Mitral Regurgitation

Focus on Percutaneous Repair

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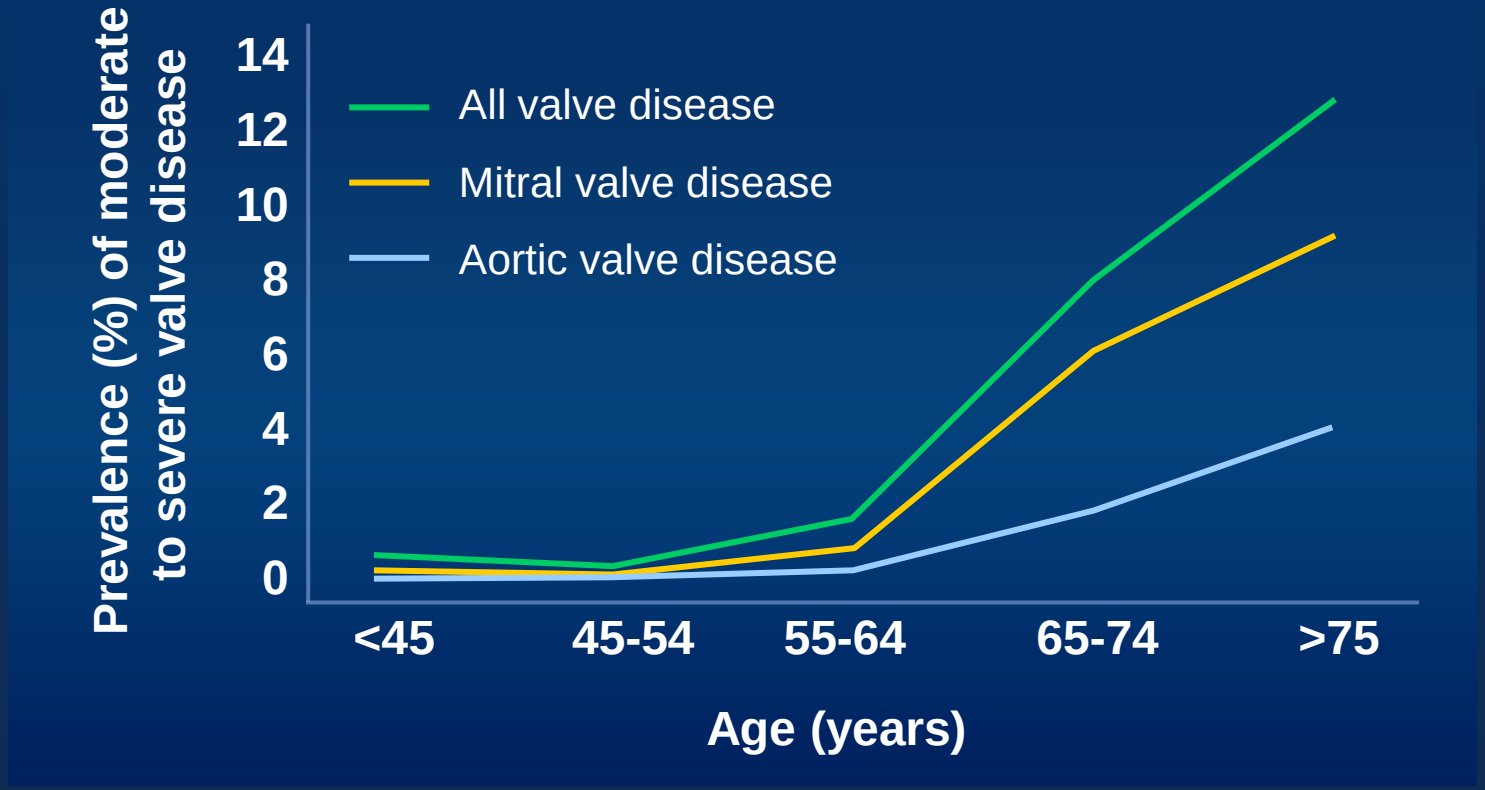
Disclosures

Medical Advisory Boards:

- **Medtronic**
- **Abbott Vascular**
- **Boston Scientific**

Structural Heart Disease

Increases with Age



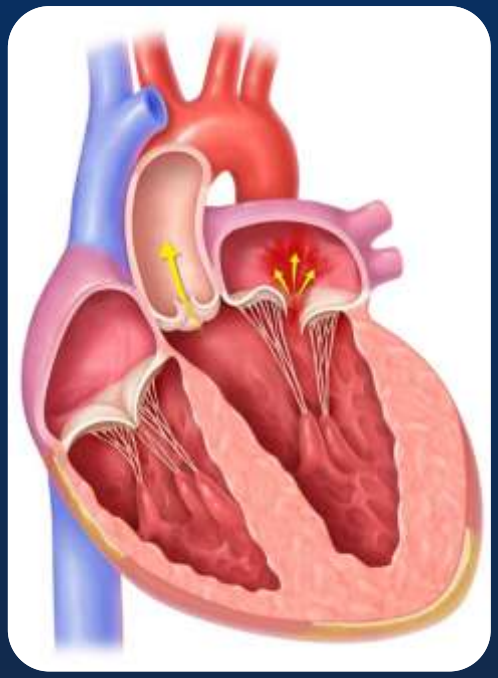
> 9.3% for ≥75 year olds (p<.0001)

Nkomo et al. Burden of Valvular Heart Diseases: A Population-based Study, Lancet, 2006; 368: 1005-11.

