

New Developments in the Management of Aortic and Mitral Valve Disorders

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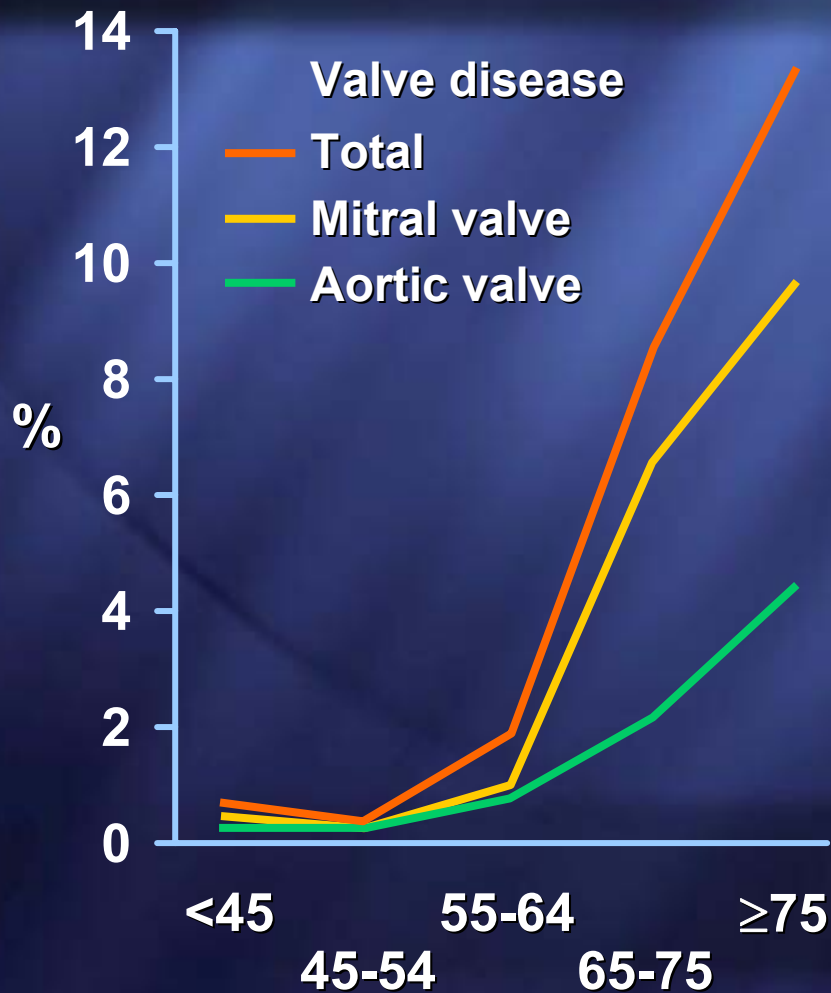
**Mayo Clinic,
Rochester, MN**

Conflicts of interest: none

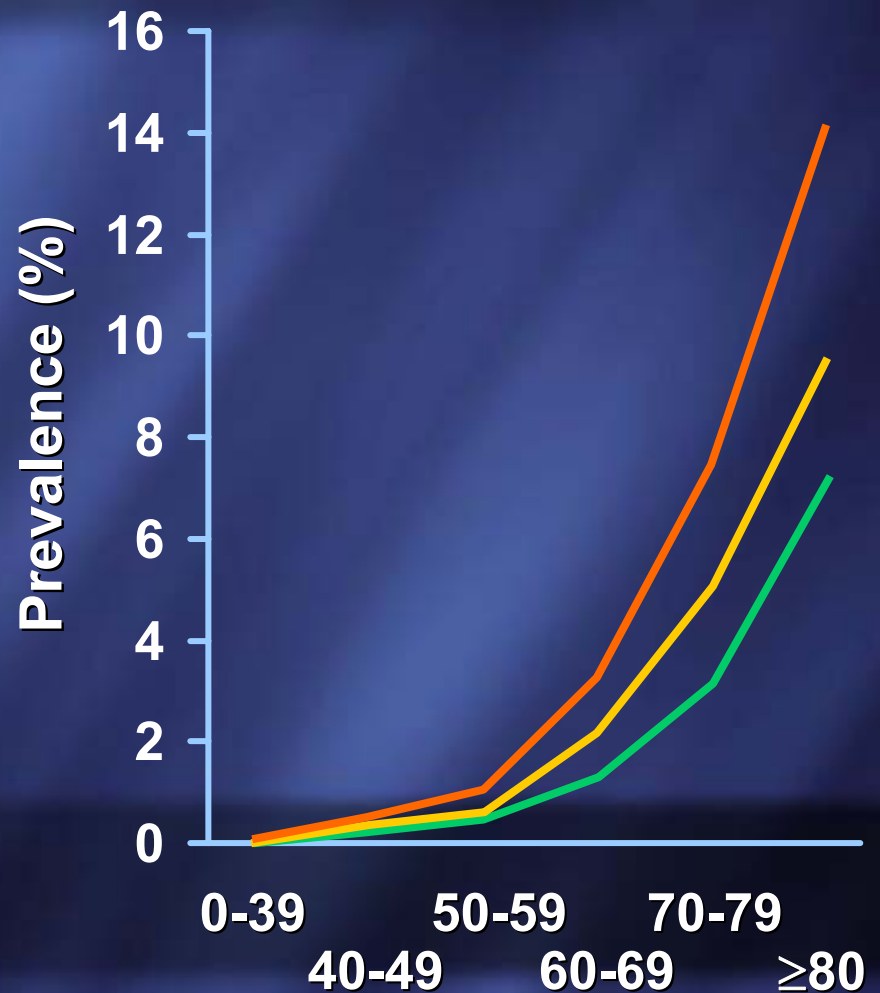
Prevalence of Valve Diseases

Moderate or severe

Population-NIH Series



Olmsted County



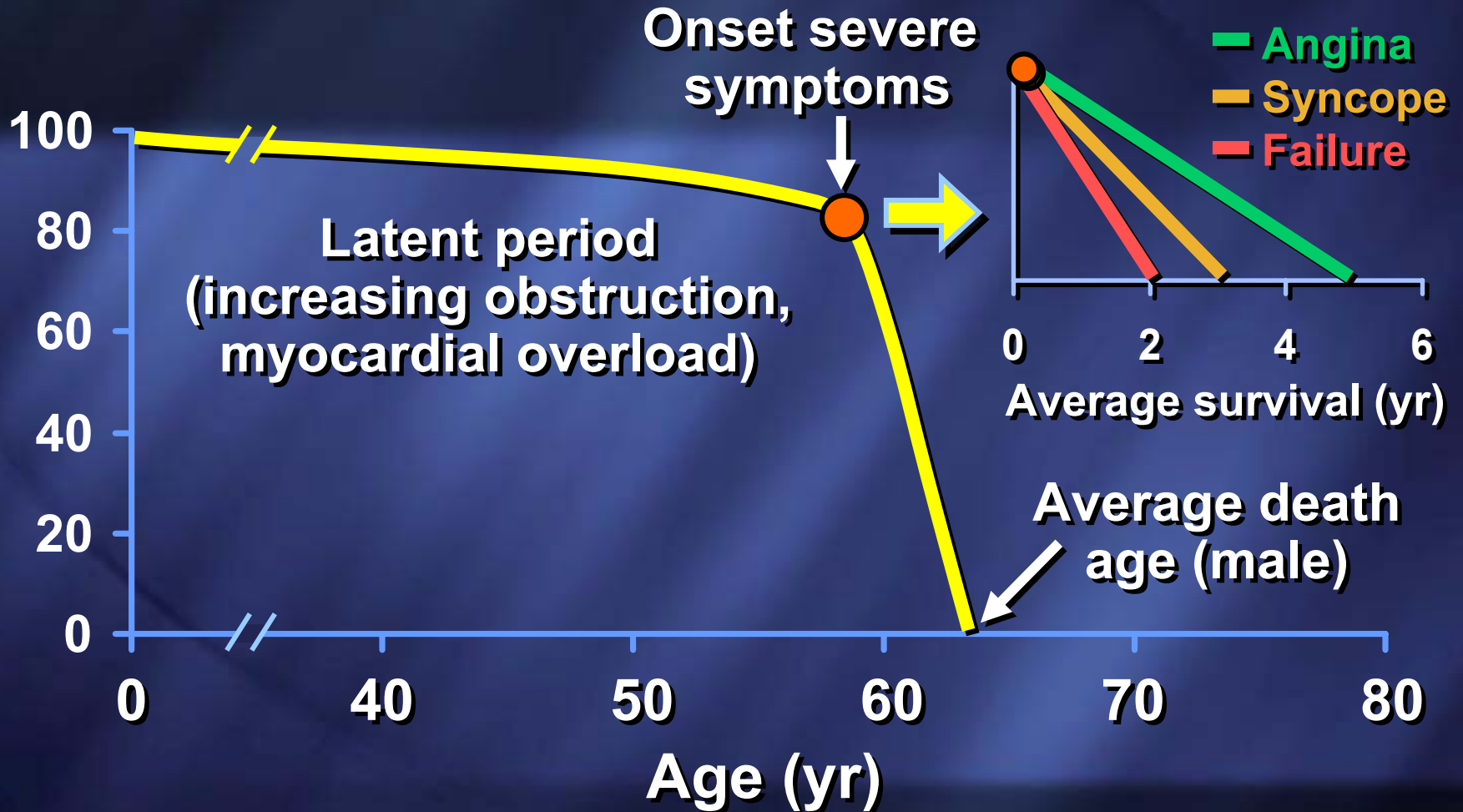
Burden of Valve Diseases in the U.S.

