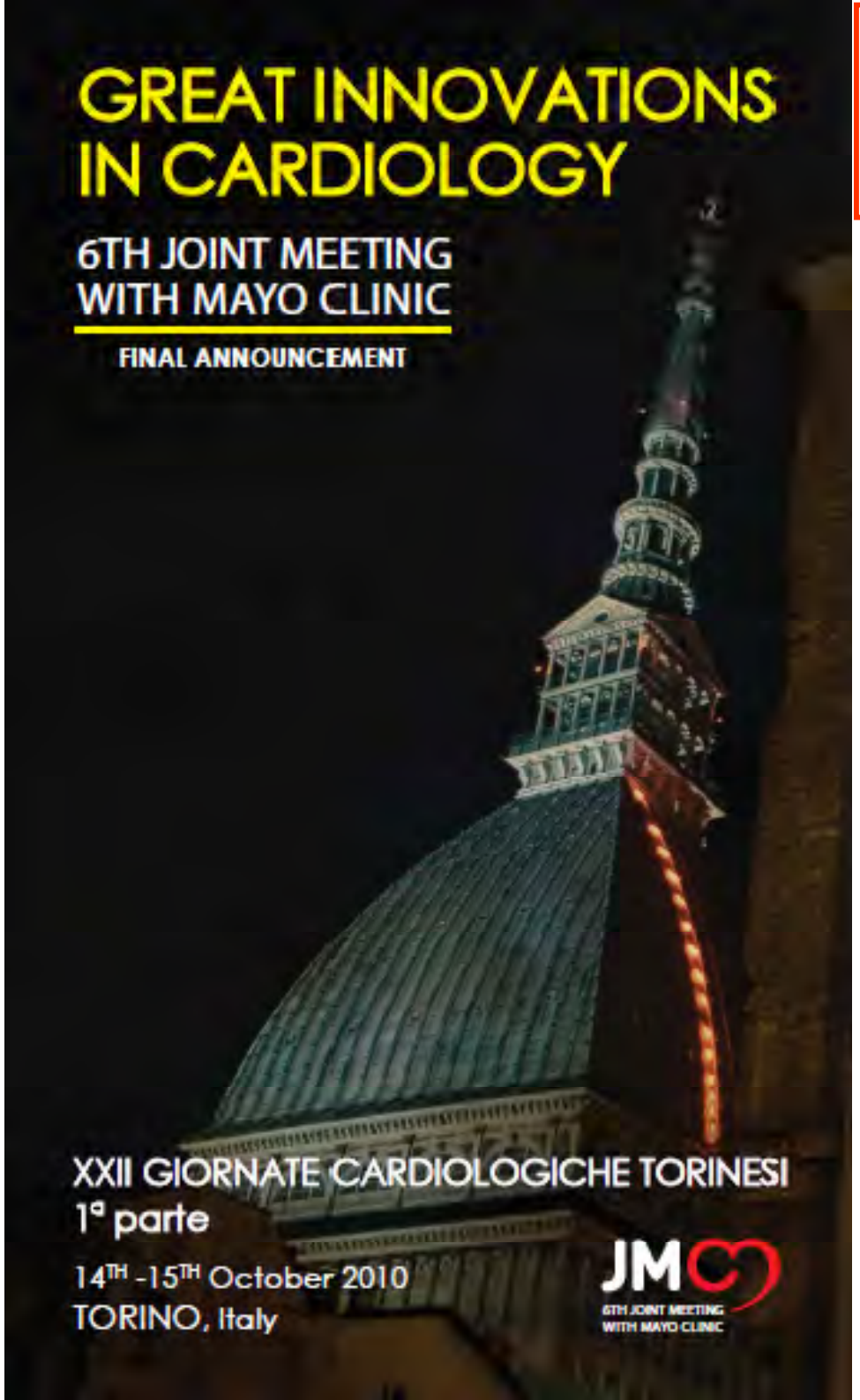


Transcatheter aortic valve therapies in old patients: what are the economic, social and ethical considerations?

Prof. Mauro Rinaldi

Head Cardiac Surgery Department

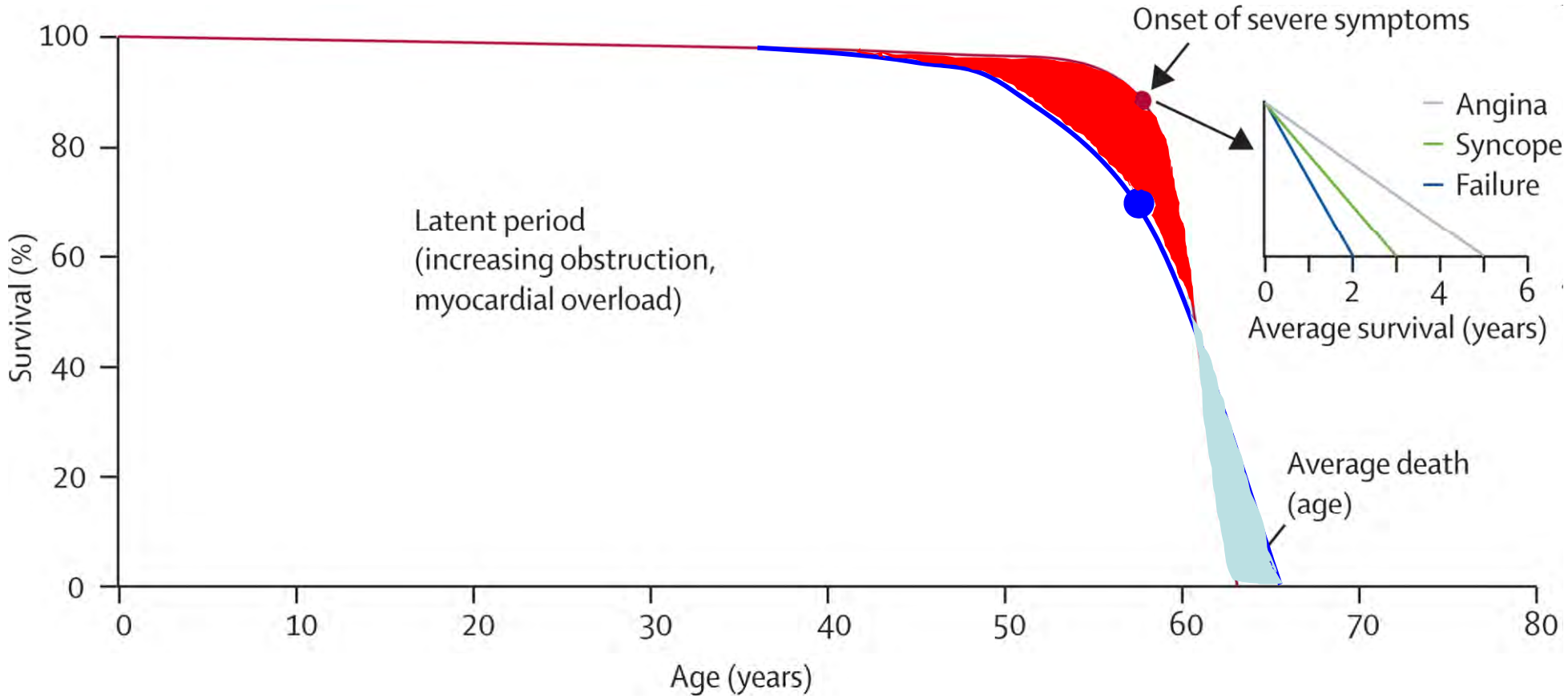
Head Heart and Lung Transplant Program

University of Turin – Molinette Hospital

Aortic Valve Disease is (increasingly) Common

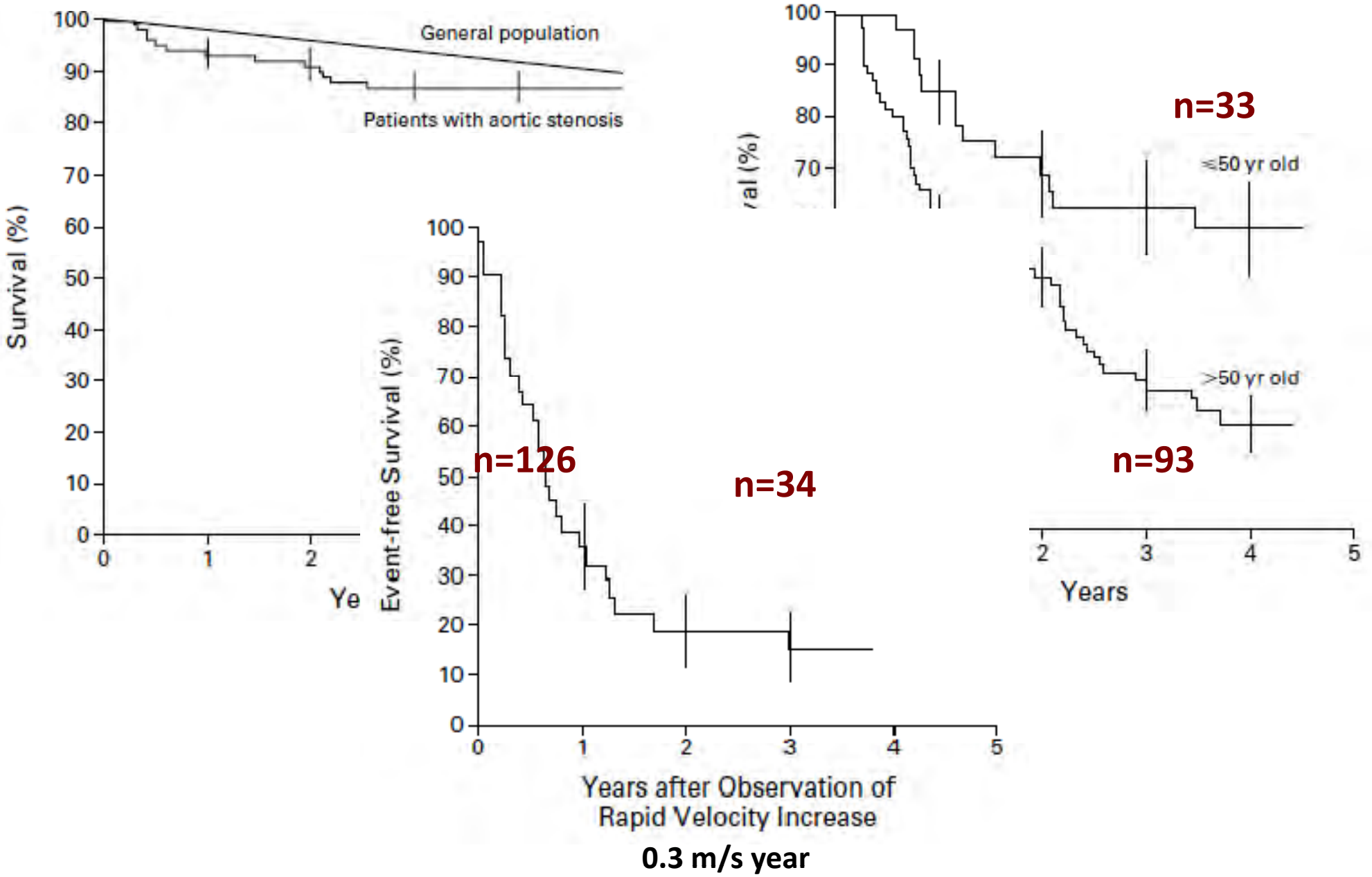
- 26% of the population above the age of 65 years has aortic valve disease
- 2% of people with aortic valve disease are symptomatic and therefore would require treatment
- As a result of an aging population, it is estimated that by the year 2025 the number of people with aortic valve disease will nearly double

