




Surgery: The "Gold Standard" treatment for Aortic Stenosis

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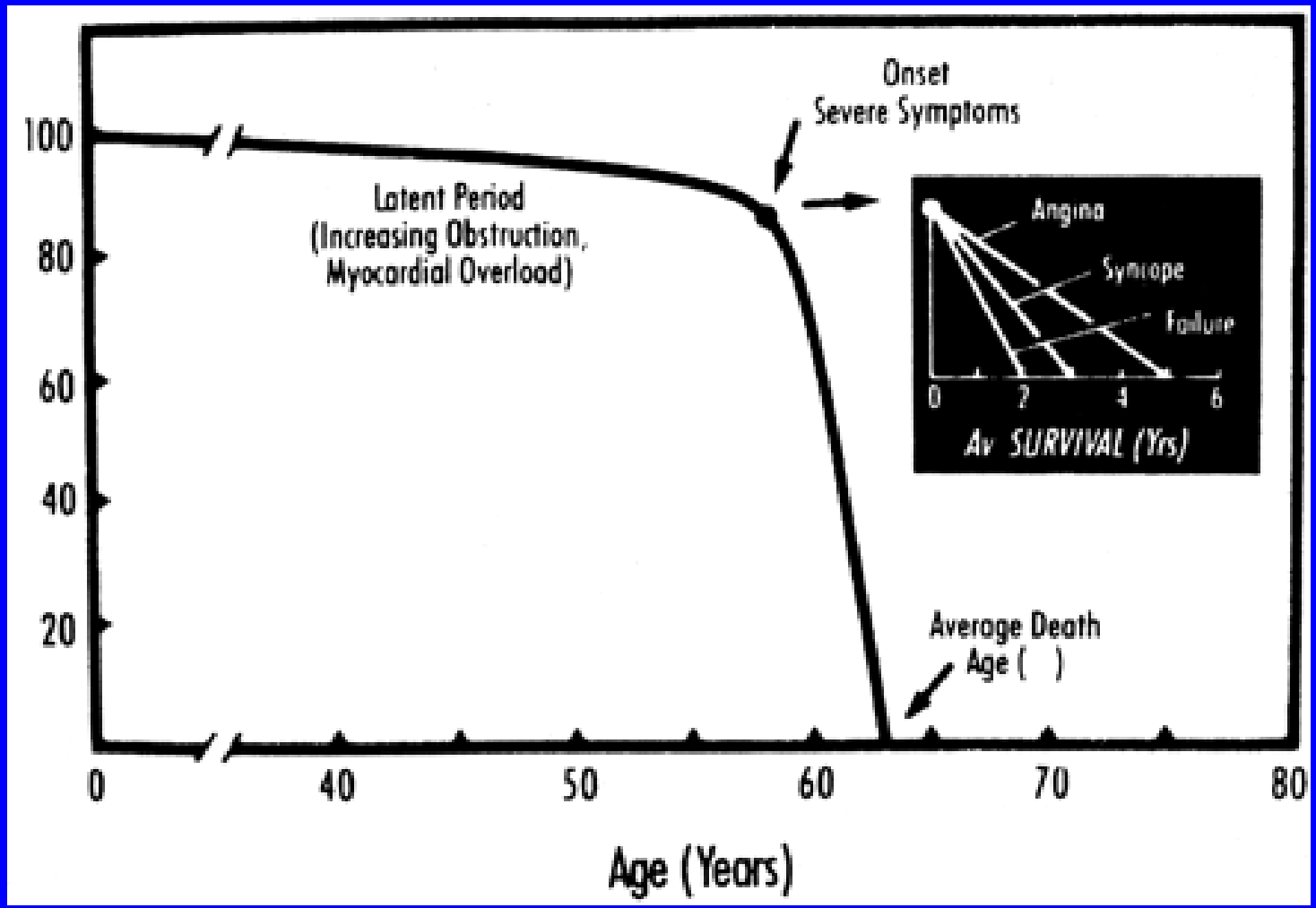
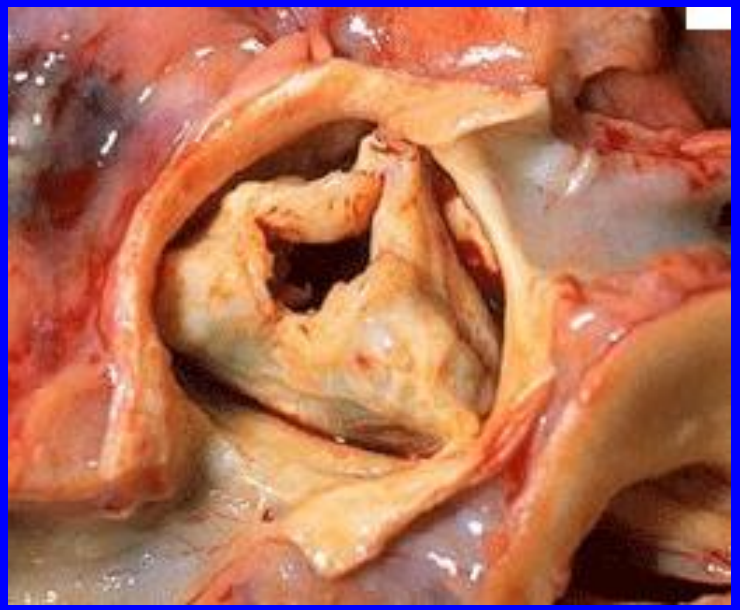
16th June 2012



Survival with Aortic Stenosis



Aortic Stenosis



Surgery for Aortic Stenosis

- History
- Safety
- Durability
- Quality of Life
- Cost
- Still evolving and improving

Surgery for Aortic Stenosis

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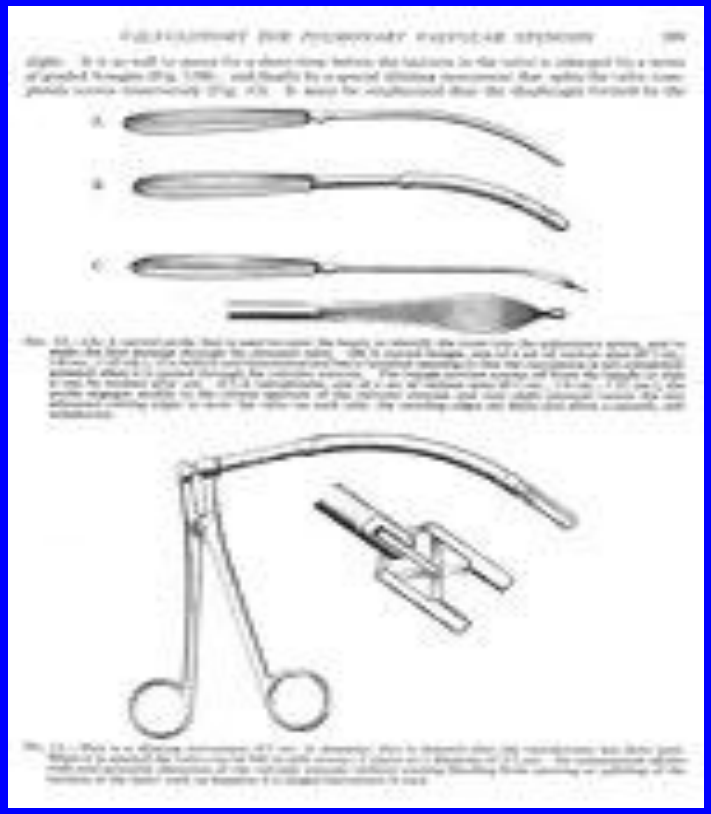
Russell Claude Brock (1903 -1980) Lord Brock of Wimbledon



LRCP, MRCS 1926, MB BS 1929, FRCS 1929, MS 1931, KT 1954, PRCS 1963 Baron 1965, FRCP 1965.