Classification of MR – 2 Types

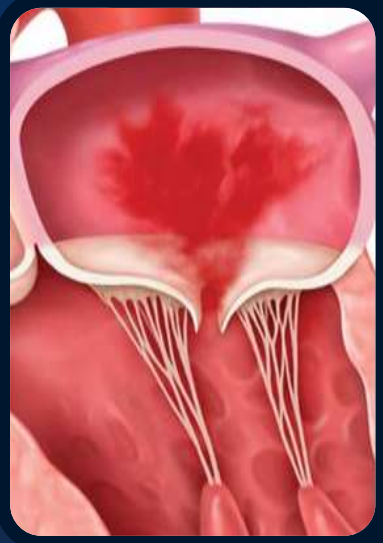
Incompetent mitral valve closure

Systolic retrograde blood flow from the LV into the LA



Primary:
Anatomic abnormality the mitral valve

- **Leaflets**
- **Subvalvular apparatus**
- **Chordae and papillary muscles**



Secondary :
LV dilation; often secondary to ischemic heart disease

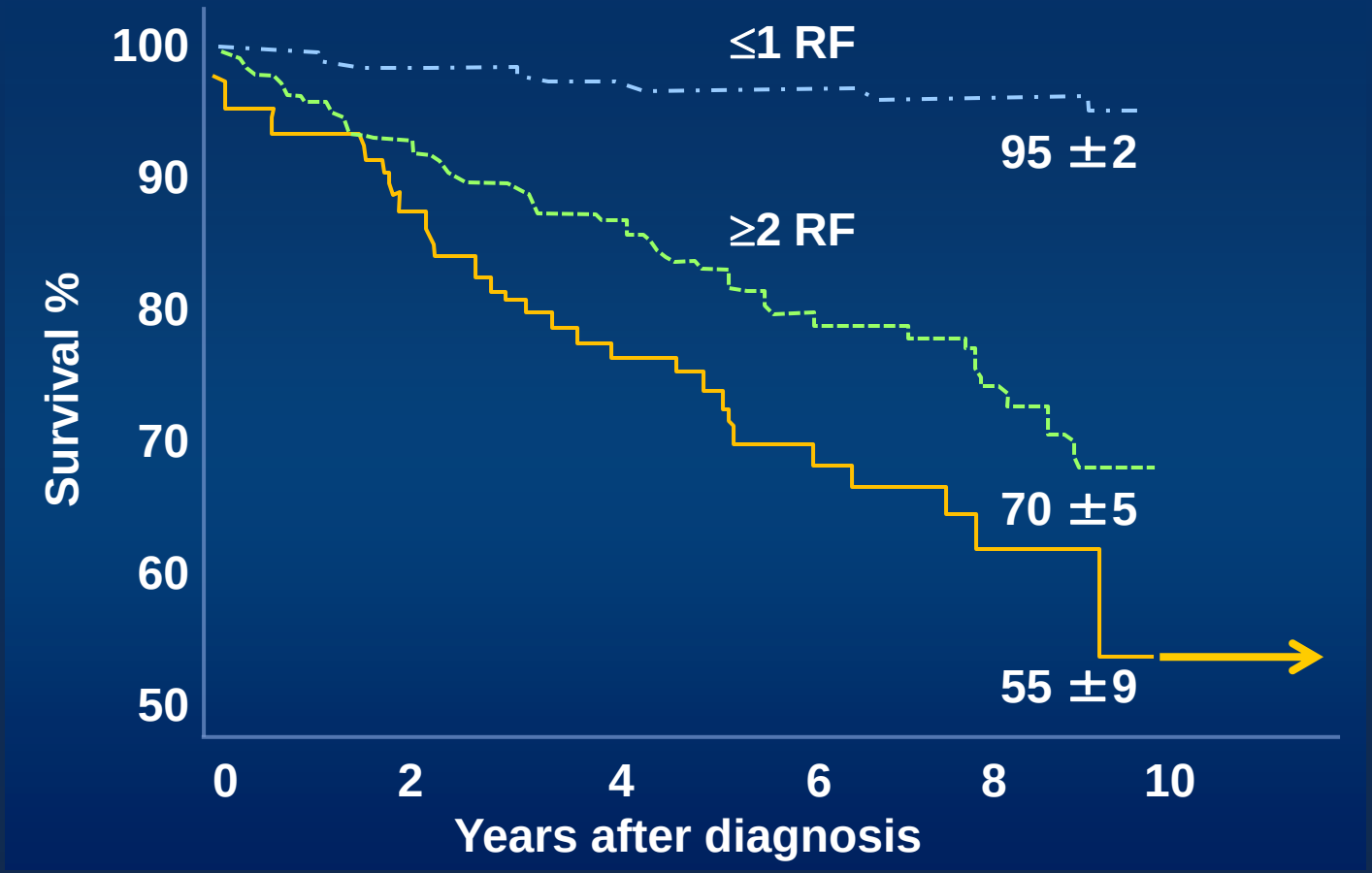
- **Leads to mitral annular dilation**
- **Incomplete coaptation of the mitral valve**

