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Mechanical vs. Bioprosthetic Aortic Valve Replacement: Time to Reconsider?

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Disclosures

- None relevant to this presentation

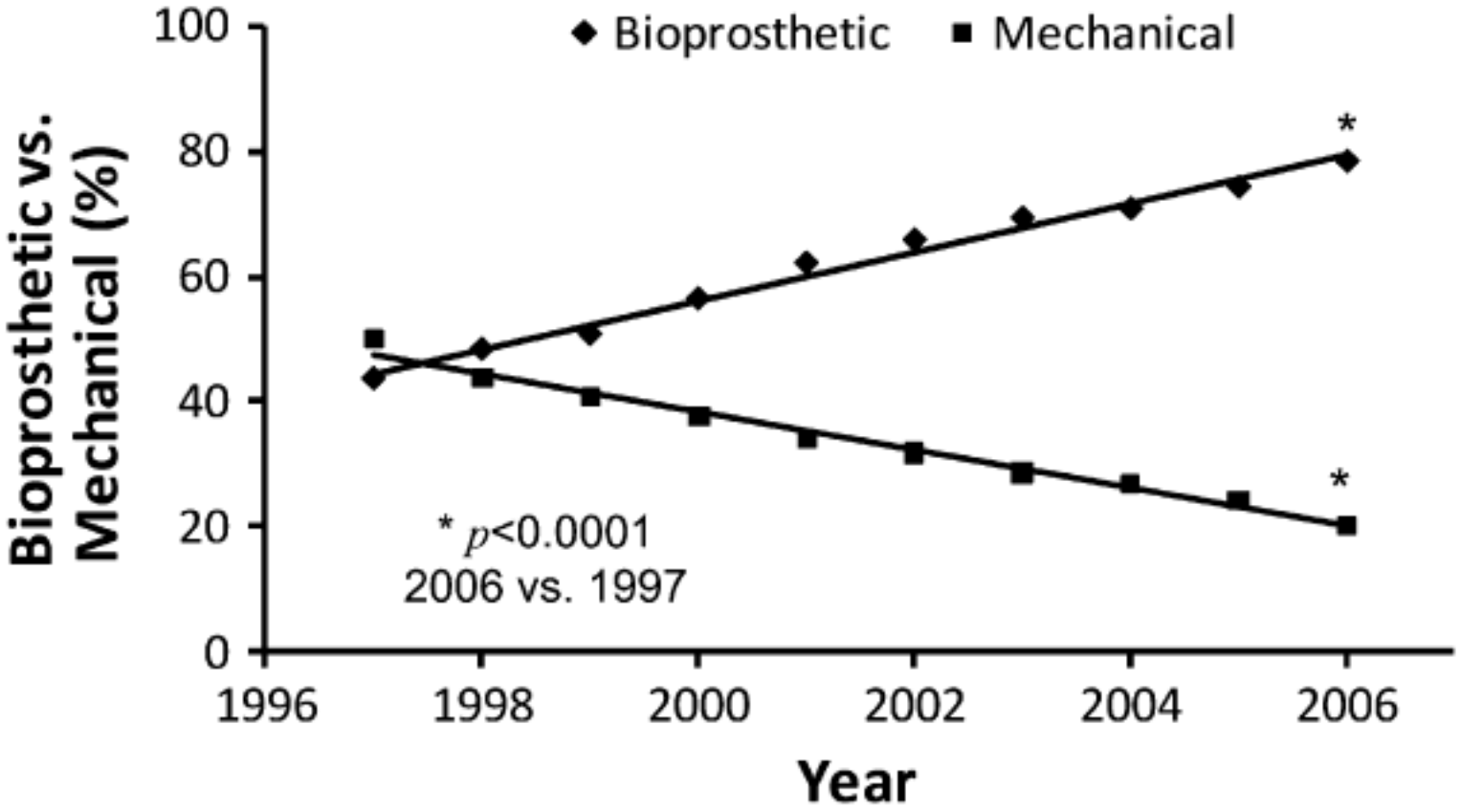
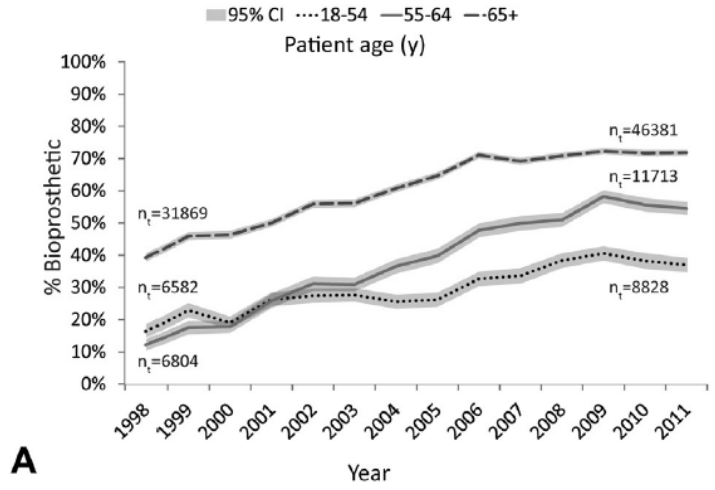
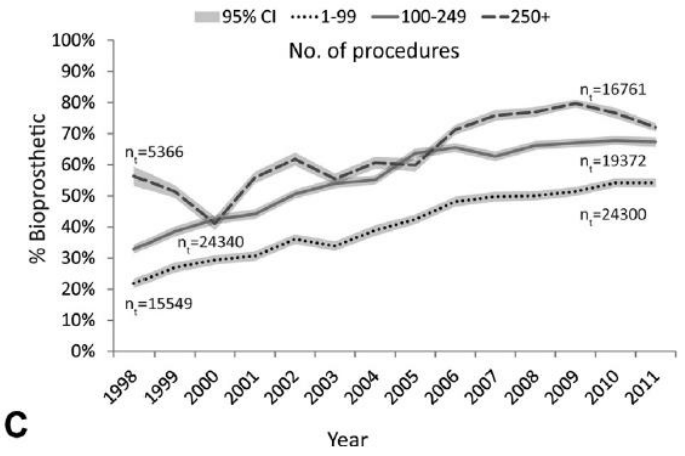


FIGURE 1. Percentage use of bioprosthetic valves relative to mechanical valves from 1997 through 2006. Bioprosthetic valve use increased progressively during 10 years. *Asterisk* indicates $P < .000001$.