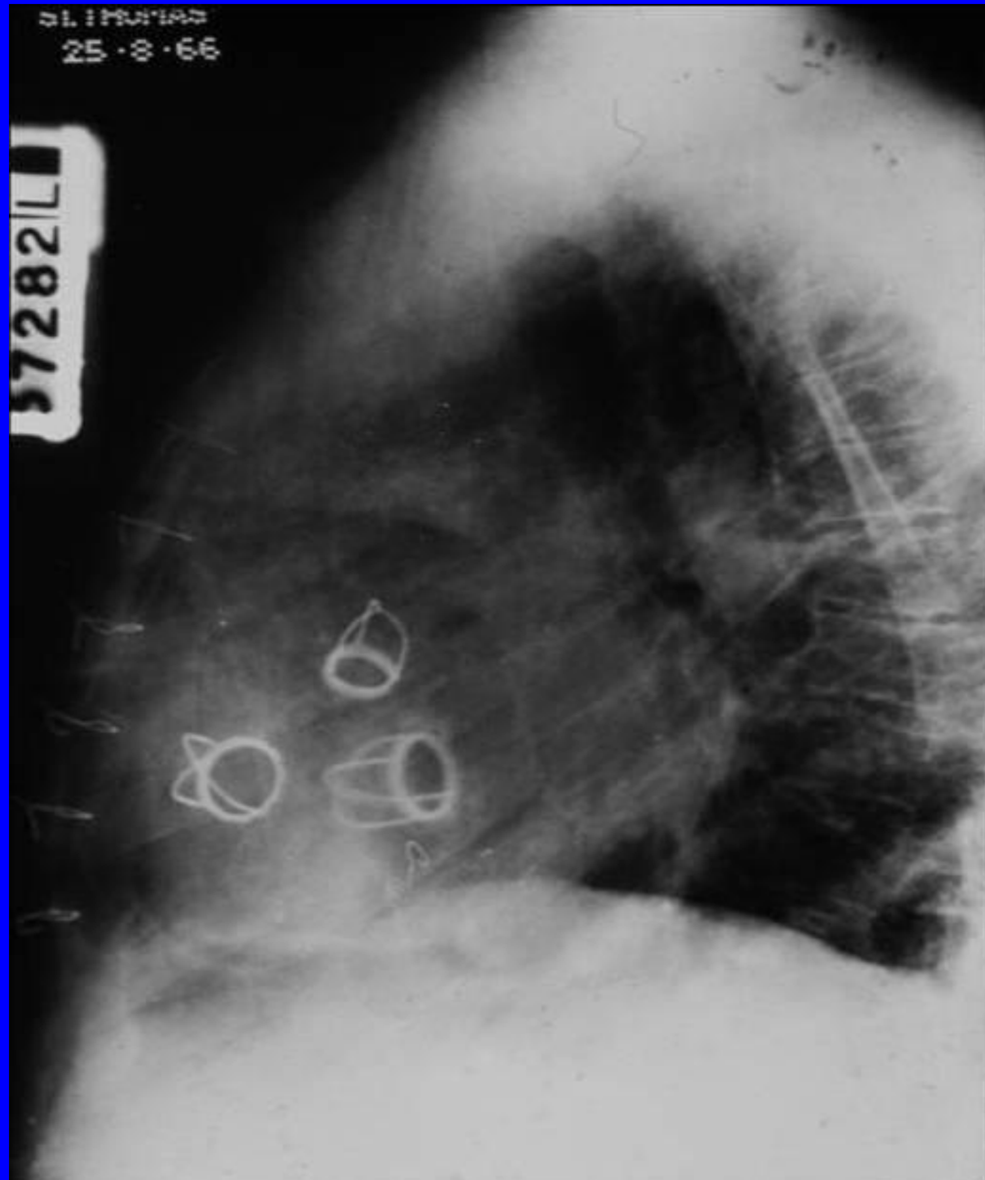
Major Dwight Harken – US Army

- 133 consecutive survivors
- First series of successful “open heart” operations

Ten Commandments - Dwight Harken

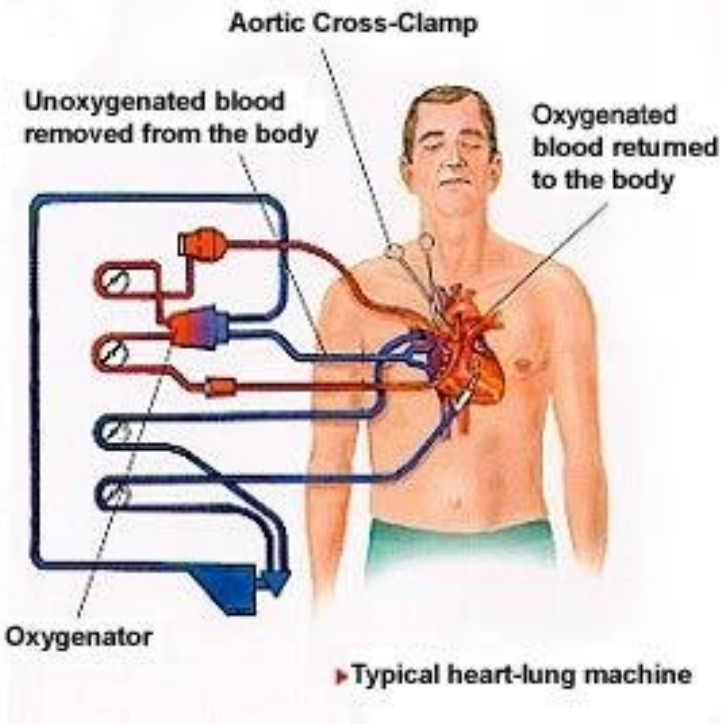
- It must not propagate emboli
- It must be chemically inert and not damage blood elements
- It must offer no resistance to physiological flows
- It must close promptly
- It must remain closed during the appropriate phase of the cardiac cycle
- It must have lasting physical and geometric features
- It must be inserted in a physiological site
- It must not annoy the patient
- It must be capable of permanent fixation
- It must be technically practical to insert

"A device is safe when it is safer than the condition it corrects"


25 · 8 · 66
7282 L

Cardiopulmonary bypass

- Cardioplegic arrest in diastole
- Bloodless operative field



- Detrimental effects of extracorporeal circulation
- Risks vs. benefits

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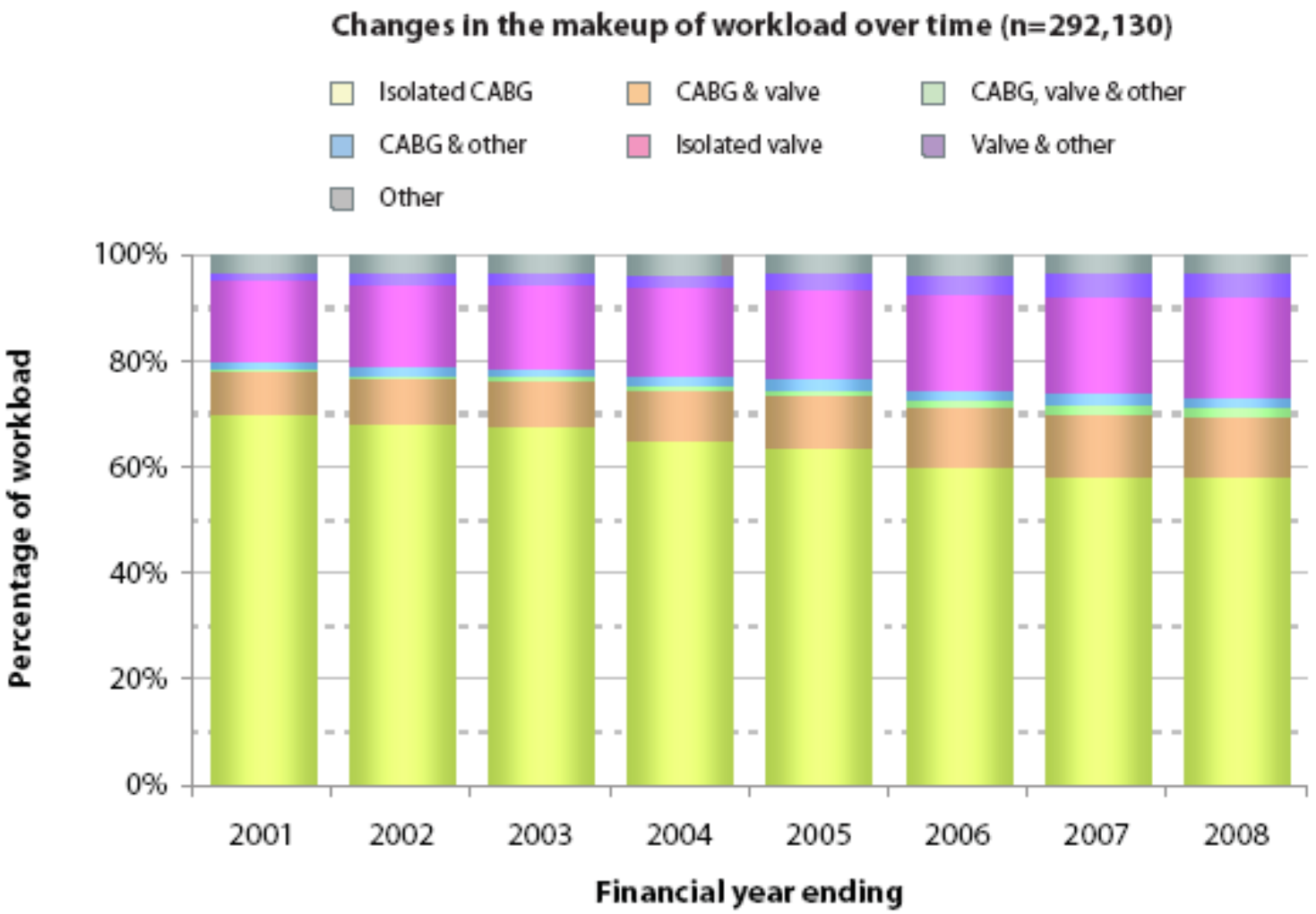
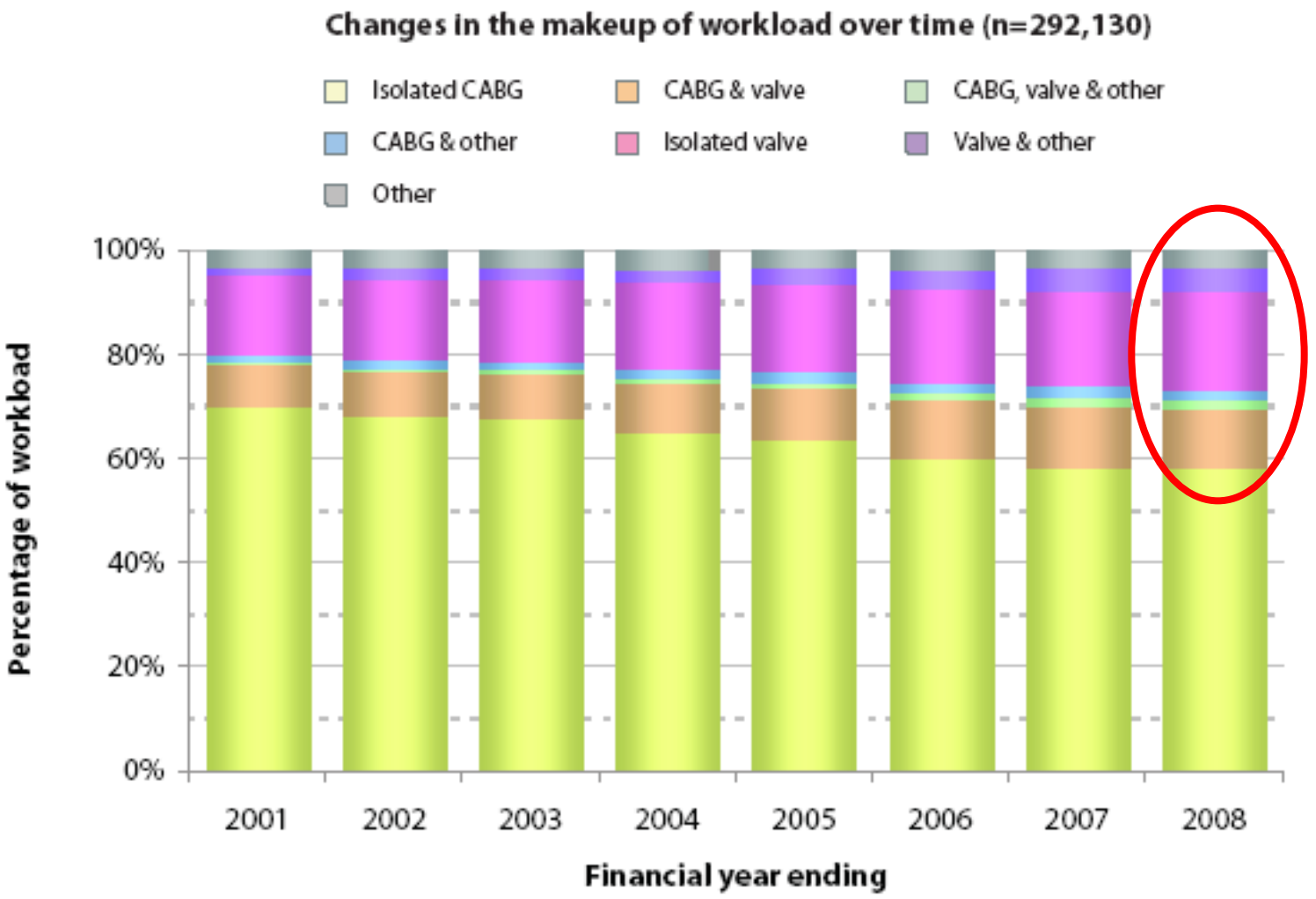
Cardiac Surgery