Year	2000	→	2030
Disease			
AS	2.5 million	→	4.6 million
MR	2.7 million	→	4.8 million

Overview

- **Natural history**
- **Assessment of morphology and severity**
- **Guidelines**
- **Surgical and percutaneous intervention**

Natural History of Aortic Stenosis



Ross J Jr. and Braunwald E: Circ 38:61, 1968

Symptoms in Aortic Stenosis

“Early”

“Late”

Angina

Syncope

Dyspnea

LV failure

Initial symptoms
in 1/3

Elderly

Survival Free of Symptoms Censored at AV Surgery



Outcome of 622 Adults with Asymptomatic AS

Multivariate Analysis – Symptoms

	HR	P
Aortic valve area (per 1 cm)	0.33	0.005
LVH	1.39	0.04

Pellikka, Circulation 111:3290-5, 2005

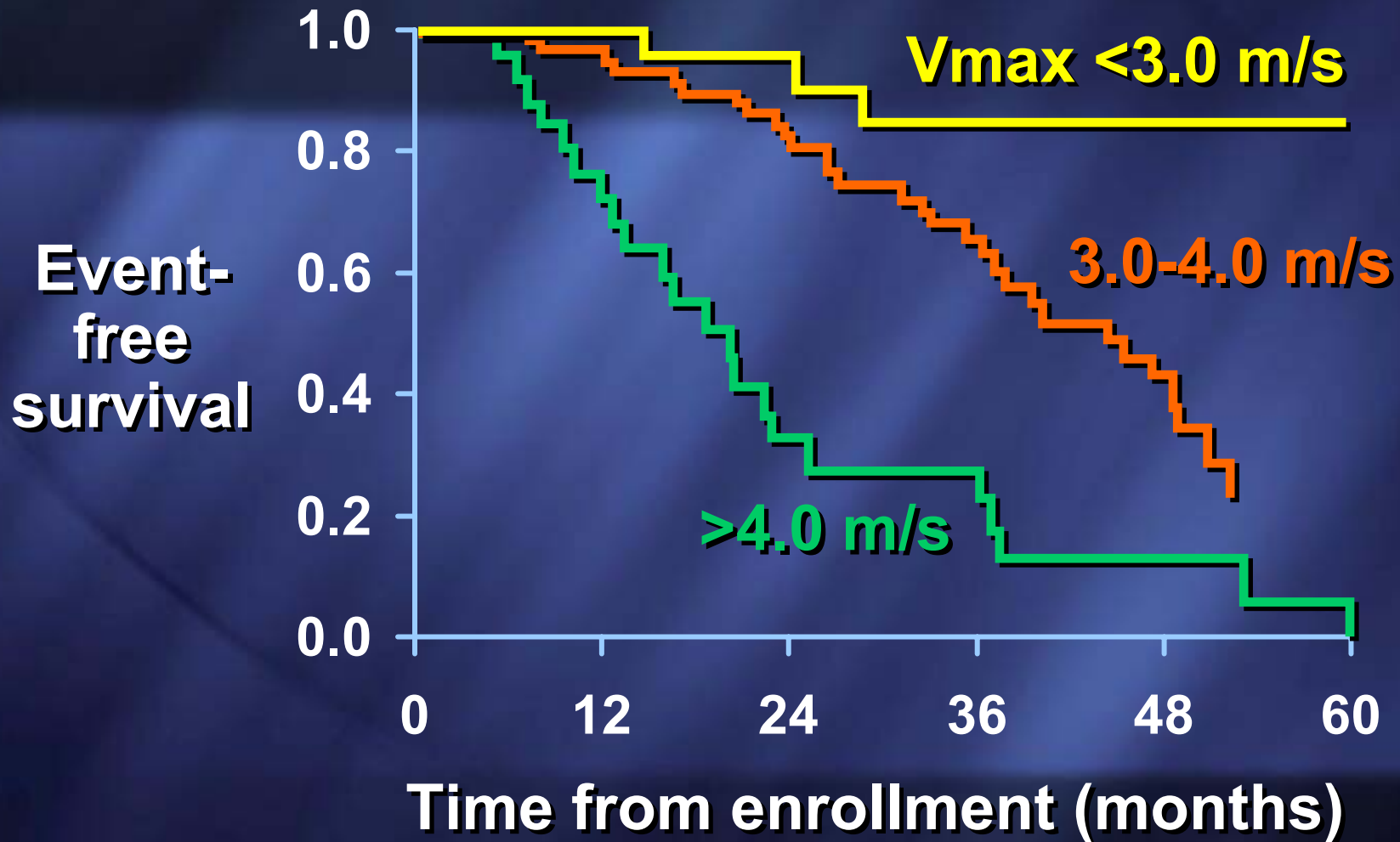
Outcome of 622 Adults with Asymptomatic AS

Multivariate Analysis – Mortality

	HR	P
Age (per year)	1.05	<0.0001
Chronic renal failure	2.41	0.004
Inactivity	2.0	0.001
Aortic valve velocity	1.46	0.03

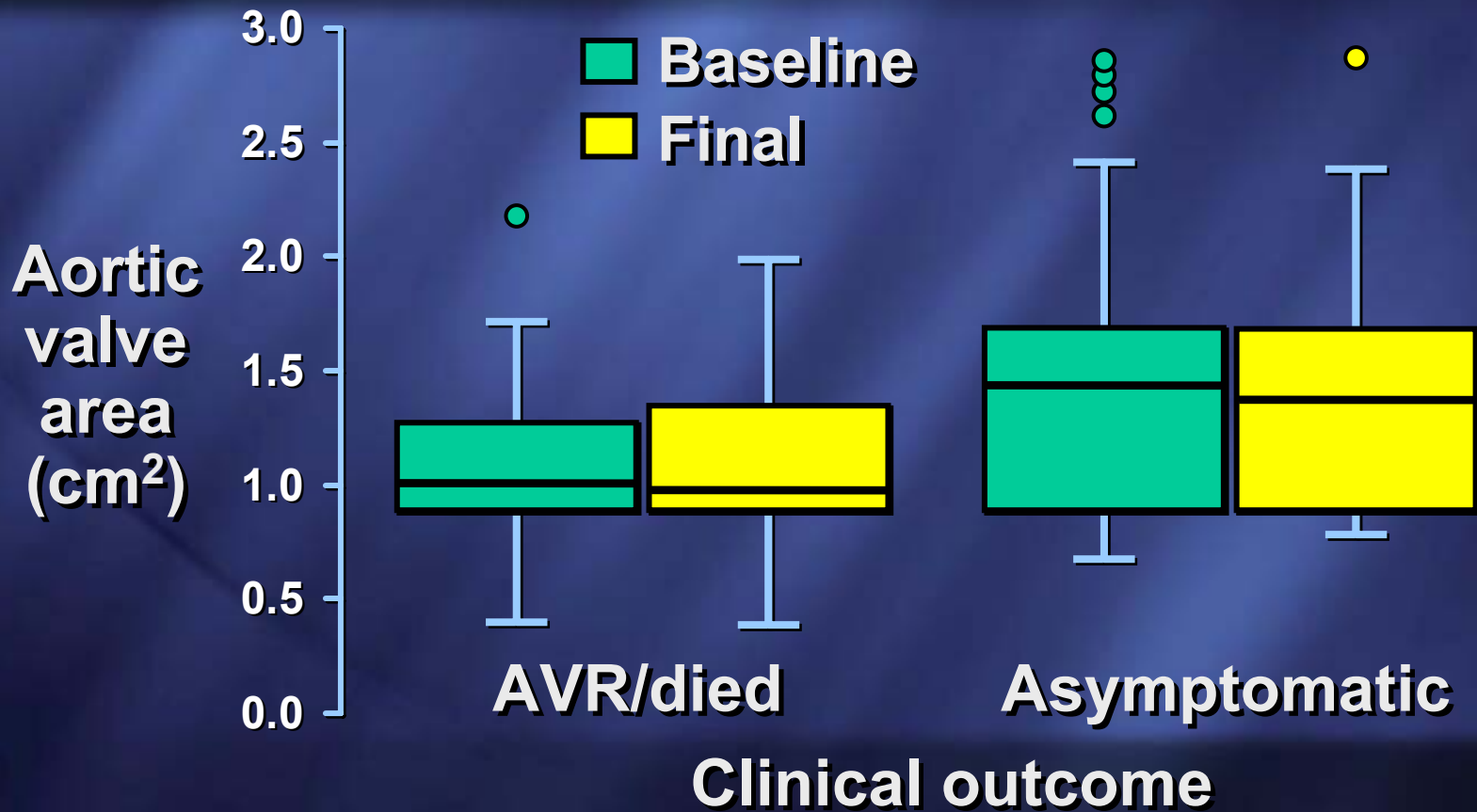
Pellikka, Circulation 111:3290-5, 2005

Survival in Asymptomatic AS



Otto CM: Circulation 95:2262, 1997

AVA for Patients Who Developed Symptoms and Required AVR Compared with Valve Area of Asymptomatic Patients (n=123)