National trends in utilization and in-hospital outcomes of mechanical versus bioprosthetic aortic valve replacements

Abby J. Isaacs, MS,[a] Jeffrey Shuhaiber, MD,[b] Arash Salemi, MD,[c] O. Wayne Isom, MD,[c] and Art Sedrakyan, MD, PhD[a]





Research

Original Investigation

Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years

Yuting P. Chiang, BA; Joanna Chikwe, MD; Alan J. Moskowitz, MD; Shinobu Itagaki, MD; David H. Adams, MD; Natalia N. Egorova, PhD

- Increase in the use of bioprosthetic valves from 15 to 74% in young patients (from 50 to 69 years old) between 1997 and 2012 in New York state

German Heart Surgery Report 2016: The Annual Updated Registry of the German Society for Thoracic and Cardiovascular Surgery

Andreas Beckmann[1] Anne-Katrin Funkat[2] Jana Lewandowski[1] Michael Frie[3] Markus Ernst[4] Khosro Hekmat[5] Wolfgang Schiller[6] Jan F. Gummert[7] Wolfgang Harringer[8]

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Thorac Cardiovasc Surg 2017;65:505–518.

- 2016 88% bioprosthetic

Explaining the shift

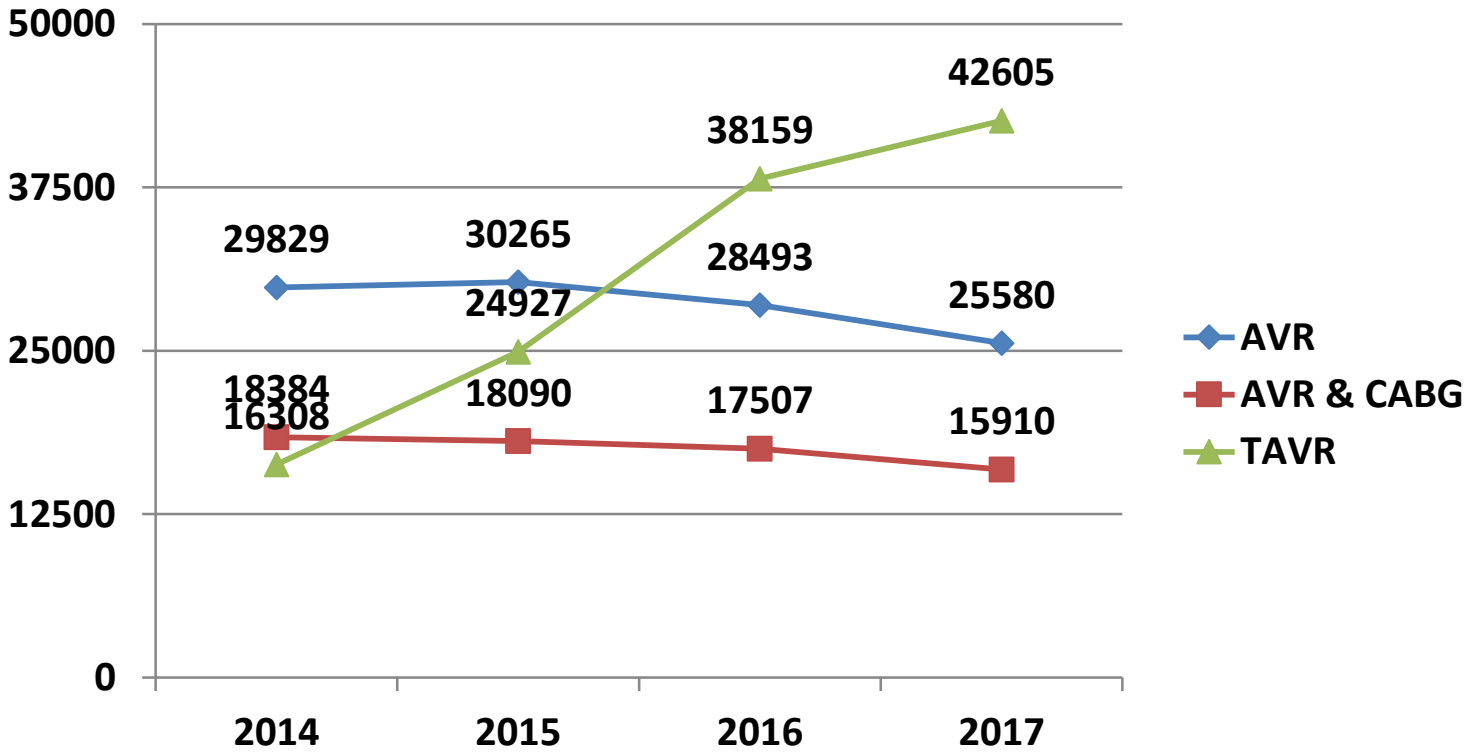
- “Anti” – Anti –coagulation
  - Many young patients refuse long-term anticoagulation
  - Elderly patients are at high risk when receiving anticoagulation.
- Reoperation to replace a failed bioprosthetic can be accomplished with minimal morbidity and mortality.
- Newer generation tissue valves are expected to provide longer reoperation-free survivals.
- “We can always do a valve in valve”

ACC/AHA 2017 Guidelines

I	C	A bioprosthesis is **recommended** in patients of any age for whom anticoagulant therapy is contraindicated, cannot be managed appropriately, or is not desired.	2014 recommendation remains current.
IIa	B-NR	An aortic or mitral mechanical prosthesis is **reasonable** for patients less than 50 years of age who do not have a contraindication to anticoagulation (141,149,151,155–157).	**MODIFIED: LOE updated from B to B-NR**. The age limit for mechanical prosthesis was lowered from 60 to 50 years of age.

ılation 20

SAVR & TAVR Volumes



STS National Database™
Using data to drive quality

STS/ACC TVT Registry Database as of 3-1-18

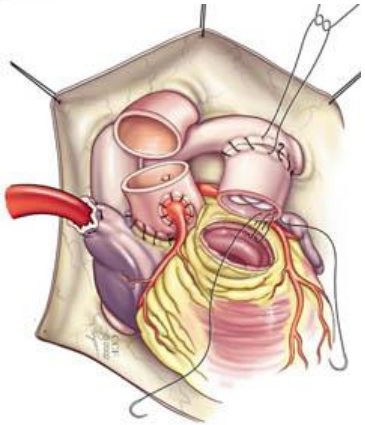
NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Questions

- Should we be using mechanical valves at all?
- If we accept universal bioprosthetic implant
- One of the biggest predictors of SVD is post implant Gradient
  - Both of which are better in TAVR (SURTAVI, PARTNER, NOTION)
- Should we be implanting surgical valves at all?
  - Should everyone just get a TAVR?

The other options

- Mechanical AVR
- Ross operation
- Aortic valve repair

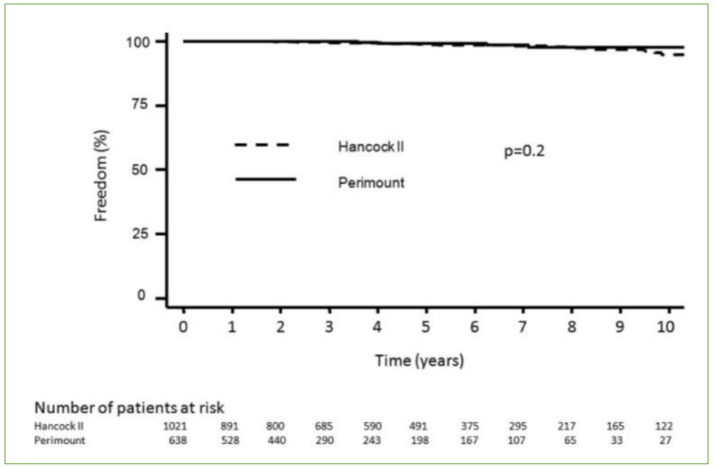


What is a reasonable expectation for valve life?