Natural History of Symptomatic Aortic Stenosis is Very Bad Without Treatment



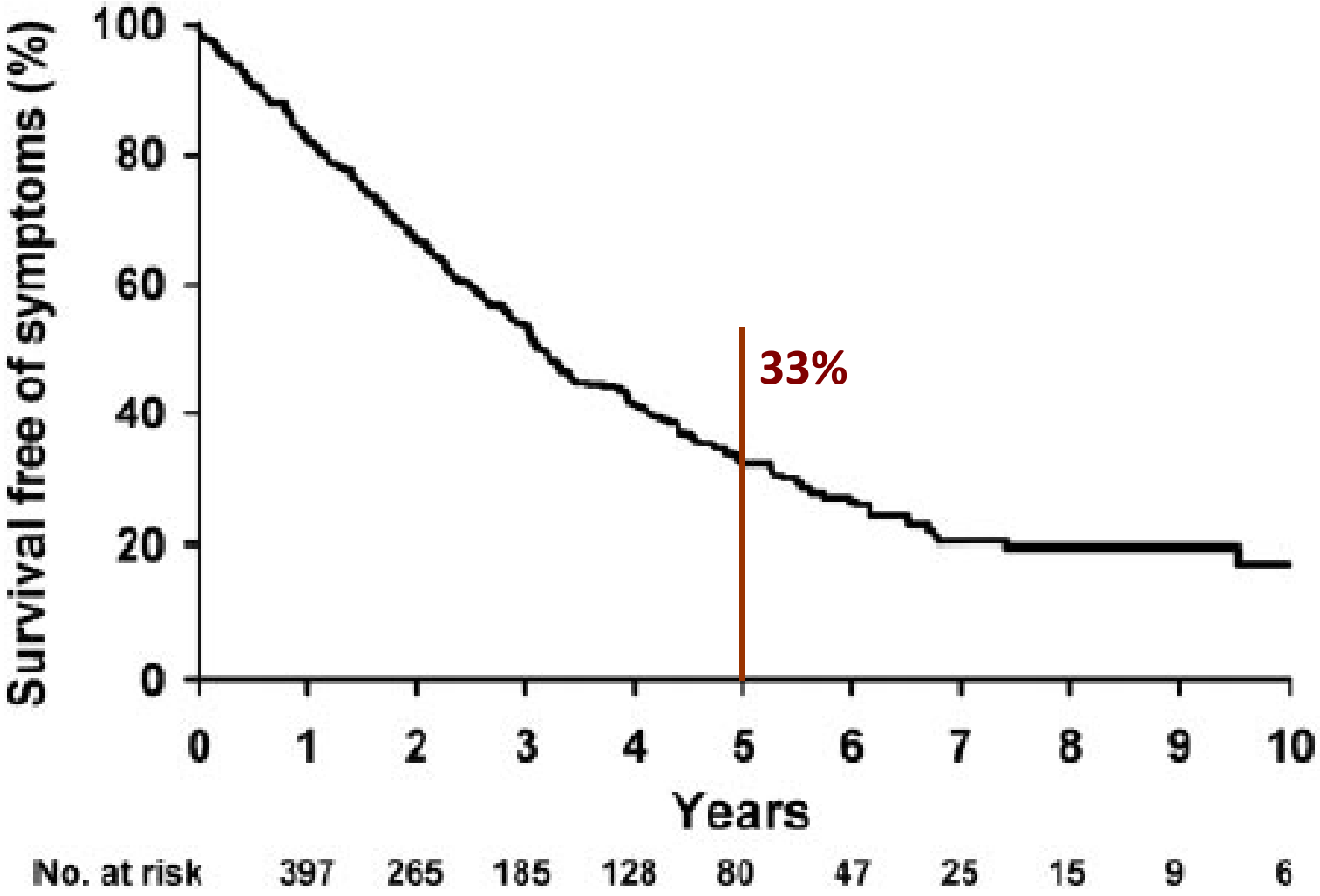
Ross J, Braunwald E. Circulation 1968;38:61-67

PREDICTORS OF OUTCOME IN SEVERE, ASYMPTOMATIC AORTIC STENOSIS



Rosenhek et al. New Eng J Med 2000;9:611-617

Outcome of 622 Adults With Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up