Prognostic Determinants

- Severity
- Left Ventricular Function
- Symptoms

Asymptomatic DMR

Natural History

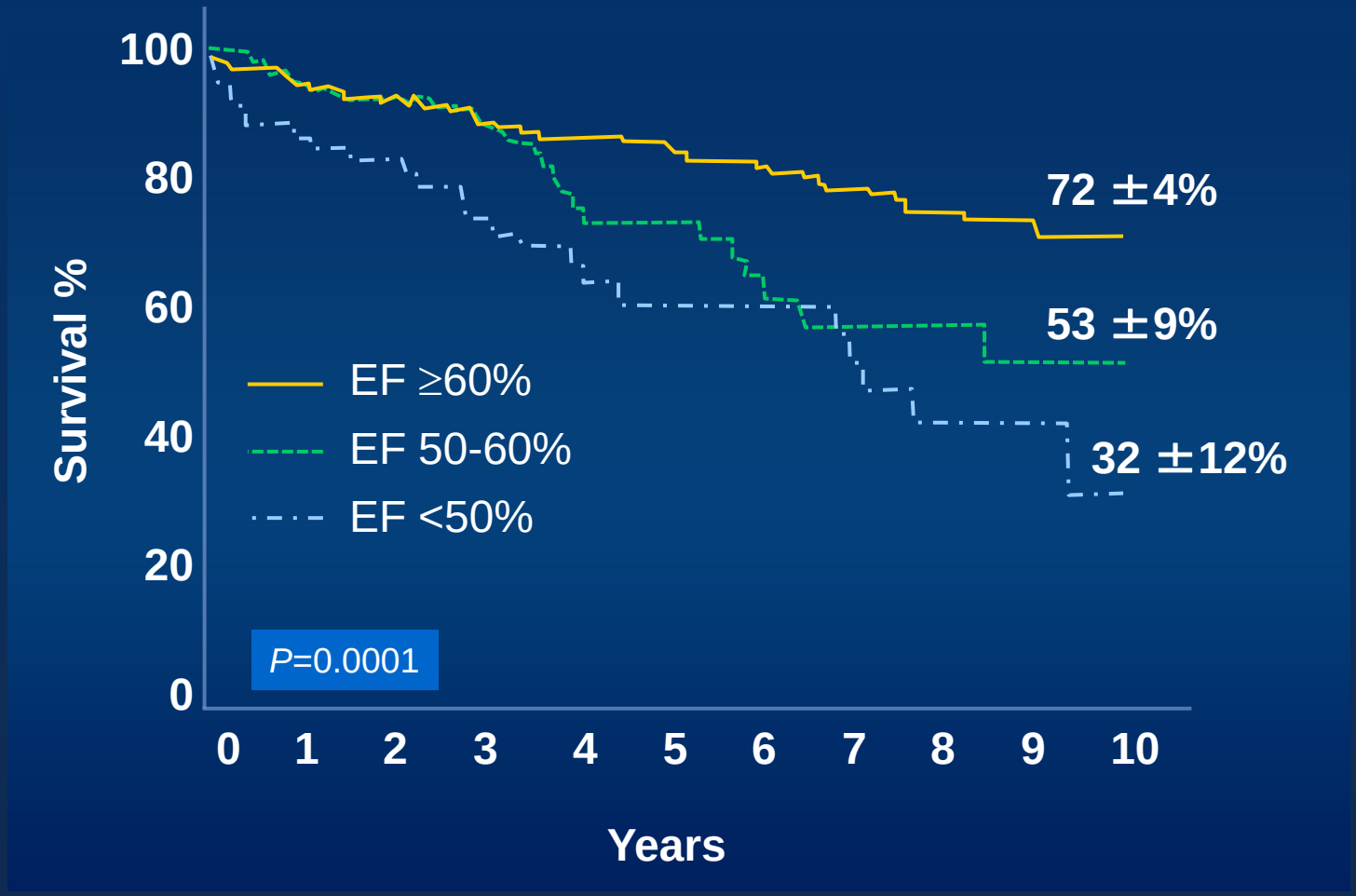


MR ≥3
or
EF <50%

Risk Factors
Age ≥50 yrs
Atrial fibrillation
LA enlargement
Flail
Mild MR

Avierinos JF, et al. Circulation 2002;106:1355

EF and Surgical Outcome

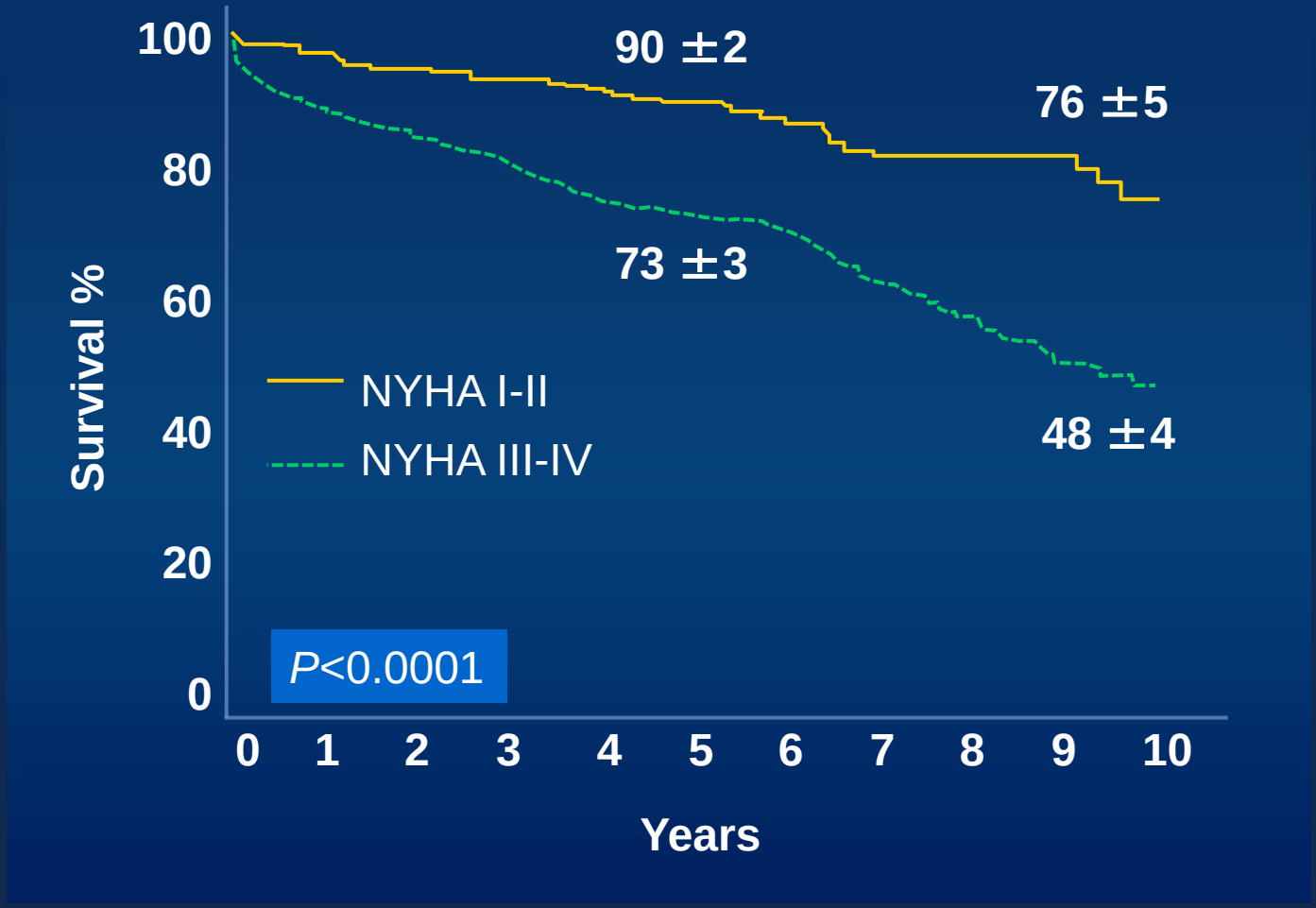