Otto: Circulation, 1997

MR with flail leaflet: Natural history

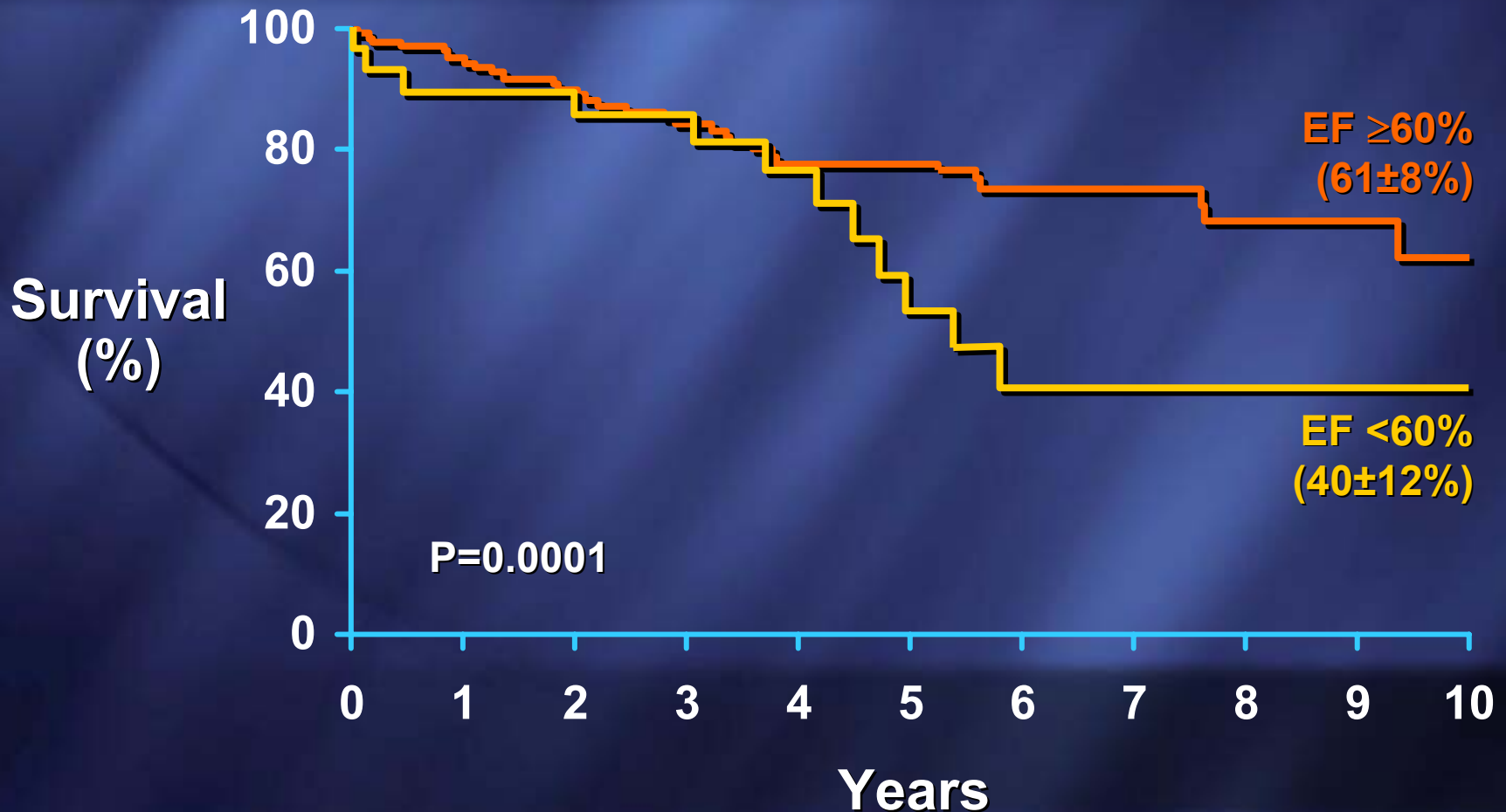
NYHA Class

229 pts



MR with flail leaflet: Natural History

Left Ventricular Ejection Fraction



Asymptomatic MVP

Risk Stratification

Primary risk factors (morb)

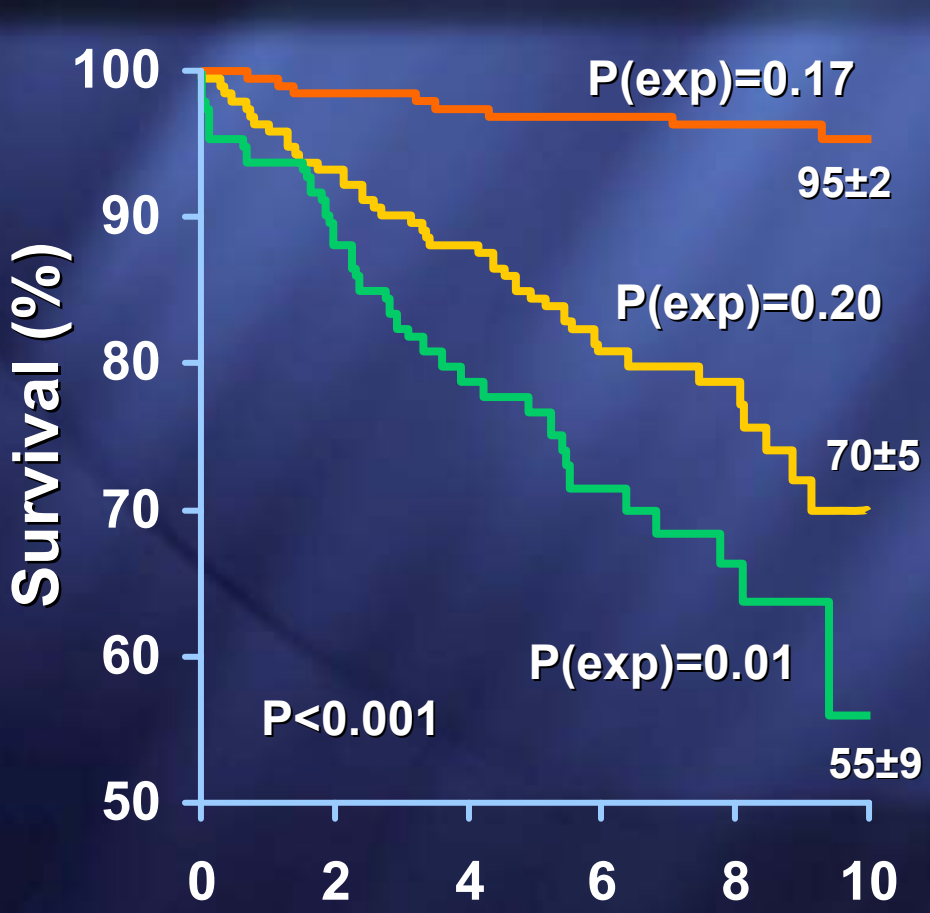
- EF <50%
- MR \geq moderate

Secondary risk factors (morb)

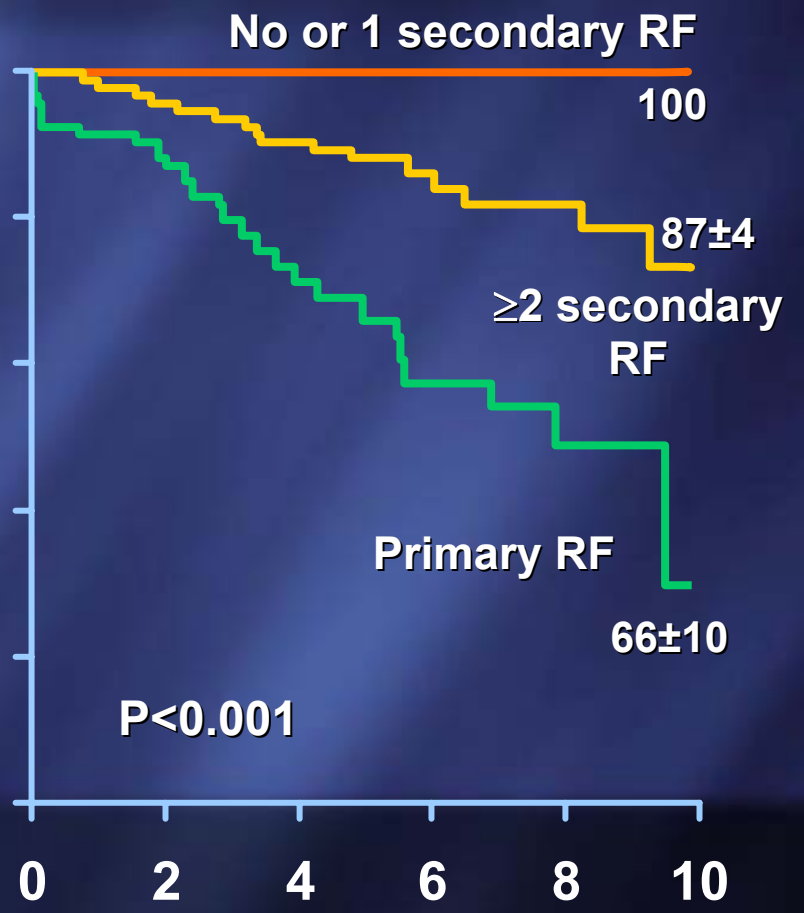
- Age \geq 50 years
- AFib
- Slight MR
- Flail leaflet
- LA \geq 40 mm

