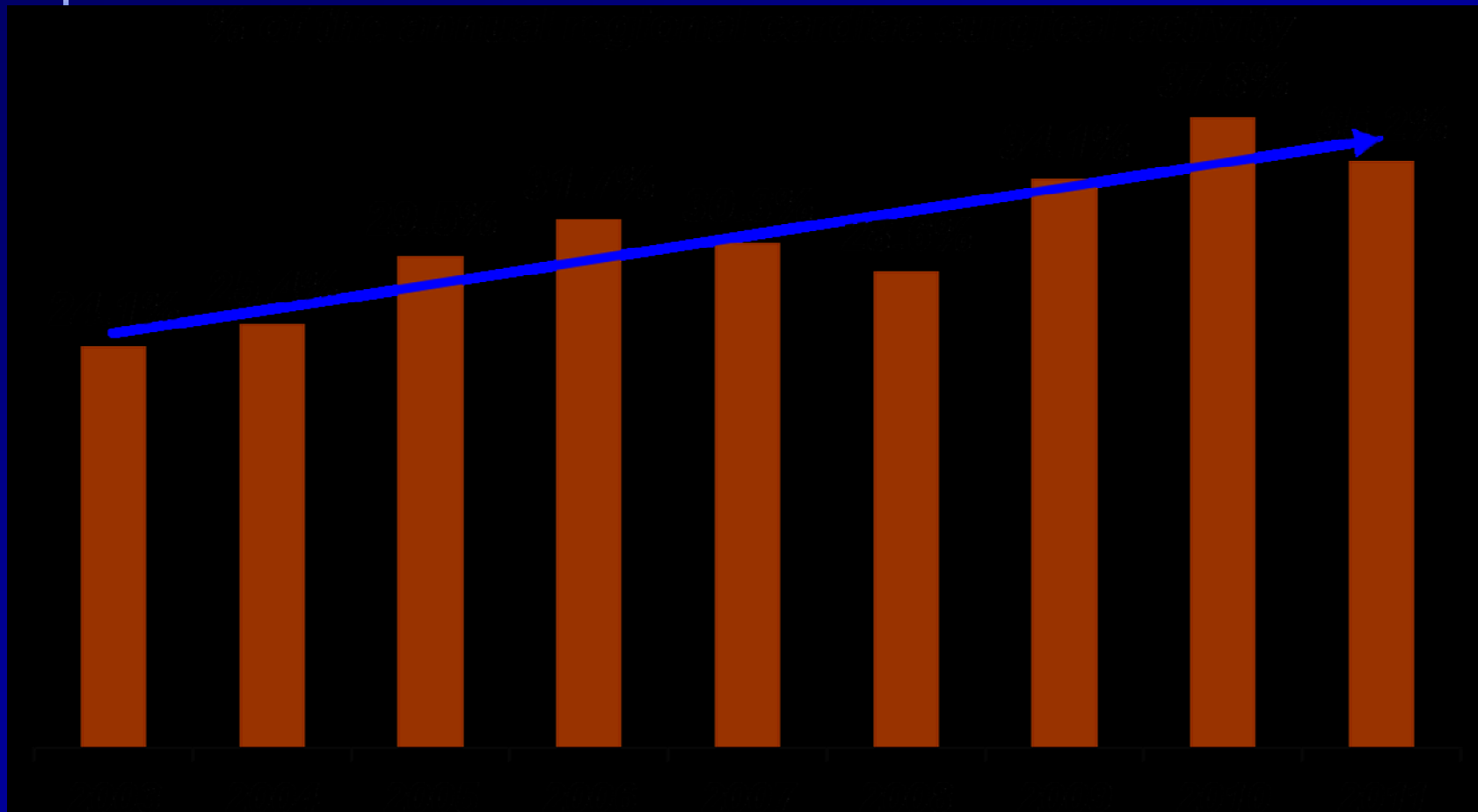
Isolated Aortic Valve Replacement



RERIC registry

Jan. 2003 - Dec. 2011

Isolated Aortic Valve Replacement



Division of Cardiac Surgery, Hesperia Hospital, Modena, Italy

Cardiac Surgery in Patients eligible for TAVI

RERIC 2003-2011

<i>Regional Patients eligible for TAVI</i>	N° of operations	% of isolated AVR
<i>Group 1: età>75 e logES>20%</i>	158	1.53
<i>Group 2: età>85 e logES>10%</i>	71	0.69
<i>Group 3: logES>20%</i>	199	1.93

Cardiac Surgery in Patients eligible for TAVI

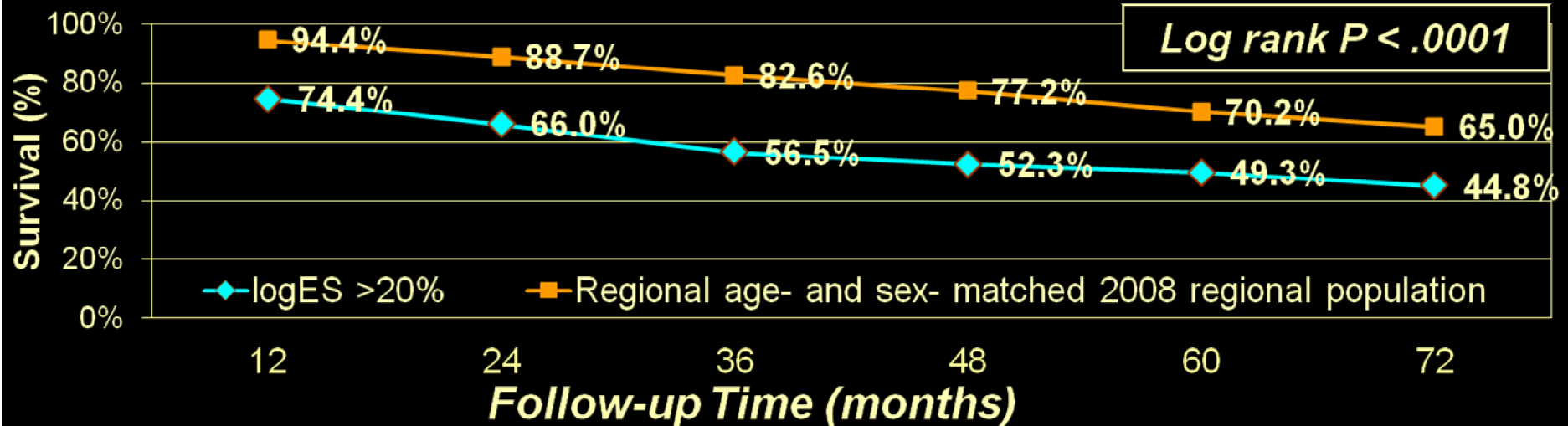
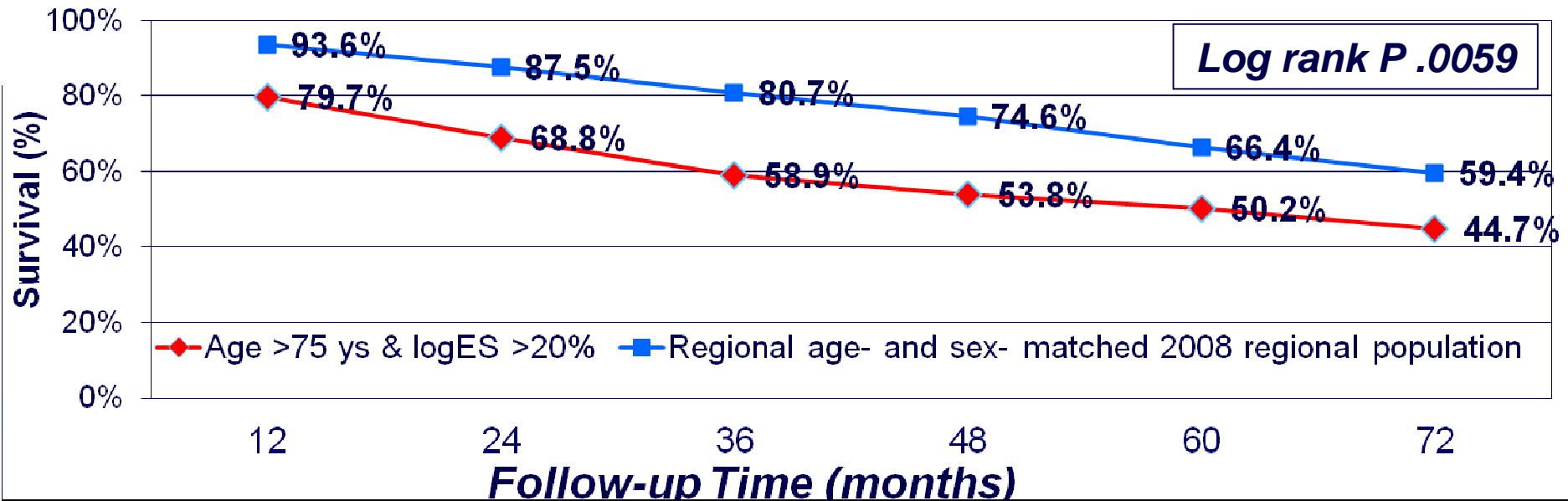
RERIC 2003-2011