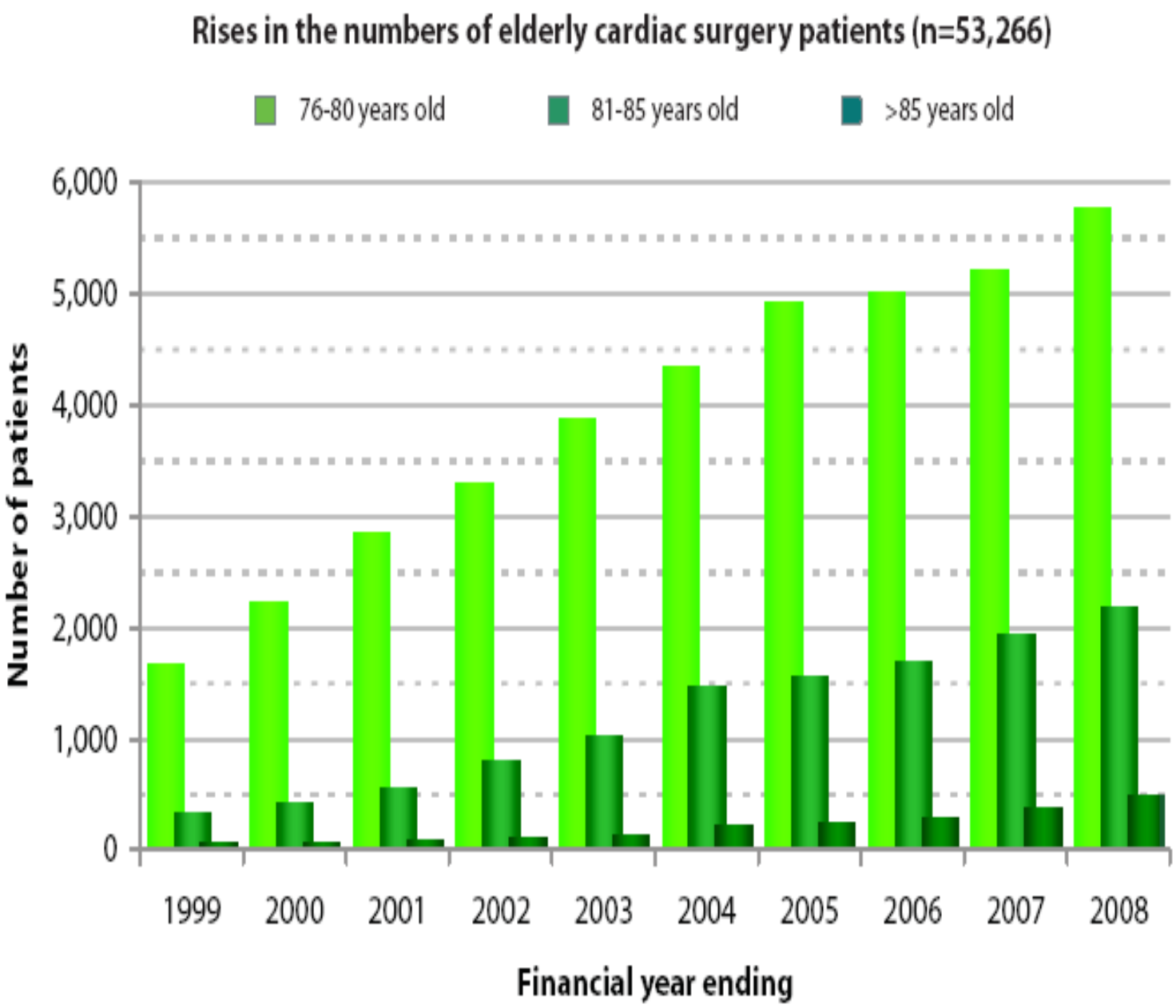
The Society for
Cardiothoracic Surgery
in Great Britain & Ireland