SVD: Comparison between surgical valves using freedom from reoperation

Valve-Related Reoperation, Structural Valve Deterioration, and Endocarditis

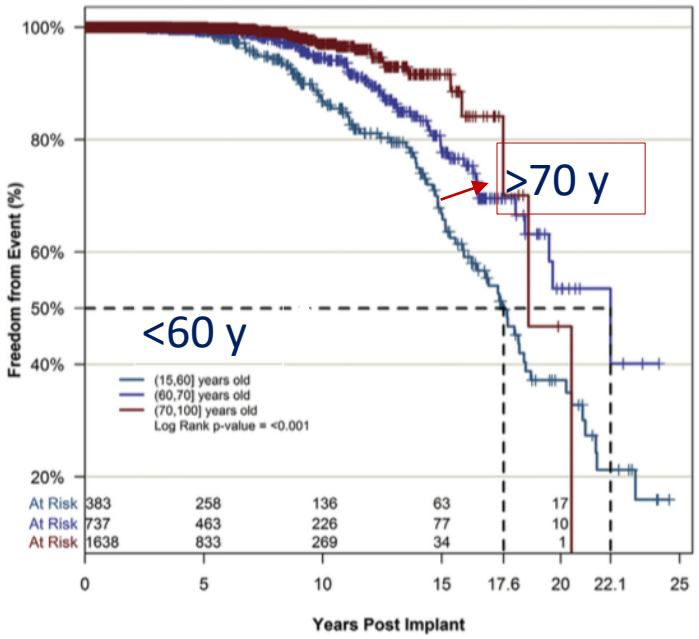
- Ten-year freedom from reoperation was 97.0% and 99.6% for the Hancock II and Perimount, respectively (*P* 0.2).
- In total, 11 reoperations (Hancock II (10) | Perimount, (1) occurred in this cohort. Structural valve deterioration (Hancock II, 97.5% 1.1%; Perimount, 97.2% 1.9% at 10 years; *P* 0.6).
- Prosthetic valve endocarditis were not different between valve types.



Freedom from reoperation:
Ten reoperations were observed among Hancock II patients and 1 reoperation was observed among Perimount patients.

Rahimtoola S. H. | Choice of Prosthetic Heart Valve in Adults: An update | JACC Vol. 55, No. 22, 2010 June 1, 2010:2413–26

Surgical bioprotheses long-term follow-up: Based on freedom SVD



Freedom from SVD by age groups:

Expected valve durability (median survival time without SVD) was 17.6 for the younger (60) and and 22.1 years for the 60 to 70 years group

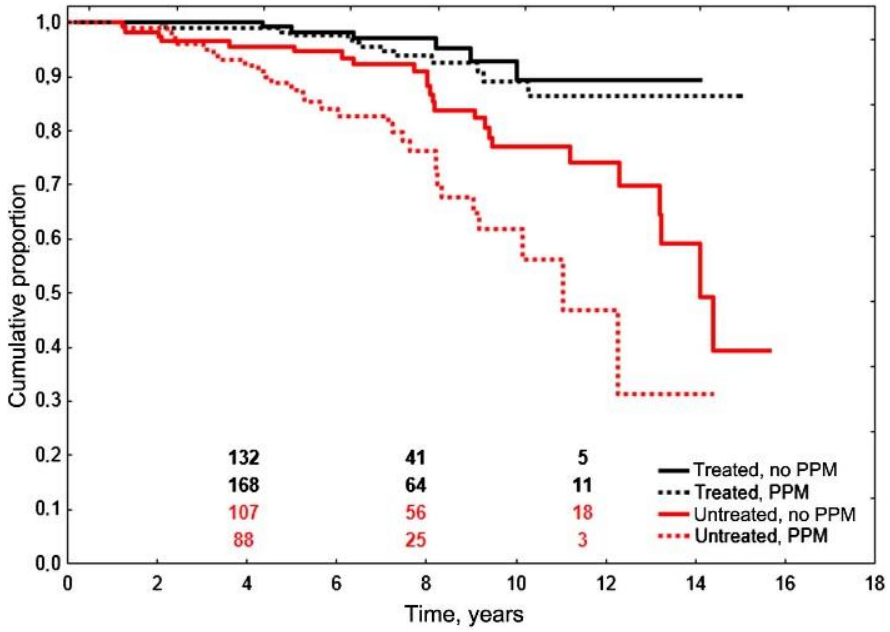
Edwards Perimount

Bourguignon T. *et al* | Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position | Ann Thorac Surg 2015;99:831–7

What causes a bioprosthetic valve to fail?

Antimineralization treatment and patient-prosthesis mismatch are major determinants of the onset and incidence of structural valve degeneration in bioprosthetic heart valves