Mortality

Regional Patients eligible for TAVI *In-hospital (%)* *30-day (%)*

<i>Group 1: age>75 & logES>20%</i>	10.5	9.8
<i>Group 2: age>85 & logES>10%</i>	9.2	9.2
<i>Group 3: logES>20%</i>	12.4	10.7

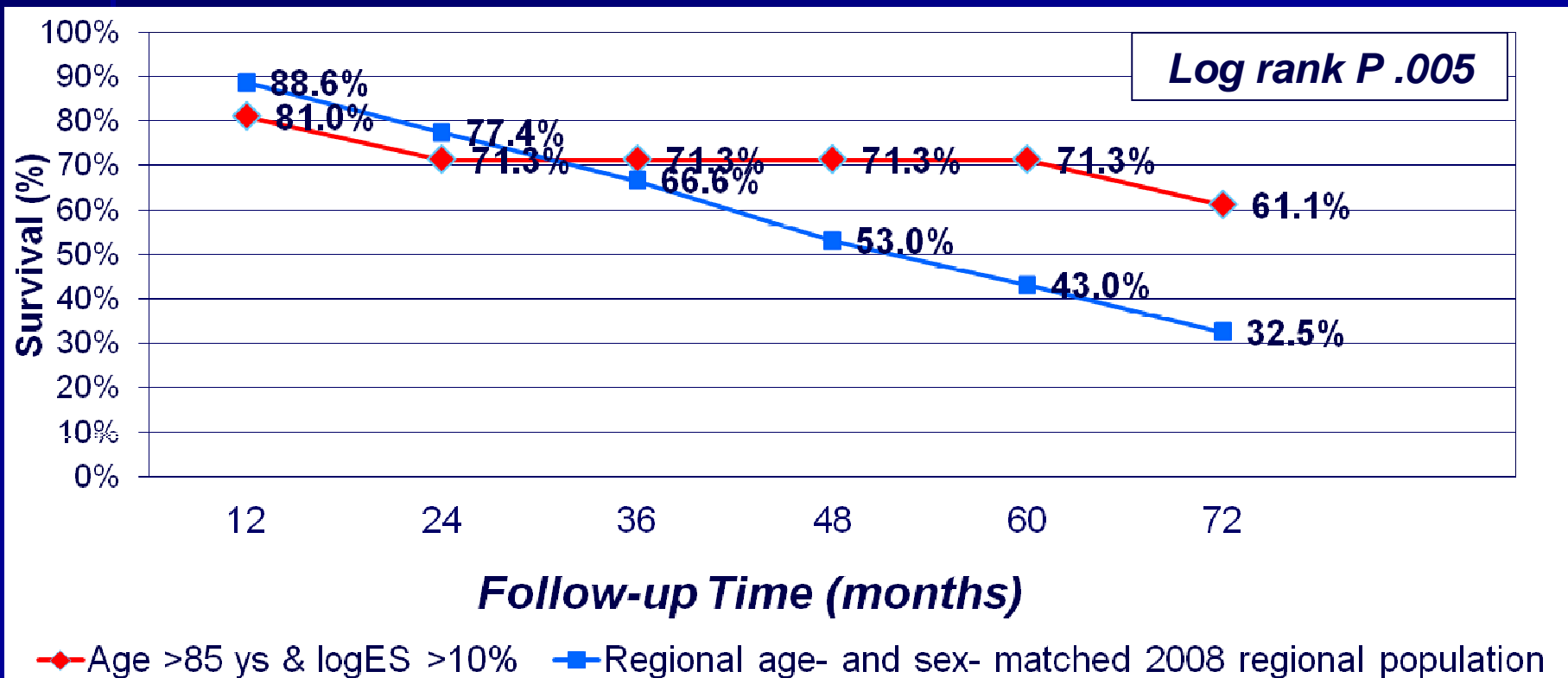
Six-year survival of the study population compared with expected survival of age- and sex- matched 2008 regional population



Cardiac Surgery in Patients eligible for TAVI

RERIC 2003-2011

*Six-year survival of the **Group 2** study population compared with expected survival of age- and sex- matched 2008 regional population*



Comparison with TAVI?

- ***Single-center experience***
- ***Multi-center experience***
- ***Meta-analysis***
- ***Studies (RCT)***
- ***Registries***

In-hospital mortality

Division of Cardiac Surgery, Hesperia Hospital, Modena, Italy

GARY

Deutsches Aortenklappenregister
German Aortic Valve RegistrY



C. W. Hamm, F.W. Mohr, H. Möllmann, D. Holzhey,
A. Beckmann, H.-R. Figulla, J. Cremer, K.-H. Kuck, R. Lange,
R. Zahn, S. Sack, G. Schuler, T. Walther, F. Beyersdorf,
M. Böhm, G. Heusch, A.-K. Funkat, T. Meinertz, T. Neumann,
K. Papoutsis, S. Schneider, A. Welz for the GARY-Executive
Board

- **Nationwide complete survey of patients with aortic valve stenosis undergoing invasive procedures:**
 - surgical (AVR),
 - catheter-based (TAVI) transfemoral ,
 - catheter-based (TAVI) transapical,
 - valvuloplasty.

Inclusion from 01/01/2011 to 31/12/2011

53 cardiac surgery units

69 cardiology units

13.860 patients

6.523 surgical AVR
without CABG

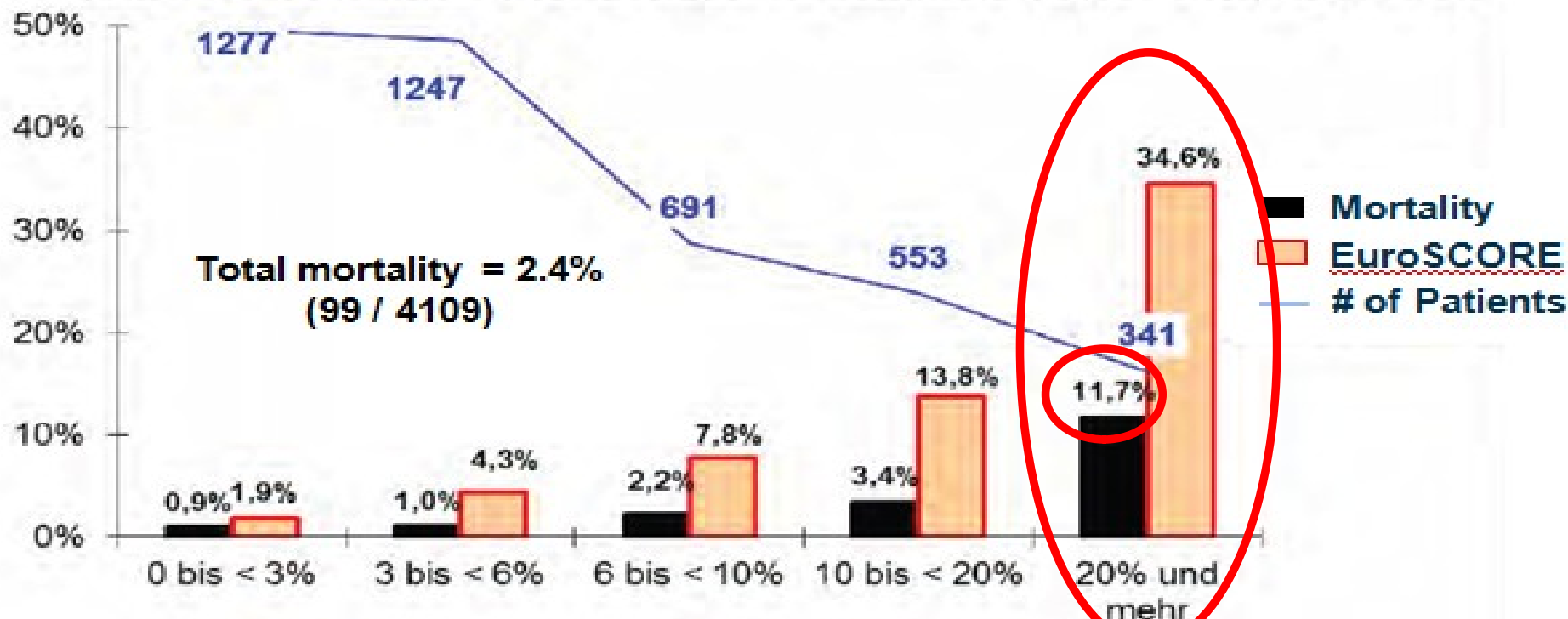
3.462 surgical
AVR with CABG

2.694 transvascular
TAVI

1.181 transapical
TAVI



Conventional Isolated AVR: N = 4109 Grouping by Logistic EuroSCORE (2010)

