

IL PERCORSO CLINICO  
DEL PAZIENTE CON PROTESI  
VALVOLARE, VALVOLE  
ARTIFICIALI PERCUTANEE



**Milano 29 Ottobre 2010**

**Lo spazio della chirurgia tradizionale  
con approccio mininvasivo e con approccio  
convenzionale**

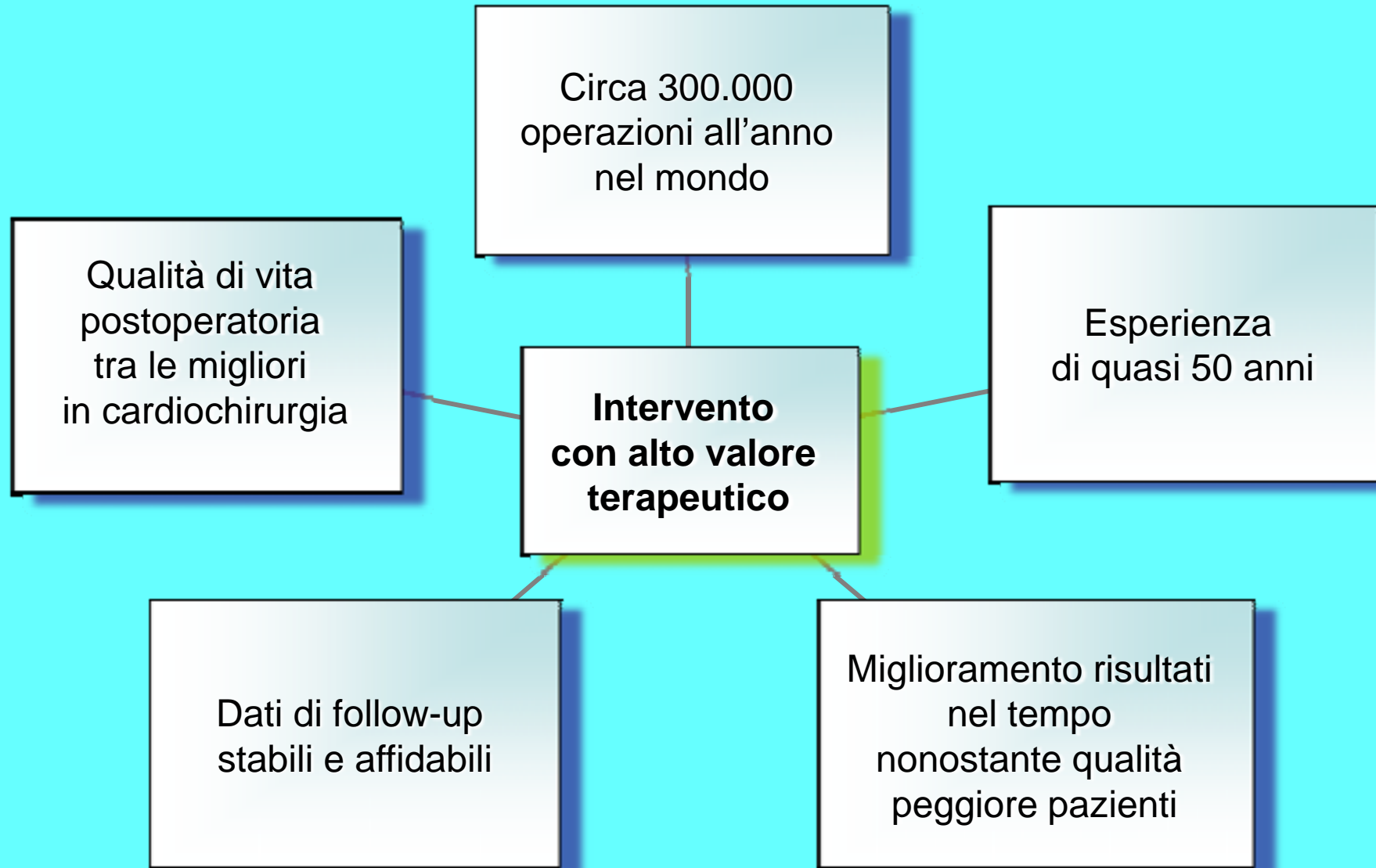
*(Questa indicazione cardine è destinata ad  
essere soppiantata?)*

**Claudio Grossi**

Dipartimento Cardiovascolare  
Osp. Santa Croce e Carle - Cuneo

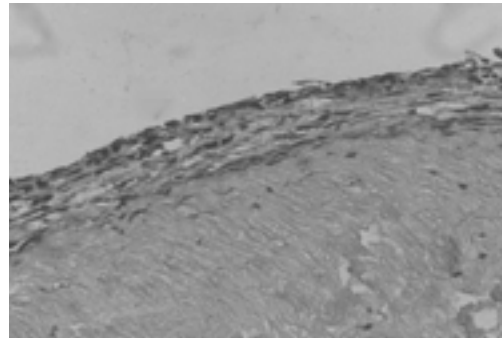
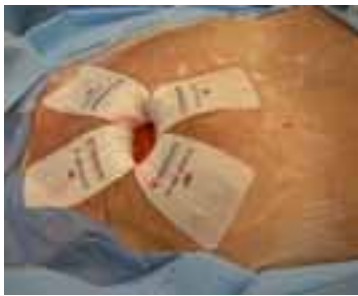


# Sostituzione valvolare aortica: "stato dell'arte"



## L'industria investe anche sulla chirurgia tradizionale

- Approcci mini-invasivi
- Valvole "sutureless"
- Tessuti più duraturi
- Valvole "ricambiabili"