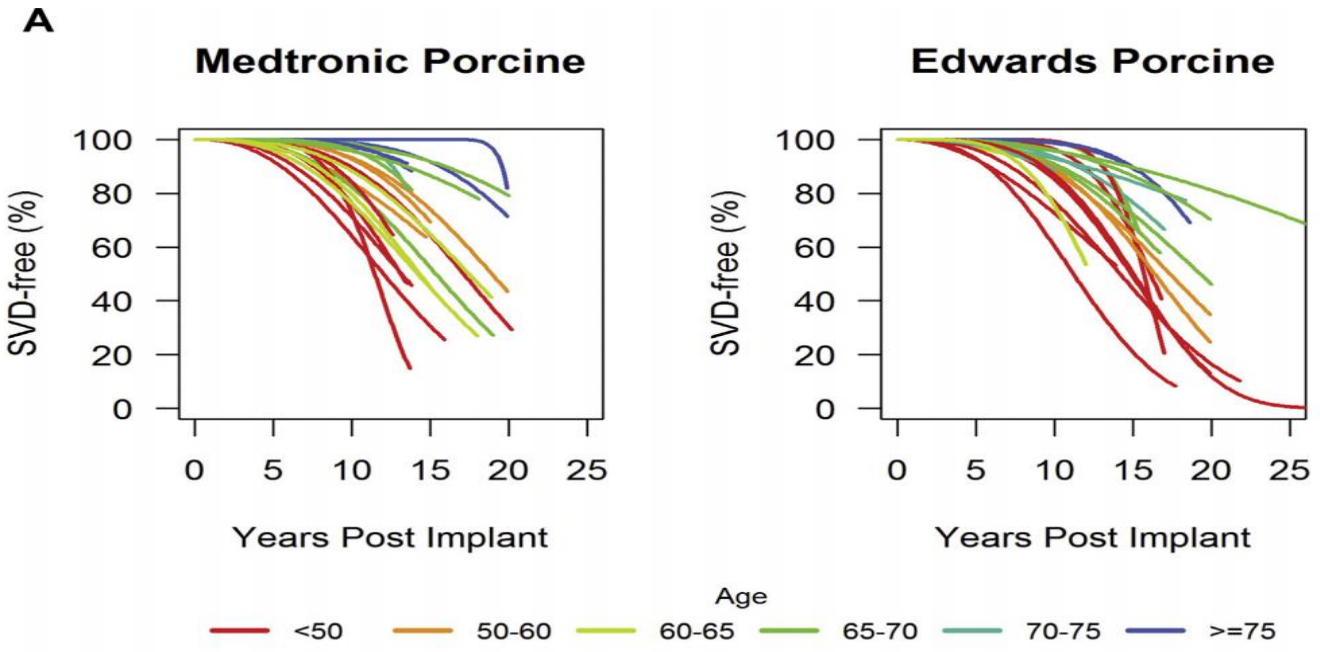
Valve durability



Mean age: 73,8 years
EOAi <0,85 cm2/m2
All AVR

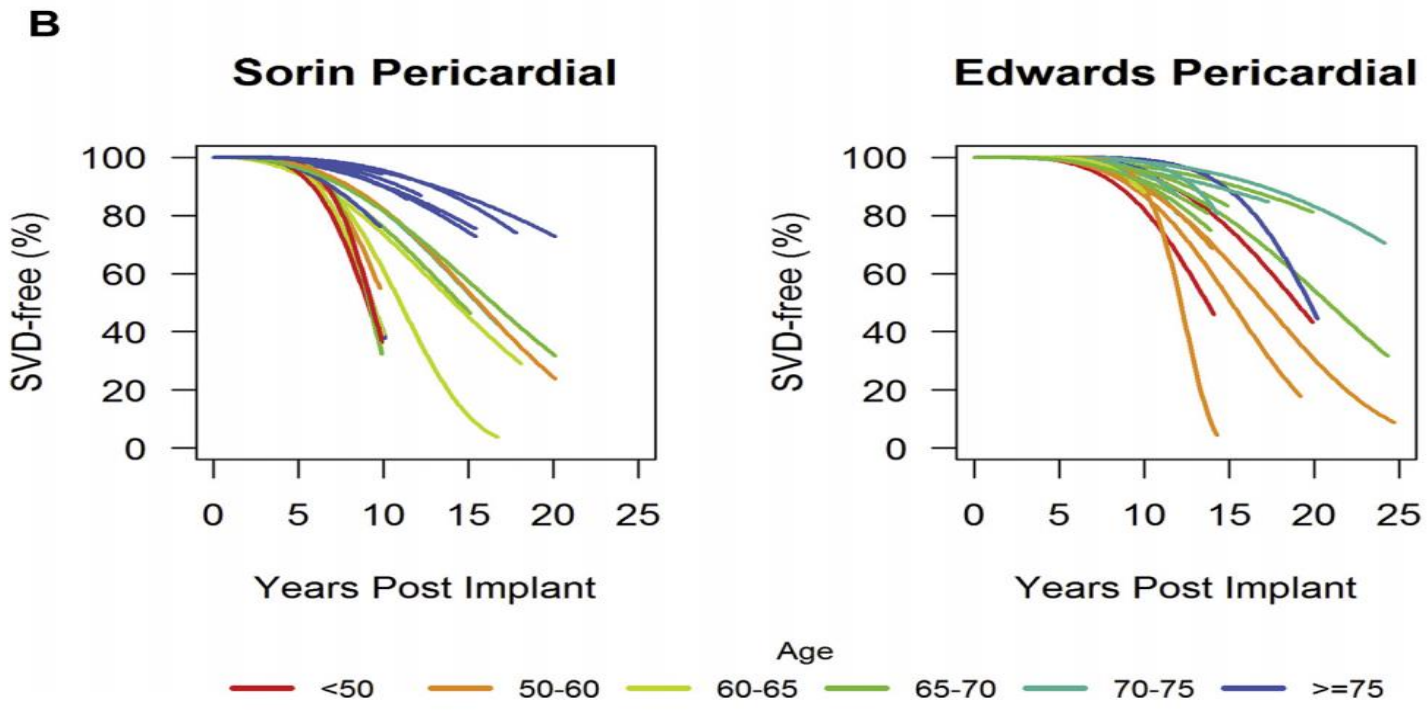
Willem Flameng et al. JTCVS 2014; 147:1219-24

Bioprosthetic Aortic Valve Durability: A Meta-Regression of Published Studies



Ann Thorac Surg 2017

Bioprosthetic Aortic Valve Durability: A Meta-Regression of Published Studies



Ann Thorac Surg 2017

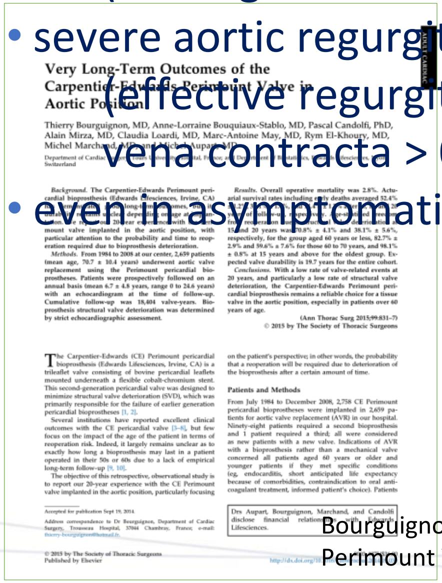
Long-term follow-up of surgical bioprothesis:

Newer Definition of SVD

Structural Valve Deterioration (SVD) and Reoperation for SVD

Strict echocardiographic assessment:

- severe aortic stenosis
  (mean gradient > 40 mm Hg) or
- severe aortic regurgitation
  (effective regurgitant orifice area > 0.30 cm2,
  vena contracta > 0.6 cm)
- even in asymptomatic patients



ADULT CARDIAC

Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position

Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Candolfi, PhD, Alain Mirza, MD, Claudia Loardi, MD, Marc-Antoine May, MD, Rym El-Khoury, MD, Michel Marchand, MD, and Michel Aupart, MD

Department of Cardiac [illegible] Switzerland

Background. The Carpentier-Edwards Perimount pericardial bioprosthesis (Edwards Lifesciences, Irvine, CA) [illegible] outcomes, but its durability [illegible] depending on age at implantation. [illegible] 20-year experience with [illegible] mount valve implanted in the aortic position, with particular attention to the probability and time to reoperation required due to bioprosthesis deterioration.

Methods. From 1984 to 2008 at our center, 2,659 patients (mean age, 70.7 ± 10.4 years) underwent aortic valve replacement using the Perimount pericardial bioprostheses. Patients were prospectively followed on an annual basis (mean 6.7 ± 4.8 years, range 0 to 24.6 years) with an echocardiogram at the time of follow-up. Cumulative follow-up was 18,404 valve-years. Bioprosthesis structural valve deterioration was determined by strict echocardiographic assessment.