Outcome of Asymptomatic MVP

Overall Survival

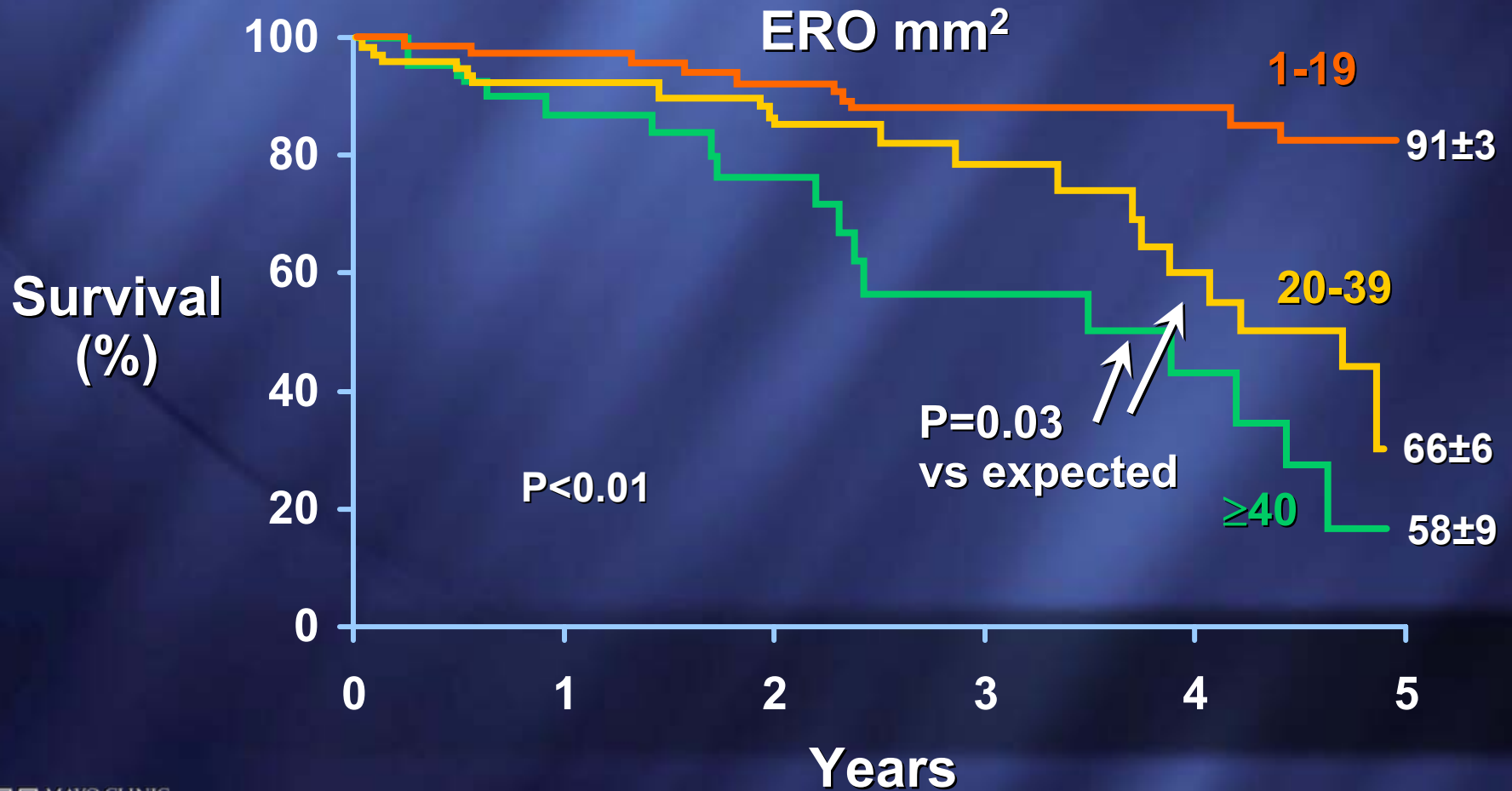


Cardiac Survival

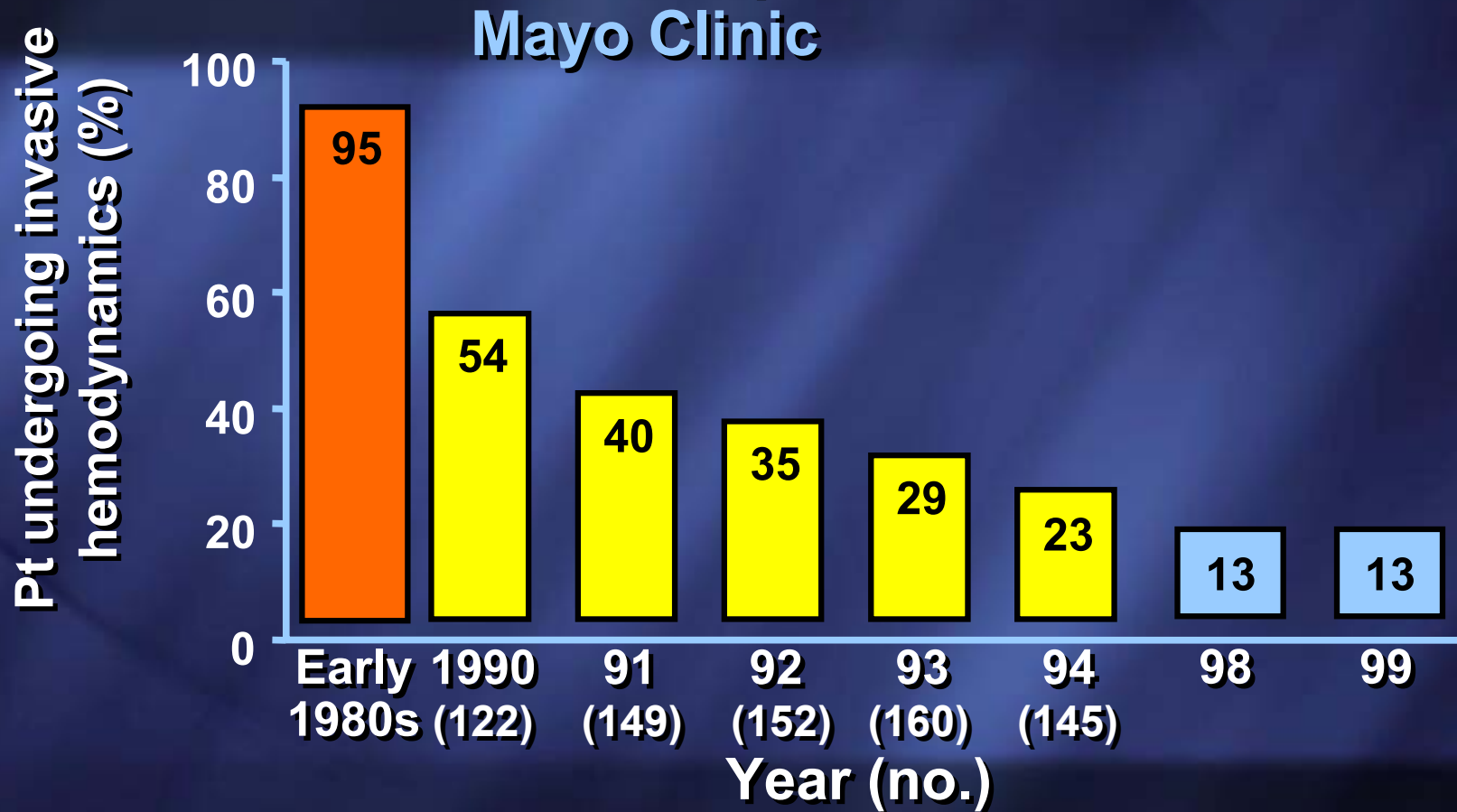


Years after diagnosis

Asymptomatic MR Natural History



% of Aortic Stenosis Patients Undergoing Invasive Hemodynamics, After Complete Doppler Exam, Prior to Valve Replacement

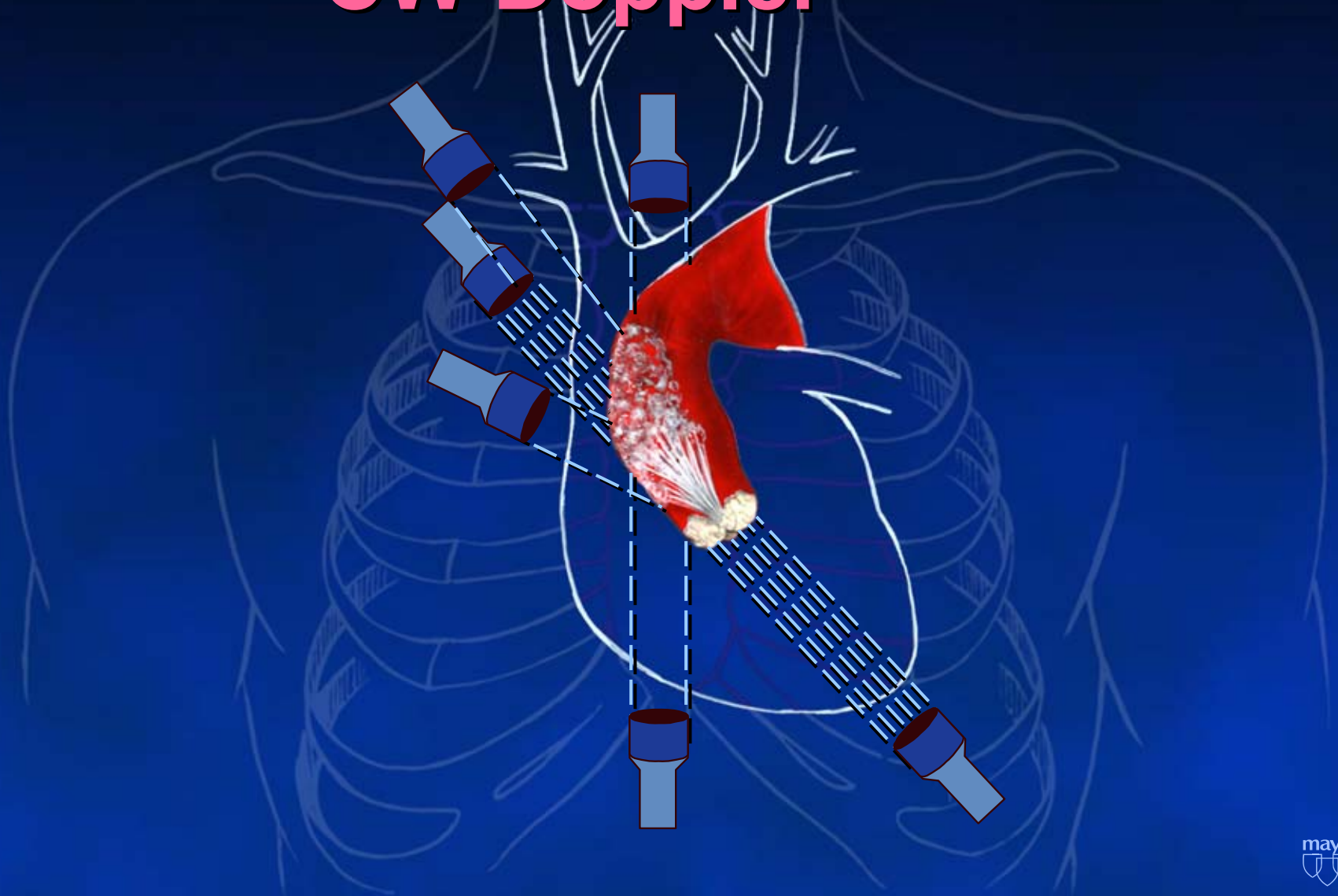


Simplified Bernoulli Equation

$$\Delta P \cong 4V^2$$

Aortic Stenosis

CW Doppler



Continuity Equation

$$AVA = A \times TVI$$

ACC/AHA 2006 Guidelines

Severity of Aortic Stenosis

AVA
(cm²)