EF <60% is Abnormal in MR

Enriquez-Sarano M, et al., Circulation 1994;90:830-837

Symptoms and Surgery

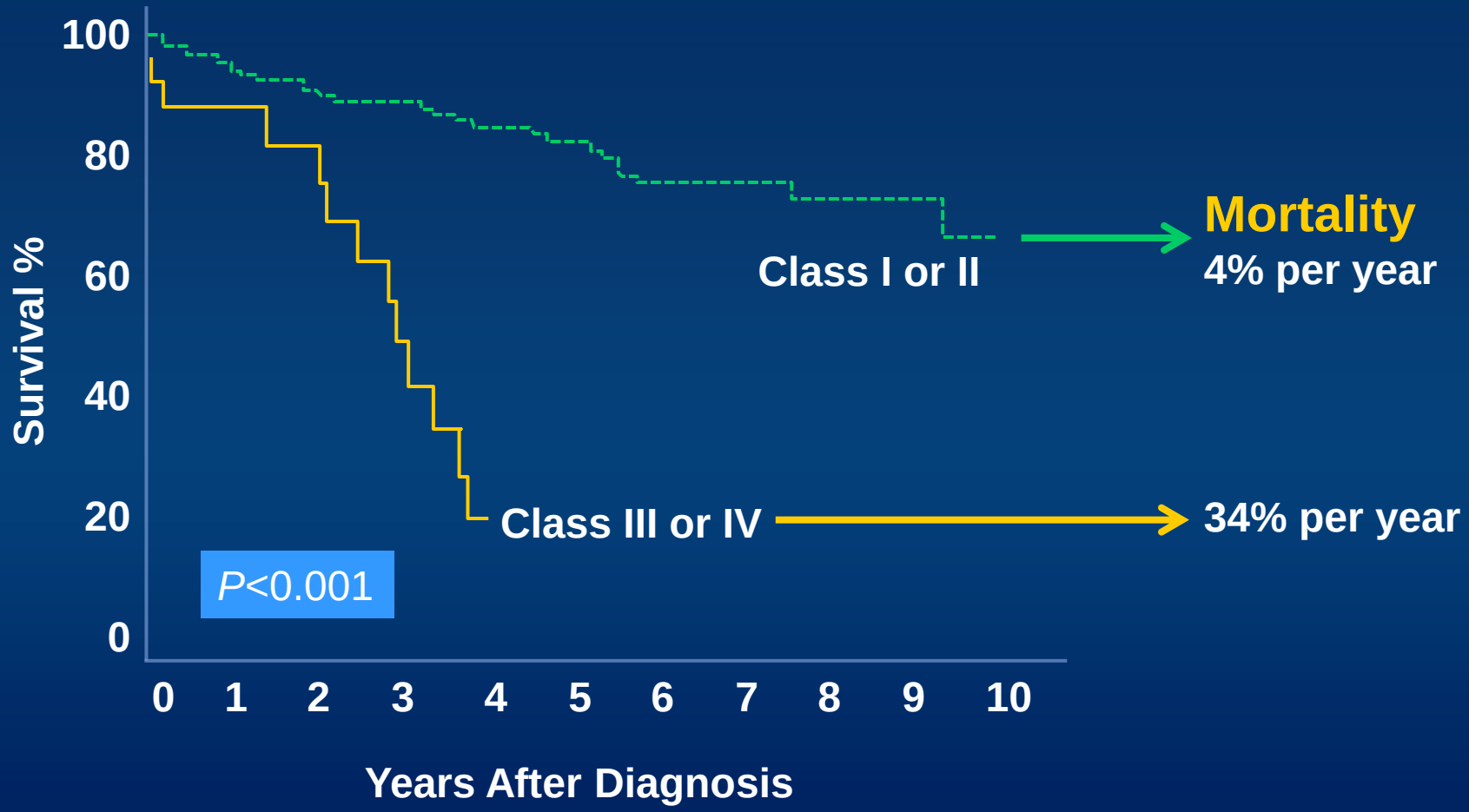
Outcome with Primary MR



Tribouilly CM et al., Circulation 1999;99:400-5

Flail Mitral Leaflet

Natural History

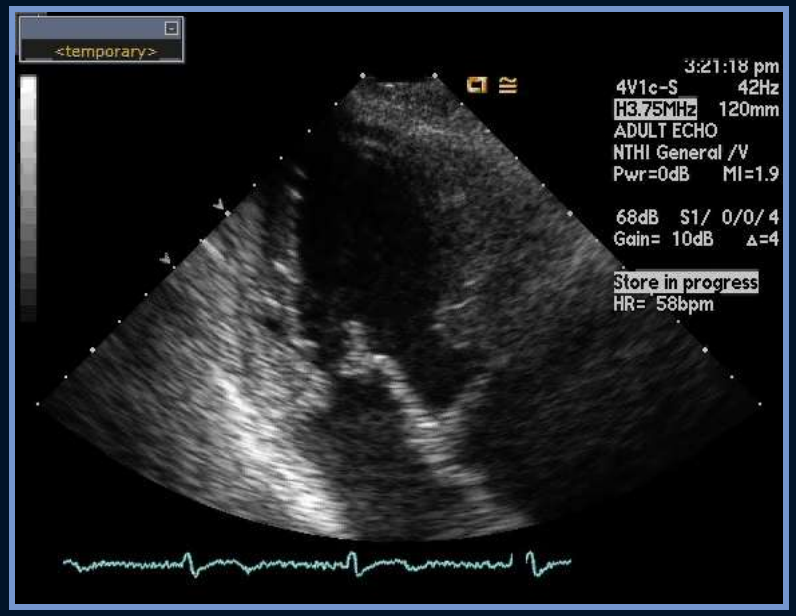


Ling L, et al. N Engl J Med 1996; 335:1417-1423