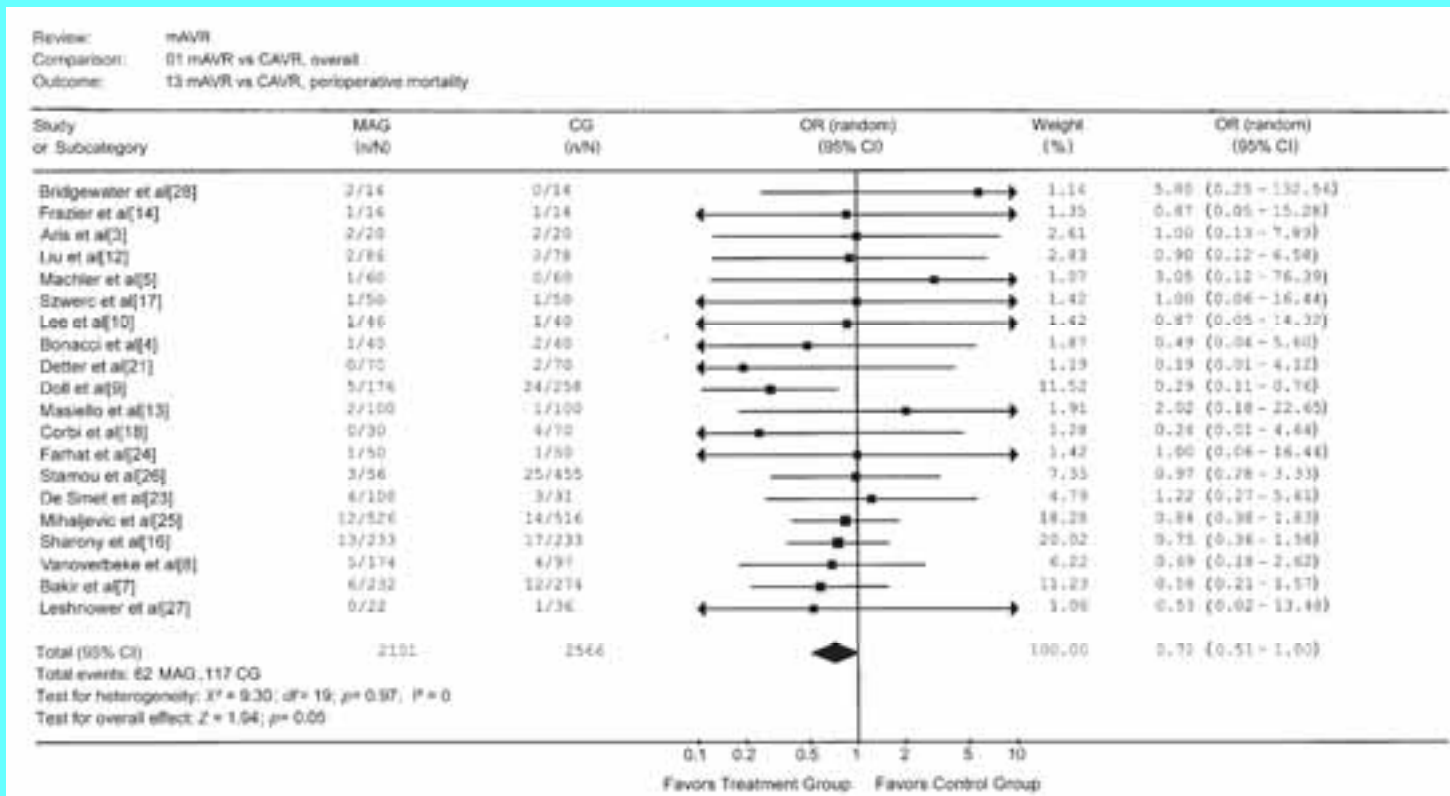


# Minimal Access Aortic Valve Replacement: Is It Worth It?

Bari Murtuza, PhD, FRCS, John R. Pepper, FRCS, Rex DeL. Stanbridge, FRCS, Catherine Jones, BSc, MBBS, Christopher Rao, MBBS, Ara Darzi, KBE, FRCS, and Thanos Athanasiou, PhD, FETCS

Departments of Cardiothoracic Surgery and Surgical Oncology and Technology, St. Mary's Hospital, Faculty of Medicine, Imperial College, and Department of Cardiothoracic Surgery, Royal Brompton Hospital, Faculty of Medicine, Imperial College, London, England

... ne vale la pena ?

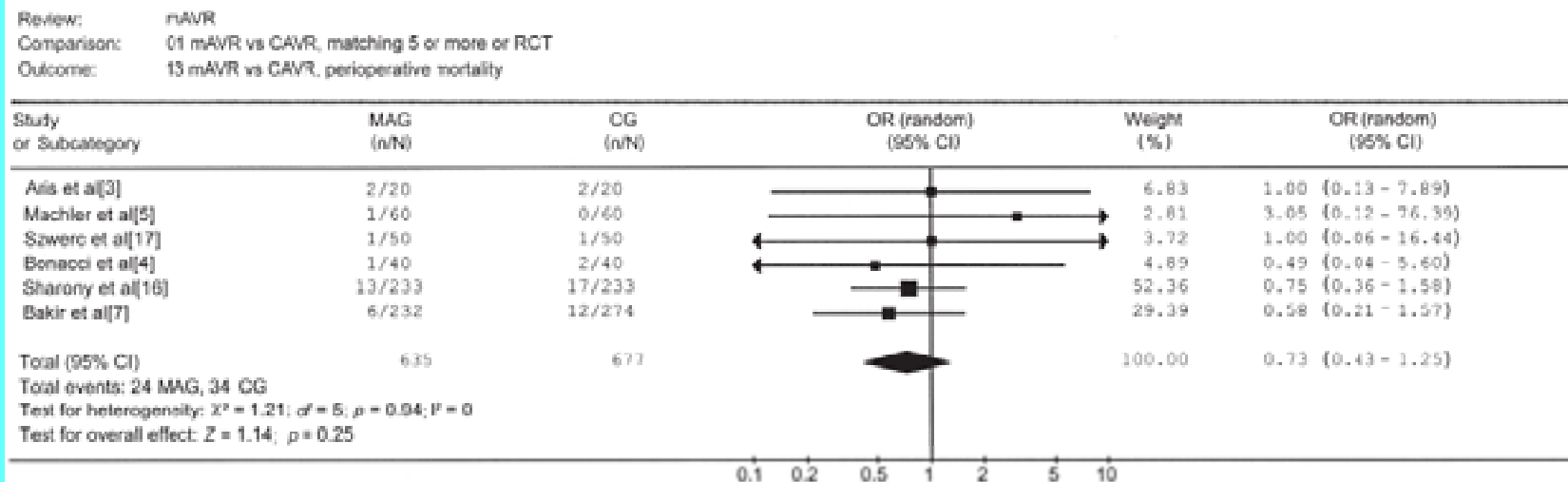


**meta-analisi delle mortalità perioperatorie**

## Minimal Access Aortic Valve Replacement: Is It Worth It?

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**Meta-analisi “sensitivity” della mortalità perioperatoria: solo trials randomizzati e studi non randomizzati di alta qualità.**

## Minimal Access Aortic Valve Replacement: Is It Worth It?

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Departments of Cardiothoracic Surgery and Surgical Oncology and Technology, St. Mary's Hospital, Faculty of Medicine, Imperial College, and Department of Cardiothoracic Surgery, Royal Brompton Hospital, Faculty of Medicine, Imperial College, London, England

### *Implications of Our Study and Conclusions:*

- Our meta-analysis suggests that mAVR is a safe alternative to cAVR and is associated with **small but significant benefits in the surrogate outcomes of ICU stay, total LOS, and ventilation time.**
- We did not find any significant differences in other secondary outcome events between the two groups.
- This suggests that minimal access AVR **can be offered on the basis of patient choice and cosmesis rather than evident clinical benefit.**
- We suggest that further RCTs in groups of patients at high risk, such as the elderly and those with poor lung function, that include data on QOL and detailed cost utilization analysis will be useful in clarifying whether mAVR can offer important clinical benefits in selected groups of patients.

## 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,<sup>a</sup> Sean M. O'Brien, PhD,<sup>b</sup> Changfu Wu, PhD,<sup>a</sup> Jo Ann H. Sikora, CRNP,<sup>a</sup> Bartley P. Griffith, MD,<sup>a</sup> and James S. Gammie, MD<sup>a</sup>

J Thorac Cardiovasc Surg 2009;137:82-90

**Objective:** More than 200,000 aortic valve replacements are performed annually worldwide. We describe changes in the aortic valve replacement population during 10 years in a large registry and analyze outcomes.

**Methods:** The Society of Thoracic Surgeons National Database was queried for all isolated aortic valve replacements between January 1, 1997, and December 31, 2006. After exclusion for endocarditis and missing age or sex data, 108,687 isolated aortic valve replacements were analyzed. Time-related trends were assessed by comparing distributions of risk factors, valve types, and outcomes in 1997 versus 2006. Differences in case mix were summarized by comparing average predicted mortality risks with a logistic regression model. Differences across subgroups and time were assessed.

**Results:** There was a dramatic shift toward use of bioprosthetic valves. Aortic valve replacement recipients in 2006 were older (mean age 65.9 vs 67.9 years,  $P < .001$ ) with higher predicted operative mortality risk (2.75 vs 3.25,  $P < .001$ ); however, observed mortality and permanent stroke rate fell (by 24% and 27%, respectively). Female sex, age older than 70 years, and ejection fraction less than 30% were all related to higher mortality, higher stroke rate and longer postoperative stay. There was a 39% reduction in mortality with preoperative renal failure.

**Conclusions:** Morbidity and mortality of isolated aortic valve replacement have fallen, despite gradual increases in patient age and overall risk profile. There has been a shift toward bioprostheses. Women, patients older than 70 years, and patients with ejection fraction less than 30% have worse outcomes for mortality, stroke, and postoperative stay.