cm²/m²

Mean
grad

Mild

>1.5

0.9

<25

Moderate

1-1.5

≥0.6

25-40

Severe

<1.0

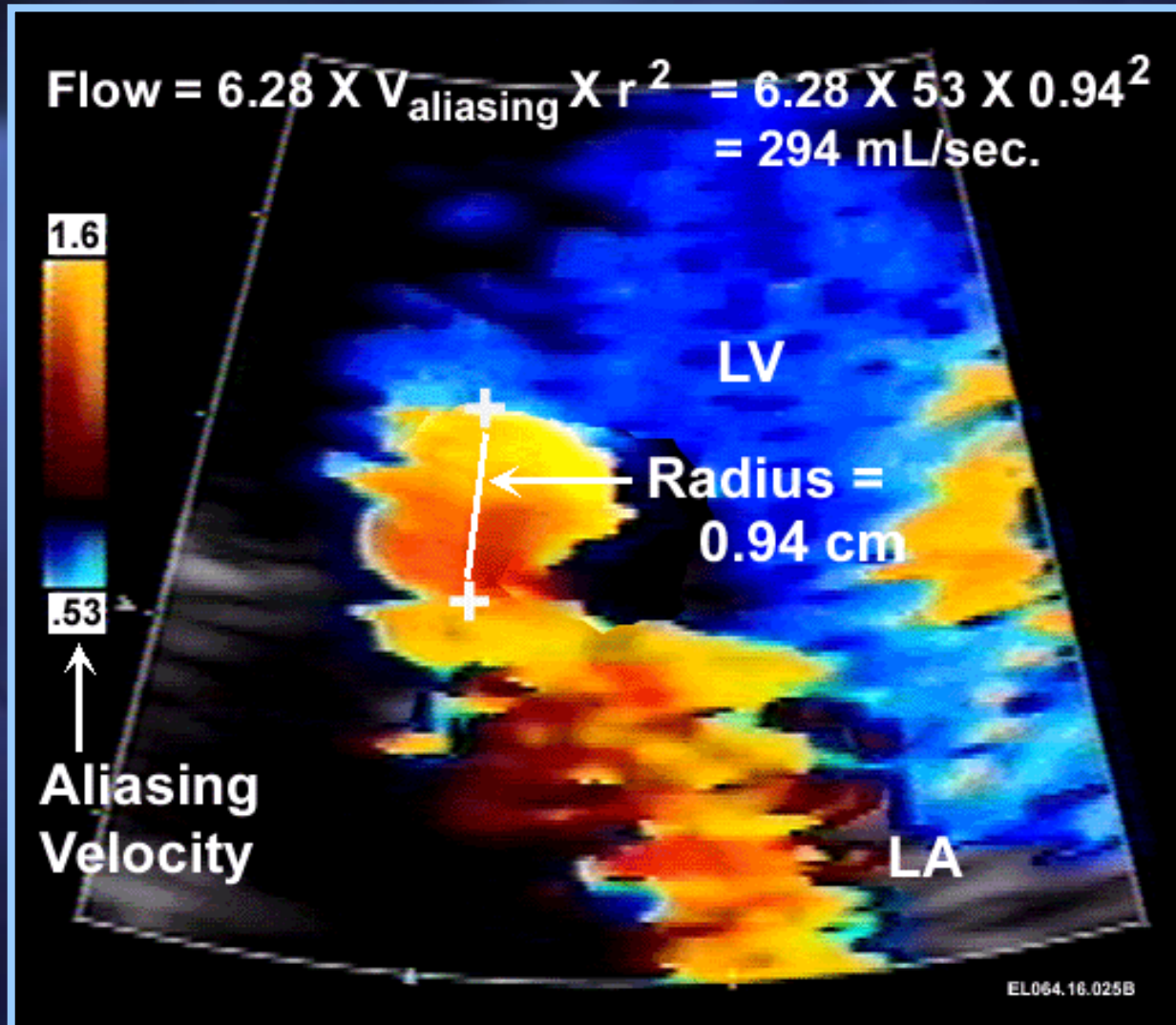
<0.6

>40

Echo/Doppler assessment

- **Morphology**
- **Severity of obstruction**
- **Associated conditions- LV size, function, hypertrophy, aortic root size, diastolic function, pulmonary artery pressure**

Flow Calculation



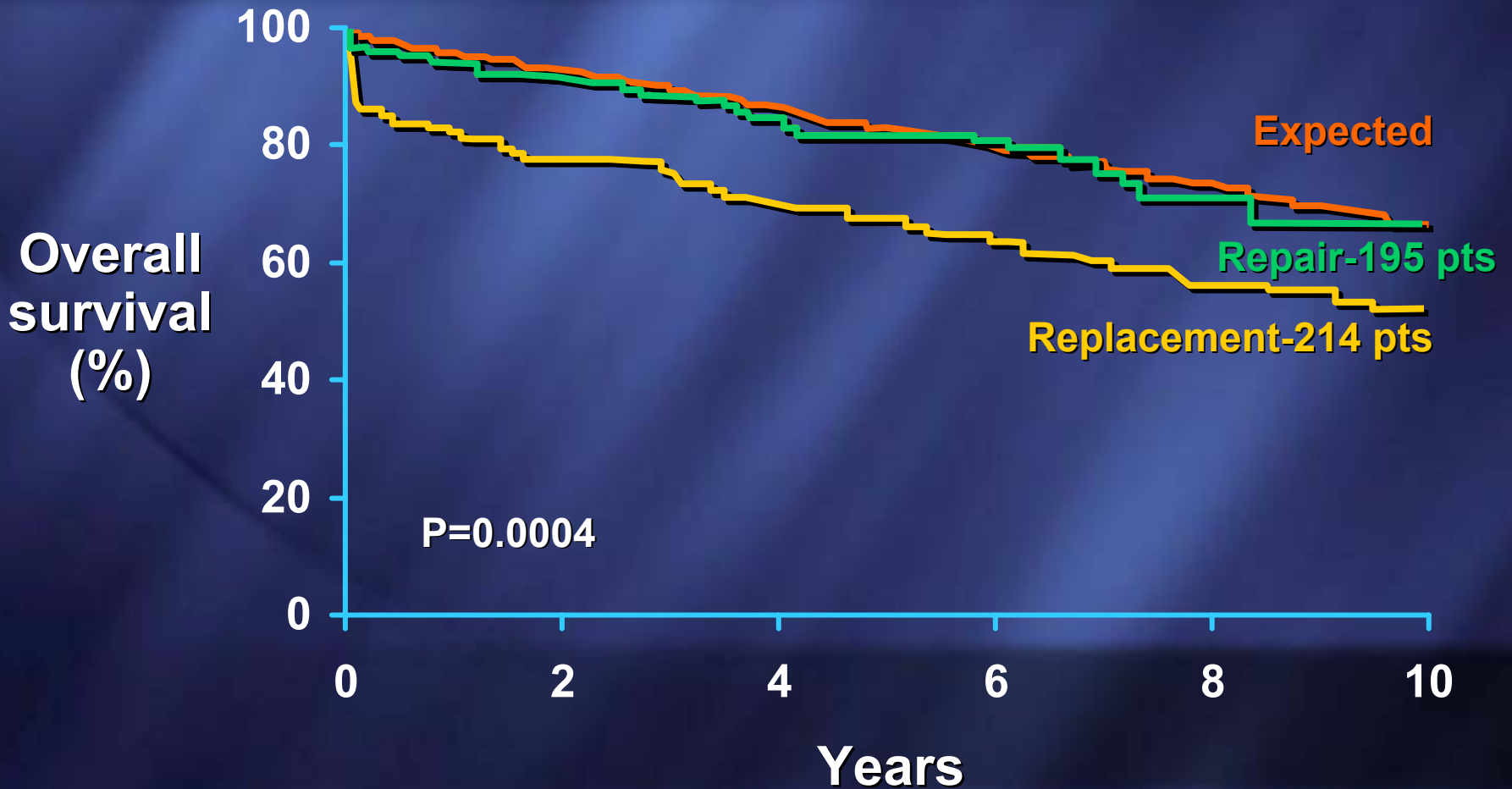
Mitral Regurgitation

Grading of Severity

ASE grade		RVol (mL)	ERO (mm²)
Mild	Grade I	<30	<20
Moderate	Grade II	30-44	20-29
	Grade III	45-59	30-39
Severe	Grade IV	≥60	≥40

Mitral Regurgitation

Mitral Valve Repair vs Replacement



Carpentier's classification

Type I

- Normal valve movement

examples

- annular dilatation
- leaflet perforation

Class II

- Excessive movement

- prolapse

Class IIIa

- Diastolic restric

- rheumatic

Class IIIb

- Systolic restric

- functional

ACC/AHA Guidelines

**Heart Failure
STEMI
Unstable angina**

Expert opinion

Data
5,000-40,000
pts
RCTs

**Valvular
Heart Disease**

Expert opinion

Data
50-600 pts
Observational Studies

ACC/AHA 2006 Guidelines for Valvular Heart Disease Indications for AVR

Class I

- Symptomatic pt with severe AS **B**
- Pt with severe AS undergoing CABG or surgery on aorta or other valves **C**
- Severe AS and EF < 50% **C**

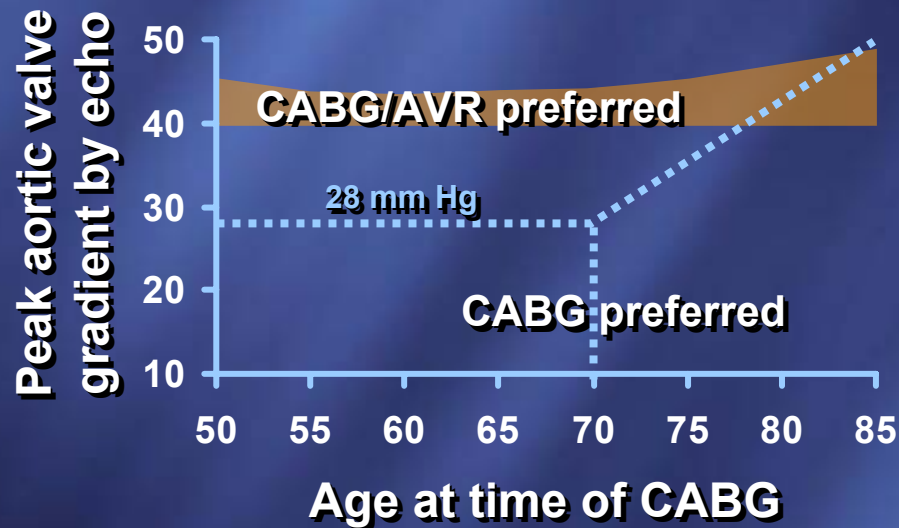
ACC/AHA 2006 Guidelines for Valvular Heart Disease Indications for AVR

Class IIa

- Pt with moderate AS undergoing CABG or surgery on aorta or other valves **B**

Should CABG Surgery Patients with Mild or Moderate AS Undergo Concomitant AVR?