Classification of MR

Primary

“The Valve”



Usually myxomatous

Secondary

“The Ventricle”

Ischemic or not

Secondary Mitral Regurgitation

A Ventricular Problem

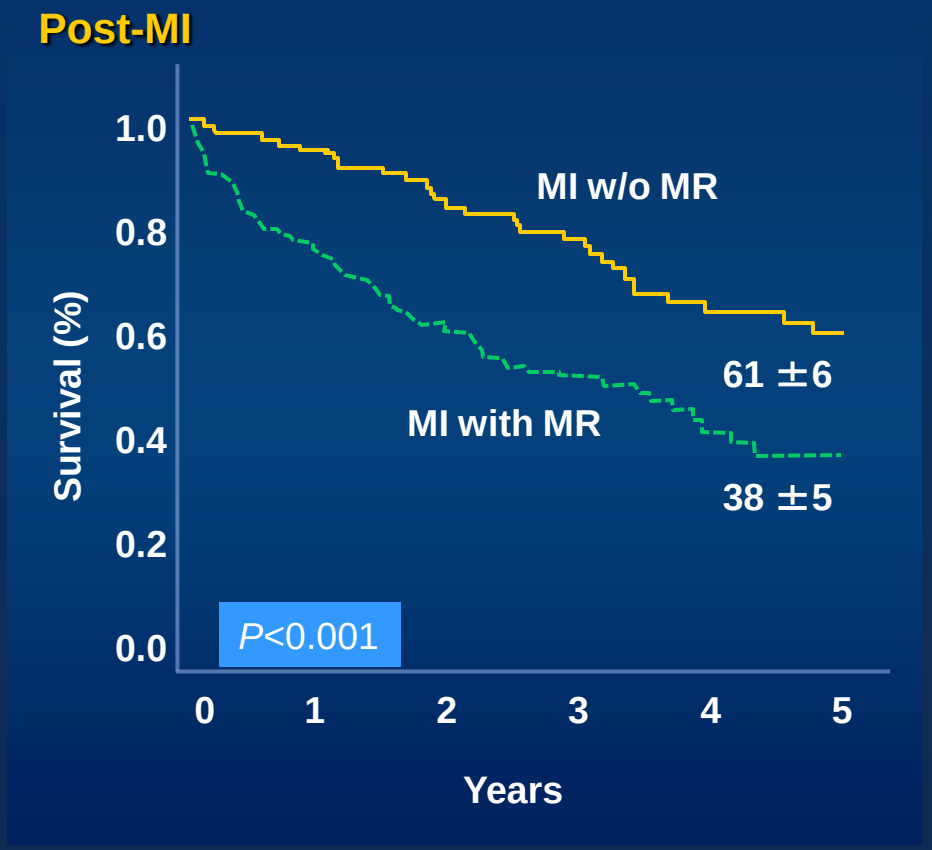
Regional or Global Dysfunction

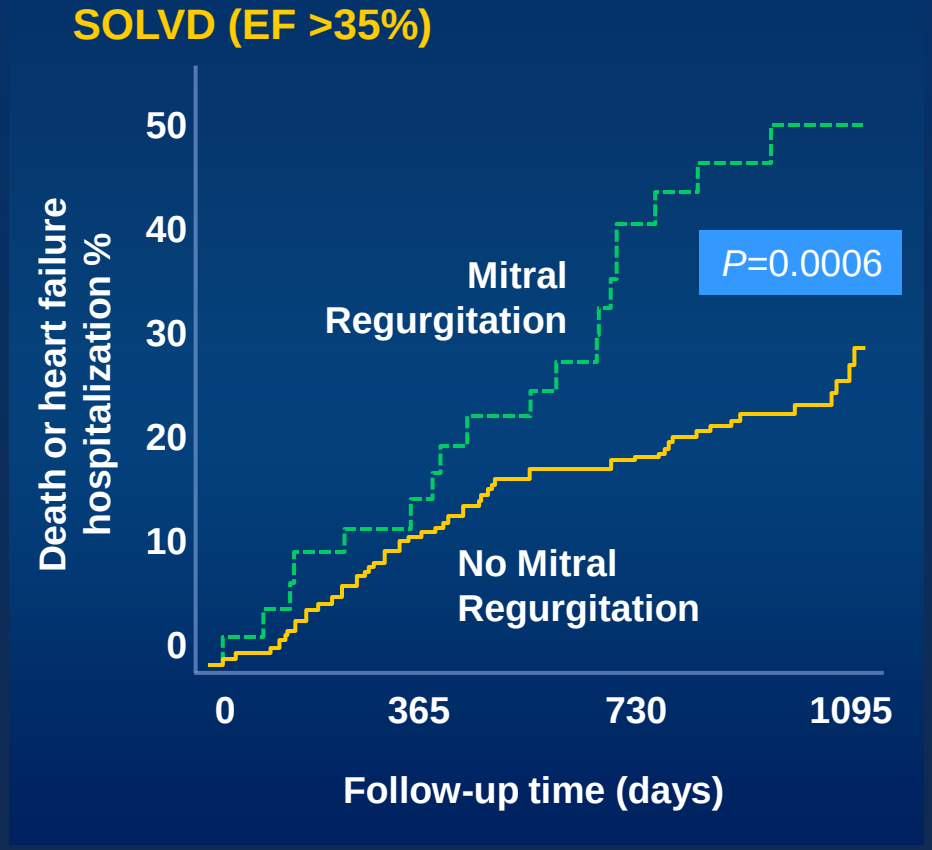
- **Papillary muscle displacement**
- **Annular flattening**
- **Leaflet tethering**