**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,\* Sean M. O'Brien, PhD,\* Changlu Wu, PhD,\* Jo Ann H. Sikora, CRNP,\* Barbara P. Griffith, MD,\* and James S. Gammie, MD\*  
*J Thorac Cardiovasc Surg* 2009;137:42-50

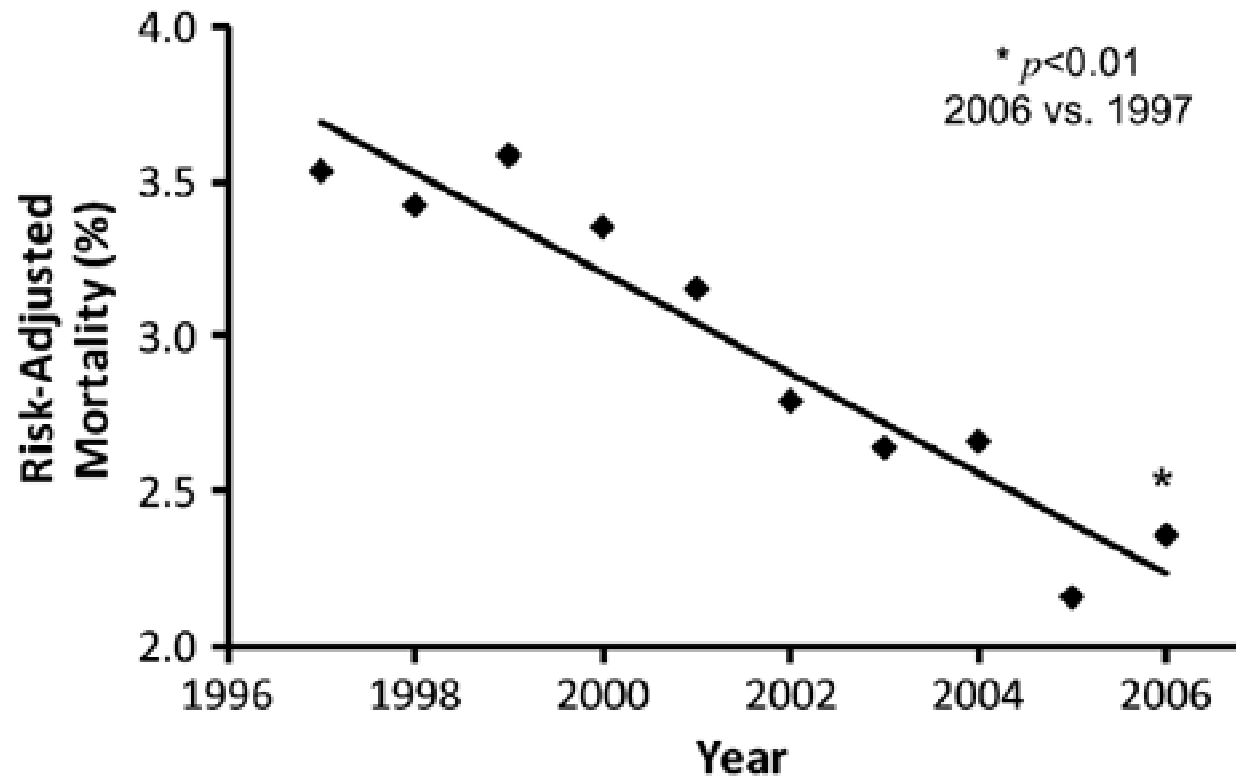


FIGURE 2. Risk-adjusted mortality for aortic valve replacement during 10 years in Society of Thoracic Surgeons database. Mortality for aortic valve replacement decreased with time. Asterisk indicates  $P < .01$ .



**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**

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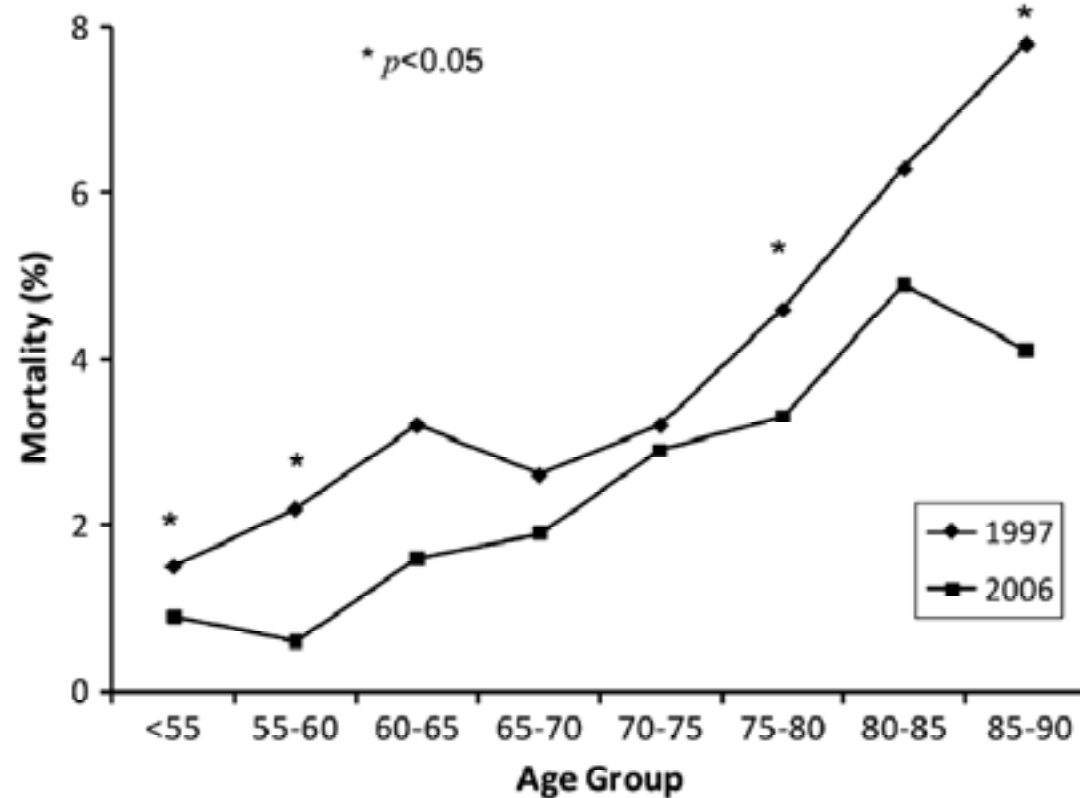


FIGURE 5. Mortality versus age in aortic valve replacement study population. Mortality was age dependent in 1997 and in 2006. For age groups as shown, mortality was less in 2006 than in 1997. Asterisk indicates  $P < .05$ .

**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**

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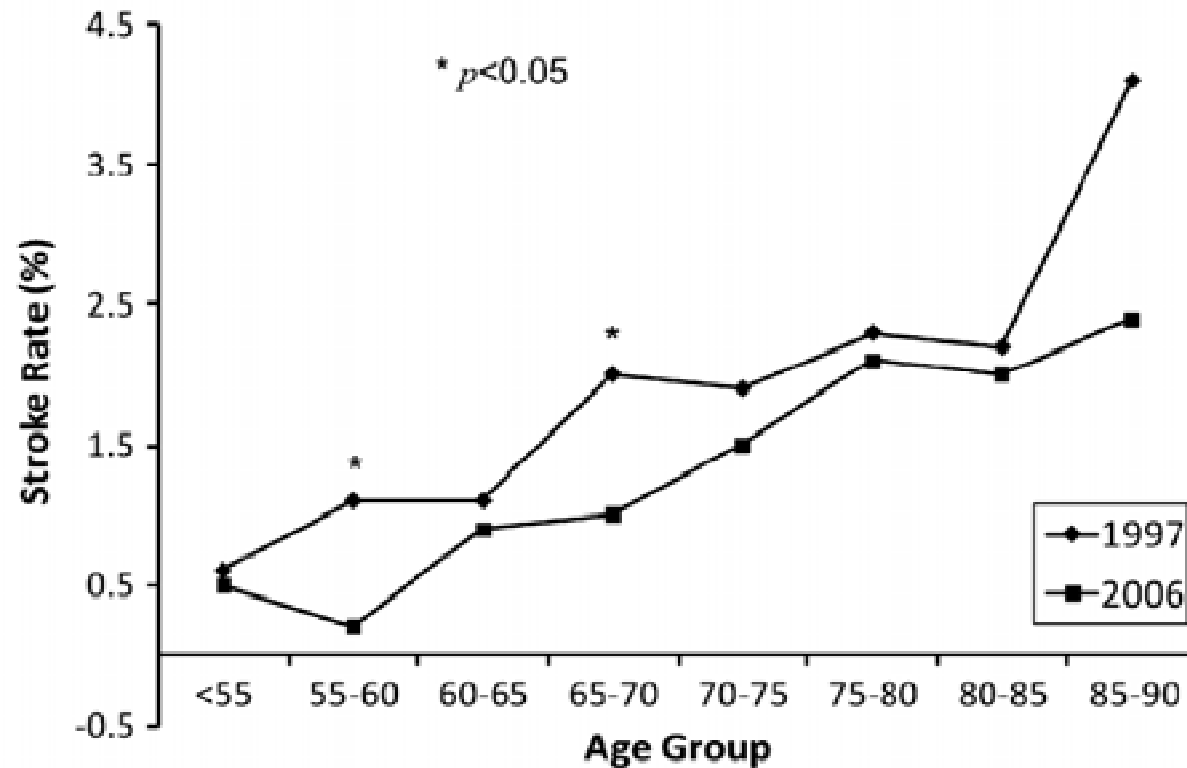