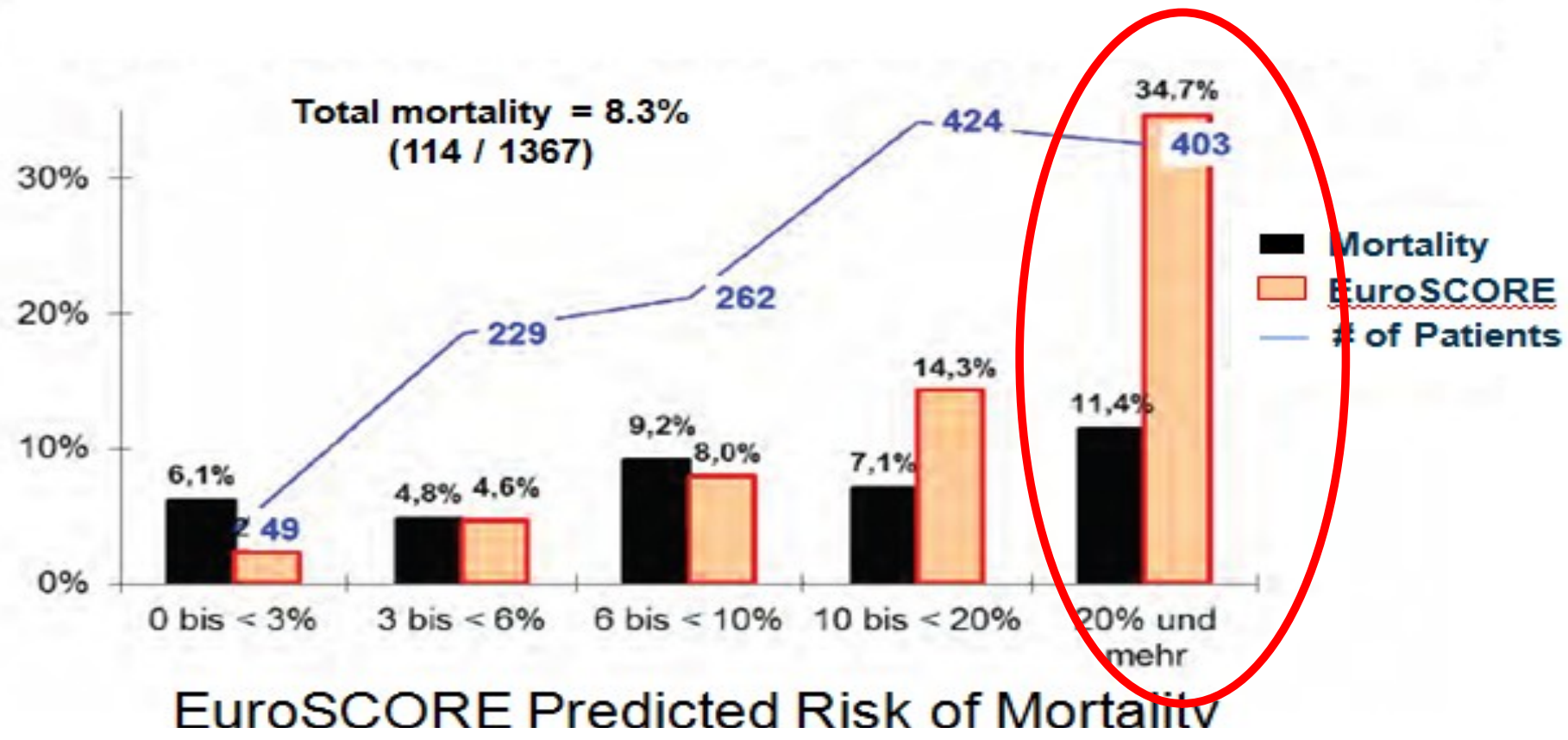


EuroSCORE Predicted Risk of Mortality

<i>Regional Patients eligible for TAVI</i>	<i>In-hospital (%)</i>	<i>30-day (%)</i>
<i>Group 1: age>75 & logES>20%</i>	10.5	9.8
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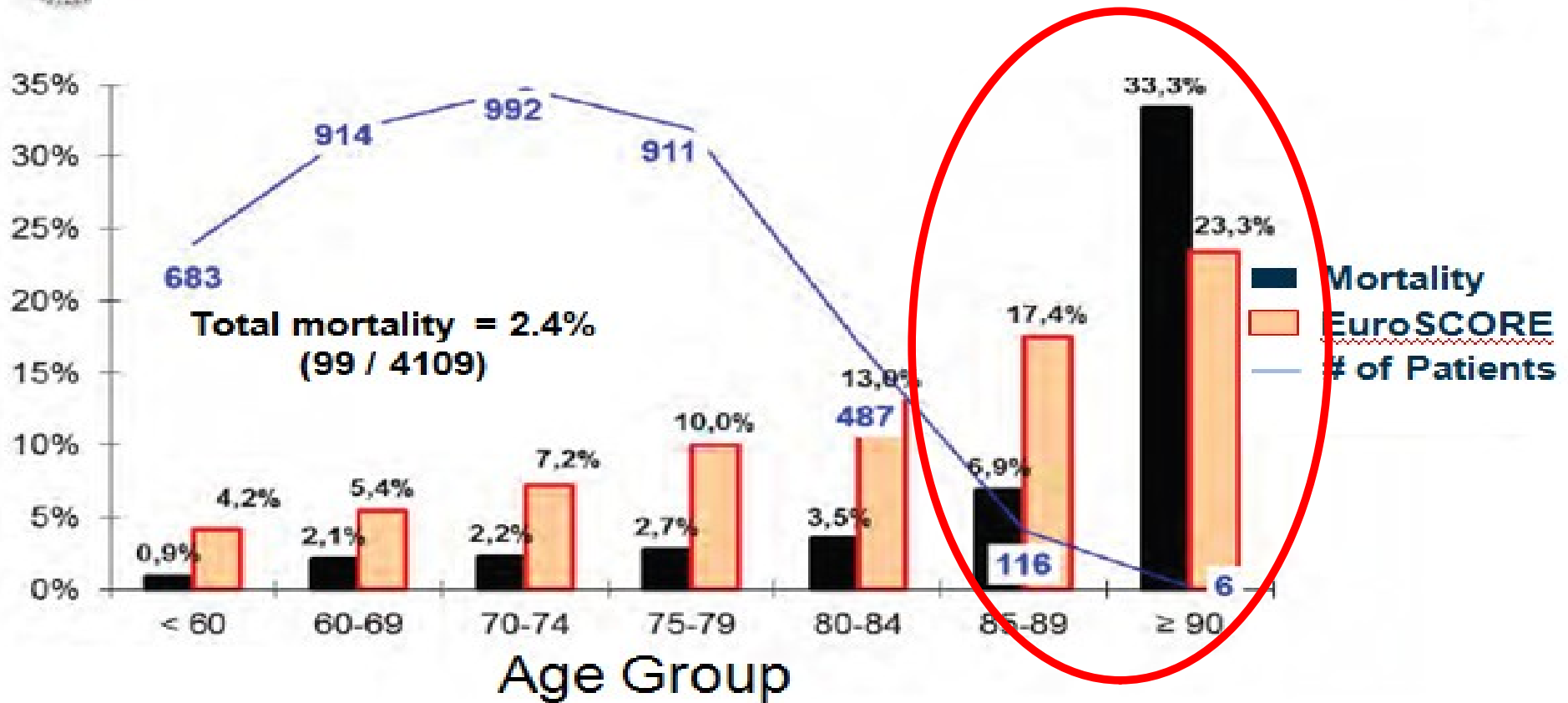
Transfemoral and Transapical TAVI: N = 1367 Results by logistic EuroSCORE (2010)



<i>Regional Patients eligible for TAVI</i>	<i>In-hospital (%)</i>	<i>30-day (%)</i>
<i>Group 1: age>75 & logES>20%</i>	10.5	9.8
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<i>Group 3: logES>20%</i>	12.4	10.7