- Markov decision analysis: Long-term, quality-adjusted outcomes of pt with AS – CABG or CABG/AVR



- Outcome influenced by AS rate of progression:
<3 mm Hg/yr – CABG if gradient <50; >10 mm Hg/yr, CABG/AVR except if >80 yr and gradient <25

Smith: JACC, 2004

ACC/AHA 2006 Guidelines

Indications for AVR

Class IIb

- **Extremely severe AS, mean grad > 60, operative mortality \leq 1%** C
- **Mild AS undergoing CABG with evidence for rapid progression** C
- **Severe AS and likelihood of rapid progression or if surgery would be delayed at symptom onset** C
- **Severe AS and abnormal response to exercise** C

MR: Indications for Mitral Valve Operation

Class I

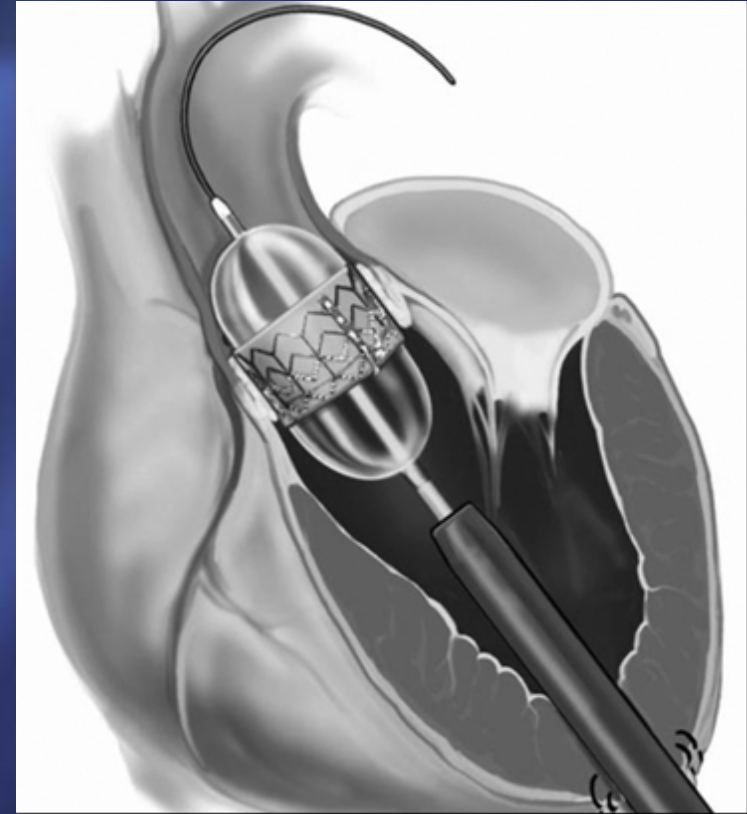
- Symptomatic patients with acute severe MR **B**
- Patients with chronic severe MR and NYHA class II, III or IV symptoms in absence of severe LV dysfunction (EF <30%) and/or end-sys dimension >55 mm **B**
- Asymptomatic patients with chronic severe MR and mild to mod LV dysfunction, EF 30-60% and/or end-sys dimension ≥ 40 mm **B**
- MV repair recommended over replacement in majority of patients with severe chronic MR who require surgery **C**

MR: Indications for Mitral Valve Operation

Class IIa

- MV repair in experienced surgical center for asymptomatic pts with chronic severe MR, preserved LV function if repair likely **B**
- MV surgery for asx pts with chronic severe MR, preserved LV function and new atrial fib **C**
- Asymptomatic patients with chronic severe MR, preserved LV function and pulmonary hypertension **C**
- MV surgery for patients with chronic severe MR due to abnormality of mitral apparatus, class II-IV sx and severe LV dysfunction if repair likely **C**

Transapical Minimally-Invasive Aortic Valve Implantation

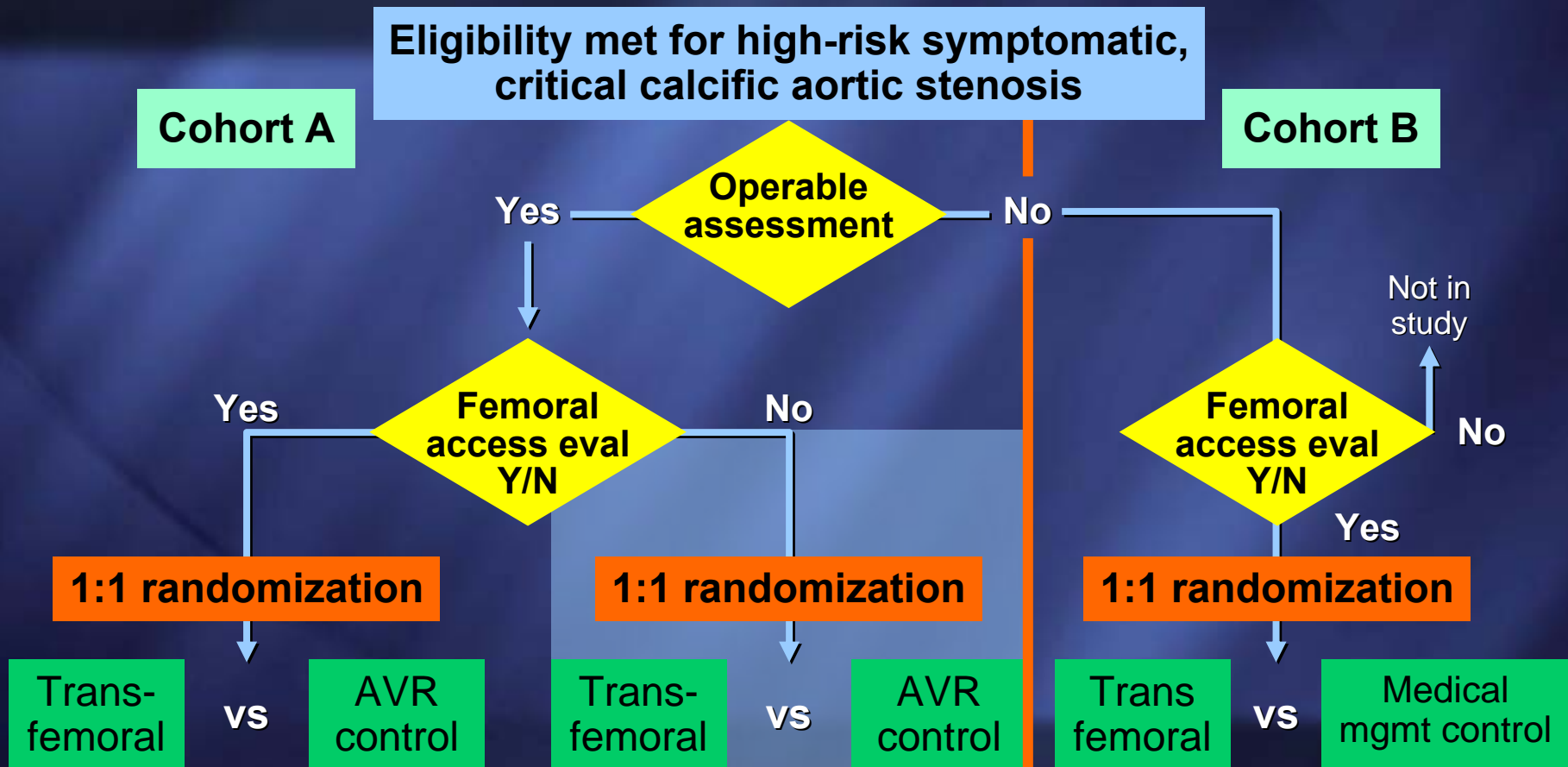


- 59 patients, 81 ± 6 years
- EuroSCORE ≥ 9
- Predicted mortality 26.8%
- Follow-up 110 ± 77 days, mortality 22%

Walther: Circulation, 2007

PARTNER Trial

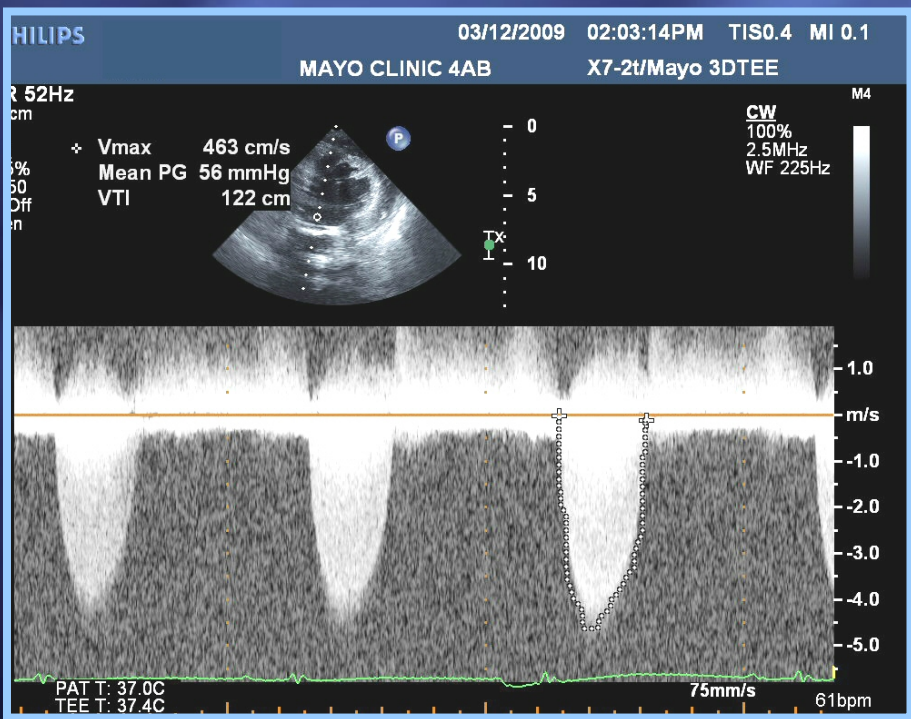
PARTNER Trial Proposal (with Transapical)