Results. Overall operative mortality was 2.8%. Actuarial survival rates including early deaths averaged 52.4% [illegible] years of follow-up, respectively. Age-stratified freedom from reoperation [illegible] 15 and 20 years was 70.8% ± 4.1% and 38.1% ± 5.6%, respectively, for the group aged 60 years or less, 82.7% ± 2.9% and 59.6% ± 7.6% for those 60 to 70 years, and 98.1% ± 0.8% at 15 years and above for the oldest group. Expected valve durability is 19.7 years for the entire cohort.

Conclusions. With a low rate of valve-related events at 20 years, and particularly a low rate of structural valve deterioration, the Carpentier-Edwards Perimount pericardial bioprosthesis remains a reliable choice for a tissue valve in the aortic position, especially in patients over 60 years of age.

(Ann Thorac Surg 2015;99:831–7)

The Carpentier-Edwards (CE) Perimount pericardial bioprosthesis (Edwards Lifesciences, Irvine, CA) is a trileaflet valve consisting of bovine pericardial leaflets mounted underneath a flexible cobalt-chromium stent. This second-generation pericardial valve was designed to minimize structural valve deterioration (SVD), which was primarily responsible for the failure of earlier generation pericardial bioprostheses [1, 2].

Several institutions have reported excellent clinical outcomes with the CE pericardial valve [3–8], but few focus on the impact of the age of the patient in terms of reoperation risk. Indeed, it largely remains unclear as to exactly how long a bioprosthesis may last in a patient operated in their 50s or 60s due to a lack of empirical long-term follow-up [9, 10].

The objective of this retrospective, observational study is to report our 20-year experience with the CE Perimount valve implanted in the aortic position, particularly focusing on the patient's perspective; in other words, the probability that a reoperation will be required due to deterioration of the bioprosthesis after a certain amount of time.

Patients and Methods

From July 1984 to December 2008, 2,758 CE Perimount pericardial bioprostheses were implanted in 2,659 patients for aortic valve replacement (AVR) in our hospital. Ninety-eight patients required a second bioprosthesis and 1 patient required a third; all were considered as new patients with a new valve. Indications of AVR with a bioprosthesis rather than a mechanical valve concerned all patients aged 60 years or older and younger patients if they met specific conditions (eg, endocarditis, short anticipated life expectancy because of comorbidities, contraindication to oral anticoagulant treatment, informed patient's choice). Patients

Accepted for publication Sept 19, 2014.

Address correspondence to Dr Bourguignon, Department of Cardiac Surgery, Trousseau Hospital, 37044 Chambray, France; e-mail: thierry-bourguignon@hotmail.fr.

Drs Aupart, Bourguignon, Marchand, and Candolfi disclose financial relationships with Edwards Lifesciences.

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http://dx.doi.org/10.[illegible]

Bourguignon T. *et al* | Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position | Ann Thorac Surg 2015;99:831–7

Assuming 15 years/valve, what will it look like for a 50 yo?

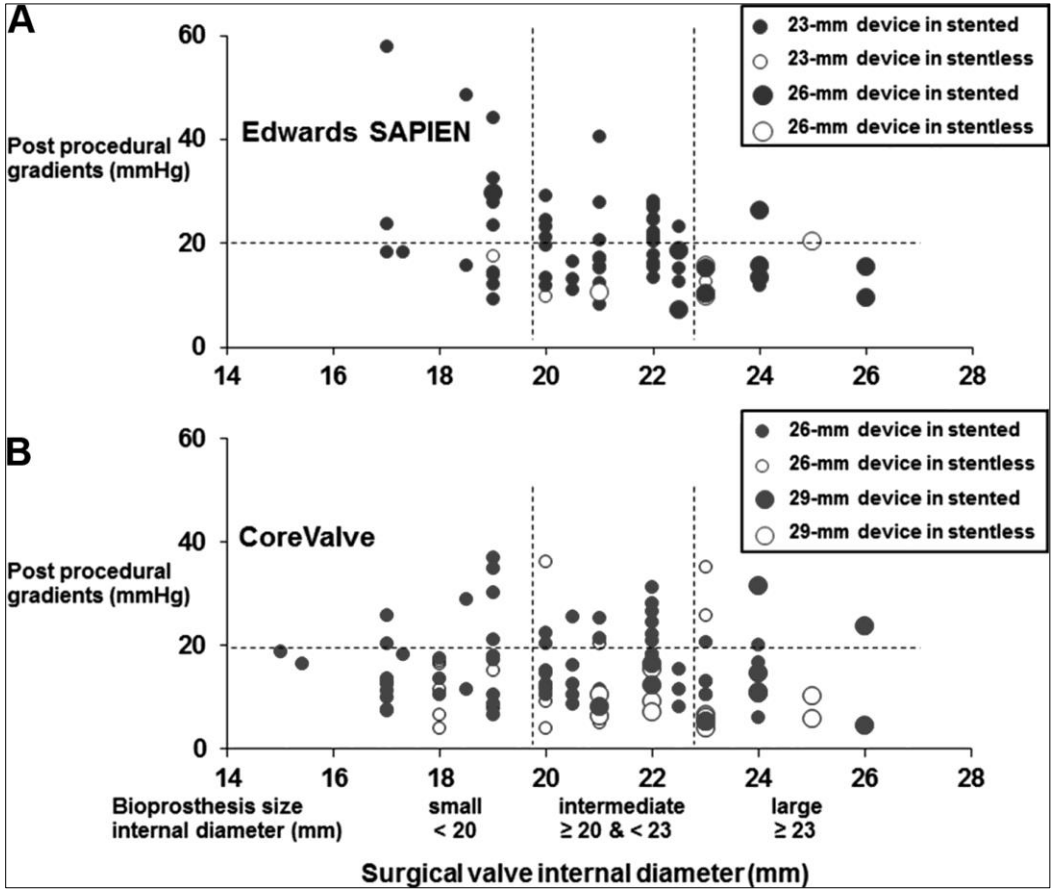
- 50 yoa, bioprosthetic SAVR
- 65 TAVR Valve in Valve
- 80 TAVR Valve in Valve in Valve

What if durability of valve is really 10 years?

- 50 yoa, bioprosthetic SAVR
- 60 yoa, Valve in Valve TAVR
- 70 yoa, Valve in Valve in Valve TAVR
- 80 yoa, Valve in Valve in Valve in Valve TAVR??