FIGURE 6. Stroke versus age in aortic valve replacement population between 1997 and 2006. Stroke rate was age dependent but also reduced as shown between 1997 and 2006. Asterisk indicates  $P < .05$ .

# Sostituzione valvolare aortica isolata



*Cuneo: maggio 00 -  
dicembre '07*

339 PAZIENTI

- **Mortalità alla dimissione 2/339 (0,58%)**
    - *reintervento con IMA perioperatorio.*
    - *intervento emergente in shock settico*
  - **Età media anni 68,4 (range 22-88)**
  - **Euroscore addittivo medio totale 5.40 (range 1-17)**
- 200 maschi e 139 femmine  
22 reinterventi  
313 elezioni, 26 urgenze /emergenze

# Percutaneous aortic valve replacement: Which patients are suitable for it? A quest for a controlled use

Francesca di Marco, MD, and Gino Gerosa, MD

Sostituzione valvolare aortica isolata: Padova ('02 -'06)

**341 Pazienti**

**Mortalità alla dimissione 1/341 (0,3%)**

**Età media anni 70 (range 23-89)**

**Euroscore addittivo medio totale 4,3**

33 reinterventi (11 con AMI pervia)

334 elezioni, 7 urgenze /emergenze

7 conversioni a Bentall per calcificazioni aorta asc.

Complicanze neurologiche 0,9%

IRA periop. 0,3%

# AVR verso TAVI

Migliore  
risultato  
a distanza

Minore  
mortalità  
operatoria

Minori  
costi

**Lo spazio della chirurgia tradizionale  
con approccio mininvasivo e con approccio  
convenzionale**



**Quale spazio per la TAVI - alternativo - alla  
chirurgia tradizionale con approccio  
mininvasivo e con approccio convenzionale ?**

## **Impianto transcateretere 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 Santoro<sup>1</sup>, Ettore Vitali<sup>2</sup>, Corrado Tamburino<sup>3</sup>, Eugenio Quaini<sup>4</sup>, Angelo Ramondo<sup>5</sup>, Francesco Pizzuto<sup>6</sup>, Daniela Innocenti<sup>7</sup>, Giuseppe Di Pasquale<sup>7</sup>

<sup>1</sup>Dipartimento Cardiologico e dei Vasi, AOU Careggi, Firenze; <sup>2</sup>Past President, Società Italiana di Chirurgia Cardiaca; Dipartimento Cardiotoracico, Humanitas Gavazzeni, Bergamo; <sup>3</sup>Presidente SIO-CISE, Cardiologia, Università degli Studi, Catania; <sup>4</sup>Coordinatore dell'Osservatorio della Società Italiana di Chirurgia Cardiaca, Milano; <sup>5</sup>Dipartimento di Scienze Cardiologiche, Cardiochirurgiche e Toraciche, Università degli Studi, Padova; <sup>6</sup>Dipartimento di Cardiologia, Università degli Studi "Tor Vergata", Roma; <sup>7</sup>Presidente, Federazione Italiana di Cardiologia, Direttore U.O. di Cardiologia, Ospedale Maggiore, Bologna

G Ital Cardiol  
2010;11(1):45-53

- Allo stato attuale, la sostituzione chirurgica della valvola aortica rappresenta il "gold standard"
- La TAVI è riservata ai pazienti con elevato rischio cardiocirurgico o con specifiche controindicazioni all'intervento;
- La valutazione del rischio cardiocirurgico e/o dell'inoperabilità rappresenta quindi il momento cruciale di tutta la fase di selezione del paziente.

# Chi sono i pazienti ad alto rischio?

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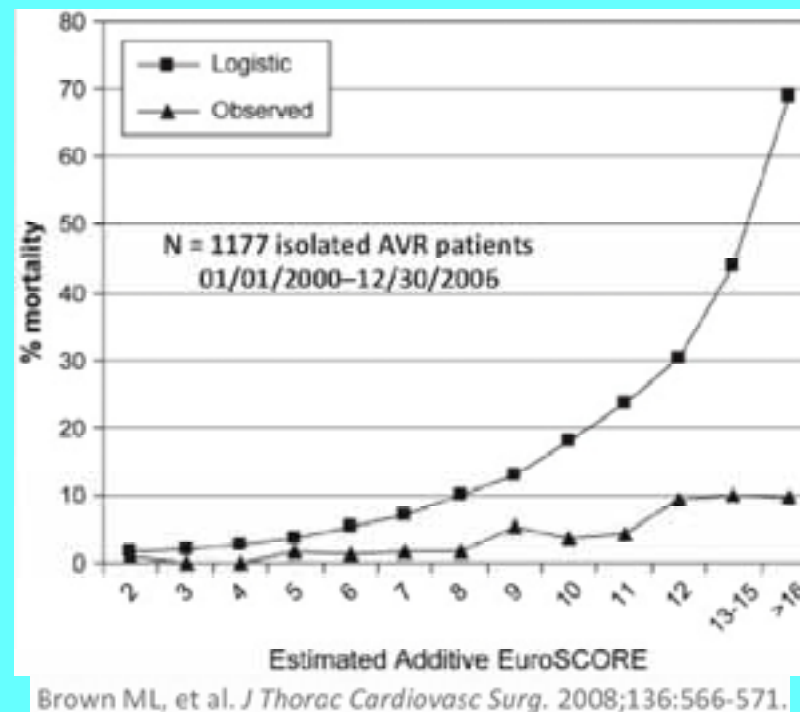
## Considerazioni

- Non abbiamo criteri sicuri per giudicare un malato "ad alto rischio"
- Forse la mortalità può non rappresentare il solo indice per la valutazione del rischio
- Esistono condizioni di patologia clinica non valutate all'interno degli "score di rischio" che limitano o gravano di notevoli problemi la possibilità di interventi tradizionali
  - Tali elementi devono necessariamente essere valutati da chi può fare lo stesso intervento tradizionale



## Gli "score" di rischio non sono la soluzione

- Oggi abbiamo una certa evidenza che gli Score di rischio attualmente in uso (Euroscore, STS Score) non sono applicabili acriticamente ai potenziali candidati a TAVI



# Valutazione comparativa AVR - TAVI

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- E' necessario uno studio comparativo tra TAVI e chirurgia tradizionale
  - E' corretto basare il nostro lavoro e lo sviluppo di una tecnica alternativa solo in base alle evidenze scientifiche, solo in relazione ai risultati clinici
  - E' necessaria l'identificazione di "score di rischio" corretti che consentano una selezione per l'appropriatezza dell'indicazione



# OBSERVANT

**OB**servational **S**tudy of **E**ffectiveness of **AVR-TAVI**  
procedures for severe **A**ortic ste**N**osis **T**reatment

Endorsed by:



DI CHIRURGIA CARDIACA onlus



ITACTA

ITALIAN ASSOCIATION OF CARDIOTHORACIC ANESTHESIOLOGISTS

## AVR o TAVI: risultato





## Fattori che "teoricamente" possono limitare l'applicazione della TAVI

- Valvola bicuspide
- Allergia o intolleranza mezzo di contrasto
- Coronaropatia associata
  - se PTCA meno terapeutica
  - con indicazione primitiva a BPAC

❑ Fattori di Economia sanitaria

## Fattori che "teoricamente" possono favorire l'applicazione della TAVI

- Età avanzata
- Reinterventi
- I.R.C., pazienti in dialisi
- BPCO
- Controindicazioni CEC
- Aorta inclampabile
- Torace ostile

# Is an Age of 80 Years or Greater an Important Predictor of Short-Term Outcomes of Isolated Aortic Valve Replacement in Veterans?