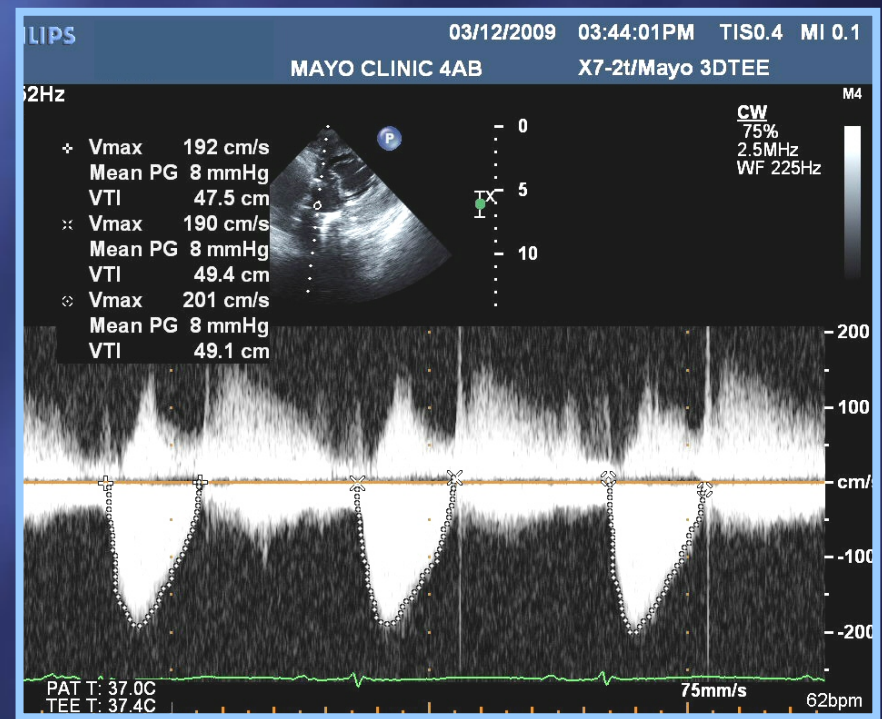
Subgroup analyses: TA vs control, TF vs control
Primary analyses: TF and TA vs control (combined)

TEE

Pre



Post



56 mm Hg to 8 mm Hg

Baseline Demographics and Risk Factors

	TF (n=463)	TA (n=575)	P
Age (yr)	81.7	80.7	NS
Female	55%	56%	NS
Pulmonary disease	25%	29%	NS
Renal dysfunction	26%	33%	0.024
Logistic EuroSCORE	25.7	29.2	<0.005
Peripheral vascular disease	11%	28%	<0.001
Carotid artery stenosis (>50%)	8%	17%	<0.001
Incidence of CAD	47%	56%	<0.006
Porcelain aorta	5%	12%	<0.001
Prior CABG	18%	27%	<0.001
Mitral valve disease	16%	33%	<0.001

Implantation Success

	TF (n=463)		TA (n=575)		Total (n=1,038)	
	No.	%	No.	%	No.	%
Acute procedure success	436	95.6	523	92.9	959	94.1
Device success comp*	428	92.4	522	90.8	950	91.5
Conversion to sAVR	8	1.7	20	3.5	28	2.7
AR >+2**	15	3.2	34	5.9	49	4.7
Valve migration	0	0.0	3	0.5	3	0.3
Valve malposition	8	1.7	8	1.4	16	1.5
Coronary obstruction	3	0.7	3	0.5	6	0.6

* Device success is a composite including AR <2+ and no valve in valve

** Site-reported

All procedural
X1 to aorta
X2 to ventricle

Major Complications (≤ 30 Days)

	TF n=463		TA n=575		Total n=1,038	
	No.	%	No.	%	No.	%
Death	29	6.3	59	10.3	88	8.5
Stroke	11	2.4	16	2.6	27	2.5
Renal failure requiring dialysis	23	5.0	69	11.7	92	8.7
Permanent pacemaker	31	6.7	42	7.3	73	7.0

Causes of Death ≤ 30 Days – Transfemoral

30-day mortality – transfemoral (29/463) = 6.3%

Related to implant* (9/463)

Heart failure	4
Bleeding event major	2
Cardiac tamponade	1
Annular dissection	1
Multiple organ failure	1

Related to procedure** (20/463)

Multiple organ failure	4
Sudden death (3 unk)	4
Sepsis	3
Heart failure	2
Gastrointestinal	1
Cardiac arrest	1
Bleeding event major	1
Circulatory disorder	1
Hematologic disorder	1
Cardiogenic shock	1
Renal failure	1

* Related to implant: direct result of valve implant

** Related to procedure: result of procedure

Causes of Death ≤30 Days – Transapical

30-day mortality – transapical (59/575) = 10.3%

Related to implant* (16/575)

Heart failure	9
Hemorrhage	3
Multiple organ failure	1
Bleeding event major	1
Aortic dissection	1
Cardiac arrest	1

Related to procedure** (43/575)

Multiple organ failure	14
Gastrointestinal	5
Cardiac arrest	4
Heart failure	4
Sepsis	4
Respiratory failure	2
Bleeding event major	1
Sudden death	1
Circulatory disorder	1
Hematologic disorder	1
Cardiac decompensation	1
Pneumonia	1
Pulmonary embolism	1
Myocardial infarction	1
Stroke	1
Renal failure	1