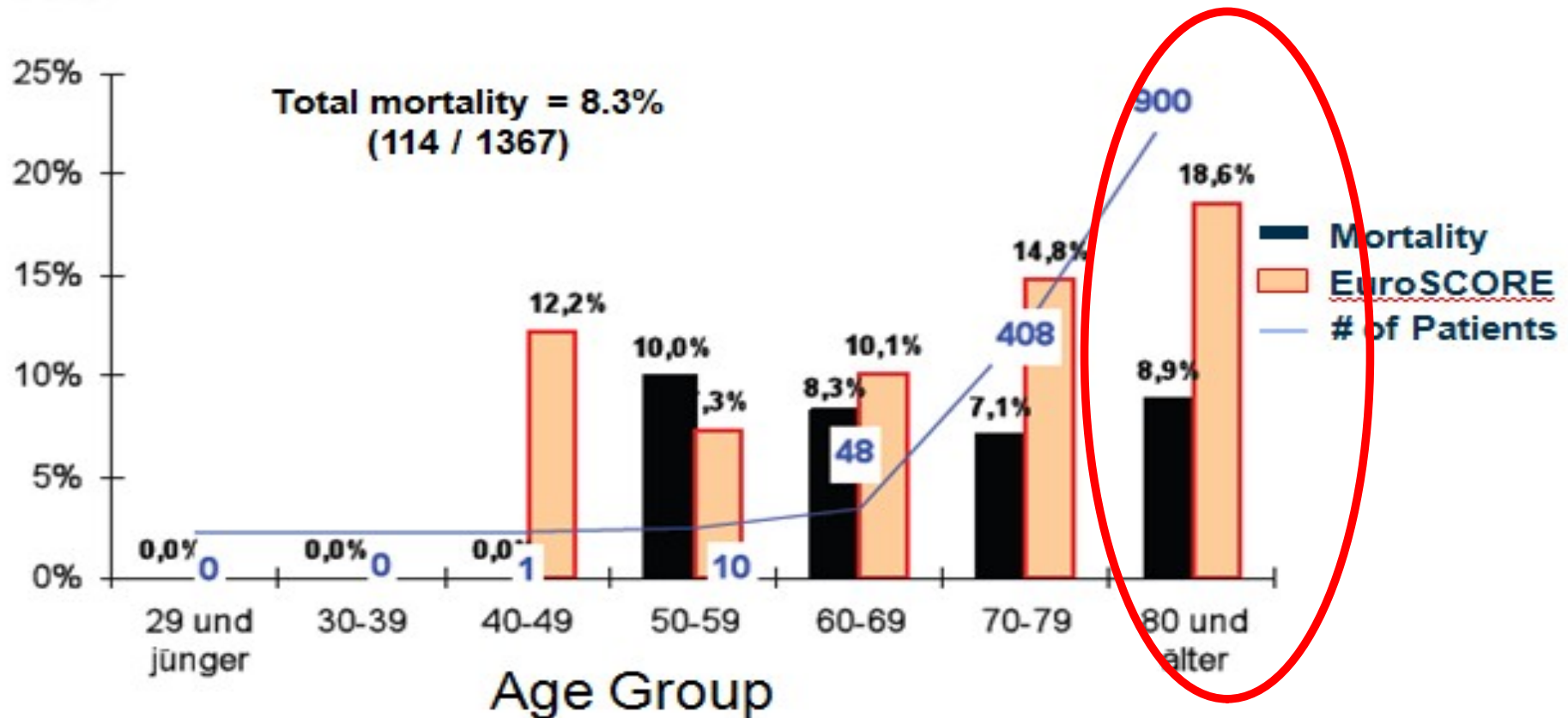
Conventional Isolated AVR: N = 4109 Grouping by Age (2010)



<i>Regional Patients eligible for TAVI</i>	<i>In-hospital (%)</i>	<i>30-day (%)</i>
<i>Group 1: age>75 & logES>20%</i>	10.5	9.8
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<i>Group 3: logES>20%</i>	12.4	10.7



Transfemoral and Transapical TAVI: N = 1367 Results by Age Group (2010)

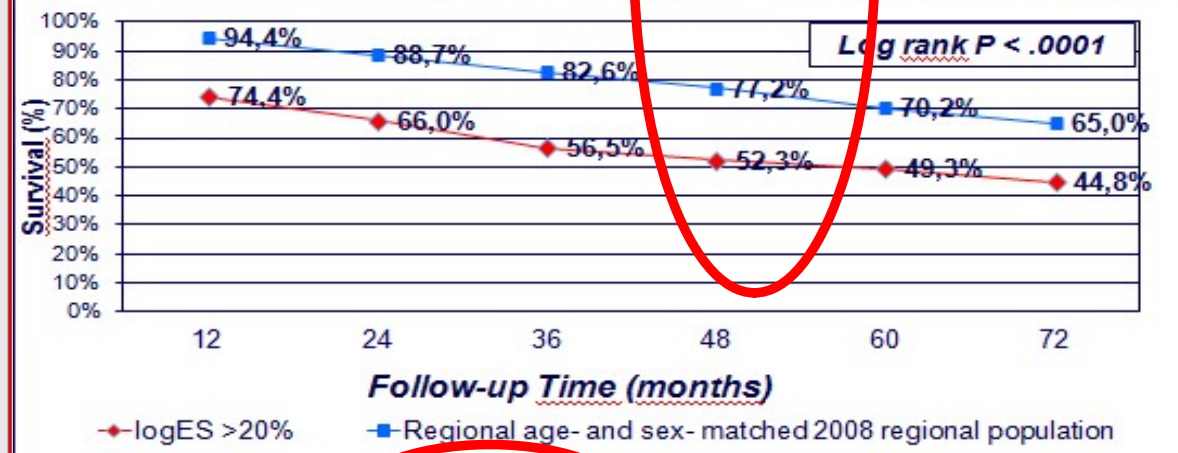
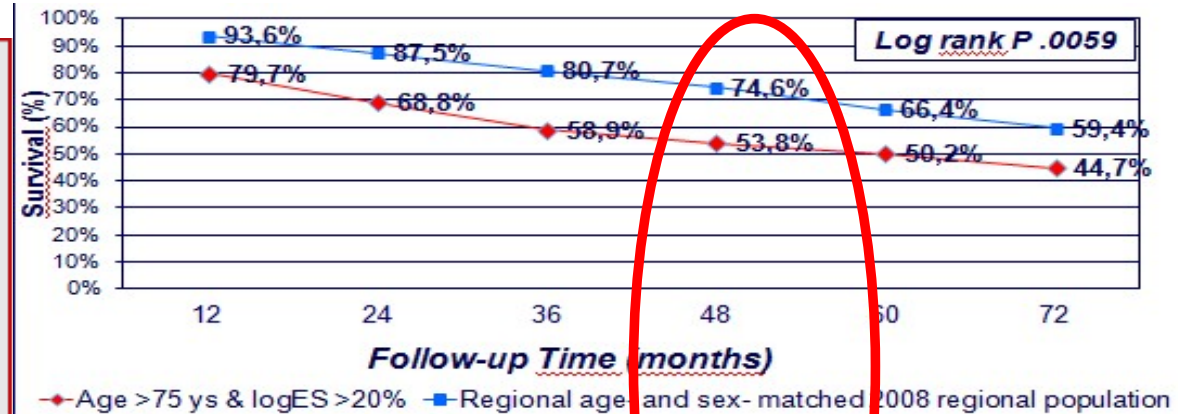
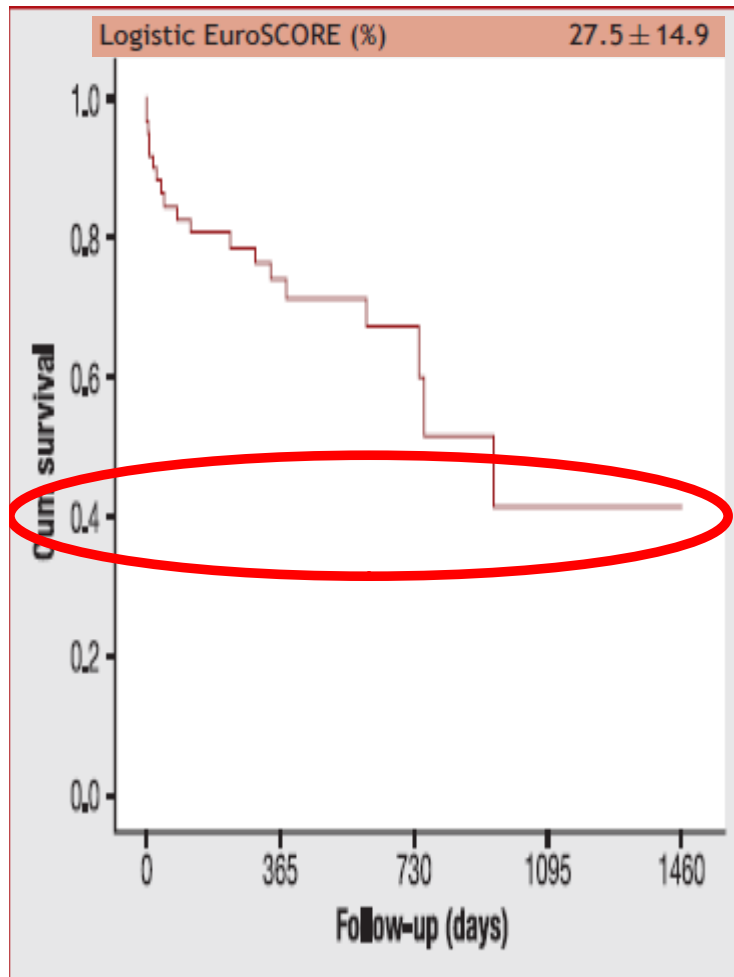


Regional Patients eligible for TAVI	In-hospital (%)	30-day (%)
Group 1: age>75 & logES>20%	10.5	9.8
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Mid-term Survival