Faisal G. Bakaeen, MD, Danny Chu, MD, Joseph Huh, MD, and Blase A. Carabello, MD

Division of Cardiothoracic Surgery, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston; The Michael E. DeBakey Veterans Affairs Medical Center, Houston; The Texas Heart Institute at St. Luke's Episcopal Hospital, Houston; and Division of Cardiology, Department of Medicine, Baylor College of Medicine, Houston, Texas

**Background.** There is a popular perception that aortic valve replacement (AVR) in octogenarians carries a high risk related primarily to advanced age.

**Methods.** Using the Department of Veterans Affairs Continuous Improvement in Cardiac Surgery Program, we identified patients who underwent AVR between 1991 and 2007. A prediction model was constructed using stepwise logistic regression methodology for outcome comparisons.

**Results.** Compared with younger patients (age < 80 years; n = 6,638), older patients (age ≥ 80; n = 503) had a higher prevalence of baseline comorbidities. In a comparison of

patients propensity-matched by risk profile (579 from each group), the older group had a higher morbidity rate (21.1% vs 15.5%;  $p < 0.05$ ) but a similar mortality rate (5.2% vs 3.3%;  $p = 0.19$ ) compared with the younger group.

**Conclusions.** After risk adjustment, age of 80 years or greater was independently associated with higher AVR-related morbidity but not mortality. Further work is needed to identify ways to reduce operative morbidity in the extremely elderly.

(Ann Thorac Surg 2010;90:769–770)  
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**Is an Age of 80 Years or Greater an Important Predictor of Short-Term Outcomes of Isolated Aortic Valve Replacement in Veterans?**

Frederic C. Johnson, MD, Danny Chin, MD, Joseph Hibb, MD, and Ellen A. Campbell, MD

(Ann Thorac Surg 2010;90:769–774)

Variable	Age < 80 n = 6,638 (%)	Age ≥ 80 n = 504 (%)
Mean age	63.2 ± 10.4	82.2 ± 2.3
Overall perioperative morbidity	1,022 (15.4)	107 (21.2)
Operative mortality	236 (3.6)	28 (5.6)

*In conclusion:*

- Octogenarians' prospects for immediate survival after AVR are **comparable with those of younger patients with similar risk profiles.**
- Physicians should consider patient age in the **context** of the entire clinical picture, rather than assigning an arbitrary cutoff age for medical versus surgical intervention.
- The decision to perform cardiac surgery in octogenarians is undoubtedly complex: selecting patients who would benefit from AVR requires good surgical judgment
- Although several factors need to be taken into consideration, **age by itself should not preclude** these patients from undergoing surgery.

## Primary isolated aortic valve surgery in octogenarians

Enrico Ferrari<sup>\*</sup>, Piergiorgio Tozzi, Michel Hurni, Patrick Ruchat, Frank Stumpe,  
Ludwig K. von Segesser

*Department of Cardiovascular Surgery, University Hospital of Lausanne (CHUV), 46 rue du Bugnon, CH-1011, Lausanne, Switzerland*

Received 8 September 2009; received in revised form 24 January 2010; accepted 26 January 2010; Available online 20 March 2010

### Abstract

**Objectives:** We reviewed our surgery registry, to identify predictive risk factors for operative results, and to analyse the long-term survival outcome in octogenarians operated for primary isolated aortic valve replacement (AVR). **Methods:** A total of 124 consecutive octogenarians underwent open AVR from January 1990 to December 2005. Combined procedures and redo surgery were excluded. Selected variables were studied as risk factors for hospital mortality and early neurological events. A follow-up (FU; mean FU time: 77 months) was obtained (90% complete), and Kaplan–Meier plots were used to determine survival rates. **Results:** The mean age was  $82 \pm 2.2$  (range: 80–90 years; 63% females). Of the group, four patients (3%) required urgent procedures, 10 (8%) had a previous myocardial infarction, six (5%) had a previous coronary angioplasty and stenting, 13 patients (10%) suffered from angina and 59 (48%) were in the New York Heart Association (NYHA) class III–IV. We identified 114 (92%) degenerative stenosis, six (5%) post-rheumatic stenosis and four (3%) active endocarditis. The predicted mortality calculated by logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) was  $12.6 \pm 5.7\%$ , and the observed hospital mortality was 5.6%. Causes of death included severe cardiac failure (four patients), multi-organ failure (two) and sepsis (one). Complications were transitory neurological events in three patients (2%), short-term haemodialysis in three (2%), atrial fibrillation in 60 (48%) and six patients were re-operated for bleeding. Atrio-ventricular block, myocardial infarction or permanent stroke was not detected. The age at surgery and the postoperative renal failure were predictors for hospital mortality ( $p$  value  $< 0.05$ ), whereas we did not find predictors for neurological events. The mean FU time was 77 months (6.5 years) and the mean age of surviving patients was  $87 \pm 4$  years (81–95 years). The actuarial survival estimates at 5 and 10 years were 88% and 50%, respectively. **Conclusions:** Our experience shows good short-term results after primary isolated standard AVR in patients more than 80 years of age. The FU suggests that aortic valve surgery in octogenarians guarantees satisfactory long-term survival rates and a good quality of life, free from cardiac re-operations. In the era of catheter-based aortic valve implantation, open-heart surgery for AVR remains the standard of care for healthy octogenarians.

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## Primary isolated aortic valve surgery in octogenarians

Enrico Ferrari\*, Piergiorgio Tozzi, Michel Humi, Patrick Ruchat, Frank Stumpe,  
Ludwig K. von Segesser*In conclusion:*

- Conventional primary, isolated AVR can be safely performed in octogenarians with acceptable mortality, good long-term survival and good quality of life.
- Patients of 80 years of age or older carrying a mid- or low-operative risk should not be denied the benefit of standard surgery that remains, so far, the standard of care for isolated AVR.

## Operative results (N: 124 patients).

	N (%)
Hospital mortality	7 (6%)

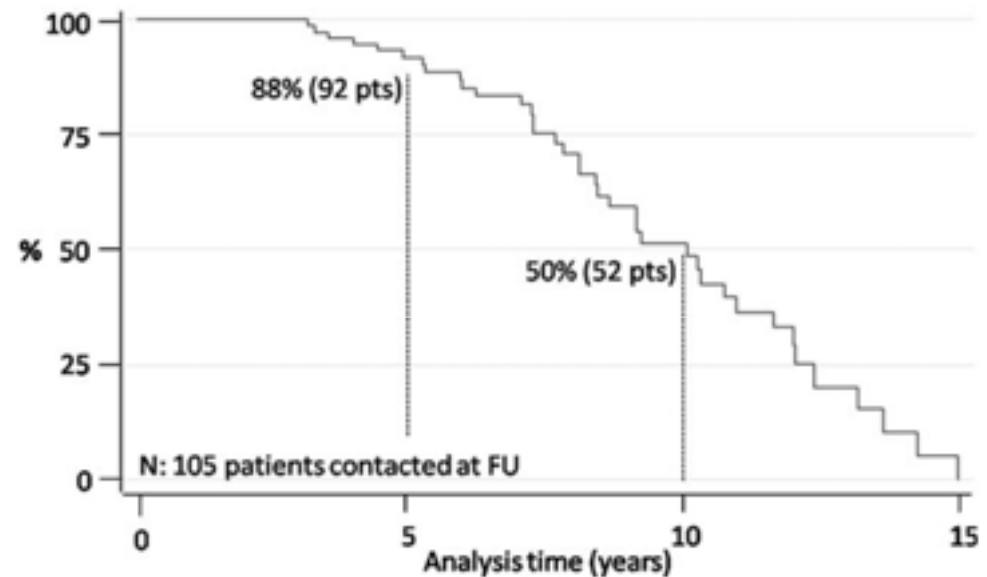


Fig. 2. Cumulative Kaplan–Meier survival curves.