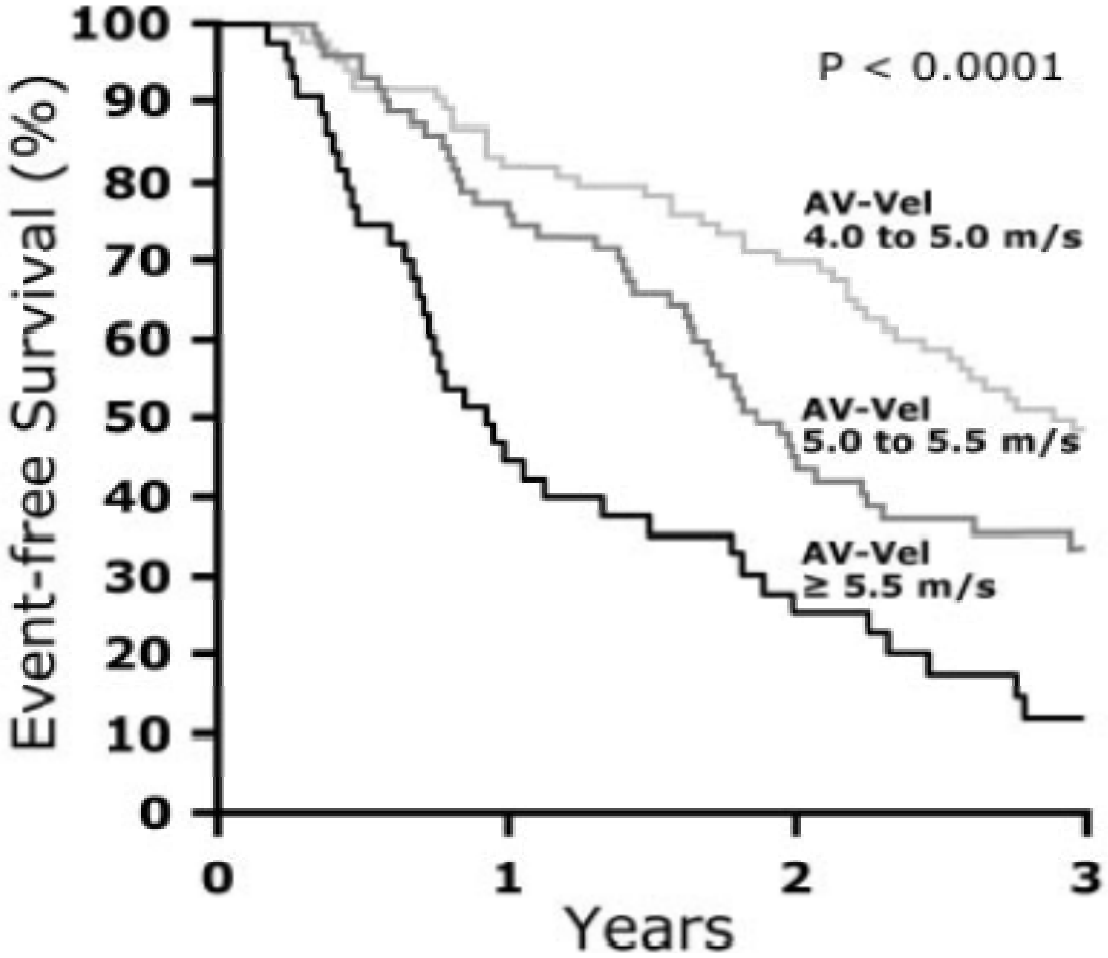


Pellika et al. Circulation 2005;111:3290-5

Natural History of Very Severe Aortic Stenosis

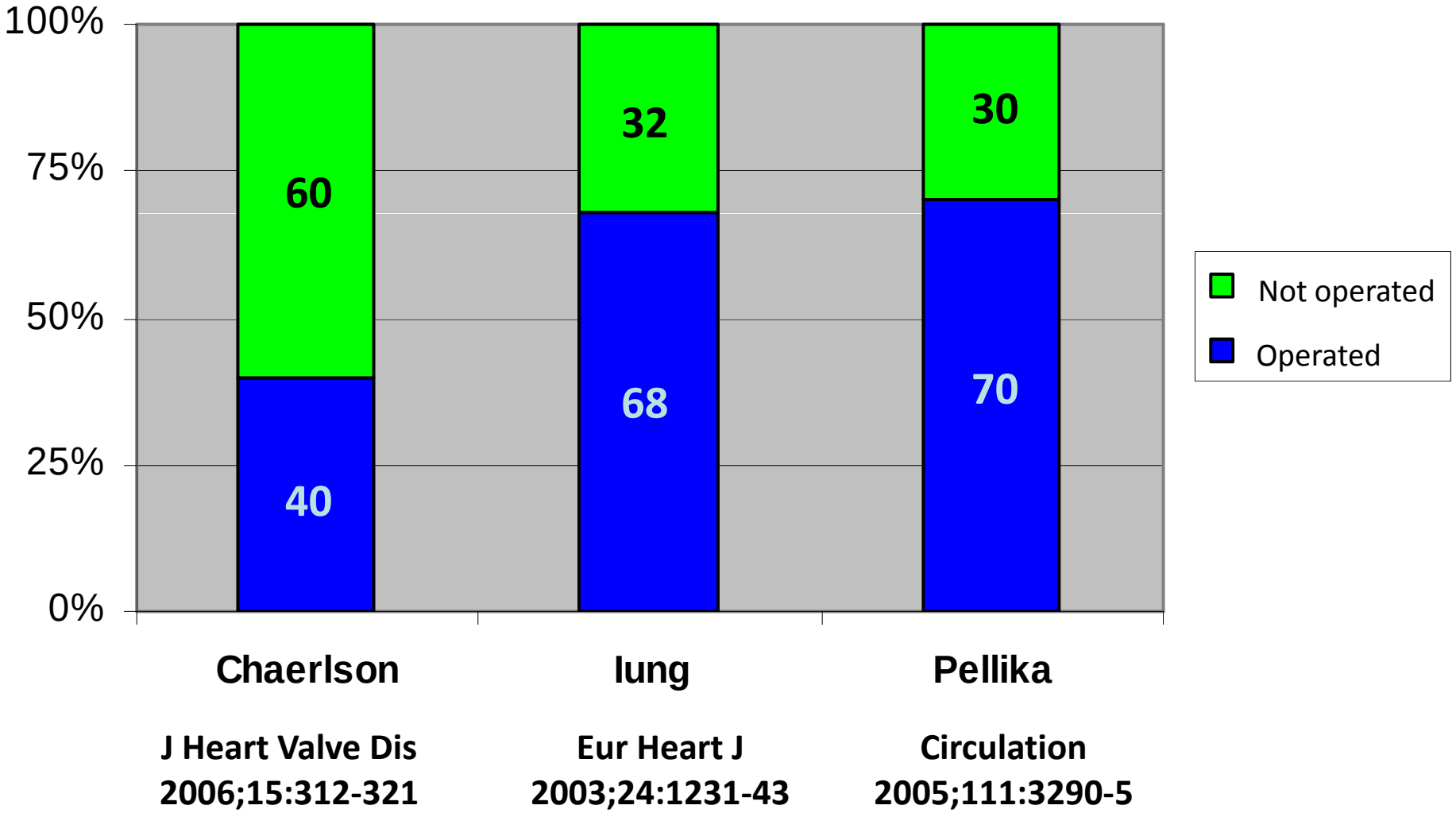
Raphael Rosenhek, MD; Robert Zilberszac; Michael Schemper, PhD; Martin Czerny, MD;

Conclusions—Despite being asymptomatic, patients with very severe aortic stenosis have a poor prognosis with a high event rate and a risk of rapid functional deterioration. Early elective valve replacement surgery should therefore be considered in these patients. (*Circulation*. 2010;121:151-156.)



Rosenhek et al. Circulation 2010;121:151-6

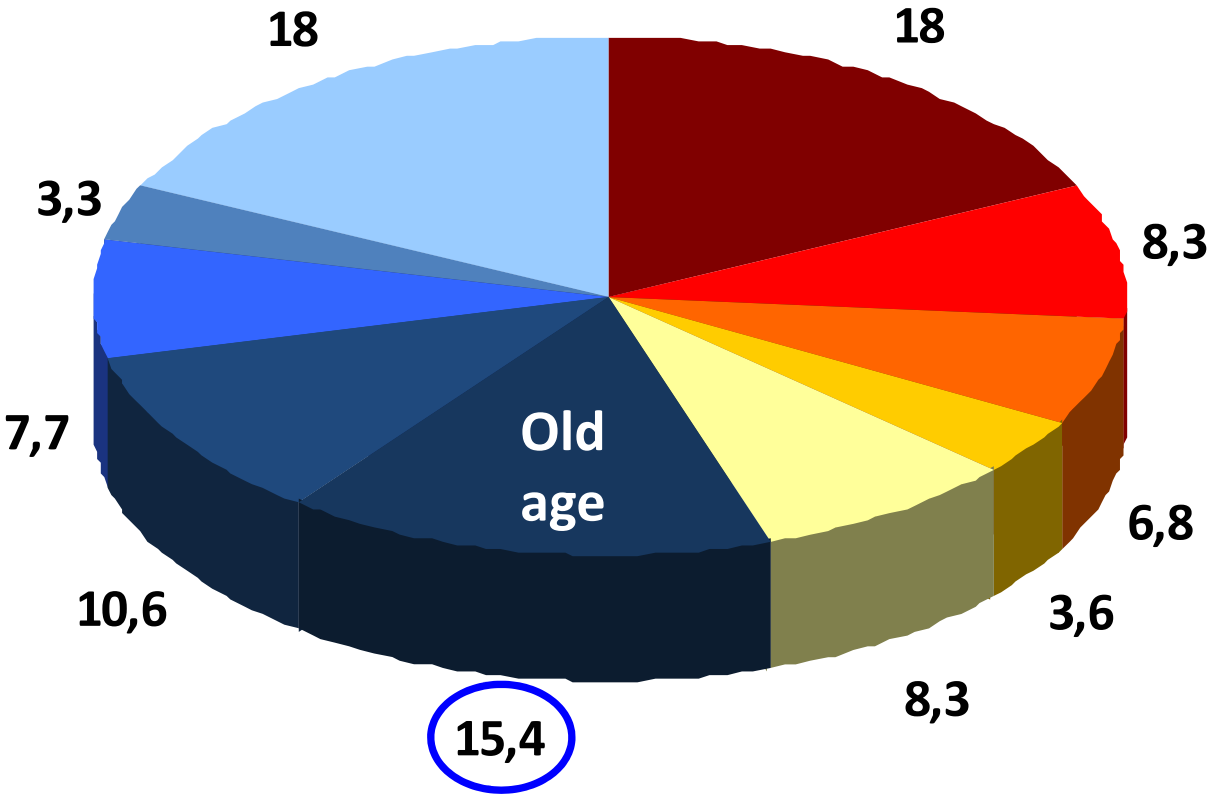
Several Patients with Severe Aortic Stenosis do not Undergo Surgery



Patients with Severe Aortic Stenosis: Why Are so Many Denied Surgery ?

Non-cardiac Causes

55.3%



Cardiac Causes

44.7%

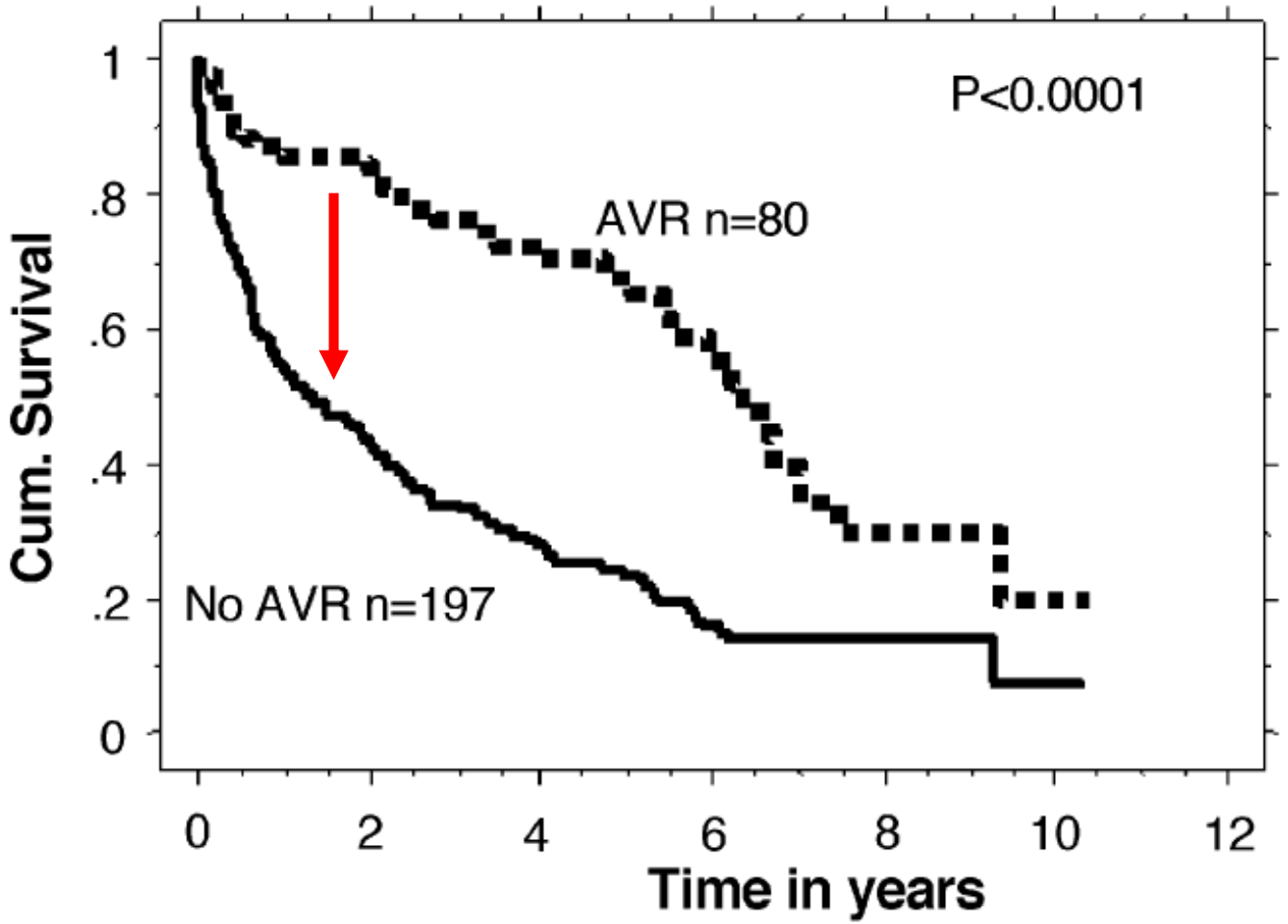
Iung et al. Eur Herat J 2003;24:1231-1243

Why Operate Old Patients ?