Trichon BH, et al. Am J Cardiol 2003;91:538-43

Secondary Mitral Regurgitation

A Harbinger of Poor Outcome





Two-fold Increase Risk of Death

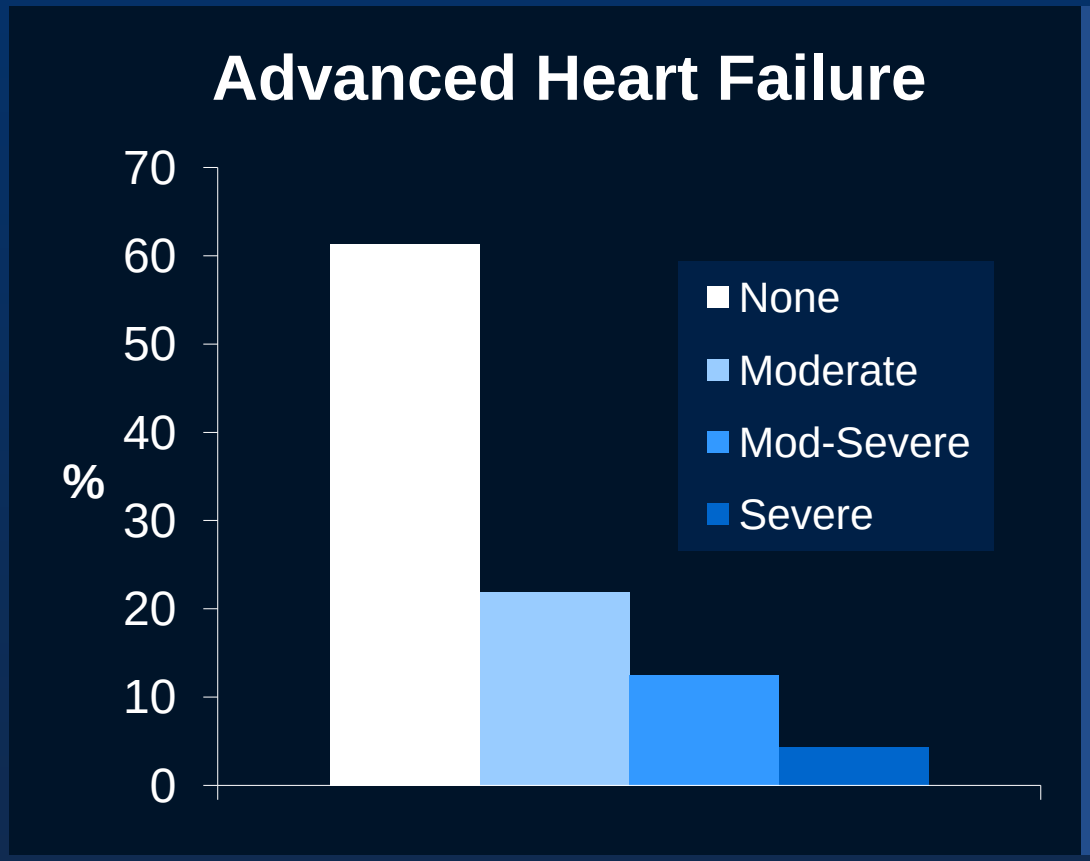
Grigioni F, et al. Circulation 2001;103:1759-64;
Basket JF, et al. Can J Cardiol 2007;23:797-800

MITRAL REGURGITATION

Untreated severe MR is associated with increased morbidity and mortality

MR and Heart Failure

Prevalence in CHF



Moderate or severe MR present in ~40%

~5 million people with heart failure in U.S.

Patel JB, et al. J Card Fail 2004;10:285-291; Go AS, et al. Circulation 2013;127:e6.