## Valve surgery in octogenarians: does it prolong life?☆

Giulio Rizzoli<sup>\*</sup>, Jonida Bejko, Tomaso Bottio, Vincenzo Tarzia, Gino Gerosa

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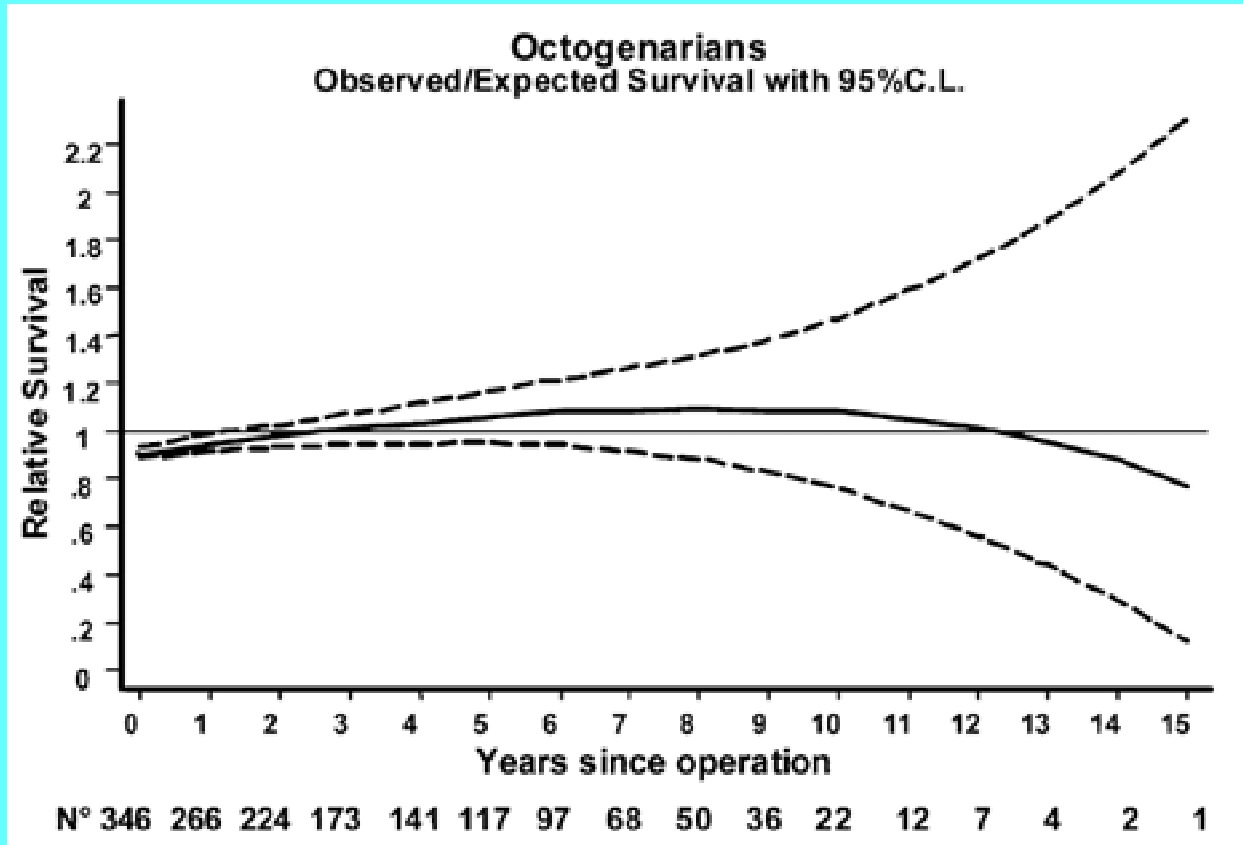
### Abstract

**Objectives:** Age-related degenerative heart-valve disease is a health issue in the present era. Octogenarians are frequently affected by concomitant diseases and, with the present lack of resources, the risk/benefit of valvular replacement therapy poses serious medical, economical and political challenge. We analysed the long-term survival of 346 octogenarians who underwent 352 operations between 1 January 1987 and 1 January 2009 and we compared it with the survival of the general population, matched for age, sex and operative year. **Methods:** The total follow-up was of 1352 years, maximum 15.7 years and was nearly complete except for a single foreigner. Heart diseases, concomitant pathologies, complications and actuarial survival of this study group were compared with 4649 younger counterparts, who received 5416 operations during the same time frame. Octogenarians were sorted by age, sex and operative year and the expected survival was calculated by applying US survival rate and added to the Kaplan–Meier plot for visual comparison. **Results:** A total of 279 aortic, 38 mitral and 35 mitro-aortic valves were replaced or repaired using 357 bioprostheses, 18 mechanical prostheses, 12 reparative operations and 24 re-operations. A total of 75% of patients were younger than 84 years, 95% were younger than 87 years and 99% younger than 90 years. Sex prevalence was 215 female versus 131 male. Operative (30 days) mortality was 5.5% and overall survival was 84.3% at 1 year, 65.4% at 5 years, 27.3% at 10 years and 5.4% at 15 years. The expected survival of the age-, sex-, operative year-matched population was 26.9% at 10 years and 7.9% at 15 years. Female operative mortality was 5.9% and survival was respectively 86.3%, 70.2%, 27.5% and 9.1%, male mortality was 4.5% and survival was respectively 81%, 56.7%, 28.8% and 0% ( $p = 0.16$ ). Expected female survival was 30% at 10 years and 10% at 15 years versus 22% and 5.6%, respectively, in males. Six octogenarians underwent re-operation, with one death. **Conclusions:** Despite the highest prevalence of concomitant diseases and the requirement of additional resources for the detection and neutralisation of risk factors, heart-valve operations in octogenarians offer excellent results that compare favourably with the expected survival of the age-, sex- and operative year-matched population, particularly after primary operations.

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Valve surgery in octogenarians: does it prolong life?<sup>†</sup>

Giulio Rizzoli<sup>\*</sup>, Jonida Bejko, Tomaso Bottio, Vincenzo Tarzia, Gino Gerosa