1. Increase Life Expectancy
2. Improve Quality of Life
3. Economize Health Care

Survival in elderly patients with severe aortic stenosis is dramatically improved by aortic valve replacement: results from a cohort of 277 patients aged ≥80 years☆

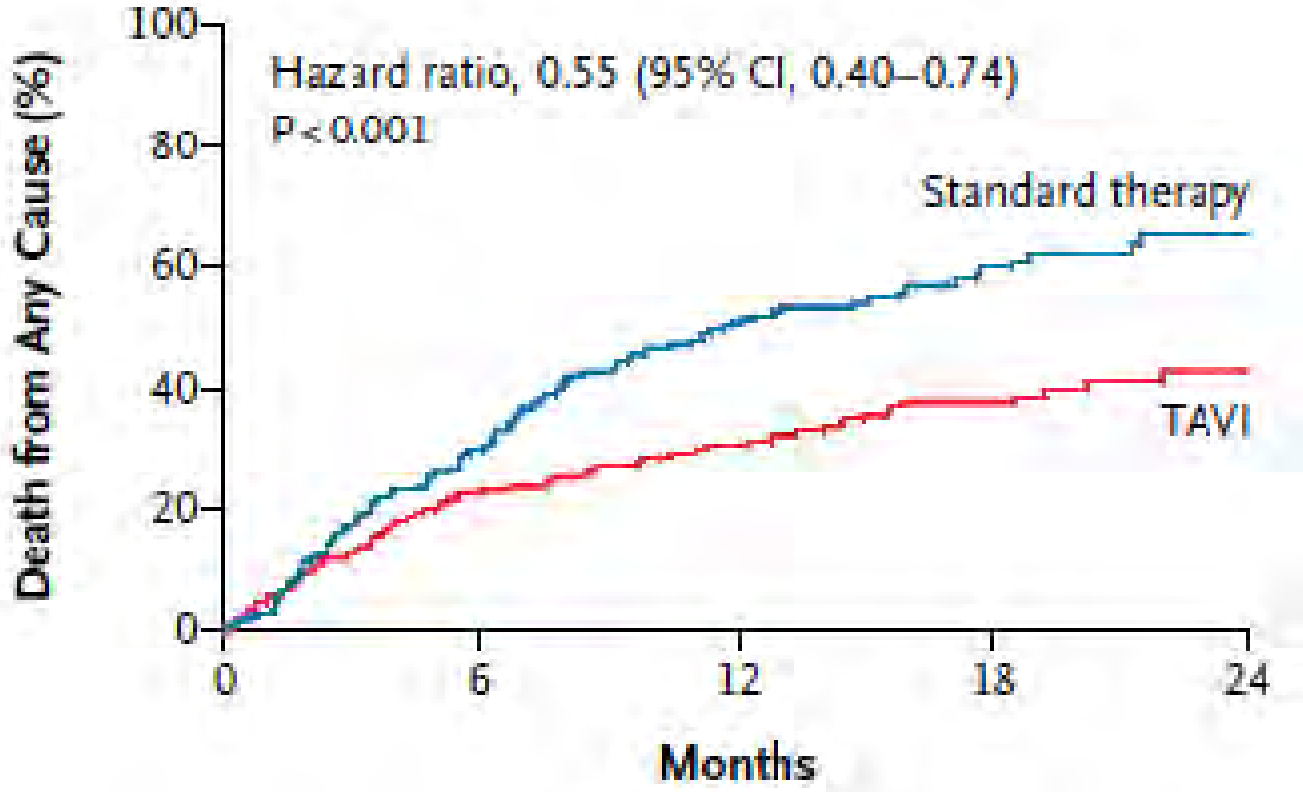
Padmini Varadarajan, Nikhil Kapoor, Ramesh C. Bansal, Ramdas G. Pai *



Eur J Cardiothorac Surg 2006;30:722-727

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Mean age = 83 years



No. at Risk

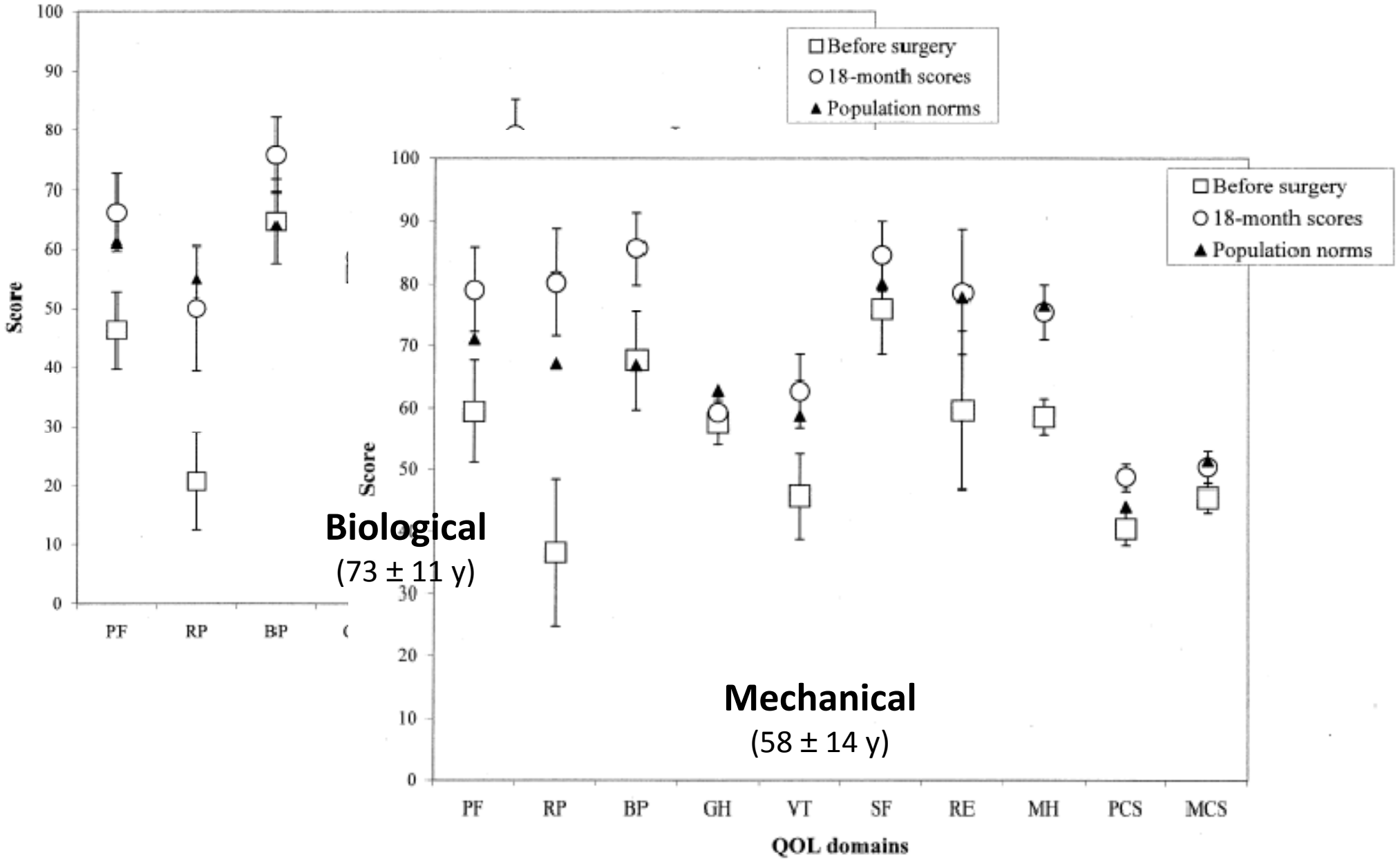
TAVI	179	138	122	67	26
Standard therapy	179	121	83	41	12

Leon M. et al. PARTENR Trial NEJM 2010

Why Operate Old Patients ?