Sixth
National Adult Cardiac Surgical Database Report 2008

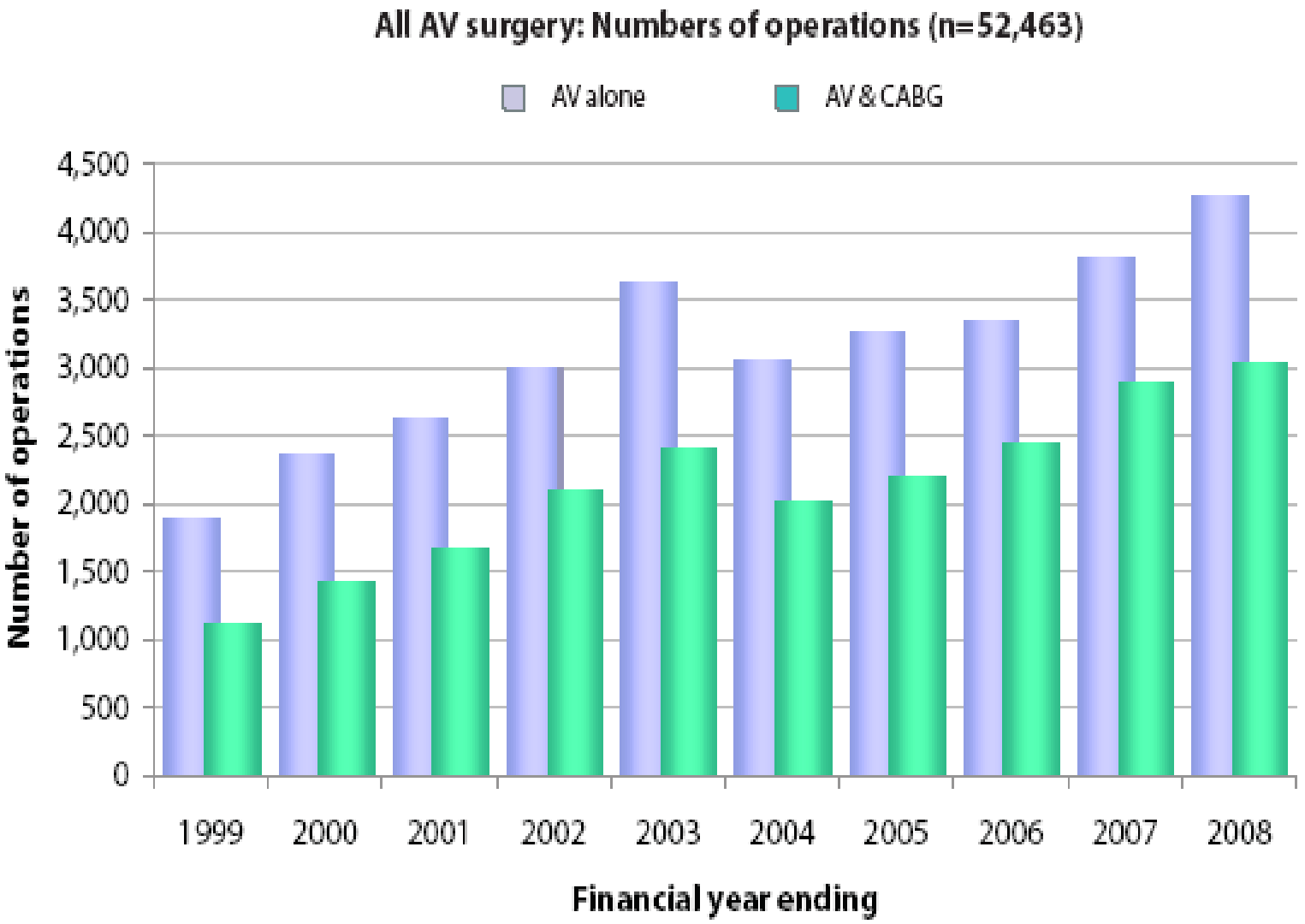
Demonstrating quality

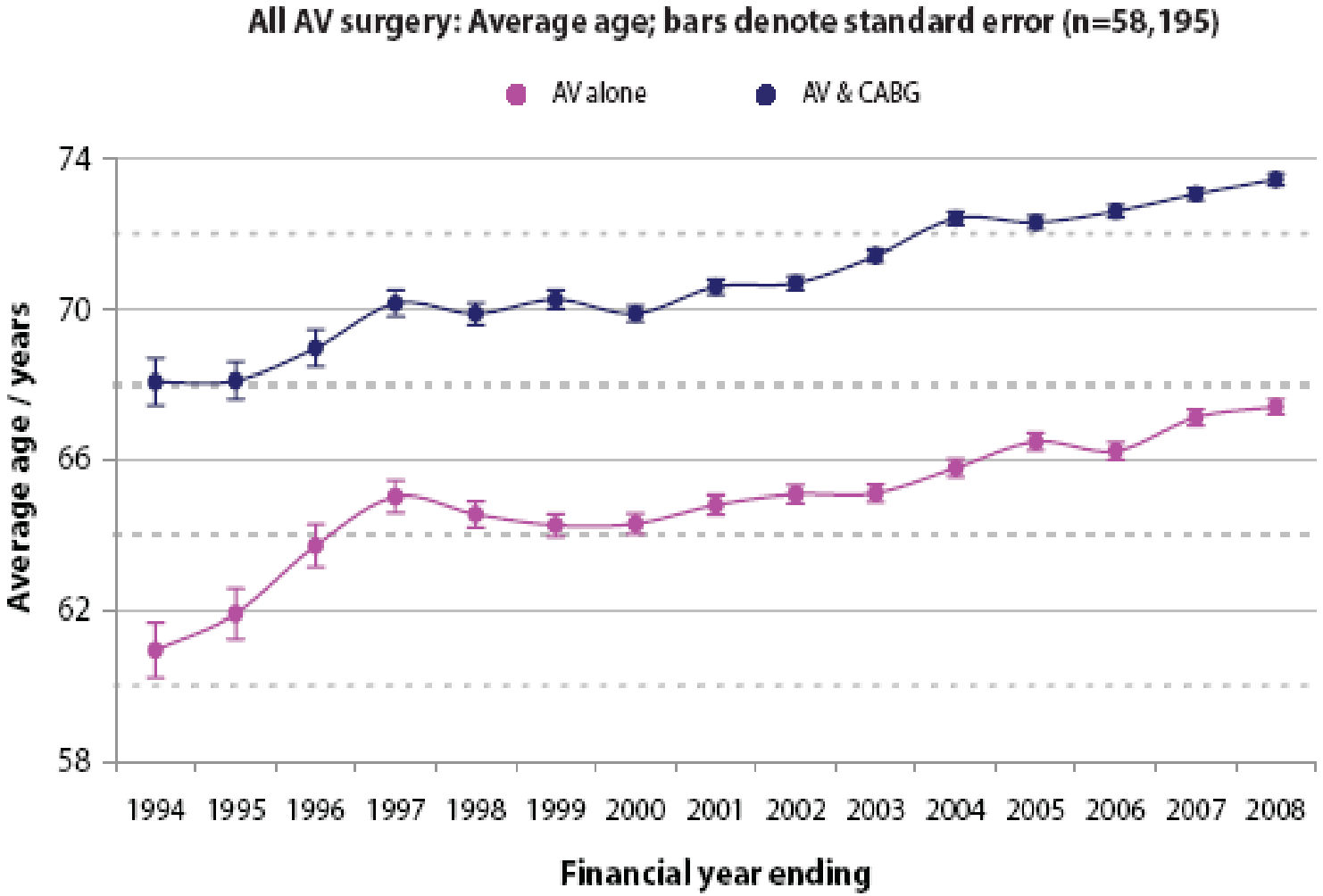

Changes in the makeup of workload over time (n=292,130)
Isolated CABG
CABG & valve
CABG, valve & other
CABG & other
Isolated valve
Valve & other
Other
Percentage of workload
100%
80%
60%
40%
20%
0%
2001
2002
2003
2004
2005
2006
2007
2008
Financial year ending

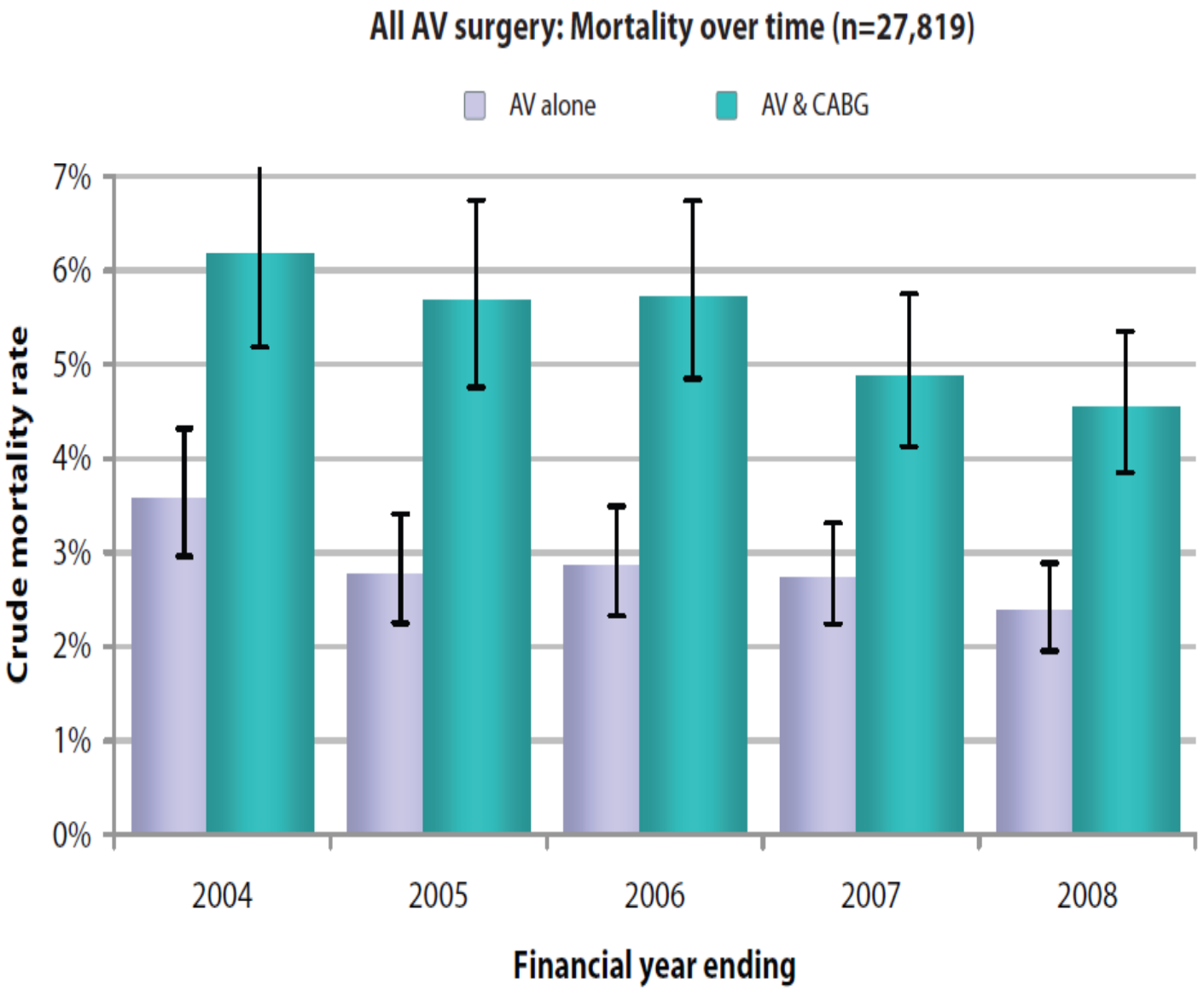

Changes in the makeup of workload over time (n=292,130)
Isolated CABG
CABG & valve
CABG, valve & other
CABG & other
Isolated valve
Valve & other
Other
100%
80%
60%
40%
20%
0%
Percentage of workload
2001
2002
2003
2004
2005
2006
2007
2008
Financial year ending


Rises in the numbers of elderly cardiac surgery patients (n=53,266)
76-80 years old
81-85 years old
>85 years old
Number of patients
6,000
5,000
4,000
3,000
2,000
1,000
0
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
Financial year ending