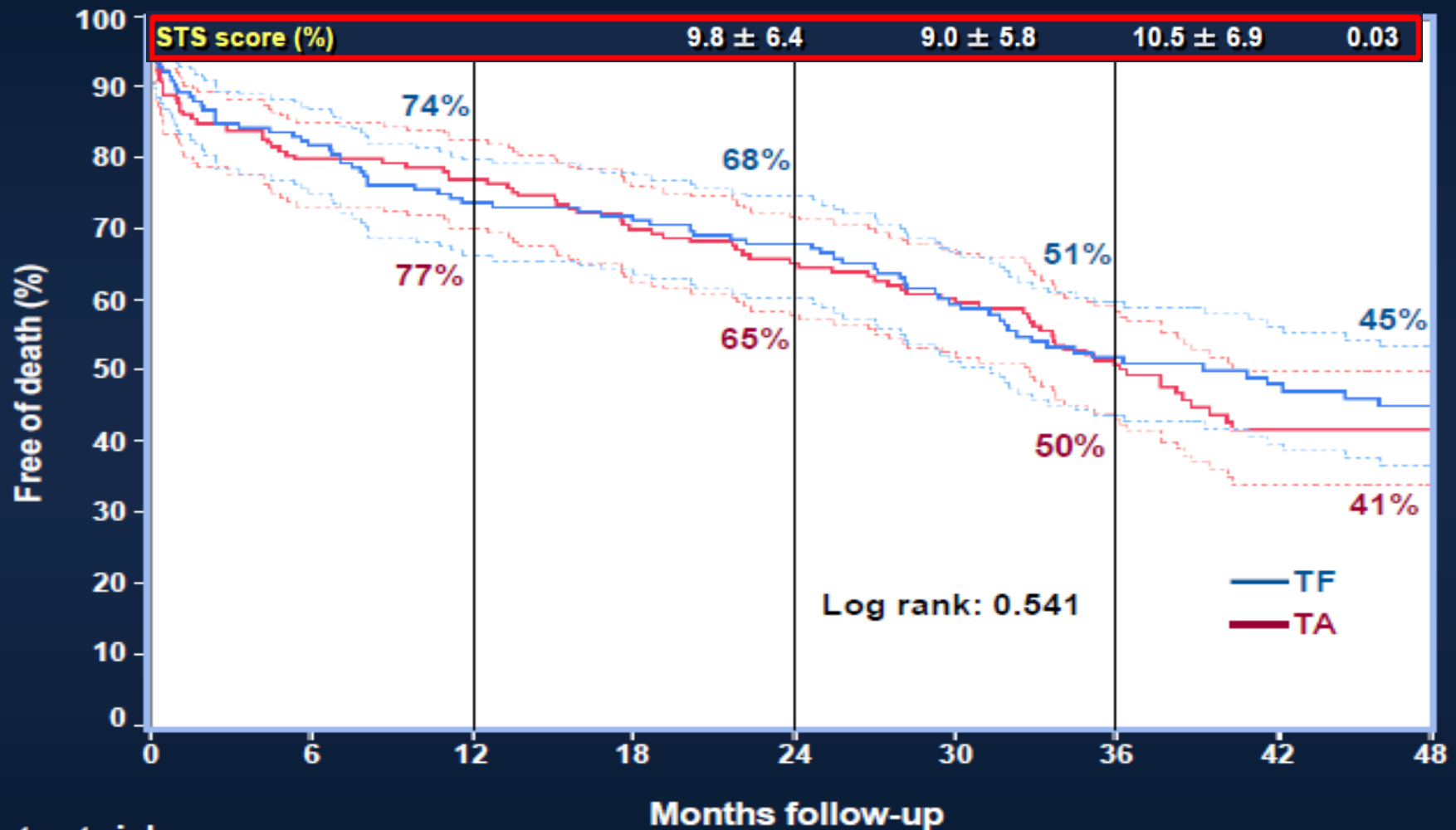
Division of Cardiac Surgery, Hesperia Hospital, Modena, Italy

Transapical aortic valve implantation in Rouen: Four years' experience with the Edwards transcatheter prosthesis



February 2012; accepted 3 February 2012
 online 21 March 2012

48-month Follow-Up Survival Curves Canadian Multicenter Experience



Patients at risk:

TF	162	132	118	111	105	78	63	46	39
TA	177	140	134	118	107	90	67	38	28

Conclusions

- n satisfactory results in the "TAVI" patients
 - acceptable in-hospital mortality
 - significant impact of surgery on the survival compared with the regional population
- n regional risk evaluation system needed
- n results "comparable" with TAVI in recent registries

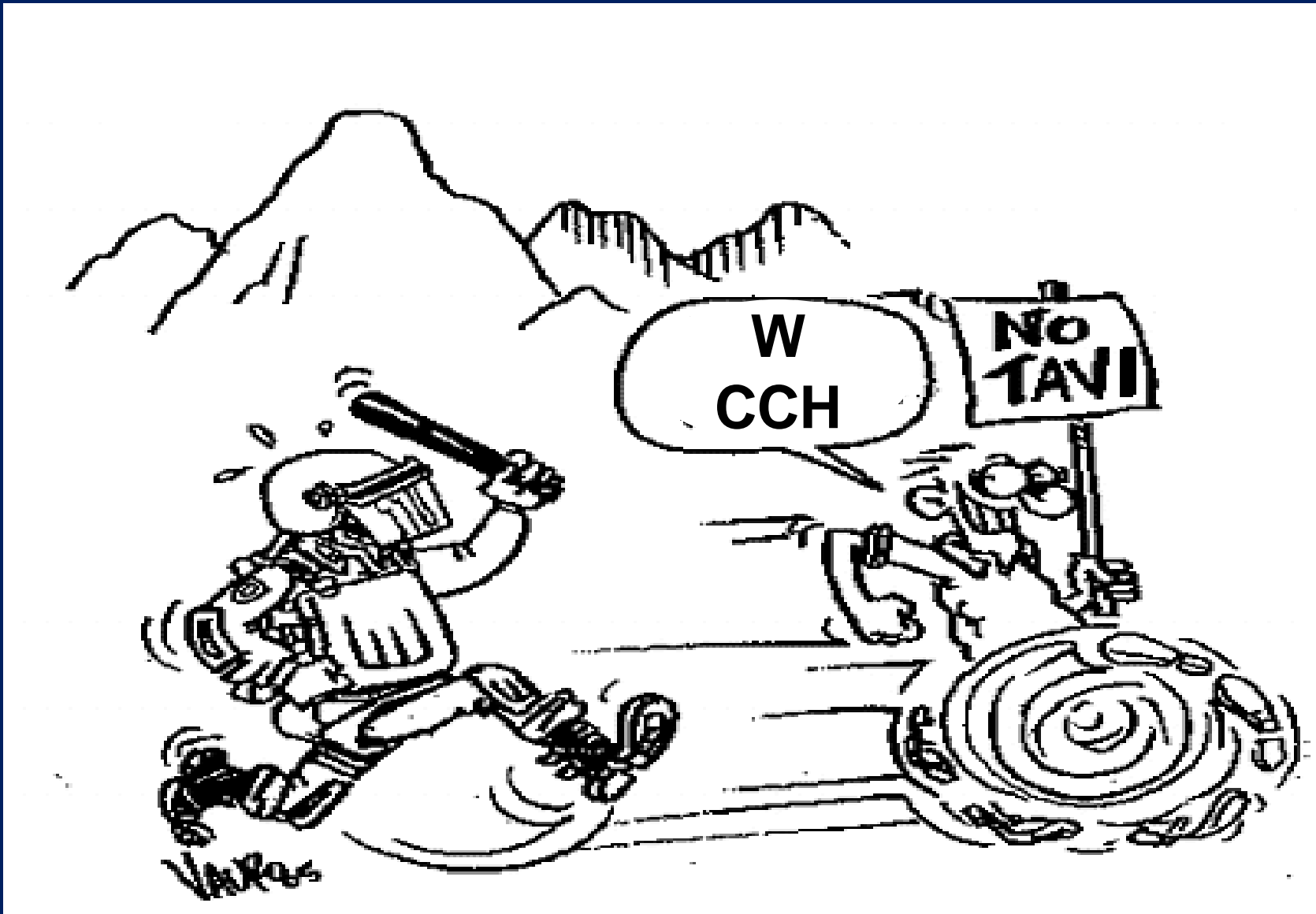
WAS THE "OLD SURGERY" REALLY SO BAD?

No, and now?

"TAVI ~ Tsunami"



Division of Cardiac Surgery, Hesperia Hospital, Modena, Italy



Percutaneous aortic valve replacement

Bruce W. Lytle, MD

See related editorial on page 294.

2007

From the Department of Thoracic and Cardiovascular Surgery, Cleveland Clinic, Cleveland, Ohio.

Received for publication Sept 7, 2006; accepted for publication Oct 9, 2006.

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J Thorac Cardiovasc Surg 2007;133:299
0022-5223/\$32.00

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doi:10.1016/j.jtcvs.2006.10.018

The concept of cardiologists implanting percutaneous aortic valves in an angiography suite evokes multiple reactions from cardiac surgeons. Rarely are these reactions particularly favorable. The opinions of cardiac surgeons regarding the development and the potential abuse of these percutaneous technologies sound familiar because similar opinions were expressed in response to the development of percutaneous coronary technologies a quarter of a century ago.

The concerns regarding percutaneous aortic valves include “we have a great operation now,” “few patients are inoperable,” “the percutaneous devices have problems,” “it will be dangerous because these devices will be misused,” and “patients will not get true informed consent.” All these arguments and concerns have some truth to them, but none will define the future of percutaneous aortic valve technologies, just as similar concerns have failed to define the anatomic treatment of coronary artery disease.