2. Improve Quality of Life

Quality of life after aortic valve replacement with tissue and mechanical implants

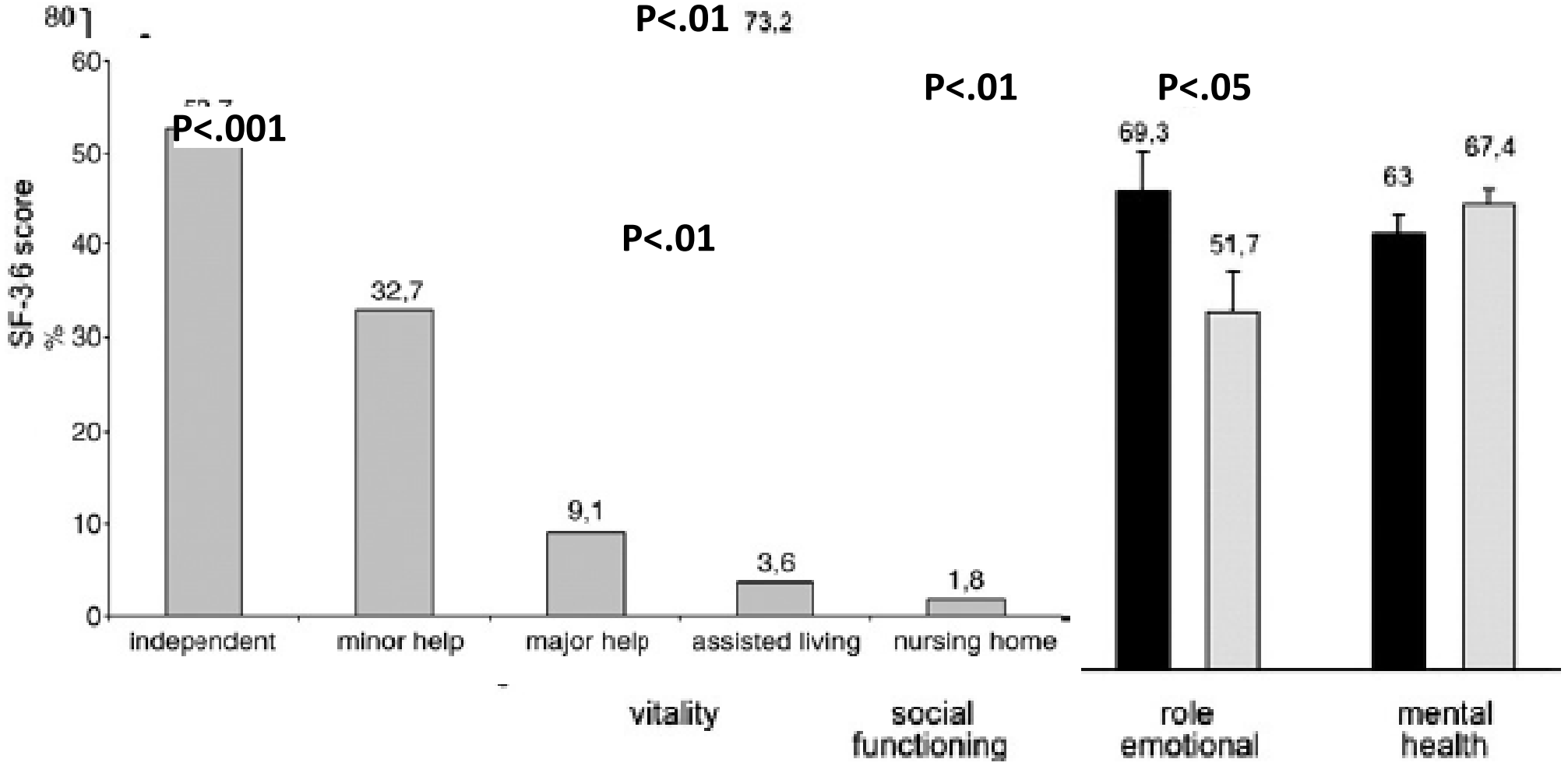


Sedrakyan at al. J Thorac Cardiovasc Surg 2004;128:266-72

Outcomes, Health Policy, and Managed Care

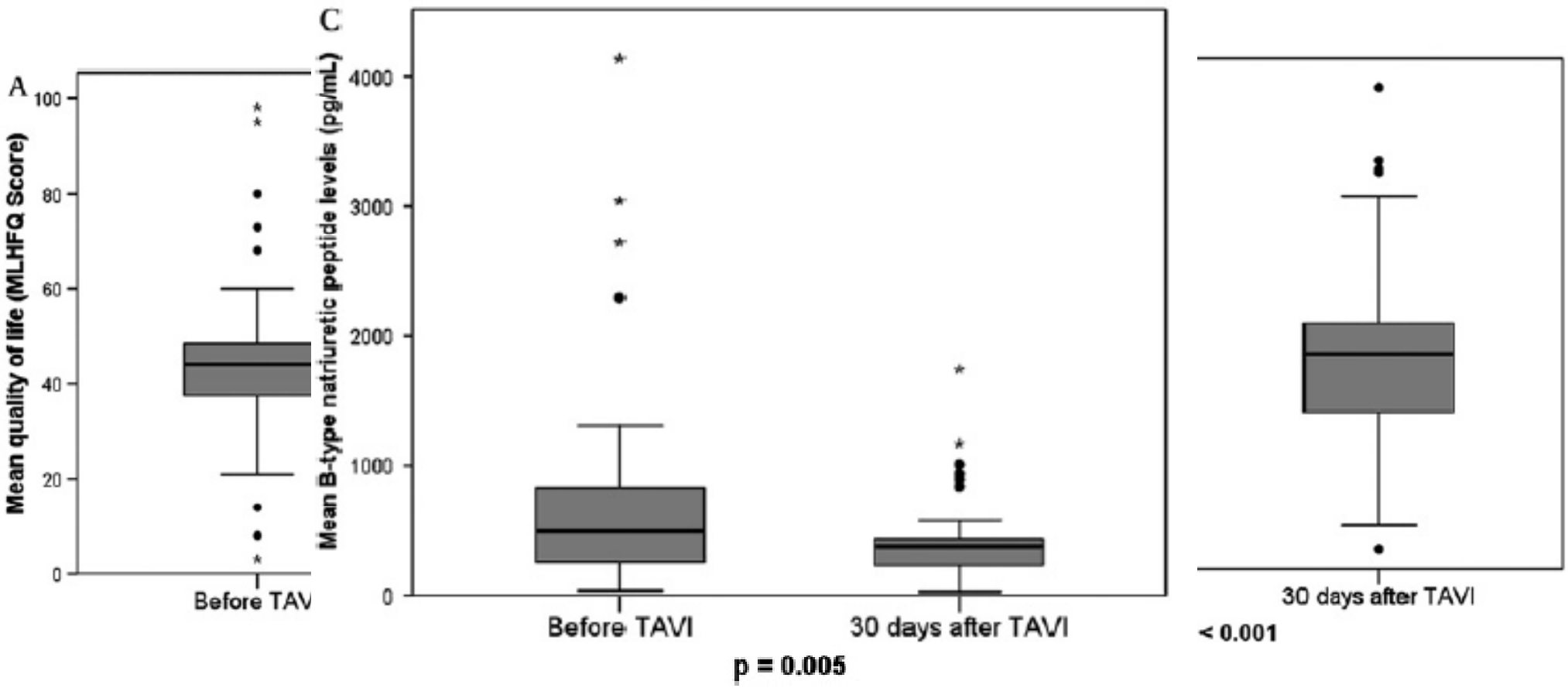
Quality of life among patients undergoing transcatheter aortic valve implantation

3 months follow-up



Krane at al. Am Heart J 2010;160:451-457

Short-term effects of transcatheter aortic valve implantation on neurohormonal activation, quality of life and 6-minute walk test in severe and symptomatic aortic stenosis



Gotzmann at al. Heart 2010;96:1102-1106.

Why Operate Old Patients ?

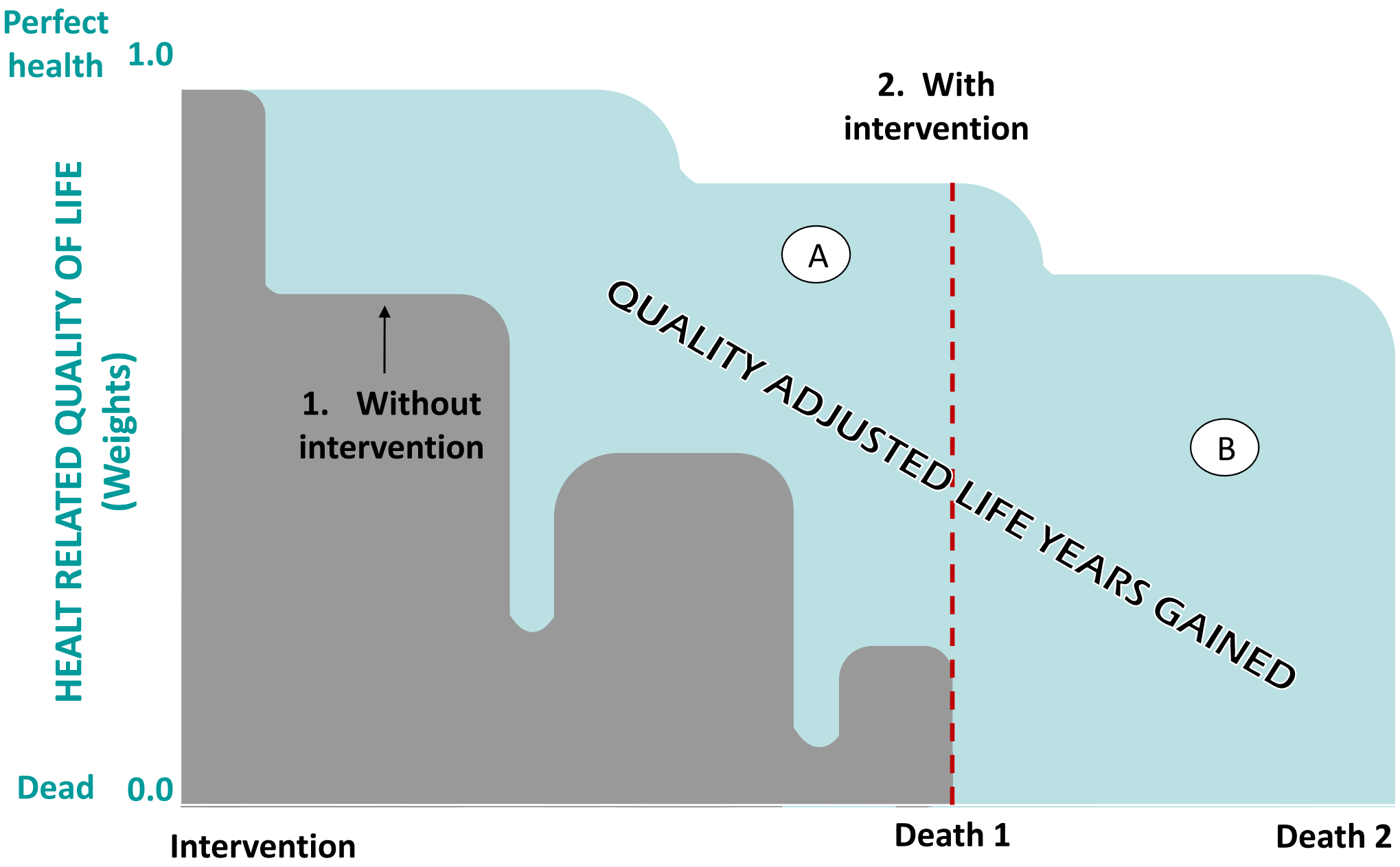
3. Economize Health Care

Economics and innovations

- Health care expenses are growing at an unsustainable rate, driven largely by the development of innovative medical technology, which tend to improve medical outcomes and increase cost
- As societies struggle to control medical expenses, cost saving alternatives ("decrementally" cost-effective technologies) may become attractive, even if they come with reduced benefit
- In theory, limited benefits could be sacrificed for substantial resource savings, permitting re-allocation to higher-value alternatives
- TAVI is, on the other side, an "incrementally" cost effective technology which is difficult to justify in a limited-resource environment