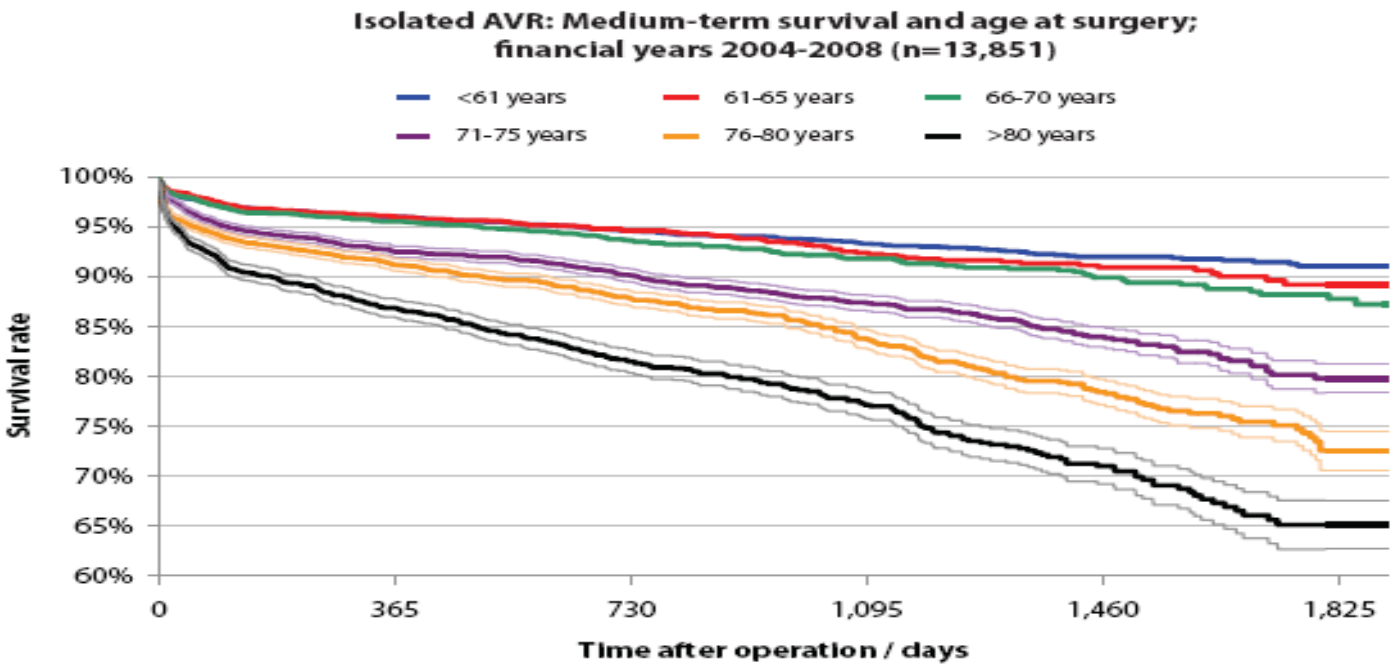
Aortic valve surgery in the UK

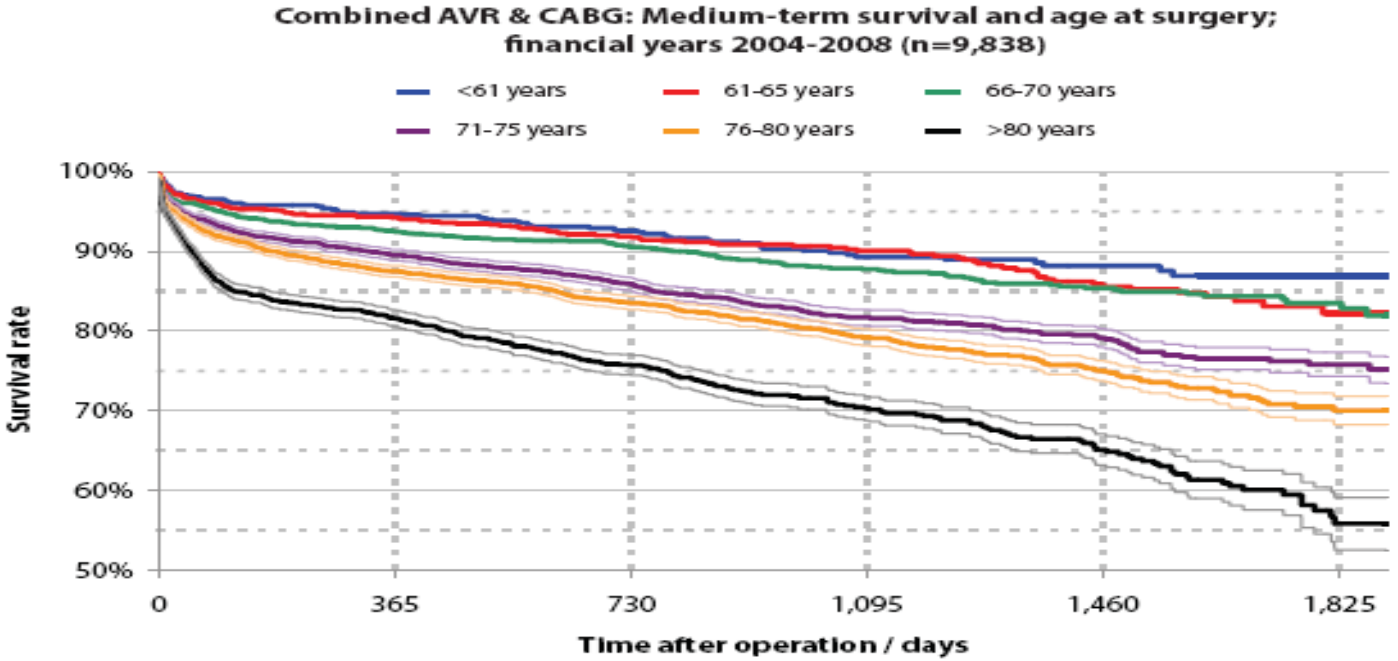



All AV surgery: Average age; bars denote standard error (n=58,195)
AV alone
AV & CABG
74
70
66
62
58
Average age / years
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
Financial year ending


All AV surgery: Mortality over time (n=27,819)
AV alone
AV & CABG
7%
6%
5%
4%
3%
2%
1%
0%
Crude mortality rate
2004
2005
2006
2007
2008
Financial year ending

		Procedure		
		Aortic valve	Aortic valve & CABG	**All**
Age at surgery / years	<61	1.7% 4,700	2.2% 999	**1.8%** **5,699**
	61-65	1.7% 2,188	2.9% 1,284	**2.2%** **3,472**
	66-70	1.9% 2,733	4.1% 2,116	**2.8%** **4,849**
	71-75	3.2% 3,130	5.0% 2,866	**4.0%** **5,996**
	76-80	3.8% 2,919	6.1% 3,069	**5.0%** **5,988**
	81-85	5.8% 1,546	7.9% 1,725	**6.9%** **3,271**
	>85	5.5% 420	10.7% 431	**8.1%** **851**
	Unspecified	NA 0	0.0% 1	**0.0%** **1**
	All	**2.8%** **17,636**	**5.3%** **12,491**	**3.8%** **30,127**


Isolated AVR: Medium-term survival and age at surgery; financial years 2004-2008 (n=13,851)
<61 years
61-65 years
66-70 years
71-75 years
76-80 years
>80 years
100%
95%
90%
85%
80%
75%
70%
65%
60%
Survival rate
0
365
730
1,095
1,460
1,825
Time after operation / days


Combined AVR & CABG: Medium-term survival and age at surgery; financial years 2004-2008 (n=9,838)
<61 years
61-65 years
66-70 years
71-75 years
76-80 years
>80 years
100%
90%
80%
70%
60%
50%
Survival rate
0
365
730
1,095
1,460
1,825
Time after operation / days

Valve Surgery in Octogenarians: A Safe Option with Good Medium-Term Results

Andrew Chukwuemeka, Michael A. Borger, Joan Ivanov, Susan Armstrong, Christopher M. Feindel, Tirone E. David

Division of Cardiovascular Surgery, Toronto General Hospital and Department of Surgery, University of Toronto

Conclusion: Valve surgery in selected octogenarians is associated with low morbidity and mortality. The outlook after surgery is very good, and surgery should not be denied to this group on the basis of age alone.

The Journal of Heart Valve Disease

2006;15:191-196

Surgery for Aortic Stenosis

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Durability of AVR

- Mechanical valves:

  40 billion cardiac cycles (100% freedom from SVD) in testing

- Biological valves: >30 year data

Long-term Durability of Porcine and Pericardial Bioprostheses for Aortic Valve Replacement.

Seeburger J, Chukwuemeka A, Borger M. *Cardiac Surgery 2009;4(3):82-9*

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EDITORIAL COMMENT

Valve Surgery in the Elderly

A Question of Quality (of Life)?*

John S. Rumsfeld, MD, PhD, FACC
Denver, Colorado

Over the next two decades, the aging of the population will force a major shift in clinical care in the U.S. By 2010, over 40 million Americans will be age 65 years and older, 18 million Americans will be over the age of 75 years, and the

12). Very limited data on valve surgery on nonagenarians suggests operative mortality in excess of 15% (13). Clearly, the elevated operative mortality risk in older persons undergoing valve surgery must be balanced against the potential benefits of the operation.

A principal goal of cardiac valve surgery is improvement in HRQL through reduction of symptoms and better physical function. Although valve surgery will be undertaken in select elderly patients for potential survival benefit (e.g., isolated severe aortic stenosis in a patient without significant comorbidities), the primary goal of the operation for most elderly persons should be improvement in HROL

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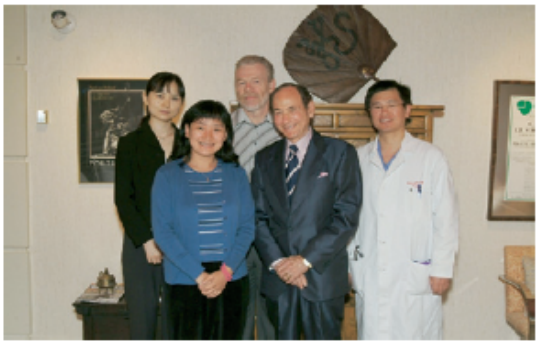
Cost of AVR

Conventional aortic valve:	£1200 - £1800
TAVI:	£20000+
Sutureless aortic valve:	£5000

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

YingXing Wu, MD, Ruyun Jin, MD, Guangqiang Gao, MD, Gary L. Grunkemeier, PhD, and Albert Starr, MD



Drs Wu, Jin, Grunkemeier, Starr, and Gao (*left to right*)

See related articles on pages 601 and 603.

Objective: With increased life expectancy and improved technology, valve replacement is being offered to increasing numbers of elderly patients with satisfactory clinical results. By using standard econometric techniques, we estimated the relative cost-effectiveness of aortic valve replacement by drawing on a large prospective database at our institution. By using aortic valve replacement as an example, this introductory report paves the way to more definitive studies of these issues in the future.

Methods: From 1961 to 2003, 4617 adult patients underwent aortic valve replacement at our service. These patients were provided with a prospective lifetime follow-up. As of 2005, these patients had accumulated 31,671 patient-years of follow-up (maximum 41 years) and had returned 22,396 yearly questionnaires. A statistical model was used to estimate the future life years of patients who are currently alive. In the absence of direct estimates of utility, quality-adjusted life years were estimated from New York Heart Association class. The cost-effectiveness ratio was calculated by the patient's age at surgery.

Results: The overall cost-effectiveness ratio was approximately $13,528 per quality-adjusted life year gained. The cost-effectiveness ratio increased according to age at surgery, up to $19,826 per quality-adjusted life year for octogenarians and $27,182 per quality-adjusted life year for nonagenarians.

Cost of TAVI – human resources

TAVI team

- Cardiac surgeons
- Interventional cardiologists
- Imaging cardiologists
- Radiologists
- Elderly care physicians
- Anaesthetist
- Critical care physicians
- Specialist nurses

- Physiotherapists
- Occupational therapists
- Rehabilitation
- Perfusionists
- Operating theatre team
- Psychologists