* Related to implant: direct result of valve implant

** Related to procedure: result of procedure

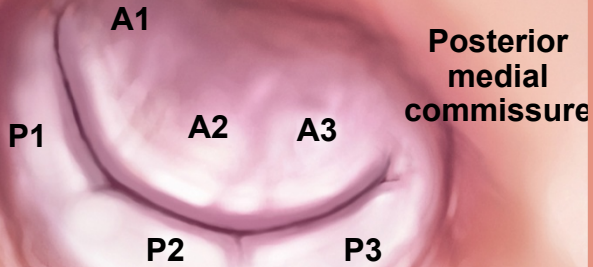
Steadily Improving Outcomes



Aortic mitral fibrosa

**Anterior
lateral
commissure**

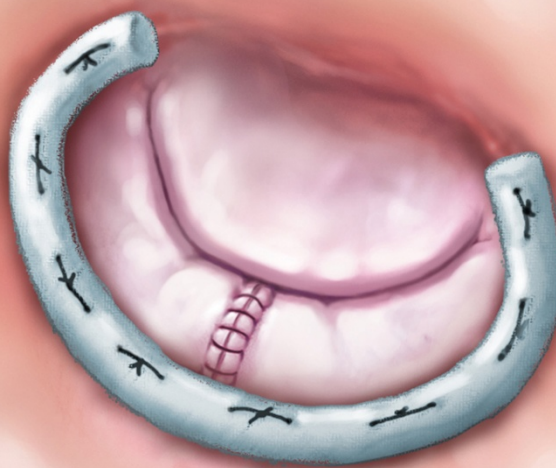
**Anterior
leaflet**



Normal

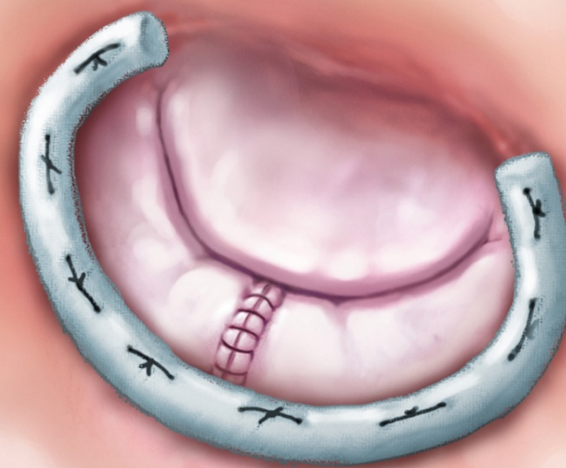
Posterior leaflet

Flail posterior leaflet



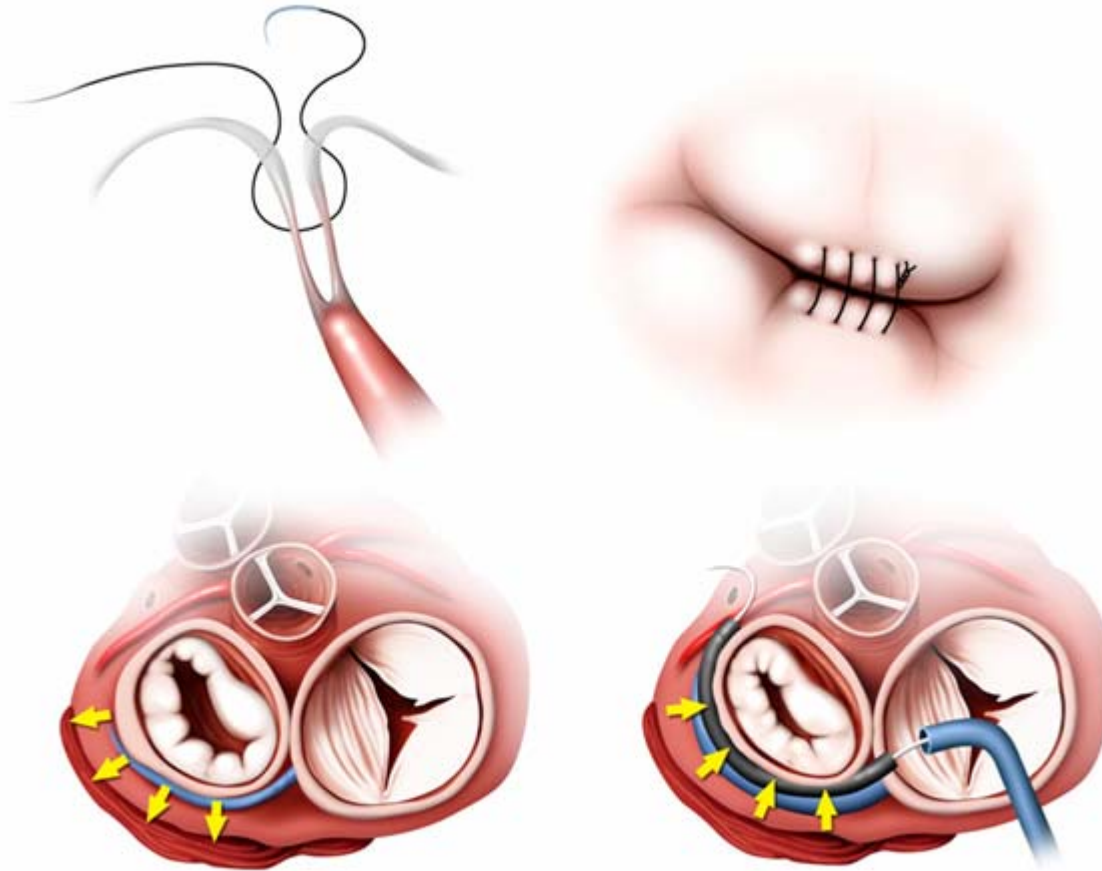
Resection of flail segment

Repaired mitral valve



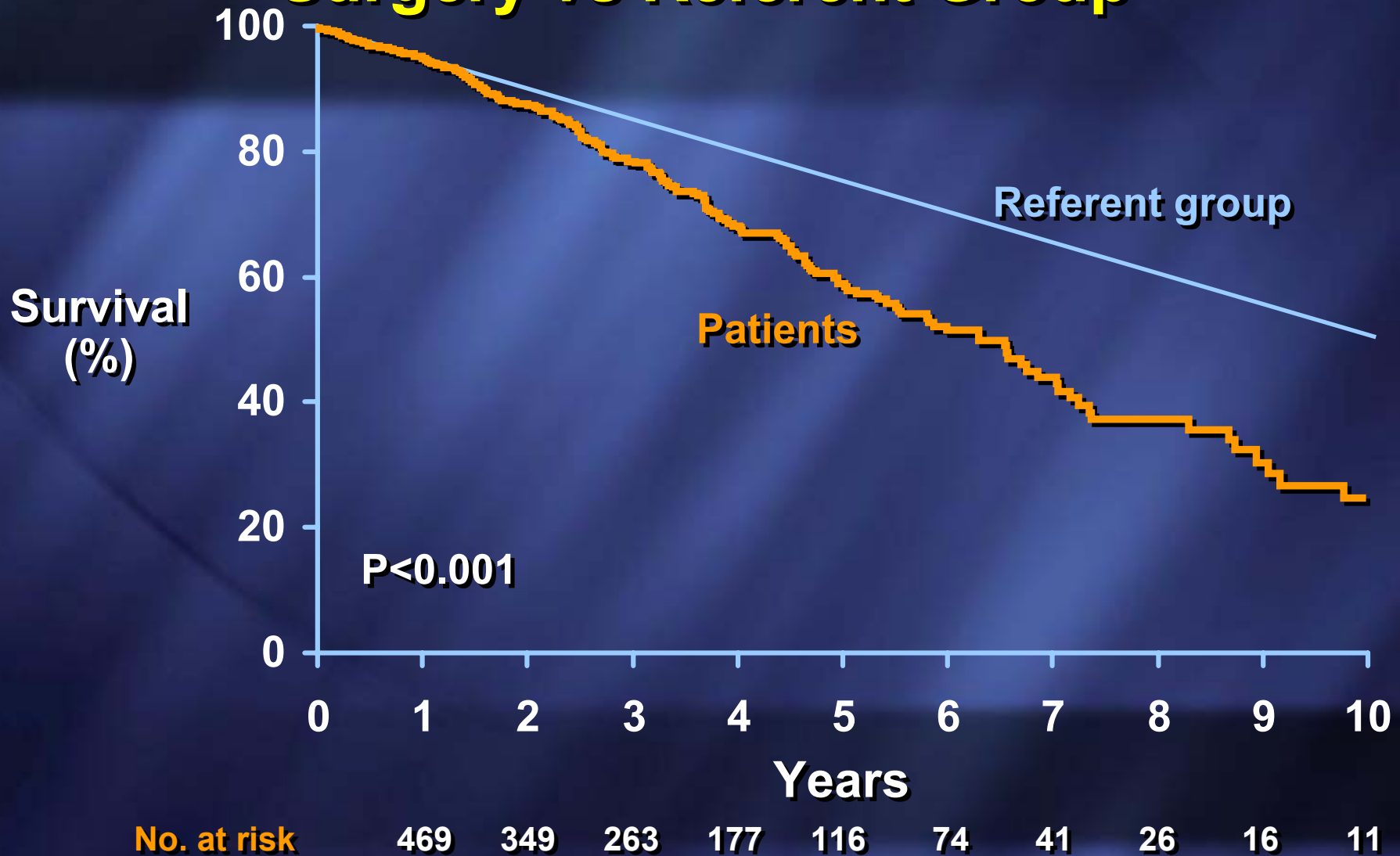
Percutaneous MV Repair

Alfieri Procedure



Mitral Annuloplasty

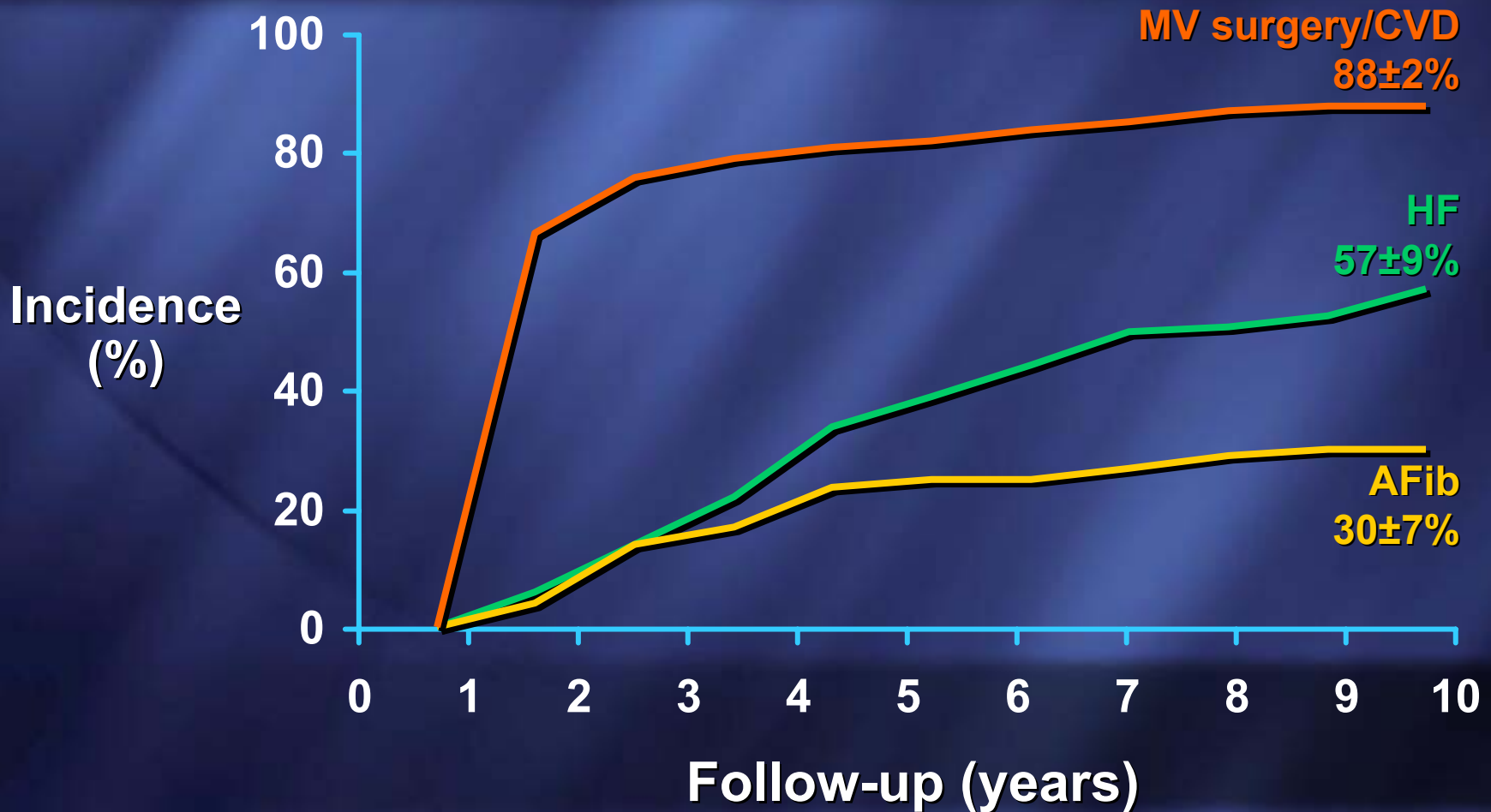
Survival of Patients Censored at Surgery vs Referent Group



Mitral Regurgitation Due to Flail Leaflet

Multicenter European Experience

304 pts with nonsurgical management



Summary

- **Follow-up is needed to understand safety and durability of percutaneous devices**
- **Prospective, randomized clinical trials needed**

Summary

- **Less-invasive alternatives to conventional valve surgery will result in earlier intervention and intervention in a larger number of patients**