Cost-effectiveness (-utility) analysis (CEA)

- CEA assess the value of a new medical technology by comparing its costs and health benefits in Quality Adjusted Life Years (QUALYs) with those of a standard
- allow to consider differences in treatments which involve changes in quality as well as quantity of life, adjusting for the preference for the benefit achieved
- Utility is a measure of preference about a health state, giving an indication of its relative value
  - Scaled 0 (death) to 1 (full health)
- Utilities are used to “weight” time according to quality of life spent during that time/health state


Perfect health
1.0
HEALT RELATED QUALITY OF LIFE (Weights)
Dead
0.0
2. With intervention
A
QUALITY ADJUSTED LIFE YEARS GAINED
1. Without intervention
B
Intervention
Death 1
Death 2

The Incremental Cost-Effectiveness Ratio (ICER)

Goal is to compare efficacy and costs within a unique indicator

T1, T2 treatment-groups of patients

$$R_{12} = \frac{C_1 - C_2}{E_1 - E_2} = \frac{\Delta C}{\Delta E}$$

Calculated when an intervention is not dominant.
Its interpretation needs a reference to a **willingness to pay threshold-ceiling** ratio:

Accept the technology if ICER < ceiling ratio

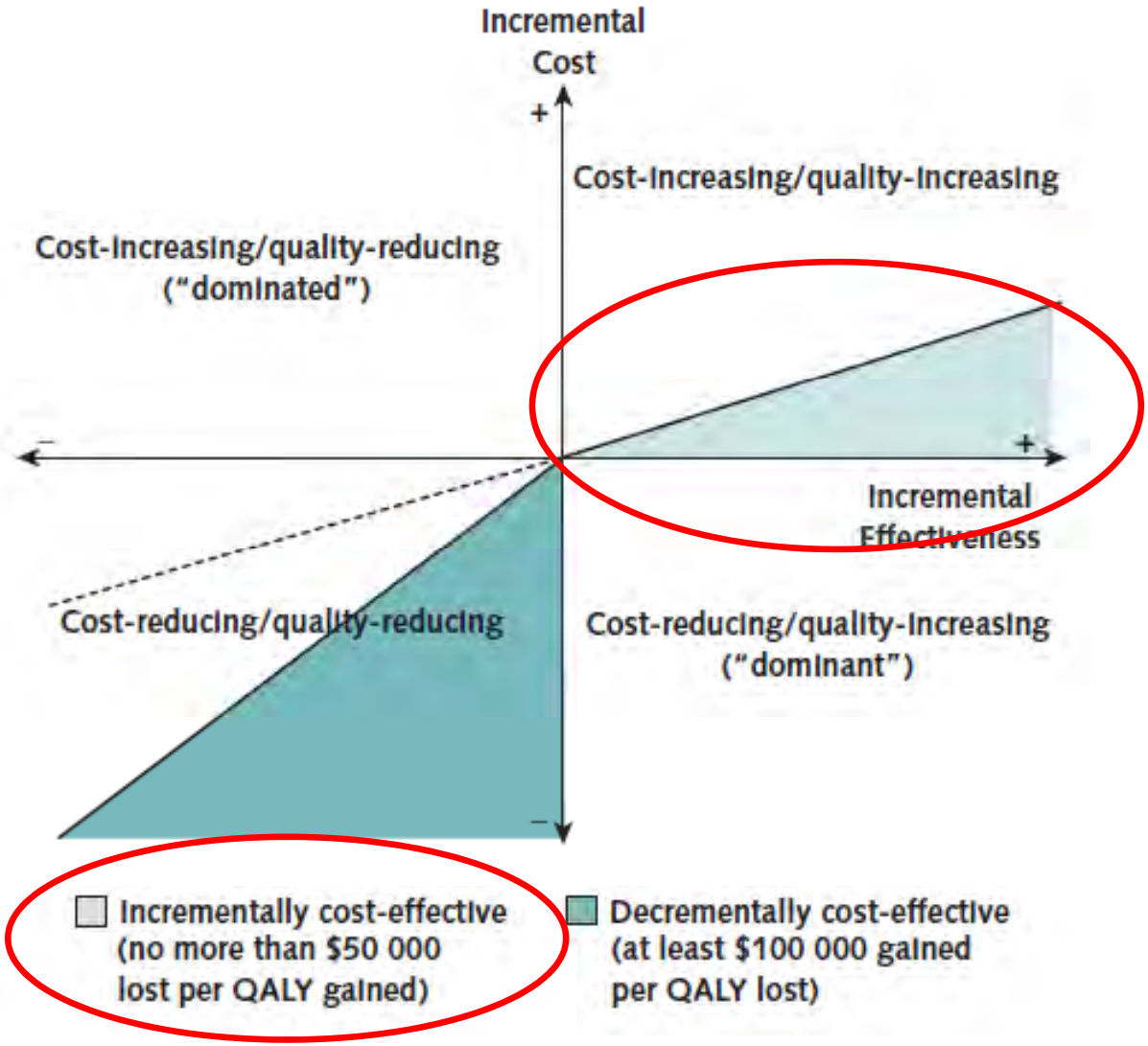
Reject the technology if ICER > ceiling ratio

The Incremental Cost-Effectiveness Ratio (ICER)

- Generally accepted ratios

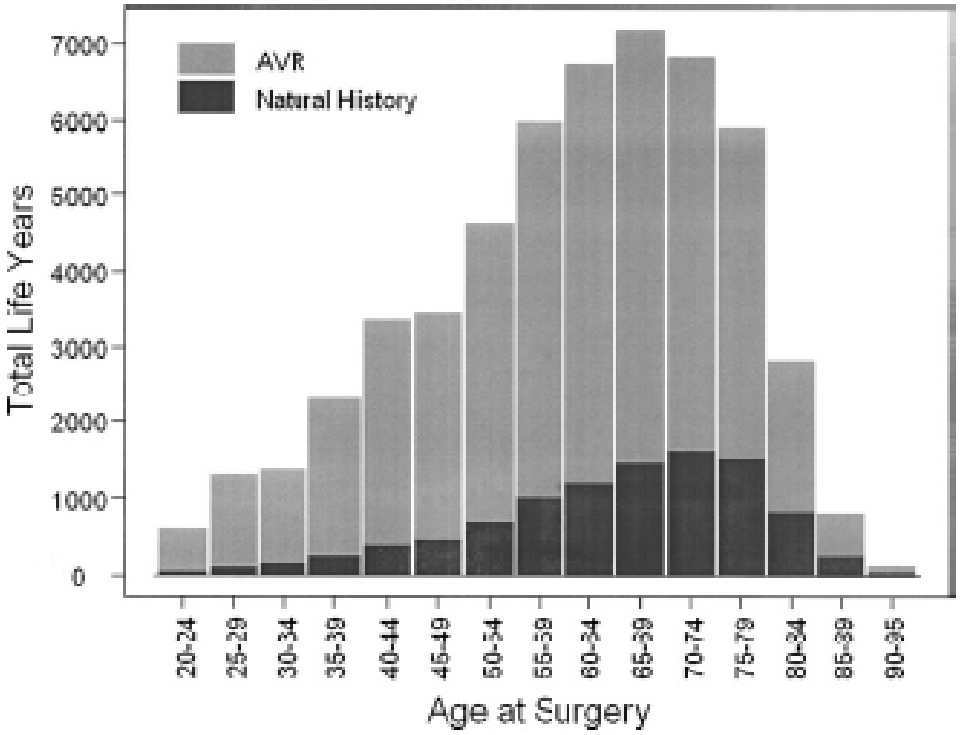
  - **Very cost-effective** **< $20000/QUALY**
  - **Cost-effective** **$20000 to $100000/QUALY**
  - **Not cost-effective** **> $100000/QUALY**

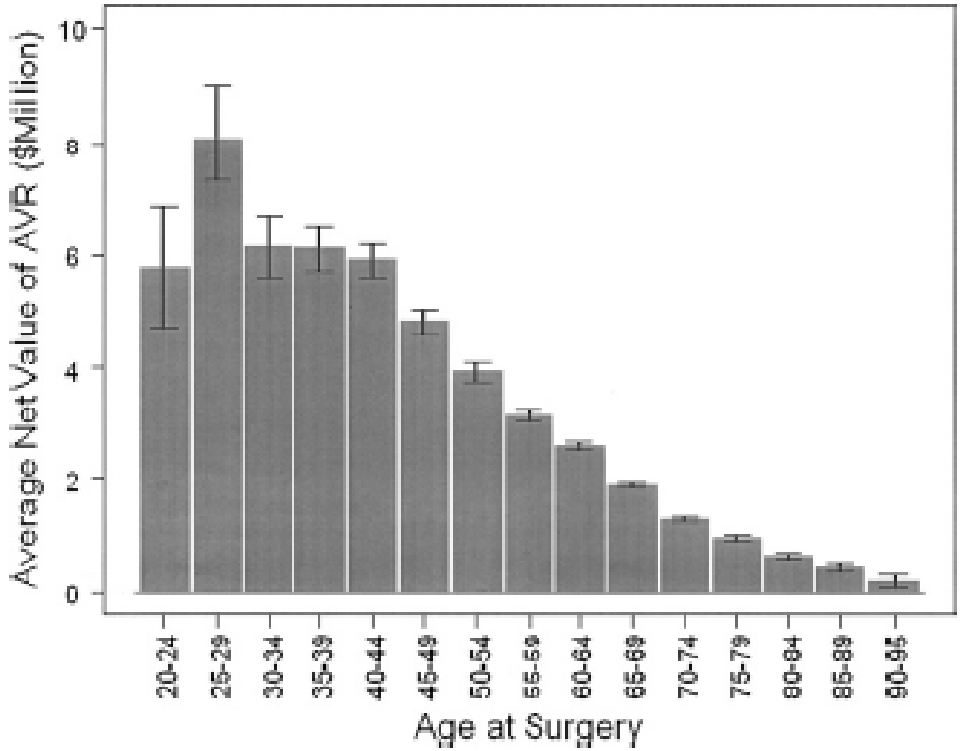
The cost-effectiveness plane



Nelson et al. Ann Intern Med. 2009;151:662-667.