“We can always place a transcatheter valve…”

- Assumptions:
  - The initial bioprosthetic is large enough to accomadate a TAVR without high gradients
    - Inspirus
  - Proximity of valve to coronary ostia and other anatomic factors will allow TAVR implantation without complication
  - You will only need one more intervention in your lifetime
    - Sparse data on Valve in Valve
    - No Data on Valve in Valve in Valve
  - The TAVR will go smoothly



***Danny Dvir et al. Circulation*. 2012;126:2335**

Mechanical Versus Bioprosthetic Aortic Valve Replacement in Middle-Aged Adults: A Systematic Review and Meta-Analysis

Dong Fang Zhao, BA, Michael Seco, BMedSc, MBBS, James J. Wu, BMusStudies, James B. Edelman, MBBS(Hons), PhD, Michael K. Wilson, MBBS, Michael P. Vallely, MBBS, PhD, Michael J. Byrom, MBChB, PhD, and Paul G. Bannon, MBBS, PhD

Sydney Medical School, University of Sydney, Sydney; Baird Institute of Applied Heart and Lung Surgical Research, Sydney; Cardiothoracic Surgery Unit and Institute of Academic Surgery, Royal Prince Alfred Hospital, Sydney; and Australian School of Advanced Medicine, Macquarie University, Sydney, Australia

Ages 50-70

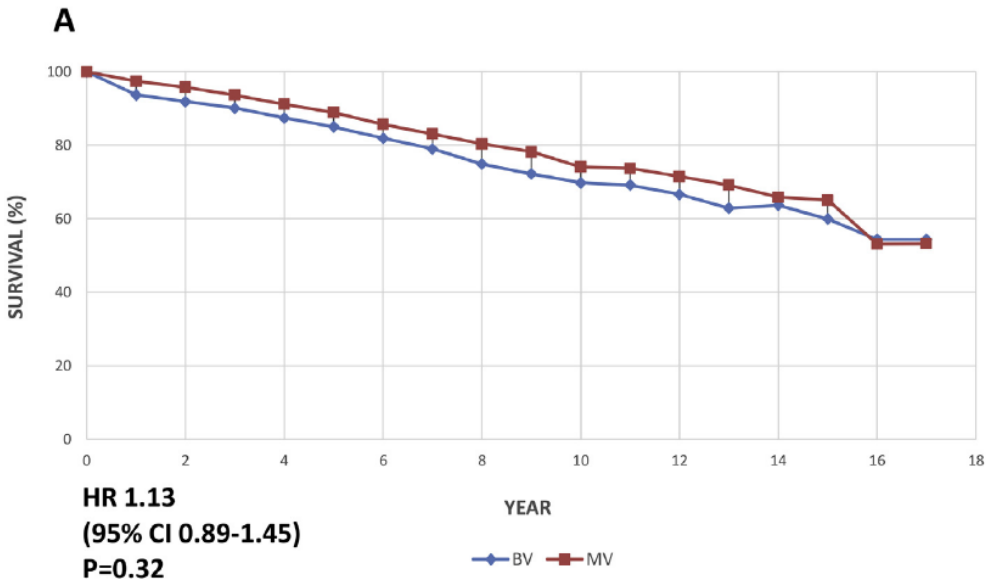
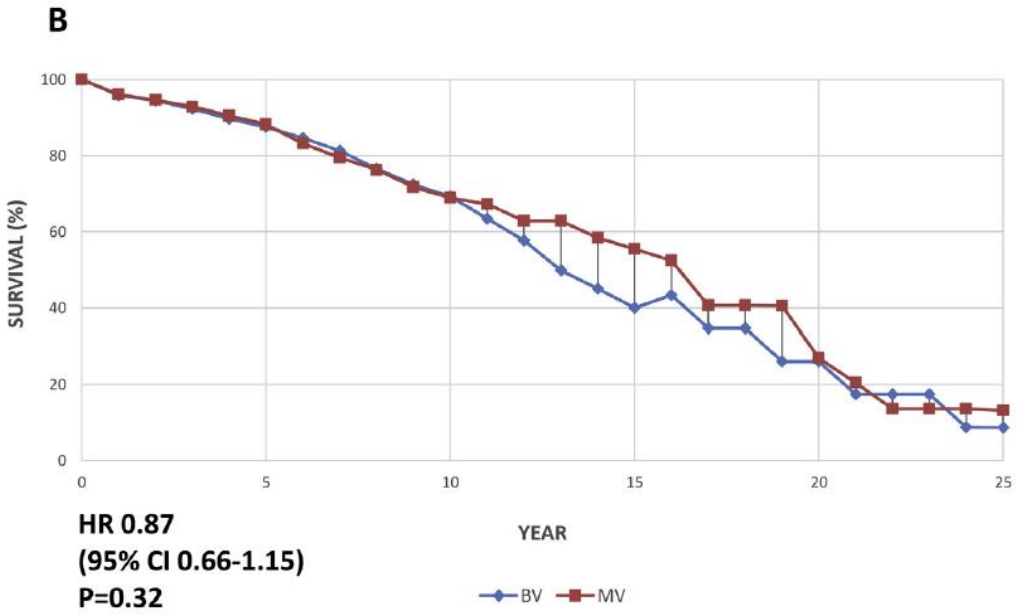
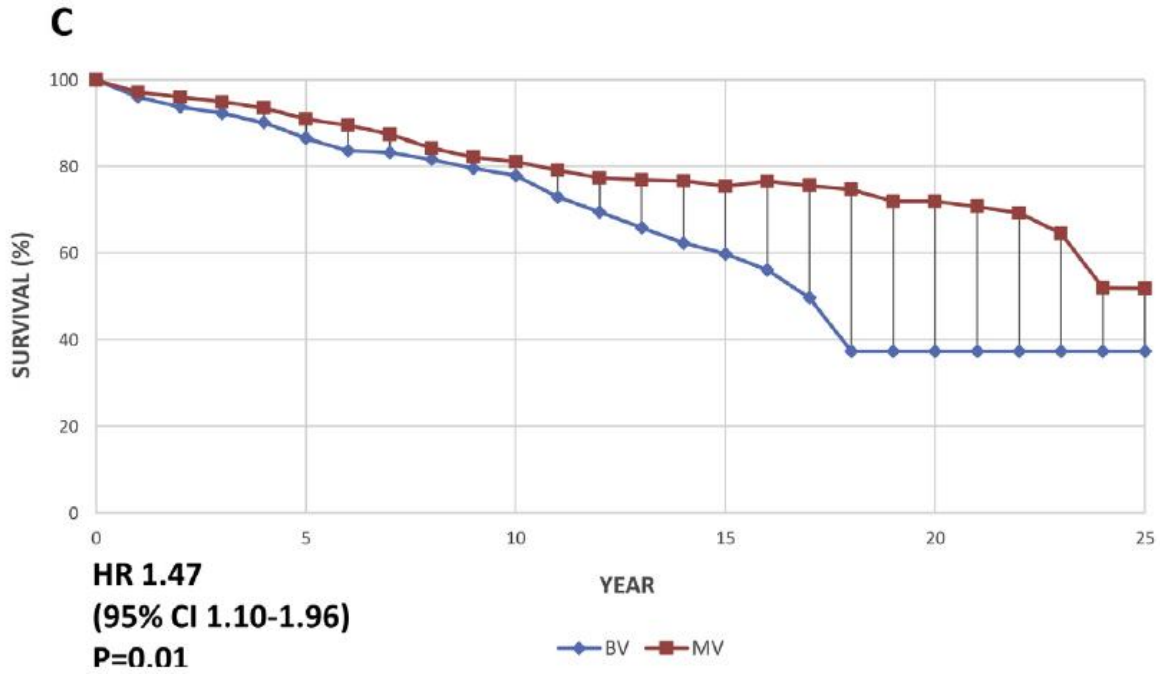


Fig 5. Overall Kaplan-Meier survival curves based on reconstructed individual study data. Aggregated survival curves for bioprosthetic valve (blue lines) compared with mechanical valve (red lines) after aortic valve replacement in patients aged (A) 50 to 70 years; (B) 60 to 70 years; and (C) less than 65 years. (CI = confidence interval; HR = hazard ratio.)