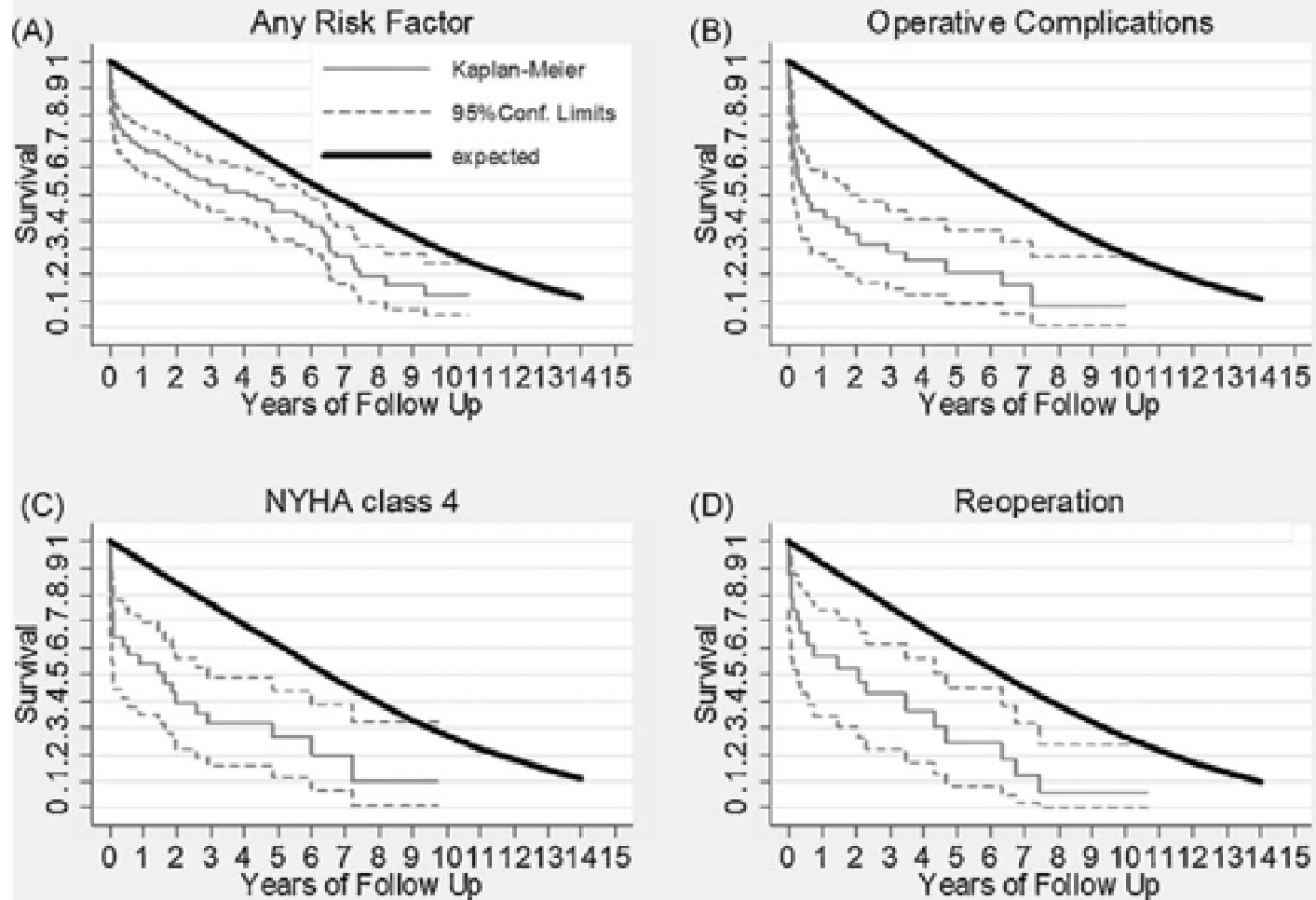


Relative risk of operated octogenarians versus the age, sex, operative year matched general population.

Valve surgery in octogenarians: does it prolong life?<sup>†</sup>

Giulio Rizzoli<sup>\*</sup>, Jonida Bejko, Tomaso Bottio, Vincenzo Tarzia, Gino Gerosa

observed vs. expected survival



## Third-Time Aortic Valve Replacement: (Ann Thorac Surg 2010;89:479–84) Patient Characteristics and Operative Outcome

Kasra Shaikhrezai, MD, MRCS, Giordano Tasca, MD, FETCS, Mohamed Amrani, PhD, FETCS, Gilles Dreyfus, MD, FETCS, and George Asimakopoulos, MD, PhD

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- **49 patients. Early mortality was 4.1%.**
  - ✓ The procedure was carried out nonelectively in 18 patients (36.7%), and severe dyspnea was present in 26 (53.1%).

*Conclusions.* Third-time AVR can be performed with low operative mortality, low cumulative operative mortality, and satisfactory long-term survival and freedom from reoperation. The procedure results in significant regression of left ventricular mass.



# Early and Late Outcomes of Aortic Valve Replacement in Dialysis Patients

(Ann Thorac Surg 2010;89:65–71)

Keisuke Tanaka, MD, Kazuyoshi Tajima, MD, Yoshiyuki Takami, MD, Noritaka Okada, MD, Sachie Terazawa, MD, Akihiko Usui, MD, PhD, and Yuichi Ueda, MD, PhD

Department of Cardiac Surgery, Nagoya University Graduate School of Medicine, and Department of Cardiovascular Surgery, Nagoya Daini Red Cross Hospital, Nagoya, Japan

Table 2. Early Outcomes by Valve Type

Complication	Mechanical No.	Bioprosthetic No.	Overall No. (%)
Stroke	0	0	0
Transient neurologic dysfunction	2	1	3 (4.1)
Bleeding requiring exploration	3	1	4 (5.5)
Deep wound infection	1	0	1 (1.4)
Ischemic colitis	2 <sup>a</sup>	0	2 (2.7)
Pneumonia	1 <sup>a</sup>	1	2 (2.7)
Pulmonary hypertension	1 <sup>a</sup>	0	1 (1.4)
Refractory ventricular arrhythmia	0	1 <sup>a</sup>	1 (1.4)
Hospital death	4/51	1/22	5/73 (6.8)
1995–2001	3/20	1/5	4/25 (16.0)
2002–2007	1/31	0/17	1/48 (2.1)

<sup>a</sup> Cause of hospital death.

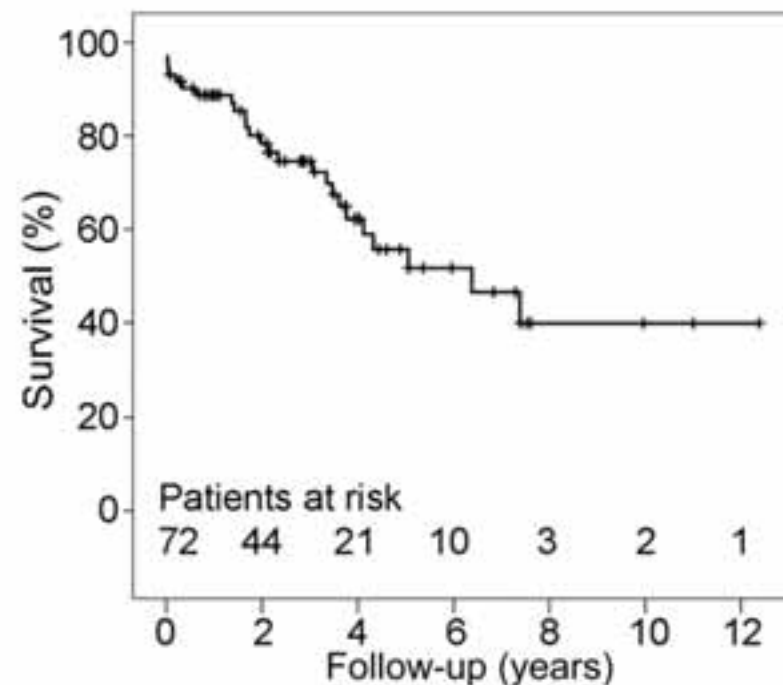


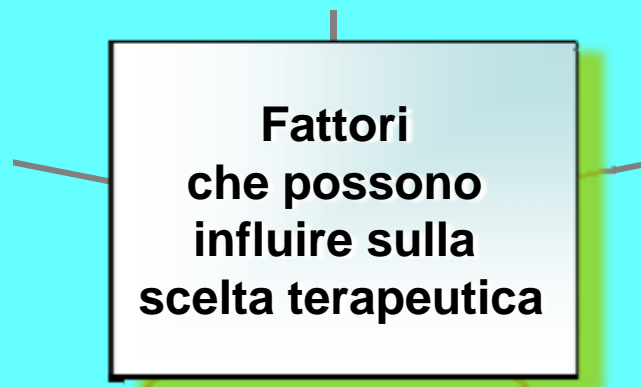
Fig 1. Kaplan-Meier survival after operation in all patients.

## Conclusions.

The results for the dialysis patients after AVR were satisfactory. Dialysis patients can be treated in AVR just like nondialysis patients.