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

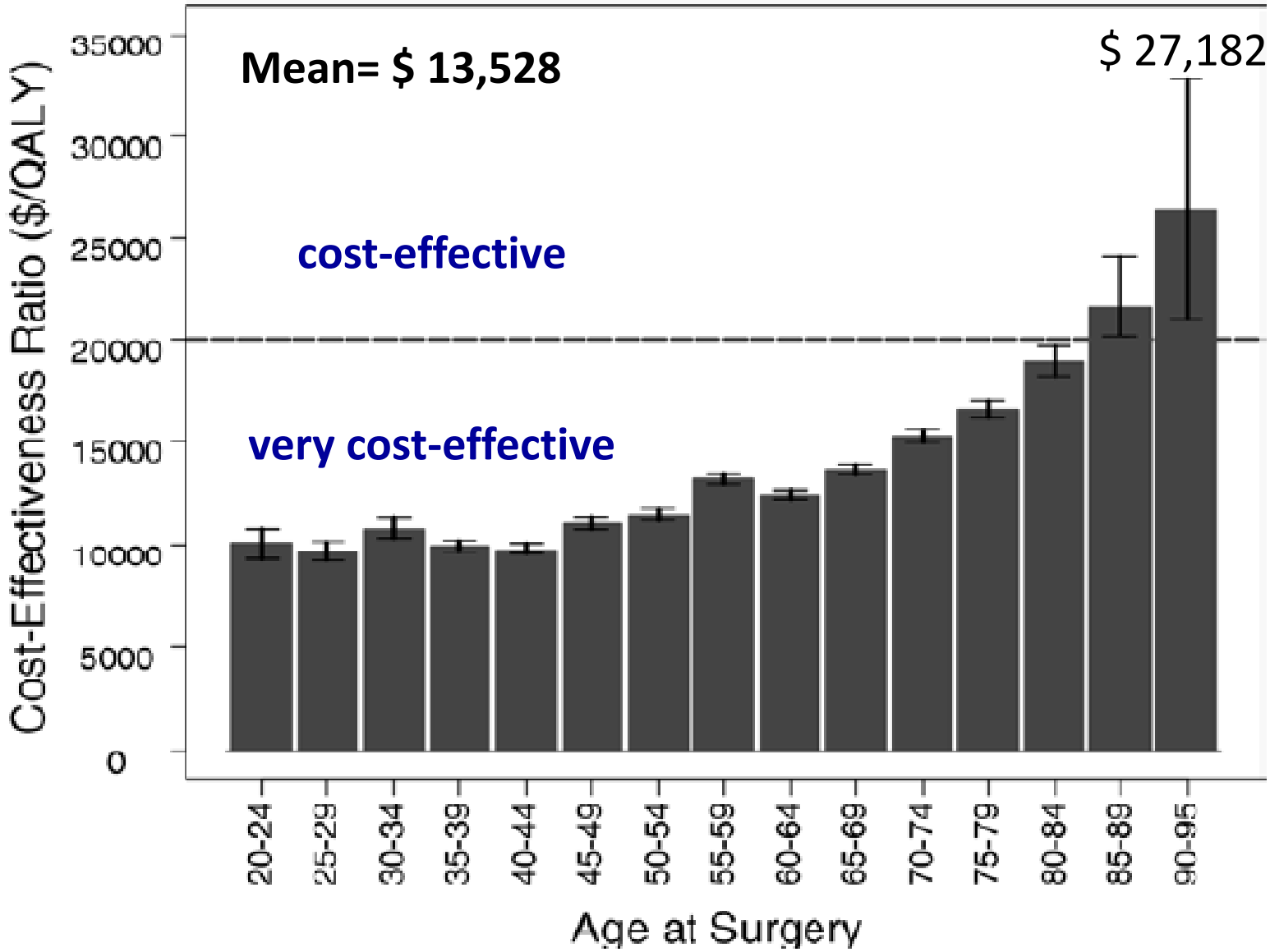




Conclusion: The return on the investment for aortic valve replacement is enormous for patients of all ages

Wu et al. J Thorac Cardiovasc Surg 2007;133:603-607

Cost-effectiveness of aortic valve replacement in the elderly: An introductory study



Wu et al. J Thorac Cardiovasc Surg 2007;133:608-13

The Cost-effectiveness of Air Bags by Seating Position

Results.—Safety belts are cost saving, even at 50% use. The addition of driver's side air bags to safety belts results in net health benefits at an incremental cost of $24 000 per QALY saved. The further addition of front passenger air bags results in an incremental net benefit at a higher incremental cost of $61 000 per QALY saved.

Graham J. JAMA 1997;278:1418-1425

Cost-benefit analysis of TF-TAVI for treatment of Aortic Stenosis

3 years study

	AVR	TAVI	medical Tx
$	76,340	38,728	32,668
QALYs	2,62	2,05	1,22

TAVI IS A VERY COST-EFFECTIVENESS TREATMENT OPTION FOR AORTIC STENOSIS IL ELDERLY POPULATION. THIS MODEL SUPPORTS ITS USE IN **HIGH RISK PATIENTS**, AS IT SIGNIFICANTLY REDUCES MORBIDITY AND MORTALITY

Diage et al. JACC 2010;56:B112 (TCT-490)

Are randomised trials needed in the era of rapidly evolving technologies?

Tom Treasure*

A sequence of the means of evaluating interventions

1 Belief in cause and effect

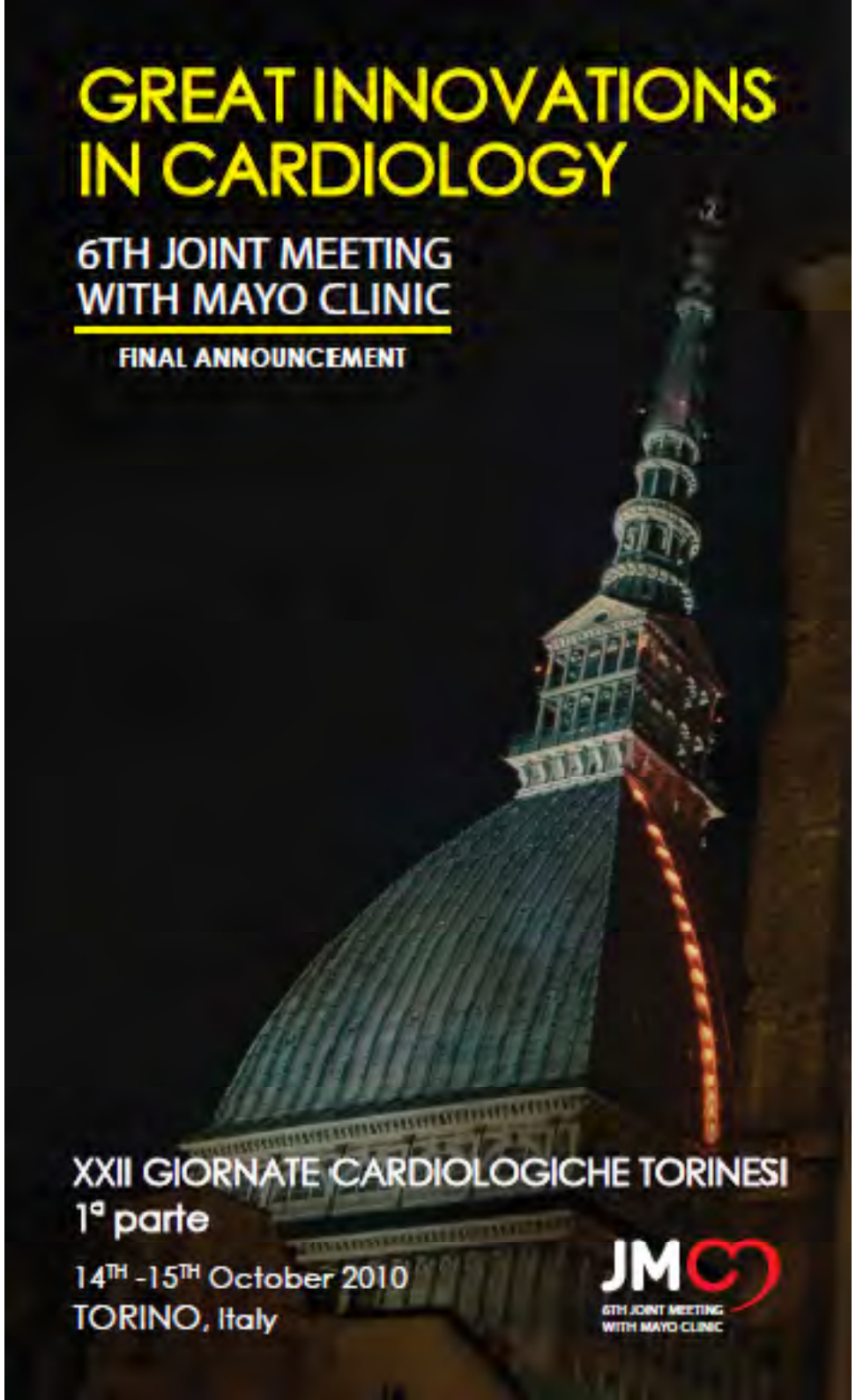
The hierarchy of evidence in evidence based medicine (EBM)