Percutaneous aortic valve devices are here to stay. First, although conventional aortic valve replacement is a safe operation in experienced hands, it is not perfectly safe and there are patients with combinations of problems including multiple previous operations, radiation heart disease, liver failure, kidney failure, and diffuse atherosclerosis for whom the risk of conventional aortic valve replacement is more than trivial. Second, today’s percutaneous devices are primitive, but progress is likely to be rapid. Percutaneous coronary interventions have been, and still are, limited by fundamental biologic processes, including the cellular and tissue response to injury (restenosis) and the complexities of the coagulation system. The engineering aspects of percutaneous coronary interventions have been successful. So far no such fundamental problems appear to limit percutaneous aortic valve technologies any more than they limit conventional aortic valve technologies. Improving the percutaneous aortic valve devices appears to be pretty much a matter of engineering, making their deficiencies more amenable to solution than the problems of restenosis have been.

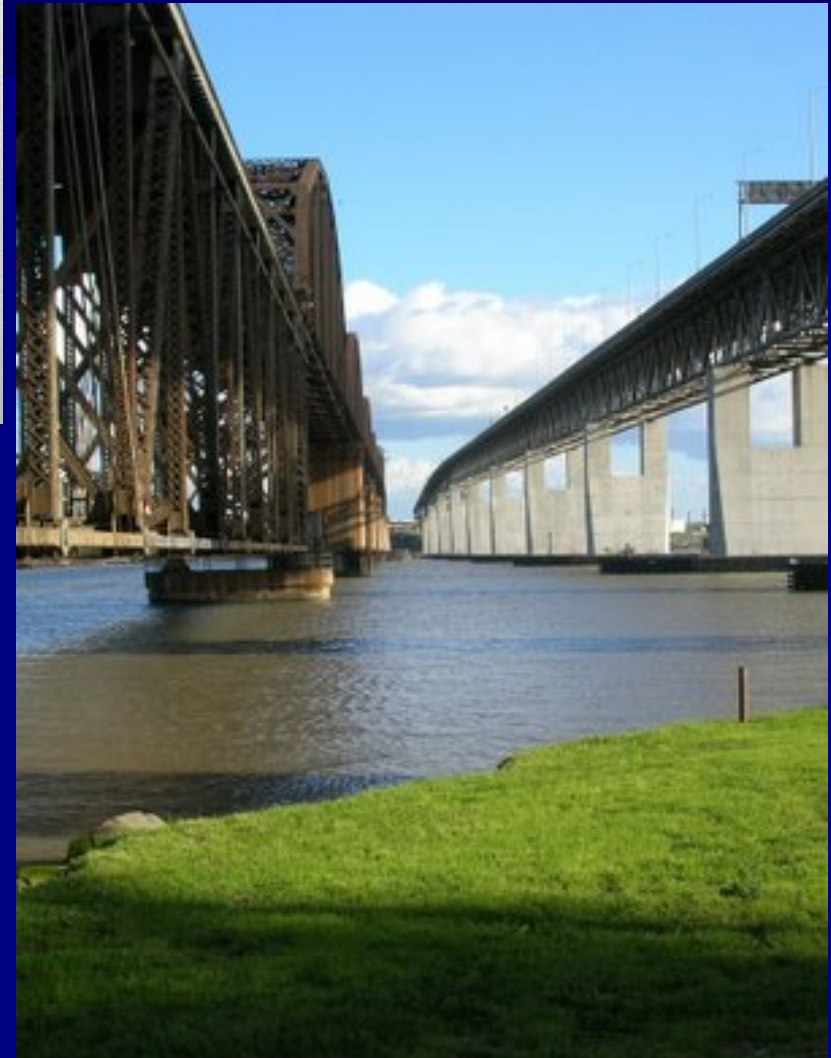
We should have learned from the coronary experience that many patients have a strong attraction to percutaneous rather than open surgical procedures, and unless the procedure-related risks of percutaneous procedures are substantially greater than the procedure-related risks of open procedures, many patients will select the less-invasive strategy even if the long-term outcomes are inferior and even if they receive accurate informed consent.

A further lesson we should have learned from the coronary experience is that expressing concern about technologies that we are not capable of using is relatively ineffective. For cardiac surgeons to have an impact on the use of percutaneous aortic valve technology and to be able to assure ourselves that patients have received informed consent and that these devices are not misused, we must be able to use these technologies ourselves. In this setting, cardiac surgeons will be able to render strong opinions with a diminished procedure-related bias.

Catheter-based valve procedures are surgery, just a different kind of surgery. For cardiac surgeons to gain expertise with multiple types of valve procedures will be a tortuous journey, but the journey must start today.

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Catheter-based valve procedures are surgery, just a different kind of surgery. For cardiac surgeons to gain expertise with multiple types of valve procedures will be a tortuous journey, but the journey must start today.



Division of Cardiac Surgery, Hesperia Hospital, Modena, Italy

Thank you

Back-up slides

Surgical Background

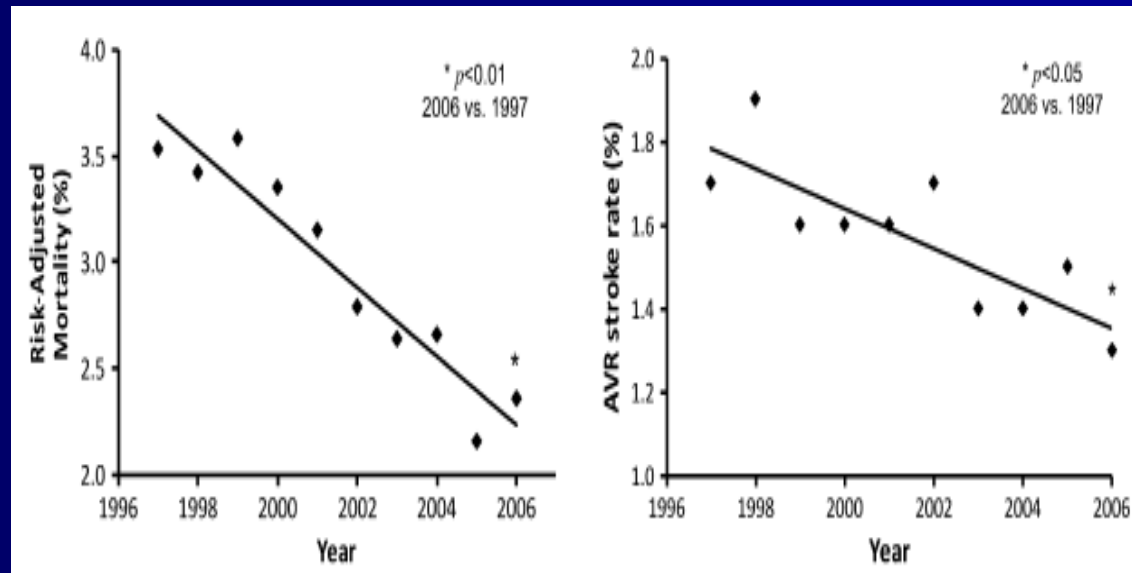
Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: Changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database

James M. Brown, MD,^a Sean M. O'Brien, PhD,^b Changfu Wu, PhD,^a Jo Ann H. Sikora, CRNP,^a Bartley P. Griffith, MD,^a and James S. Gammie, MD^a

The Journal of Thoracic and Cardiovascular Surgery • January 2009

Surgical Background

- n gradual increases in patient age and overall risk profile
- n shift toward bioprostheses
- n reduction in morbidity and mortality



"Young TAVI" Background

NCBI Resources How To Sign in to NCBI

PubMed.gov PubMed Transcatheter Aortic Valve Implantation Search

US National Library of Medicine National Institutes of Health

Display Settings: Summary, 20 per page, Sorted by Recently Added

Results: 1 to 20 of 1310

1. [Recent Valves used for Transluminal Implantation in Patients with Aortic Valve Stenosis.](#)
Toutouzas KP, Stathogiannis KE, Latsios GS, Synetos AG, Stefanadis CI. *Recent Pat Cardiovasc Drug Discov.* 2012 Oct 31. [Epub ahead of print]

2. [TAVI 2012: state of the art.](#)
Reinöhl J, von Zur Mühlen C, Moser M, Sorg S, Bode C, Zehender M. *J Thromb Thrombolysis.* 2012 Nov 1. [Epub ahead of print]

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Results by year

Transcatheter aortic valve implantation in patients with mitral prosthesis.

6. Barbanti M, Ussia GP, Latib A, De Marco F, Fiorina C, Santoro G, Bedogni F, Colombo A, Bruschi G, Etori F, Agostini C, Brambilla N, Petronio AS, Tarantini G, Napodano M, De Carlo M, Confessore P, Tamburino C. *J Am Coll Cardiol.* 2012 Oct 30;60(18):1841-2. doi: 10.1016/j.jacc.2012.07.037. No abstract available. PMID: 23099216 [PubMed - in process] [Related citations](#)

Titles with your search terms

“..patients eligible for TAVI..”