# AVR o TAVI: scelta terapeutica



# The value of aortic valve replacement in elderly patients: An economic analysis

YingXing Wu, MD, Gary L. Grunkemeier, PhD, and Albert Starr, MD

J Thorac Cardiovasc Surg 2007;133:603-7

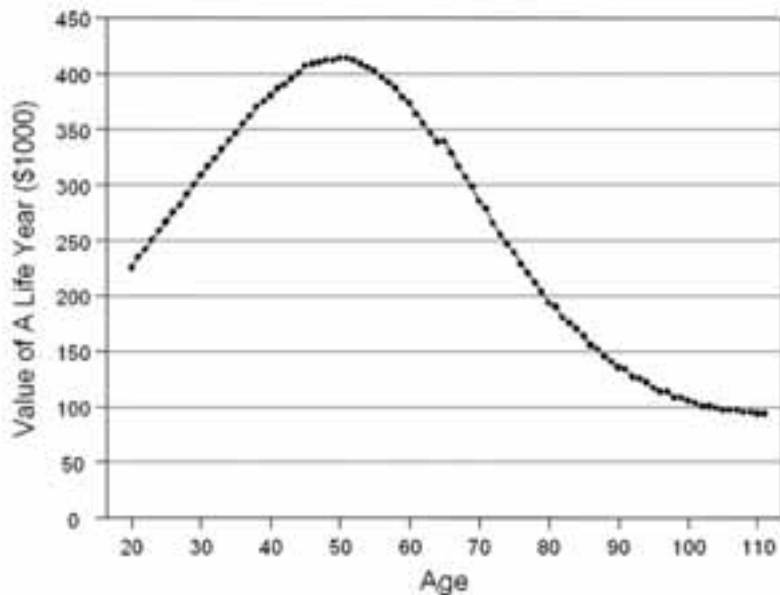


Figure 2. Value of life-year by age in 2005 dollars, as derived from Murphy and Topel.<sup>3</sup>

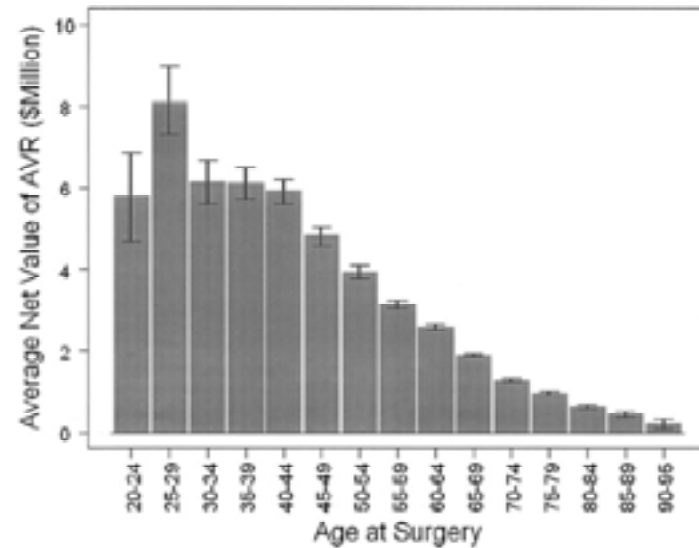


Figure 4. Average net value gained after aortic valve replacement by age at surgery (gray bar). Error bars indicate 95% range from 1000 times simulation. AVR, aortic valve replacement.

...the mean net value decreases according to age at surgery but is still worth: \$600,000 for octogenarians and \$200,000 for nonagenarians.

## Risvolto economico

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- 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)



In 2009, the device / procedural cost is the main limitation to an immediate expansion of TAVI to patients at high surgical risk

France (no reimbursement): 600 pts / y  
Germany (reimbursement): 2000 pts / y

# AVR o TAVI: quello che non sappiamo



Interactive CardioVascular and Thoracic Surgery

Suppl. 2 to Vol. 11 (September 15, 2010)

Abstracts - 24th EACTS

**MAGNETIC RESONANCE IMAGING EVALUATION OF CEREBRAL EMBOLISATION DURING PERCUTANEOUS AORTIC VALVE IMPLANTATION: COMPARISON OF TRANSFEMORAL AND TRANSAPICAL APPROACH USING EDWARDS SAPIEN VALVE**

P. Astarci<sup>1</sup>, D. Glineur<sup>2</sup>, J. Kefer<sup>3</sup>, J. Renkin<sup>4</sup>, J. Vanoverschelde<sup>1</sup>, G. El Khoury<sup>5</sup>, C. Grandin<sup>1</sup>

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**Methods:**

- Magnetic resonance imaging (MRI) was performed before and 48 h after the procedure.
- MRI studies were analysed by an independent radiologist according to the National Institute of Health Stroke Scale.
- All patients had a clinical neurological assessment before and after the procedure.
- 35 procedures, 21 were transfemoral and 14 were transapical.
- Ten patients with similar risk factors who underwent a classical aortic valve replacement have been considered as a control group.

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Results:

- **Of the 35 patients, 32 had new cerebral lesions,**
- 19 in the transfemoral and 13 in the transapical group.
- The mean number of embolic lesions per patient was 6.0 for the transfemoral and 6.6 for the transapical patients (P=0.777).
- The mean volume of embolic lesions was 447.4 mm<sup>3</sup> for transfemoral and 1230.3 mm<sup>3</sup> for the transapical group (P=0.256).
- None of the 10 control patients had new cerebral lesions.
- All patients were neurologically asymptomatic.

**Immagini istologiche di lembi protesici valvolari aortici:  
effetto del “crimpaggio”**





## Transcatheter Aortic Valve Implantation. Where are we?

Peter P. T. de Jaegere<sup>1\*</sup>, MD; Carlos Ruiz<sup>2</sup>, MD; Philipp Bonhoeffer<sup>3</sup>, MD; Alec Vahanian<sup>4</sup>, MD; Jean Marco<sup>5</sup>, MD; Patrick W. Serruys<sup>1</sup>, MD

EuroIntervention 2009;5:169-171

- Even in the absence of a true proof of safety and efficacy, the continuous and ingenious changes in the hardware most likely will be one of the major forces that boost its application...
- The mandate of the FDA is to “promote the public health by ensuring that medical devices are safe, effective, and available in a timely manner”
- This implies that we as physicians, who have the final responsibility for the patients, must provide the evidence.
- It is a complex issue which contains many questions; the “what”, the “how”, the “why”...



## Criticità

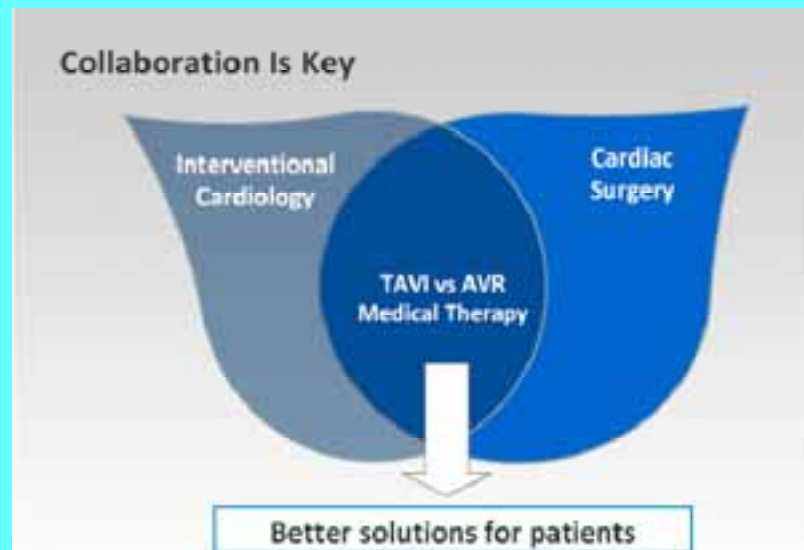
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- ❑ Pressione considerevole da parte del “mercato” e anche da parte degli stessi ammalati perché la TAVI viene considerata una tecnica con minor impatto invasivo: questo non vuol dire con minori rischi e maggior vantaggio.
- ❑ Secondo le linee guida europee ed il consenso delle società italiane non è corretto tenere conto delle scelte personali del malato, se non condivise, riguardo a quale tecnica utilizzare

# Criticità

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- ❑ Esiste un grosso problema di comunicazione sul paziente:
  - sulla base di quali elementi l'ammalato può scegliere ?
  - a quale medico chiedere spiegazioni ?



CORRO DA SOLO.

CERCA DI NON  
ARRIVARE SECONDO.