6 'Anecdotes'

Eur J Cardiothorac Surg 2009;35:474—479

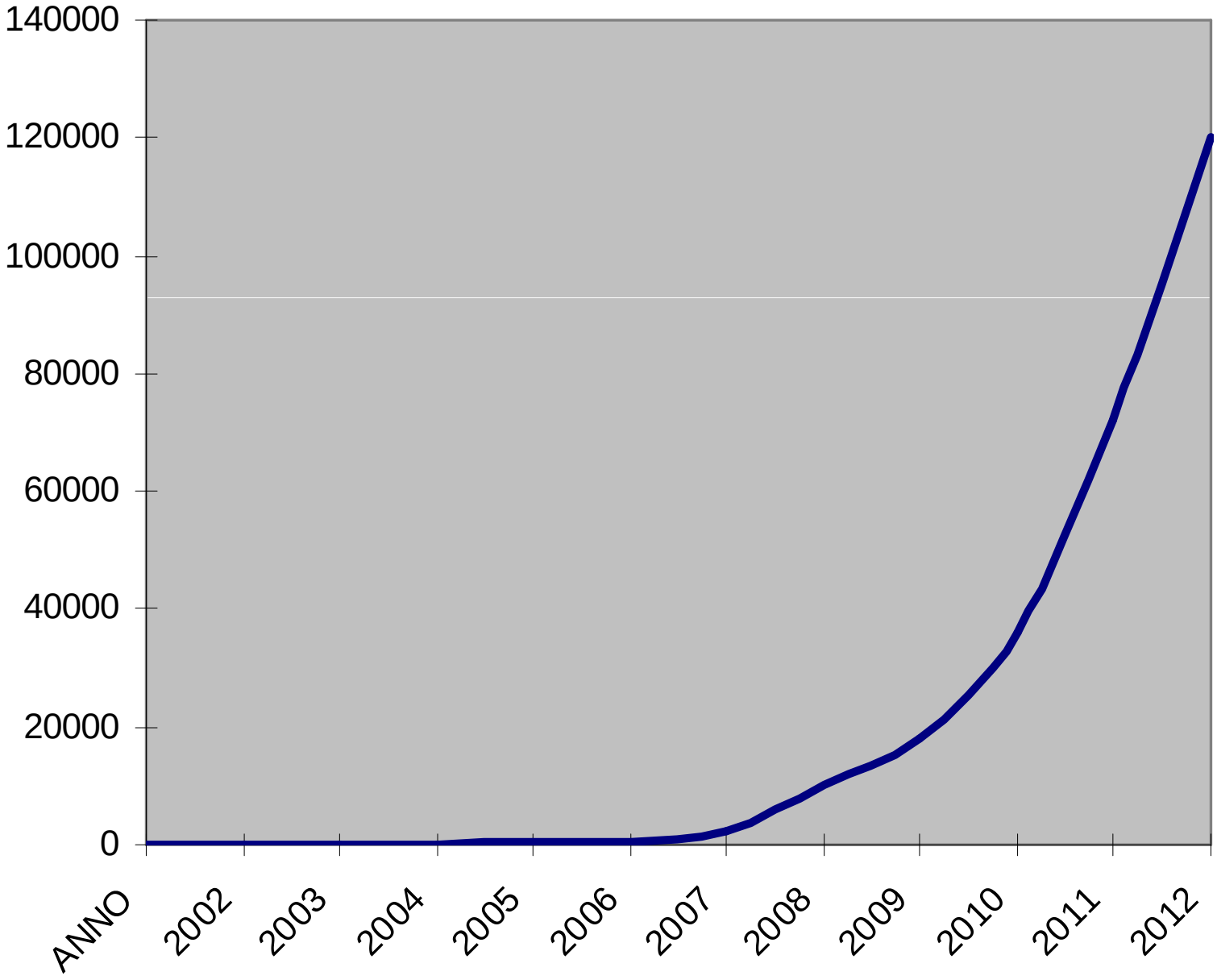
CONCLUSIONS

1. TAVI and AVR increase life expectancy
2. TAVI (as AVR) improve the Quality of Life
3. TAVI is a cost-effectiveness procedure in old, high-risk or otherwise inoperable patients
4. Symptomatic Aortic Stenosis should be treated (AVR or TAVI) in all patients with a reasonable life expectancy
5. As soon as we do not have longer follow-up it is unethical to offer TAVI to moderate-risk patients that can undergo traditional surgery


GREAT INNOVATIONS
IN CARDIOLOGY
6TH JOINT MEETING
WITH MAYO CLINIC
FINAL ANNOUNCEMENT
XXII GIORNATE CARDIOLOGICHE TORINESI
1ª parte
14TH -15TH October 2010
TORINO, Italy
JMC
6TH JOINT MEETING
WITH MAYO CLINIC

Thank you

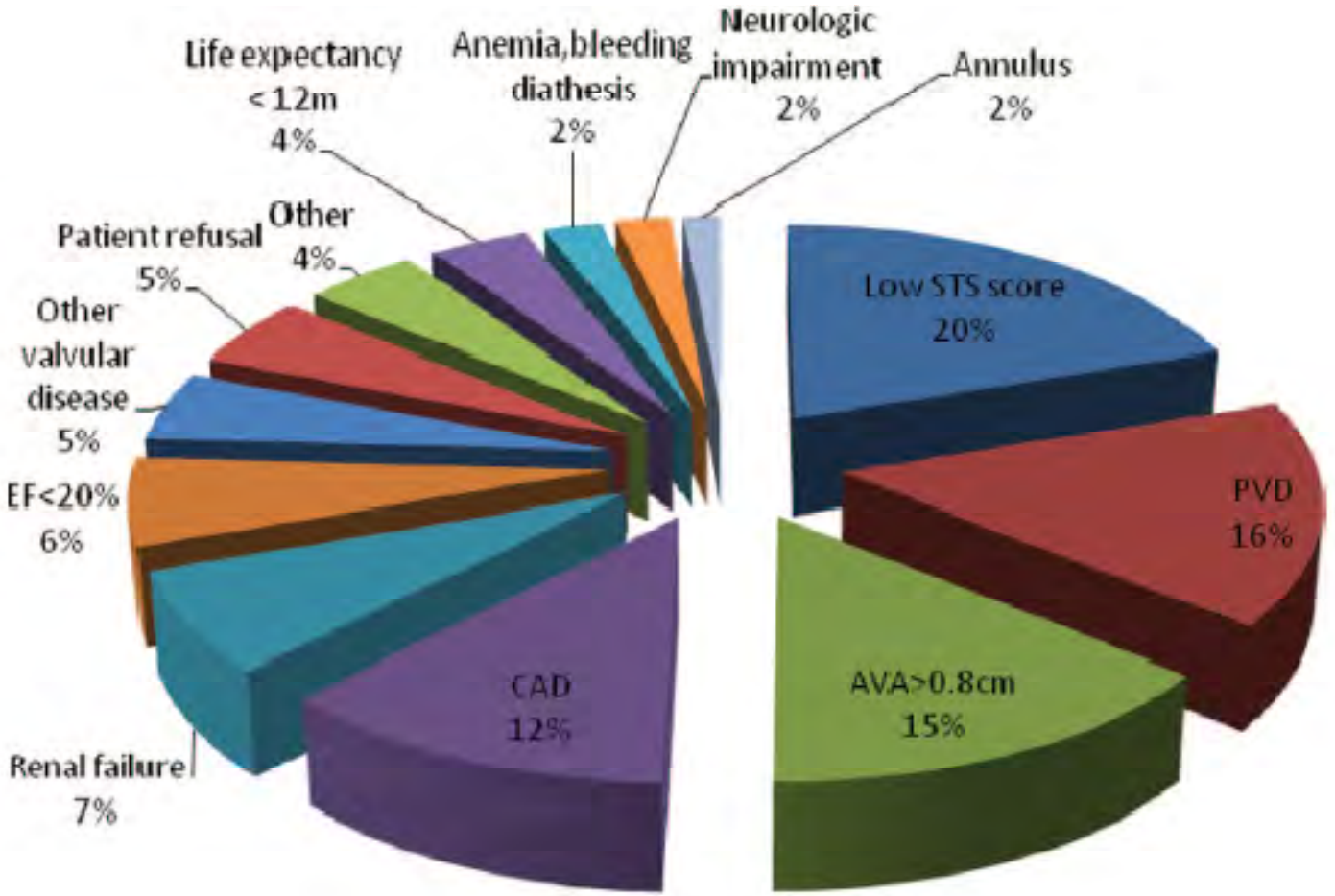
TAVI TENDENCIES



Outcome of Octagenarians After AVR or AVR combined with CABG

Reference	n° of patient	patient characteristics	in-hospital mortality
Ferrari E. 2010 Eur J Cardiothorac Surg. 38:128-33	124	≥ 80 years (Isolated AVR)	5,4%
Leontyev 2009 Ann Thorac Surg. 87(5):1440-5	282	≥ 80 years (Isolated AVR)	7,8%
Gulbins 2008 Clin Res Cardiol 97:176-80	236	≥ 80 years (91% CABG)	9,3%
Filsoufi 2008 J Am Geriatr Soc. 56:255-61	231	≥ 80 years (48% CABG)	5,2%
Melby 2007 Ann Thorac Surg. 83:1651-6	245	≥ 80 years (57% CABG)	9,0%
Kolh 2007 Eur J Cardiothorac Surg. 31:600-6	220	≥ 80 years (26% CABG)	9,0%
Bose 2007 J Cardiothorac Surg. 13;2:33	68	≥ 80 years (46% CABG)	13,0%
Langanay 2006 J Heart Valve Dis. 15:630-7	442	≥ 80 years (19% CABG)	7,5%

Main Causes for Rejection from TAVI Trials



- 75 (20.7%) had two reasons for rejection
- 26 (7.1%) had three reasons for rejection

Ben-Dor at al. Circulation. 2010;122:S37–S42