Ages 60-70


B
100
80
60
40
20
0
SURVIVAL (%)
0
5
10
15
20
25
YEAR
HR 0.87
(95% CI 0.66-1.15)
P=0.32
BV
MV

Ages < 65


C
100
80
60
40
20
0
SURVIVAL (%)
0
5
10
15
20
25
YEAR
BV
MV
HR 1.47
(95% CI 1.10-1.96)
P=0.01

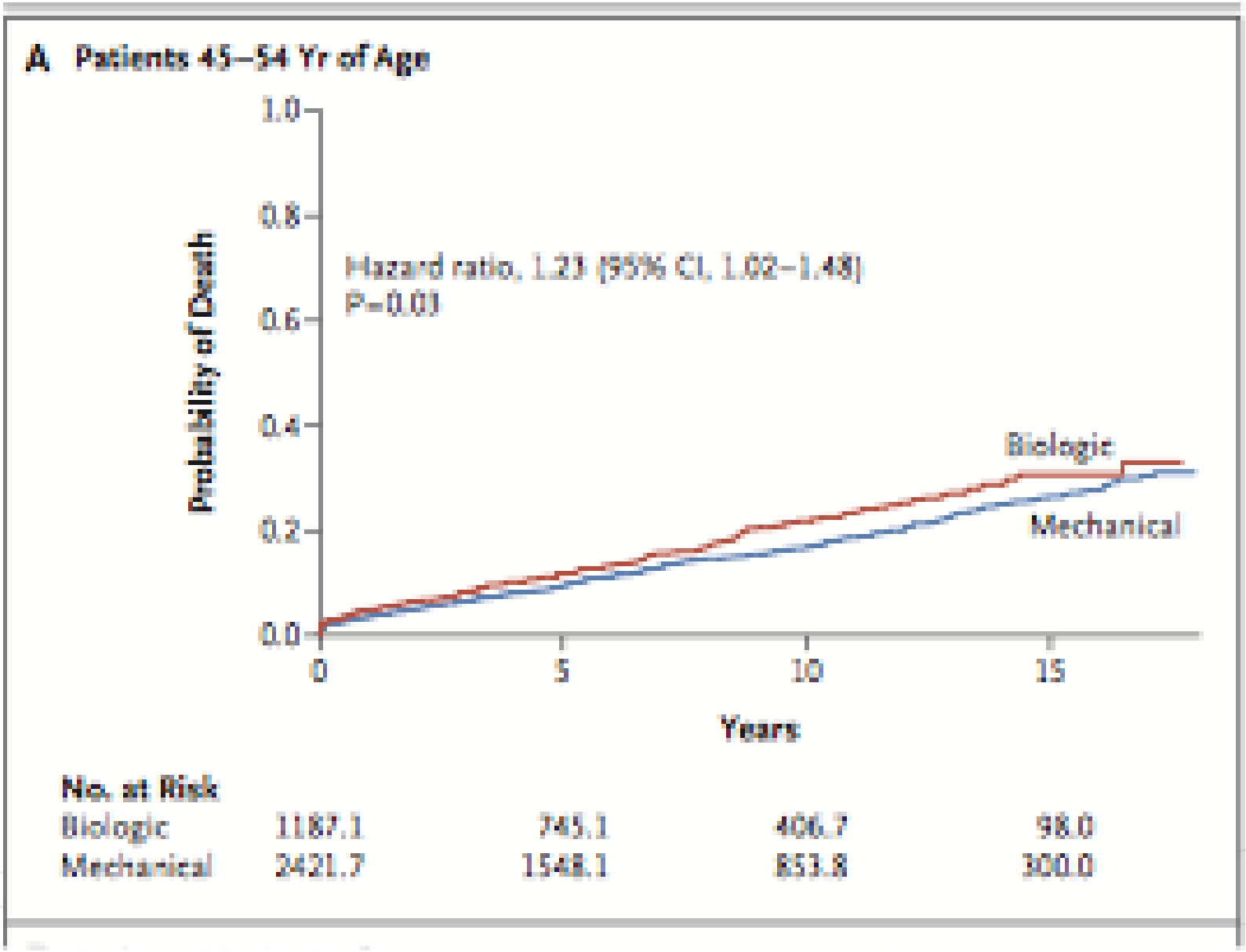
- For 50-70 mortality equal, suggests the bleeding and thrombotic complications favor tissue valve.
- Less than 65 group favored mechanical
  - Larger percentage of 50 year olds and lower…mean 50.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Mechanical or Biologic Prostheses for Aortic-Valve and Mitral-Valve Replacement

Andrew B. Goldstone, M.D., Ph.D., Peter Chiu, M.D., Michael Baiocchi, Ph.D., Bharathi Lingala, Ph.D., William L. Patrick, M.D., Michael P. Fischbein, M.D., Ph.D., and Y. Joseph Woo, M.D.


A Patients 45–54 Yr of Age
Probability of Death
1.0
0.8
0.6
0.4
0.2
0.0
Hazard ratio, 1.23 (95% CI, 1.02–1.48)
P=0.03
Biologic
Mechanical
0
5
10
15
Years
No. at Risk
Biologic 1187.1 745.1 406.7 98.0
Mechanical 2421.7 1548.1 853.8 300.0