Surgery for Aortic Stenosis

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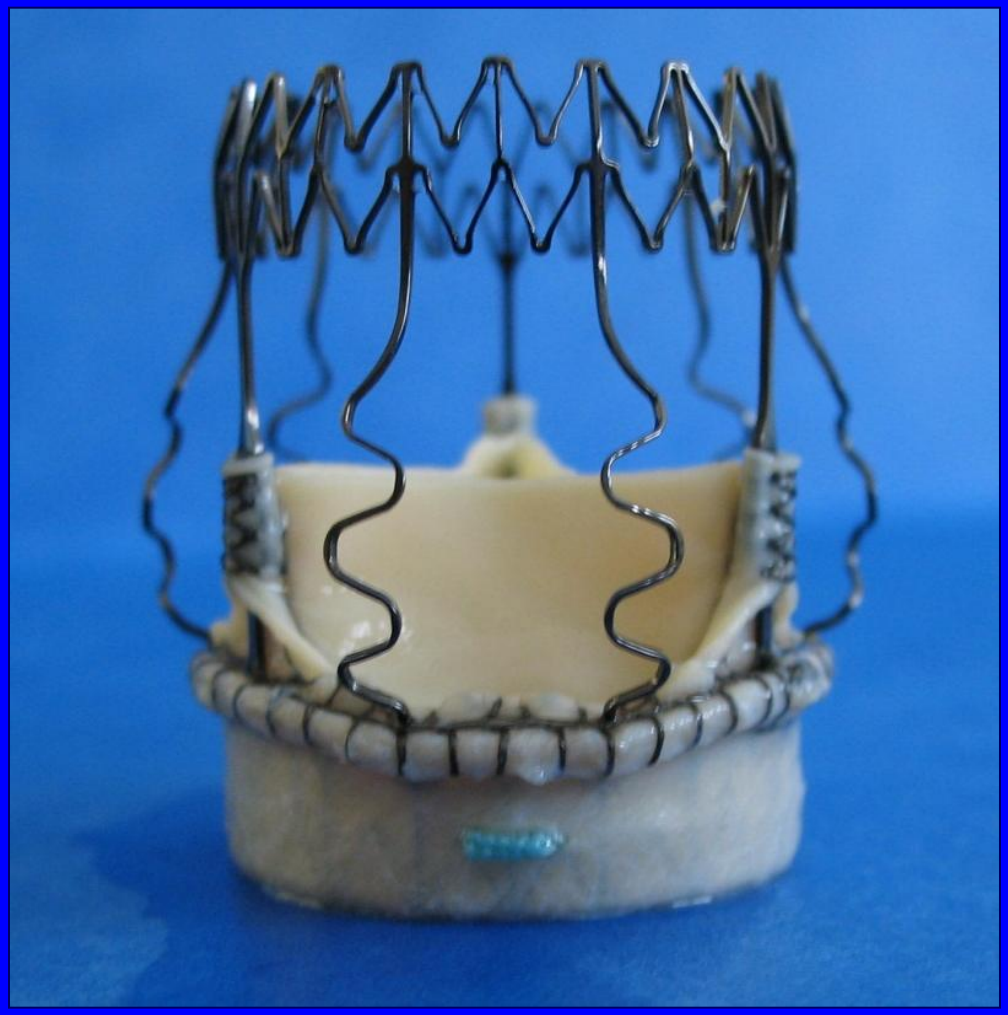
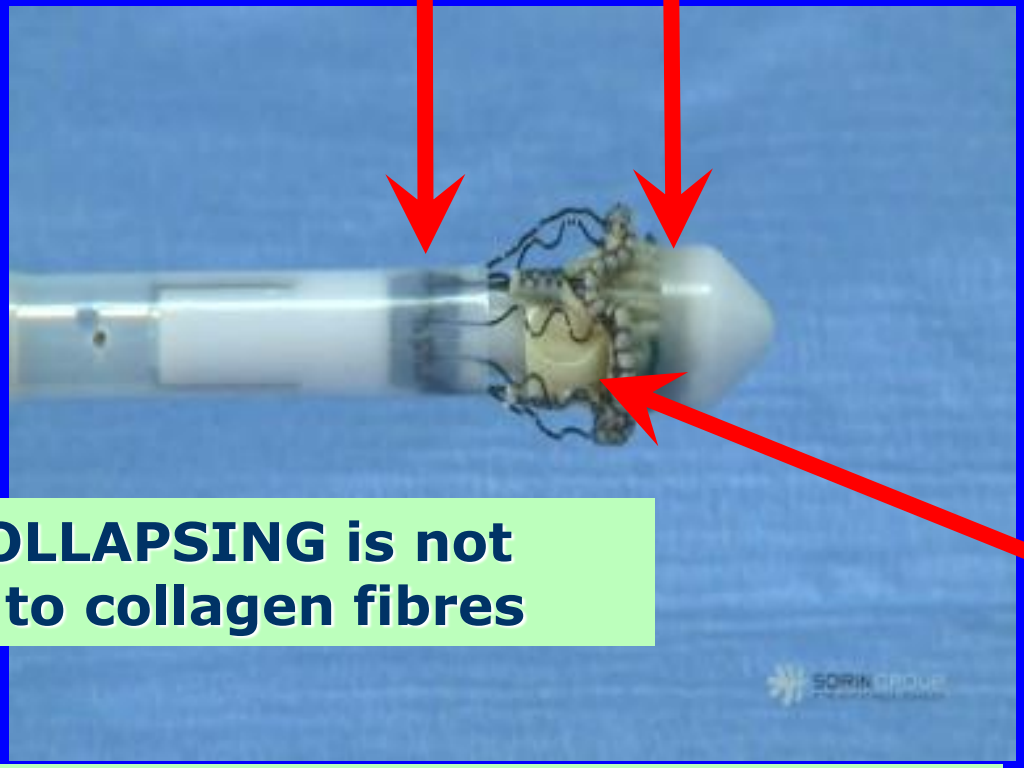
Novel sutureless AVR



Sutureless AVR



DEVICE COLLAPSING is not traumatic to collagen fibres

COLLAPSING IS NOT CRIMPING

Sutureless AVR

PERCEVAL S		N	Mean ± SD (min)	STS Database	Δ %
PUMP TIME	TOTAL	175	**58.7 ± 30.3**		
	Isolated	115	**49.3 ± 20.4**	116	**-58**
	Concomitant (CABG, myectomy)	60	**76.8 ± 37.5**	172	**-55**
CROSS-CLAMP TIME	TOTAL	175	**33.9 ± 15.5**		
	Isolated	115	**29.0 ± 11.4**	72	**-60**
	Concomitant (CABG, myectomy)	60	**43.2 ± 17.9**	112	**-61**

Sutureless AVR

Scoring system	Mortality % (Mean±SD)
Logistic Euroscore	**13.11 ± 8.65**
Range	**5.14 - 58.84**
STS score	**11.36 ± 10.69**
Range	**1.70 – 67.50**

	In hospital		Early (≤30 days)		Late (>30 days)		Overall survival at 6 months	STS DB* ≤30 days
	N	%	N	%	N	%/pts-yr		
Valve related	1	0.6	1	**0.6**	2	1.59	98.8	**4.3%**
Non valve related	7	3.9	4	**2.2**	14	11.13	90.2	

"In times of change, the learners inherit the Earth while the learned find themselves beautifully equipped to deal with a world that no longer exists."

The Future of Cardiac Surgery: The Times, They Are a Changin'

Bruce Lytle, MD, and Michael Mack, MD

Cleveland Clinic Foundation, Cleveland, Ohio, Medical City Dallas Hospital, Dallas, Texas

"In times of change, the learners inherit the Earth, while the learned find themselves beautifully equipped to deal with a world that no longer exists."

Eric Hoffer

The last 50 years have been halcyon days for cardiac surgeons. The technological innovations of cardiopulmonary bypass and heart valve prostheses led to the development of the specialty in the early 1960s. The subsequent development of coronary bypass surgery, an

ment of cardiovascular disease outside of our specialty has been dramatic and profound, particularly in regard to percutaneous technologies. The disruptive technology of percutaneous transluminal intervention (PCI) of coronary artery disease has progressed from the primitive and relatively ineffective use of balloon angioplasty in the late 1970s to the reproducible and largely safe interventions employing drug-eluting stents and platelet inhibitors that are available today for the treatment of a greatly

TAVI RESULTS – PARTNER B

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

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

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

ABSTRACT

Table 2. Clinical Outcomes at 30 Days and 1 Year.*

Outcome	30 Days			1 Year		
	TAVI (N=179)	Standard Therapy (N=179)	P Value†	TAVI (N=179)	Standard Therapy (N=179)	P Value†
	no. of patients (%)			*no. of patients (%)*		
Death						
From any cause	9 (5.0)	5 (2.8)	0.41	55 (30.7)	89 (49.7)	<0.001
From cardiovascular cause‡	8 (4.5)	3 (1.7)	0.22	35 (19.6)	75 (41.9)	<0.001
Repeat hospitalization§	10 (5.6)	18 (10.1)	0.17	40 (22.3)	79 (44.1)	<0.001
Death from any cause or repeat hospitalization§	19 (10.6)	22 (12.3)	0.74	76 (42.5)	126 (70.4)	<0.001
Stroke or TIA						
All	12 (6.7)	3 (1.7)	0.03	19 (10.6)	8 (4.5)	0.04
TIA	0	0	—	1 (0.6)	0	1.00
Stroke						
Minor	3 (1.7)	1 (0.6)	0.62	4 (2.2)	1 (0.6)	0.37
Major	9 (5.0)	2 (1.1)	0.06	14 (7.8)	7 (3.9)	0.18
Death from any cause or major stroke	15 (8.4)	7 (3.9)	0.12	59 (33.0)	90 (50.3)	0.001
Myocardial infarction						
All	0	0	—	1 (0.6)	1 (0.6)	1.00
Periprocedural	0	0	—	0	0	—
Vascular complications						
All	55 (30.7)	9 (5.0)	<0.001	58 (32.4)	13 (7.3)	<0.001
Major	29 (16.2)	2 (1.1)	<0.001	30 (16.8)	4 (2.2)	<0.001
Acute kidney injury						
Creatinine >3 mg/dl (265 μmol/liter)¶	0	1 (0.6)	1.00	2 (1.1)	5 (2.8)	0.45
Renal-replacement therapy‖	2 (1.1)	3 (1.7)	1.00	3 (1.7)	6 (3.4)	0.50
Major bleeding	30 (16.8)	7 (3.9)	<0.001	40 (22.3)	20 (11.2)	0.007
Cardiac reintervention						
Balloon aortic valvuloplasty	1 (0.6)**	2 (1.1)	1.00	1 (0.6)	66 (36.9)††	<0.001
Repeat TAVI‡‡	3 (1.7)	NA	—	3 (1.7)	NA	—
Aortic-valve replacement	0	3 (1.7)	0.25	2 (1.1)**	17 (9.5)	<0.001
Endocarditis	0	0	—	2 (1.1)	1 (0.6)	0.31
New atrial fibrillation	1 (0.6)	2 (1.1)	1.00	1 (0.6)	3 (1.7)	0.62
New pacemaker	6 (3.4)	9 (5.0)	0.60	8 (4.5)	14 (7.8)	0.27

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 9, 2011 VOL. 364 NO. 23

Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

CONCLUSIONS

In high-risk patients with severe aortic stenosis, transcatheter and surgical procedures for aortic-valve replacement were associated with similar rates of survival at 1 year, although there were important differences in periprocedural risks. (Funded by Edwards Lifesciences; Clinical Trials.gov number, NCT00530894.)