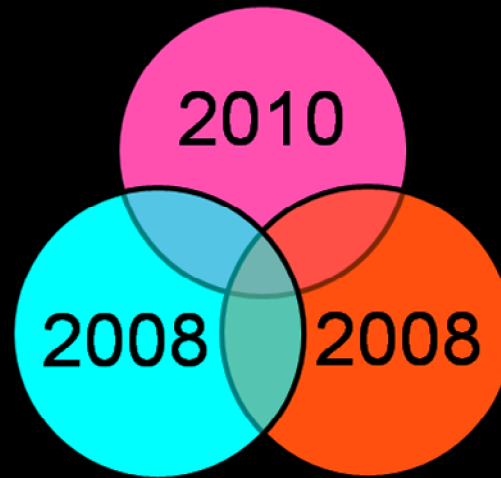
Impianto transcatetere di protesi valvolare aortica in pazienti con stenosi valvolare severa sintomatica

Documento di Consenso Federazione Italiana di Cardiologia (FIC) - Società Italiana di Chirurgia Cardiaca (SICCH)

Gennaro Santoro¹, Ettore Vitali², Corrado Tamburino³, Eugenio Quaini⁴, Angelo Ramondo⁵, Francesco Pizzuto⁶, Daniela Innocenti¹, Giuseppe Di Pasquale⁷

¹Dipartimento Cardiologico e dei Vasi, AOU Careggi, Firenze, ²Past President, Società Italiana di Chirurgia Cardiaca, Dipartimento Cardiovascolare, Humanitas Gavazzeni, Bergamo, ³Presidente SICI-GISE, Cardiologia, Università degli Studi, Catania, ⁴Coordinatore dell'Osservatorio della Società Italiana di Chirurgia Cardiaca, Milano, ⁵Dipartimento di Scienze Cardiologiche, Cardiocircolatorie, Università degli Studi "Tor Vergata", Roma, ⁶Dipartimento di Cardiologia, Ospedale Maggiore, Bologna, Direttore U.O.

(G Ital Cardiol 2010; 11 (1):



AHA Scientific Statement

Percutaneous and Minimally Invasive Valve Procedures

A Scientific Statement From the American Heart Association Council on Cardiovascular Surgery and Anesthesia, Council on Clinical Cardiology, Functional Genomics and Translational Biology Interdisciplinary Working Group, and Quality of Care and Outcomes Research Interdisciplinary Working Group

Todd K. Rosengart, MD, FAHA, Chair; Ted Feldman, MD; Michael A. Borger, MD, PhD; Thomas A. Vassiliades, Jr, MD; A. Marc Gillinov, MD, FAHA; Katherine J. Hoercher, RN; Alec Vahanian, MD; Robert O. Bonow, MD, FAHA; William O'Neill, MD, FAHA

Abstract—The incidence of valvular heart disease is expected to increase over the next several decades as a large proportion of the US demographic advances into the later decades of life. At the same time, the next several years can be anticipated to bring a broad transition of surgical therapy to minimally invasive (minithoracotomy and small port) access and the more gradual introduction of percutaneous approaches for the correction of valvular heart disease. Broad acceptance of these technologies will require careful and sometimes perplexing comparisons of the outcomes of these new technologies with existing standards of care. The validation of percutaneous techniques, in particular, will require the collaboration of cardiologists and cardiac surgeons in centers with excellent surgical and catheter experience and a commitment to trial participation. For the near term, percutaneous techniques will likely remain investigational and will be limited in use to patients considered to be high risk or to inoperable surgical candidates. Although current-generation devices and techniques require significant modification before widespread clinical use can be adopted, it must be expected that less invasive and even percutaneous valve therapies will likely have a major impact on the management of patients with valvular heart disease over the next several years. (*Circulation*. 2008;117:1750-1767.)

) 29, 1463–1470

SPECIAL ARTICLE

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

Alec Vahanian^{1*}, Ottavio Alfieri^{2*}, Nawwar Al-Attar¹, Manuel Antunes³, Jeroen Bax⁴, Bertrand Cormier⁵, Alain Cribier⁶, Peter De Jaegere⁷, Gerard Fournial⁸, Arie Pieter Kappetein⁷, Jan Kovac⁹, Susanne Ludgate¹⁰, Francesco Maisano², Neil Moat¹¹, Friedrich Mohr¹², Patrick Nataf¹, Luc Piérard¹³, José Luis Pomar¹⁴, Joachim Schofer¹⁵, Pilar Tornos¹⁶, Murat Tuzcu¹⁷, Ben van Hout¹⁸, Ludwig K. Von Segesser¹⁹, and Thomas Walther¹²

Cardiac Surgery in Patients eligible for TAVI

RERIC 2003-2011

30-day mortality, multivariate analysis

Regional patients

Group 1: age >75 & logES >20%

<i>Preoperative characteristics</i>	<i>OR</i>	<i>95% CI</i>	
<i>Central neurological dysfunction</i>	4.3	1.1	17.2
<i>Congestive heart failure</i>	5.5	1.7	17.9

Cardiac Surgery in Patients eligible for TAVI

RERIC 2003-2011

30-day mortality, multivariate analysis

Regional patients

Group 2: age>85 & logES>10%

<i>Preoperative characteristics</i>	<i>OR</i>	<i>95% CI</i>	
<i>Diabetes</i>	8.9	1.9	42.4

Cardiac Surgery in Patients eligible for TAVI

RERIC 2003-2011

30-day mortality, multivariate analysis

Regional patients

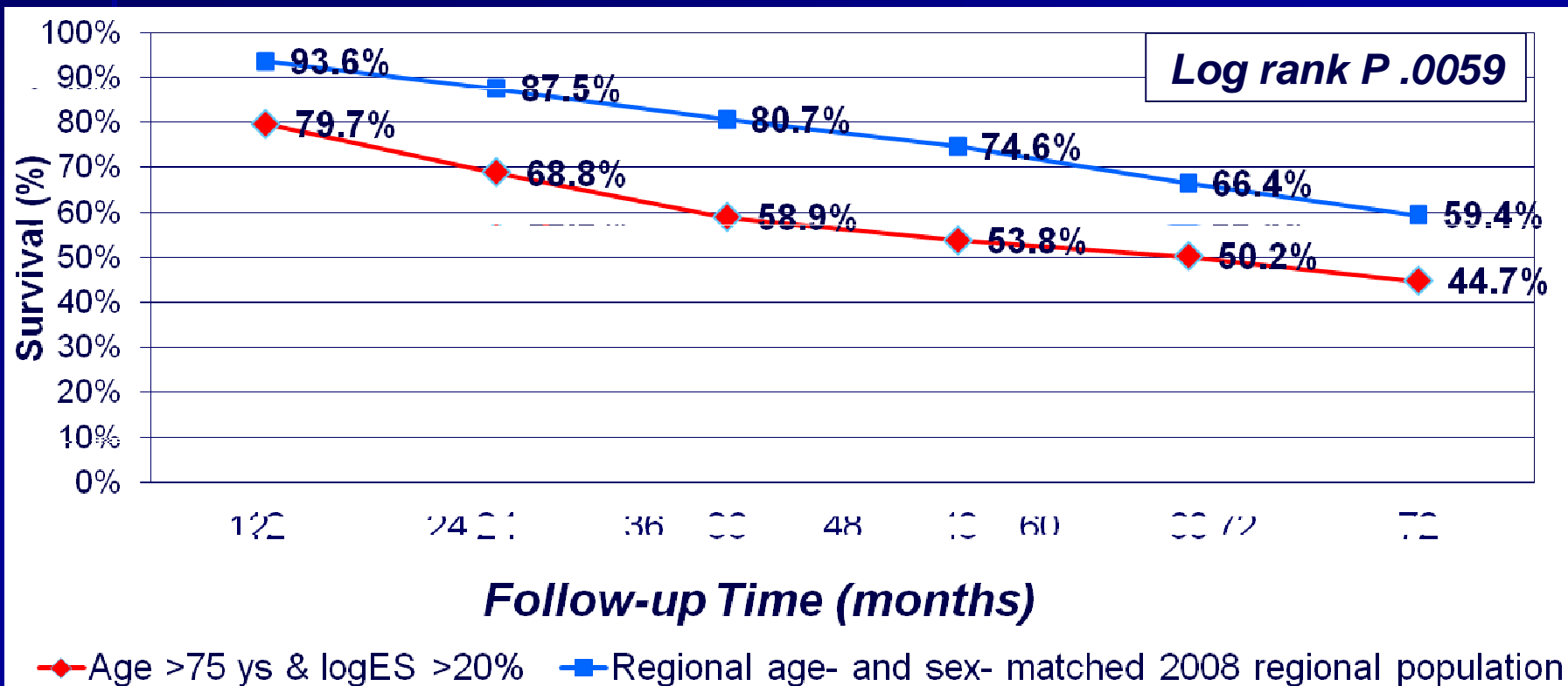
Group 3: logES>20%

<i>Preoperative characteristics</i>	<i>OR</i>	<i>95% CI</i>	
<i>Congestive heart failure</i>	4.6	1.7	12.2