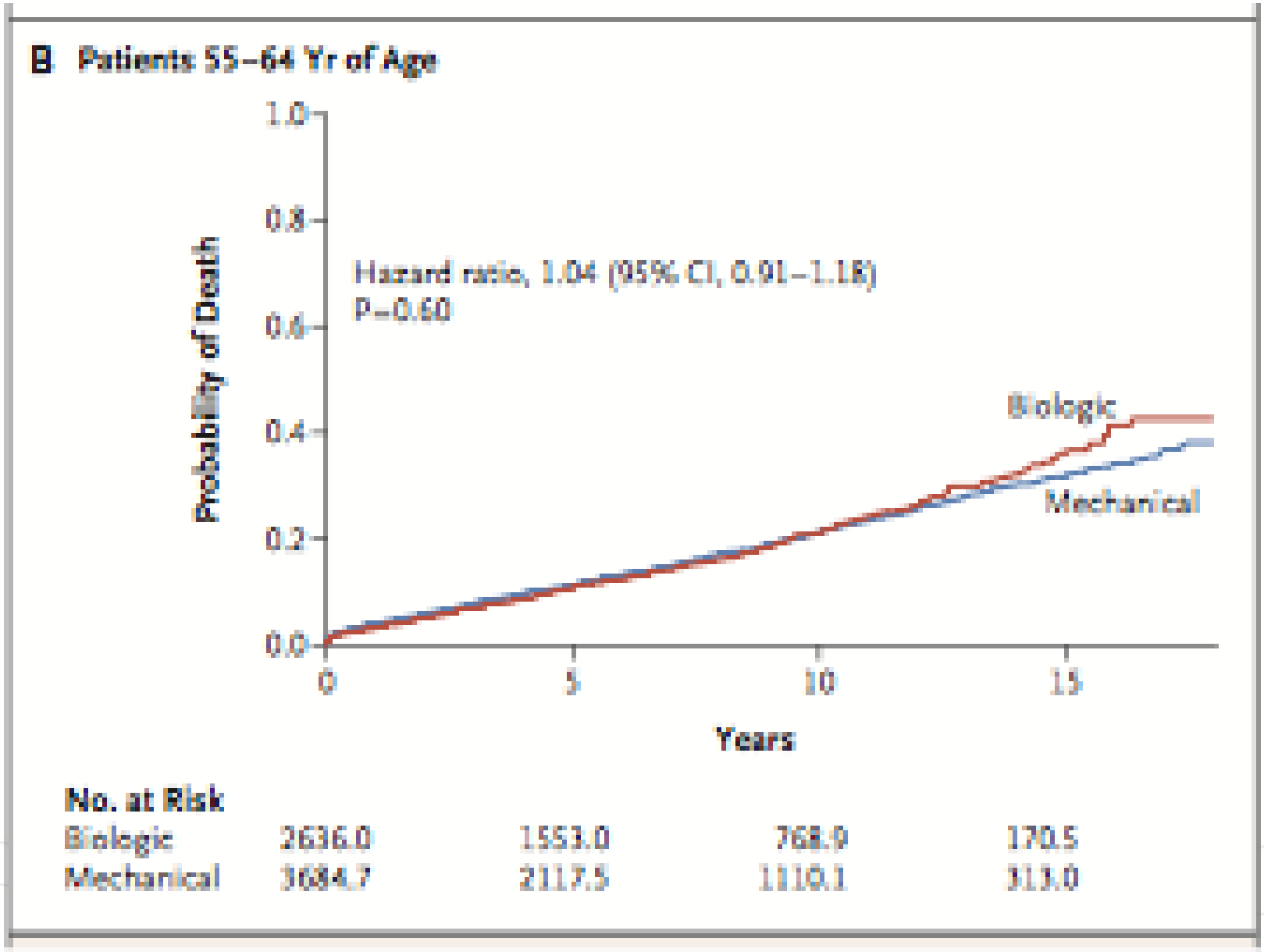

B Patients 55–64 Yr of Age
Probability of Death
1.0
0.8
0.6
0.4
0.2
0.0
Hazard ratio, 1.04 (95% CI, 0.91–1.18)
P=0.60
Biologic
Mechanical
0
5
10
15
Years
No. at Risk
Biologic 2636.0 1553.0 768.9 170.5
Mechanical 3684.7 2117.5 1110.1 313.0

Table 2. Between-Group Differences in Mortality among Recipients of Mechanical and Biologic Aortic-Valve Prostheses.*

Variable	Patients 45 to 54 Yr of Age			Patients 55 to 64 Yr of Age		
	Biologic Prosthesis (N = 1187.1)	Mechanical Prosthesis (N = 2421.7)	P Value	Biologic Prosthesis (N = 2636.0)	Mechanical Prosthesis (N = 3684.7)	P Value
Mortality at 15 yr — %	30.6	26.4	0.03	36.1	32.1	0.60
Hazard ratio (95% CI)						
Weighted proportional-hazards model	1.23 (1.02 to 1.48)	Reference	0.03	1.04 (0.91 to 1.18)	Reference	0.60
Weighted proportional-hazards model, with multivariable adjustment†	1.25 (1.03 to 1.52)	Reference	0.02	1.05 (0.92 to 1.21)	Reference	0.47
Weighted proportional-hazards model, with hospital as random effect‡	1.28 (1.08 to 1.53)	Reference	0.005	1.11 (0.98 to 1.25)	Reference	0.12
Restricted mean survival time at 15 yr (95% CI)§						
Difference — days	−167.9 (−296.5 to −39.3)	Reference	0.01	−5.4 (−101.8 to 91.0)	Reference	0.91
Ratio	0.97 (0.94 to 0.99)	Reference	0.01	1.00 (0.98 to 1.02)	Reference	0.91
Ratio of restricted mean time lost	1.23 (1.05 to 1.42)	Reference	0.008	1.01 (0.91 to 1.12)	Reference	0.91

CONCLUSIONS

The long-term mortality benefit that was associated with a mechanical prosthesis, as compared with a biologic prosthesis, persisted

Table 2 Considerations for implanting a mechanical or bioprosthetic aortic valve

Patient characteristic	Consider favouring mechanical valve	Consider favouring bioprosthetic valve
Age <60	X	
Age 60–70	Unclear	Unclear
Age >70 years		X
Age <60 but life expectancy <10 years		X
Age <60 but pregnancy wish		X
Age <60 but hazardous occupation (e.g. sports, mining, stunt(wo)man, etc)		X
Preoperative lifelong anticoagulation indication (e.g. AF, PVD, hypercoagulable state)	X	
Reoperations for valve thrombosis because of compliance failure or inadequate INR regulation		X
High bleeding risk		X
Contra-indication for anticoagulation treatment		X
End-stage renal failure on dialysis		X
Metabolic syndrome	X	
Hyperparathyroidism	X	
Small aortic annulus	X	

These factors should be weighted and could potentially lean towards performing mechanical or bioprosthetic valve implantation. Presence of any of these factors does not exclude the opportunity to perform valve replacement with another type of valve.
AF, atrial fibrillation; INR, International normalized ratio; PVD, peripheral vascular disease.

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]

Outcomes of Middle-Aged Patients 15 Years Post-Implant: Mechanical vs Bioprosthetic Valves

	OR	95% CI
Survival	1.10	0.89-1.36
Freedom From Stroke	1.14	0.77-1.71
Freedom From Endocarditis	1.51	0.63-3.63
Freedom From Reoperation	1.95	1.16-3.30
Freedom From Thromboembolic Events	0.61	0.44-0.86
Freedom From Major Bleeding	0.40	0.19-0.84

Conclusions

- There continues to be a dramatic shift towards bioprosthetic valve implantation.
- Younger patients must be given a very realistic expectation of the need for re-intervention and implications throughout their lifetime
- Patients younger than 55 receive a mortality benefit from a mechanical Aortic valve.
- The future likely belongs to TAVR
- However, still awaiting long term data
- Paucity of data for Valve in Valve, and Valve in Valve in Valve etc
- Mechanical valve should be strongly considered for patients < 55 yoa