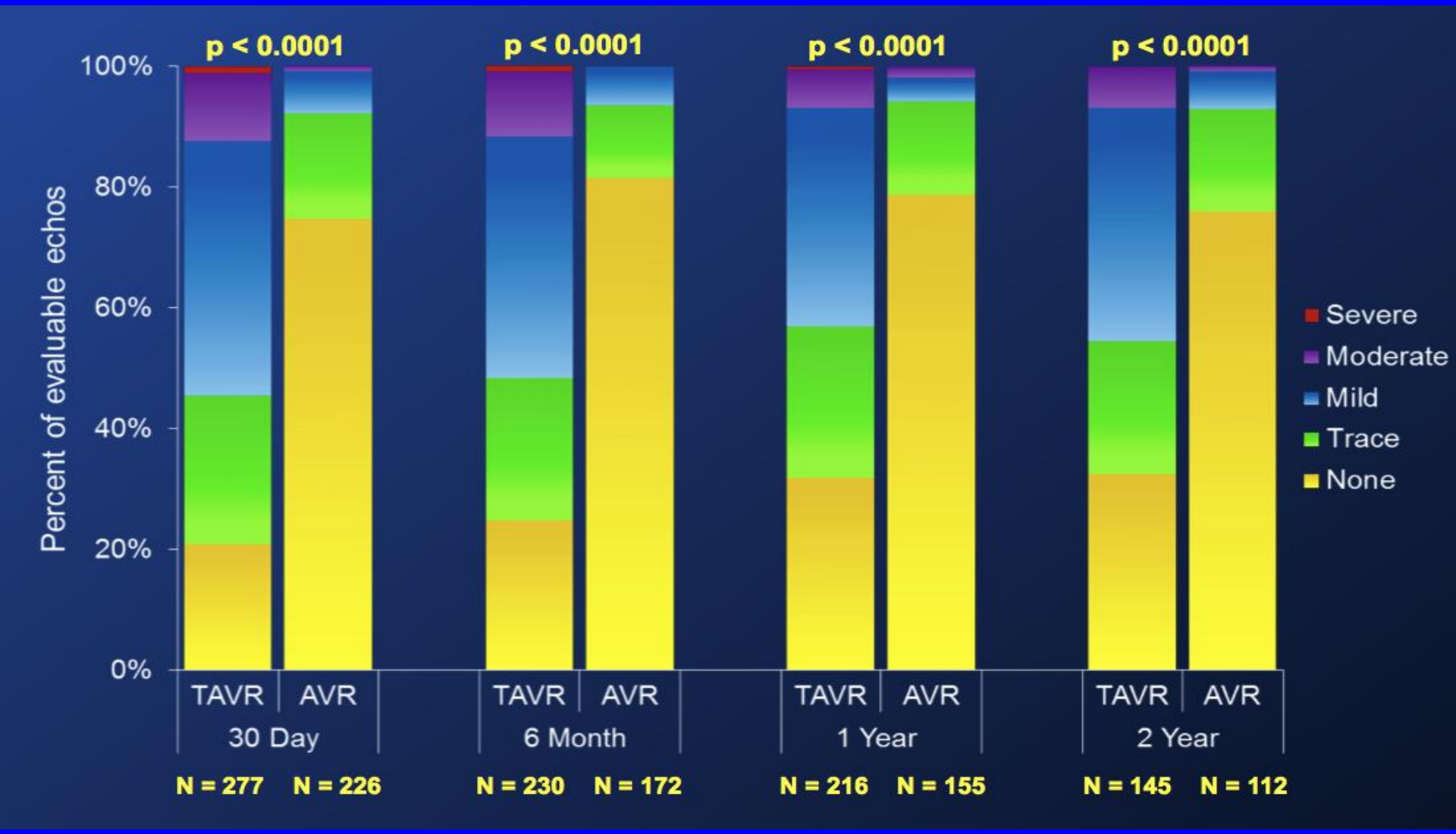
Table 2. Clinical Outcomes at 30 Days and 1 Year in the Intention-to-Treat Population.*

Outcome	30 Days			1 Year		
	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value
	no. of patients (%)			*no. of patients (%)*		
Death						
From any cause	12 (3.4)	22 (6.5)	0.07	84 (24.2)	89 (26.8)	0.44
From cardiac causes	11 (3.2)	10 (3.0)	0.90	47 (14.3)	40 (13.0)	0.63
Repeat hospitalization	15 (4.4)	12 (3.7)	0.64	58 (18.2)	45 (15.5)	0.38
Death or repeat hospitalization	25 (7.2)	33 (9.7)	0.24	120 (34.6)	119 (35.9)	0.73
Stroke or transient ischemic attack						
Either	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
Transient ischemic attack	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
Stroke						
Minor	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84
Major	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07
Death from any cause or major stroke	24 (6.9)	28 (8.2)	0.52	92 (26.5)	93 (28.0)	0.68
Myocardial infarction	0	2 (0.6)	0.16	1 (0.4)	2 (0.6)	0.69
Vascular complication						
Any	59 (17.0)	13 (3.8)	<0.001	62 (18.0)	16 (4.8)	<0.001
Major	38 (11.0)	11 (3.2)	<0.001	39 (11.3)	12 (3.5)	<0.001
Acute kidney injury						
Creatinine >3 mg/dl (265 μmol/liter)	4 (1.2)	4 (1.2)	0.95	12 (3.9)	8 (2.7)	0.41
Renal-replacement therapy	10 (2.9)	10 (3.0)	0.95	18 (5.4)	20 (6.5)	0.56
Major bleeding	32 (9.3)	67 (19.5)	<0.001	49 (14.7)	85 (25.7)	<0.001
Endocarditis	0	1 (0.3)	0.32	2 (0.6)	3 (1.0)	0.63
New-onset atrial fibrillation†	30 (8.6)	56 (16.0)	0.006	42 (12.1)	60 (17.1)	0.07
New pacemaker	13 (3.8)	12 (3.6)	0.89	19 (5.7)	16 (5.0)	0.68

Table 2. Clinical Outcomes at 30 Days and 1 Year in the Intention-to-Treat Population.*

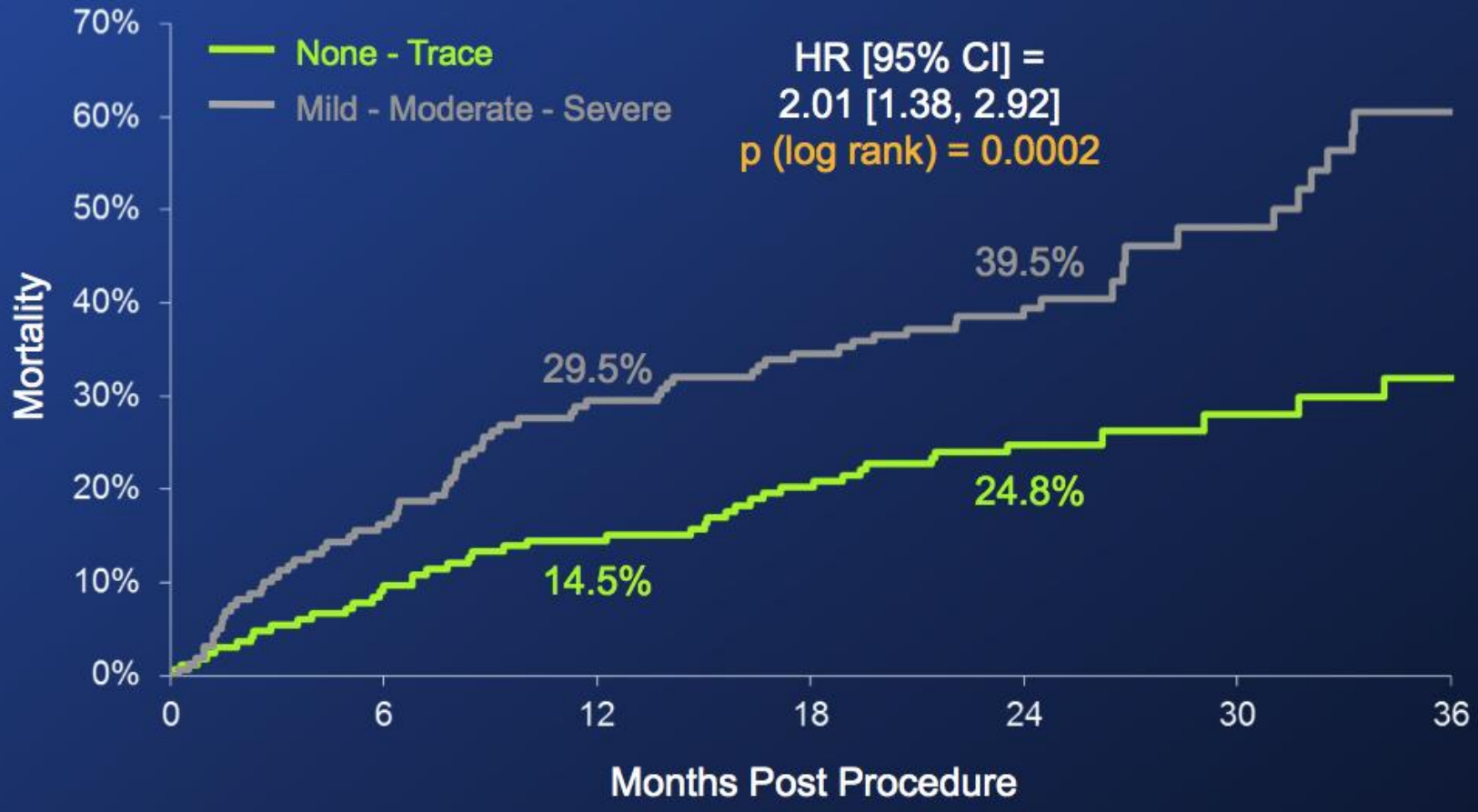
Outcome	30 Days			1 Year		
	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value
	no. of patients (%)			*no. of patients (%)*		
Death						
From any cause	12 (3.4)	22 (6.5)	0.07	84 (24.2)	89 (26.8)	0.44
From cardiac causes	11 (3.2)	10 (3.0)	0.90	47 (14.3)	40 (13.0)	0.63
Repeat hospitalization	15 (4.4)	12 (3.7)	0.64	58 (18.2)	45 (15.5)	0.38
Death or repeat hospitalization	25 (7.2)	33 (9.7)	0.24	120 (34.6)	119 (35.9)	0.73
Stroke or transient ischemic attack						
Either	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
Transient ischemic attack	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
Stroke						
Minor	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84
Major	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07
Death from any cause or major stroke	24 (6.9)	28 (8.2)	0.52	92 (26.5)	93 (28.0)	0.68
Myocardial infarction	0	2 (0.6)	0.16	1 (0.4)	2 (0.6)	0.69
Vascular complication						
Any	59 (17.0)	13 (3.8)	<0.001	62 (18.0)	16 (4.8)	<0.001
Major	38 (11.0)	11 (3.2)	<0.001	39 (11.3)	12 (3.5)	<0.001
Acute kidney injury						
Creatinine >3 mg/dl (265 μmol/liter)	4 (1.2)	4 (1.2)	0.95	12 (3.9)	8 (2.7)	0.41
Renal-replacement therapy	10 (2.9)	10 (3.0)	0.95	18 (5.4)	20 (6.5)	0.56
Major bleeding	32 (9.3)	67 (19.5)	<0.001	49 (14.7)	85 (25.7)	<0.001
Endocarditis	0	1 (0.3)	0.32	2 (0.6)	3 (1.0)	0.63
New-onset atrial fibrillation†	30 (8.6)	56 (16.0)	0.006	42 (12.1)	60 (17.1)	0.07
New pacemaker	13 (3.8)	12 (3.6)	0.89	19 (5.7)	16 (5.0)	0.68