Cardiac Surgery in Patients eligible for TAVI

RERIC 2003-2011

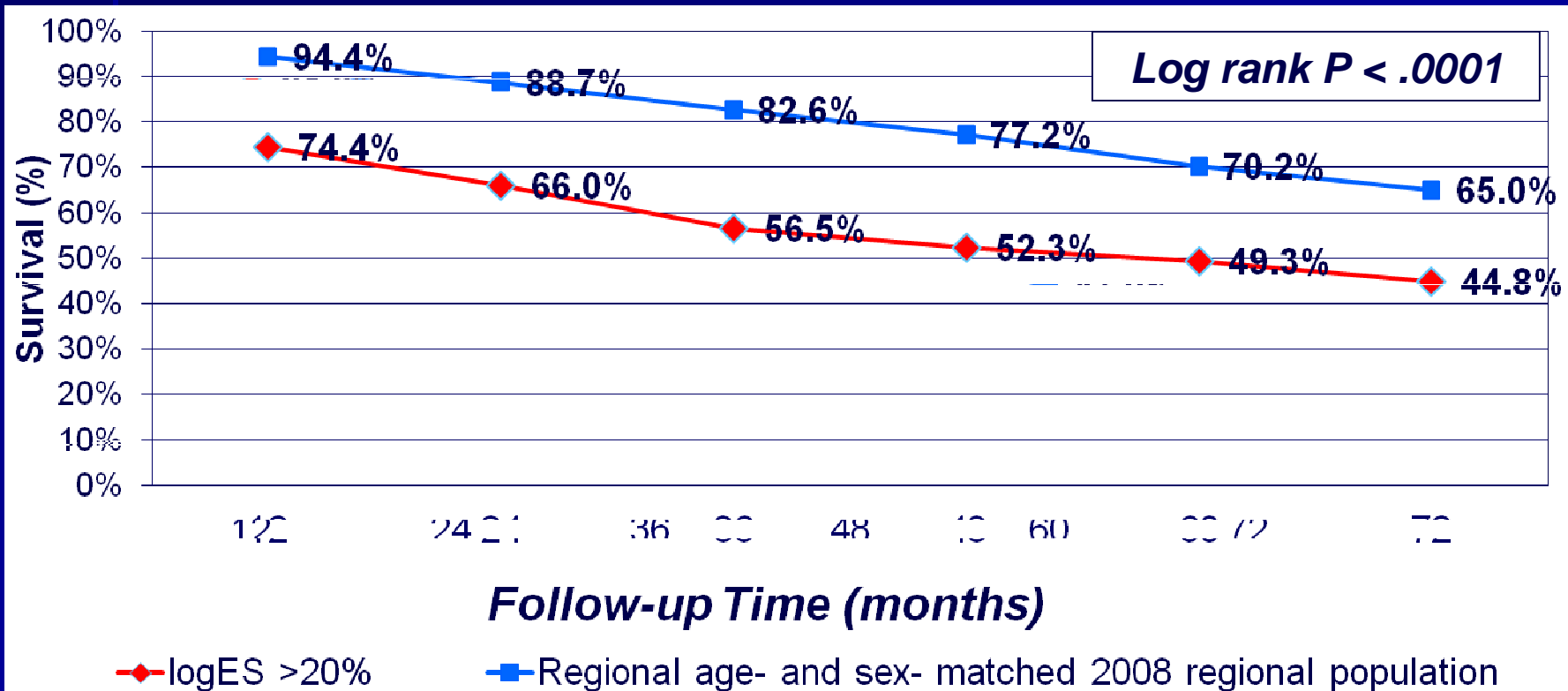
*Six-year survival of the **Group 1** study population compared with expected survival of age- and sex- matched 2008 regional population*



Cardiac Surgery in Patients eligible for TAVI

RERIC 2003-2011

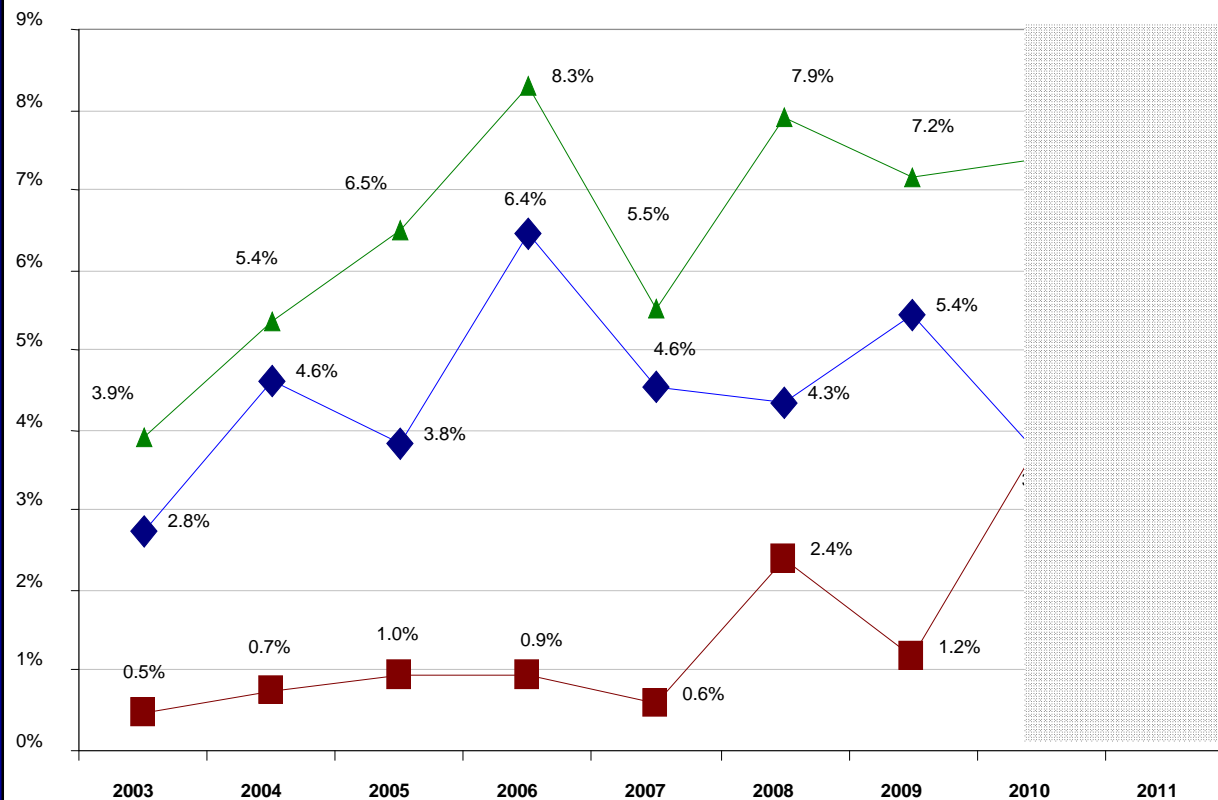
*Six-year survival of the **Group 3** study population compared with expected survival of age- and sex- matched 2008 regional population*



Cardiac Surgery in Patients eligible for TAVI

RERIC C 2003-2011

Patients eligible for TAVI undergoing isolated AVR: percentage for year



- ◆ Group1: age>75 & logES>20%
- Group2: age>85 & logES>10%
- ▲ Group3: logES>20%

Cardiac Surgery in Patients eligible for TAVI

RERIC 2003-2011

<i>Preoperative characteristics</i>	<i>Age>75 & logES>20% (N°=203)</i>		<i>logES>20% (N°=302)</i>	
	<i>N°</i>	<i>%</i>	<i>N°</i>	<i>%</i>
<i>Age • 80 years</i>	142	69.6%	142	46.7%
<i>Female</i>	106	52.0%	146	48.0%
<i>Bioprosthesis</i>	142	89.9%	187	84.6%
<i>Body mass index > 30</i>	34	16.7%	50	16.5%
<i>Emergency status</i>	7	3.4%	25	8.2%
<i>Urgency status</i>	39	19.1%	70	23.0%
<i>Previous PCI +/- stent</i>	32	15.7%	39	12.8%
<i>Recent myocardial infarction</i>	26	12.8%	39	12.8%
<i>Congestive heart failure</i>	42	20.6%	78	25.7%
<i>Unstable angina</i>	7	3.4%	20	6.6%
<i>Pulmonary arterial pressure >60 mmHg</i>	16	7.8%	25	8.2%
<i>Haemodynamic instability</i>	12	5.9%	40	13.2%
<i>Cardio-pulmonary resuscitation</i>	0	0.0%	1	0.3%
<i>Cardiac shock</i>	6	2.9%	15	4.9%
<i>EF <30%</i>	25	12.3%	46	15.1%
<i>EF 30%-50%</i>	72	35.3%	113	37.2%
<i>NYHA 3,4</i>	146	71.6%	227	74.7%
<i>CCS 3, 4</i>	15	7.4%	31	10.2%
<i>Diabetes</i>	33	16.2%	66	21.8%
<i>Dialysis</i>	2	1.0%	9	3.0%
<i>Creatinine • 2 mg/dl</i>	19	9.3%	37	12.2%
<i>Severe COPD</i>	36	17.7%	44	14.5%
<i>Hypertension</i>	163	79.9%	229	75.6%
<i>Peripheral neurological dysfunction</i>	19	9.3%	30	9.9%
<i>Central neurological dysfunction</i>	24	11.8%	35	11.5%
<i>Extra-cardiac vasculopathy</i>	119	58.3%	153	50.3%
<i>Active infective endocarditis</i>	20	9.8%	73	24.0%
<i>Active neoplasm</i>	4	2.0%	5	1.6%