PARTNER A: UPDATE – 2 year results



PARAVALVULAR LEAK

PARTNER A: UPDATE – 2 year results



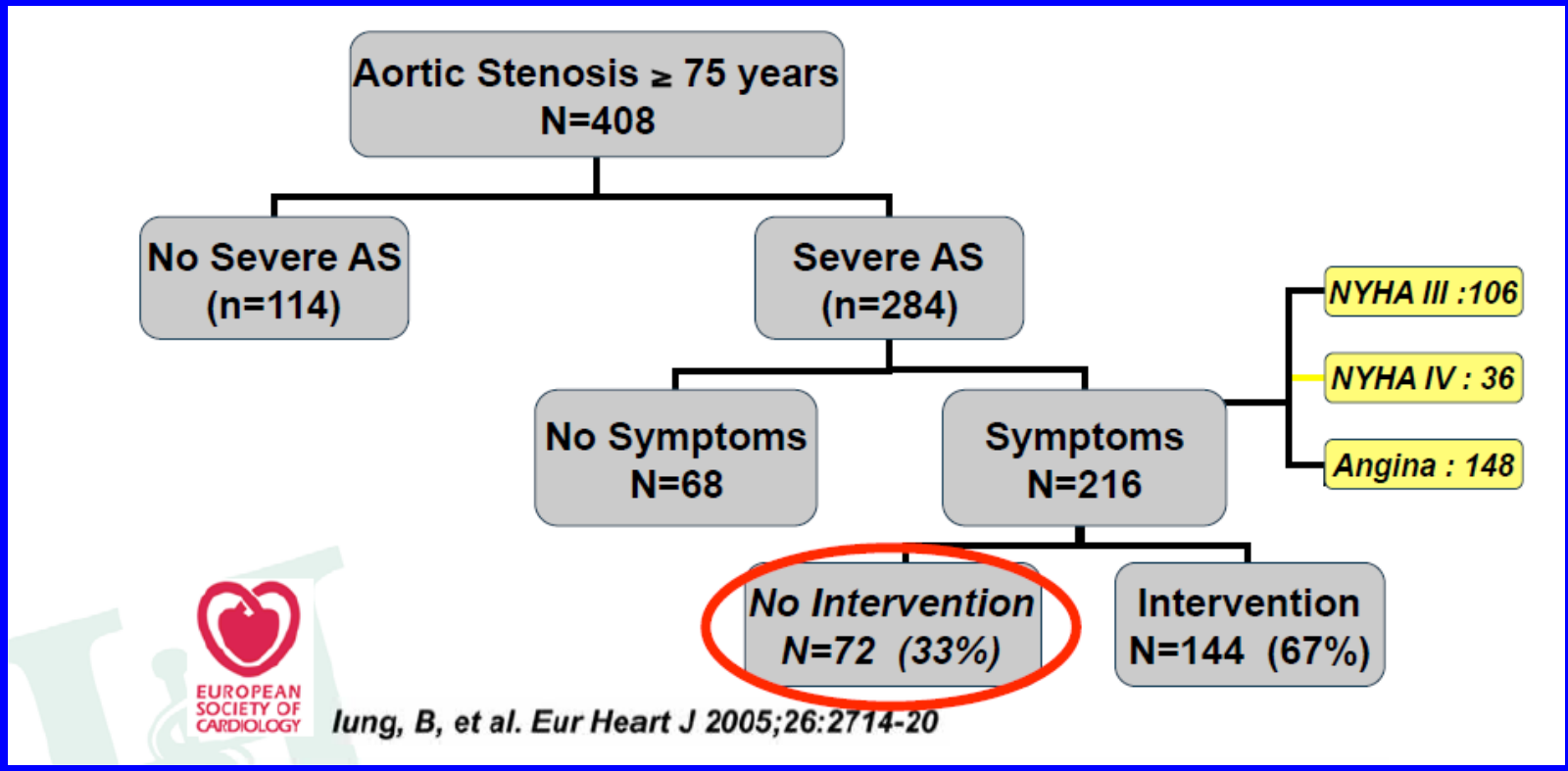
Numbers at Risk

None-Tr	167	149	140	126	87	41	16
Mild-Mod-Sev	160	134	112	101	64	26	12

Euro Heart Survey

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

Eur Heart J 2003 Jul;24(13):1231-43



1 in 3 patients with severe symptomatic AS **did not have** surgery

Cribier's Index Case

- 57 year old male
- Severe calcific aortic stenosis
- LVEF 14%, AVA 0.6cm^2, 30mmHg gradient
- No myocardial reserve on Dobutamine stress echo
- Cardiogenic shock, pulmonary oedema, oliguria

- PMH
  - PVD with aorto-bifemoral bypass graft
  - Ca lung Rx
  - Chronic pancreatitis
  - Interstitial lung disease

- Subacute ischemia of right leg on current presentation

Special Report

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description

Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

Background—The design of ecome an important area for investigation. A percutaneou cardial leaflets mounted within a balloon-expandable stent ation studies, the first human implantation was performed c shock, subacute leg ischemia, and other associated nonc for this patient, and balloon valvuloplasty had been perf

Methods and Results—With th cessfully implanted within the

Received September 5, 2002; revision

From the Department of Cardiology (y of Rouen, Rouen, France; the Centre d'Experimentation et de Recherche Appli vascular Research Foundation (M.B.L.), Lenox Hill Hospital, New York, NY; an

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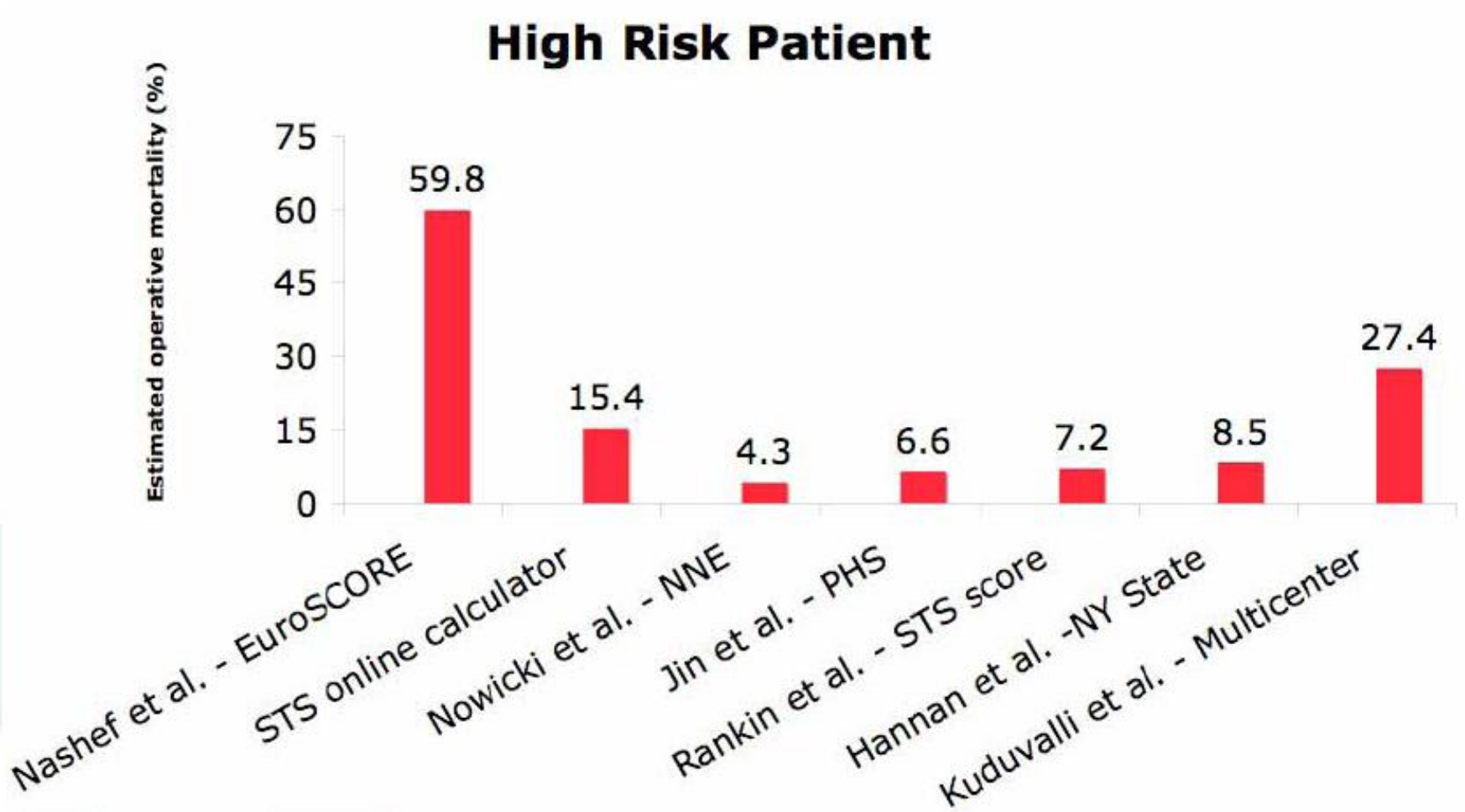
Circulation is available at http://www. : 10.1161/01.CIR.0000047200.36165.B8

85 year old female, EF 30%, renal dysfunction and pulmonary hypertension



Patient A vs. Patient B

Same age and predicted risk
One passes the "eyeball test" – one does not

Photos courtesy of Michael J. Mack, MD
Medical City Dallas

Frailty

Frail Patients Are at Increased Risk for Mortality and Prolonged Institutional Care After Cardiac Surgery.
Circulation 2010;121:973-8

- Complex interaction between age and chronic illness
- Chronological age is not the same as biological age
- Subjective

- Parameters:
  - gait, 5m walk speed, grip strength, ADL, biological markers (albumin, bilirubin, lung function tests), +++

Risk scoring and frailty in TAVI

- Not yet settled
- Many more patients needed

- Avoid futile, expensive treatment at the end of life (**dying “with” not “from” aortic stenosis**)

- Aim: identify a level of risk where a mortality benefit allows cost-effective treatment

Aortic Valve Replacement