General Principles of Therapy

Degenerative

No medical option for valve

Surgery for symptoms or LV dysfunction

Asymptomatic if repairable and low risk

Functional

Medical therapy first

Consider CRT

Surgery only in highly selected patients with HF

Timing of Surgical Intervention

ACC/AHA Guidelines – Primary MR

Consider surgery *when*

Symptoms

or

LV dysfunction (EF<60%, ESD≥40 mm)

Try to repair

Nishimura R, et al., J Am Coll Cardiol 2014;63:2438-88

Timing of Surgical Intervention

ACC/AHA Guidelines – Primary MR

Prophylactic Repair

Can be done *if*

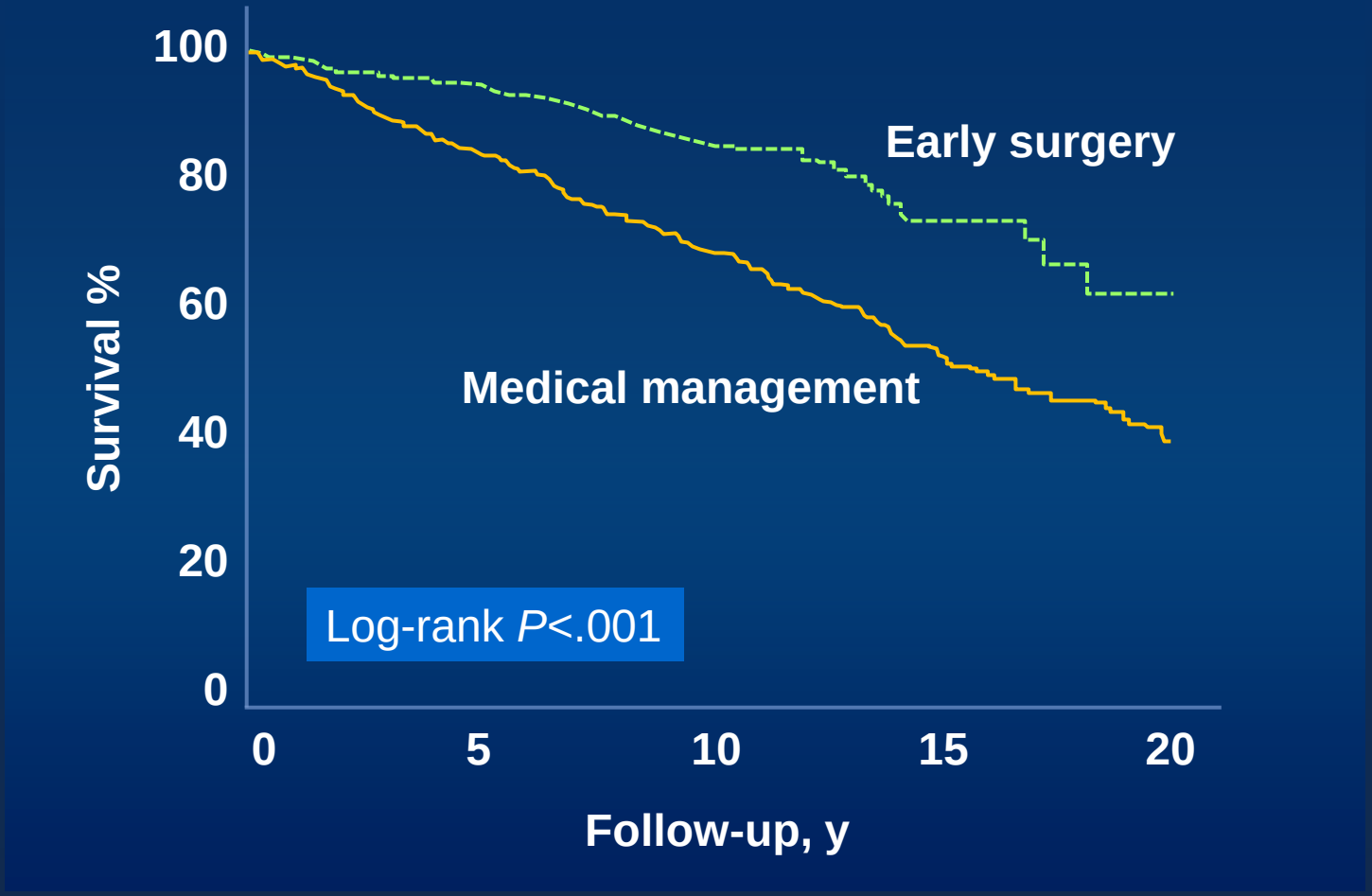
likelihood of success >95%

and

mortality rate <1%

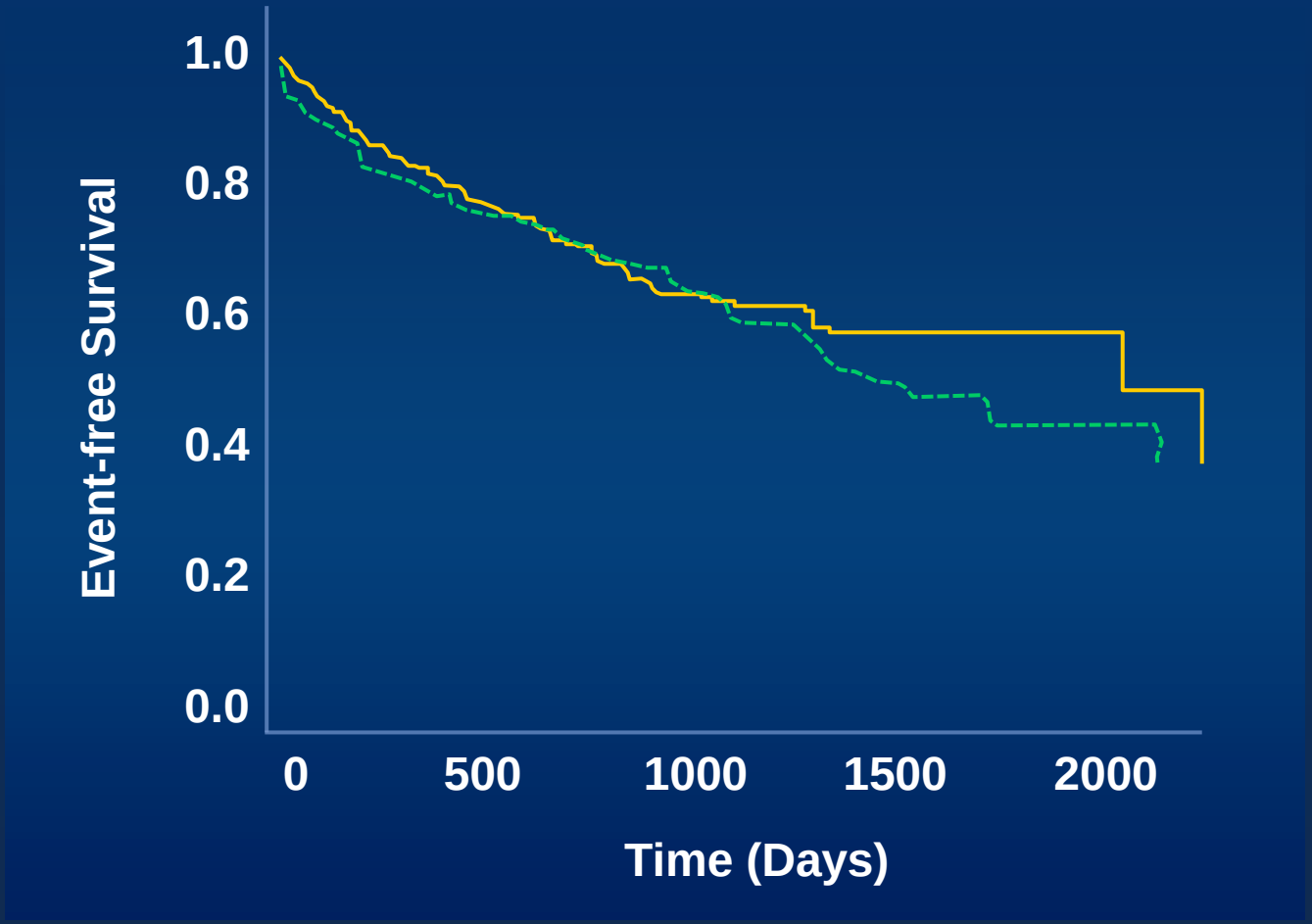
Early Surgery Is Better

Patients without Class I Indications



Suri R et al., JAMA 2013;310:609-16

Surgery for Functional MR

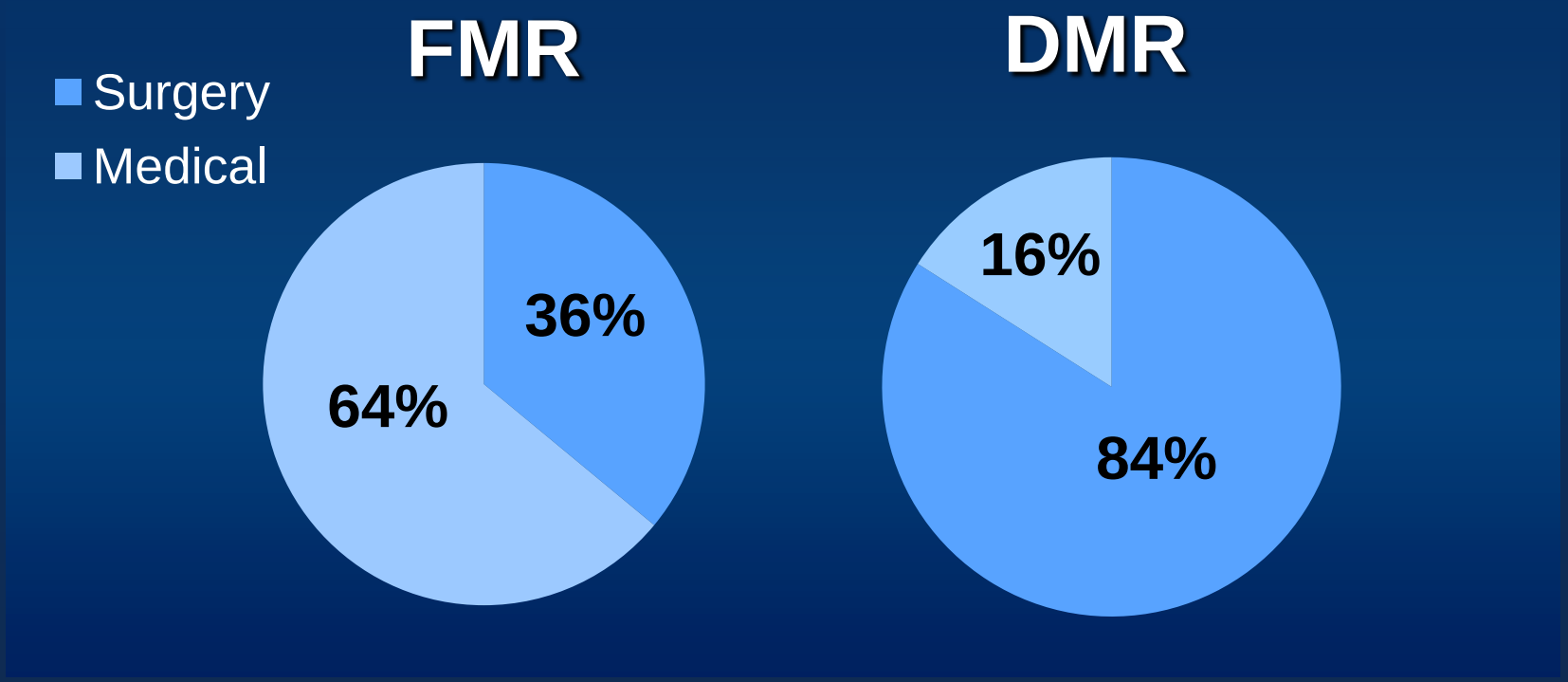


No Mortality Benefit

Wu AH, et al. J Am Coll Cardiol 2005;45:381-87

Medical Management

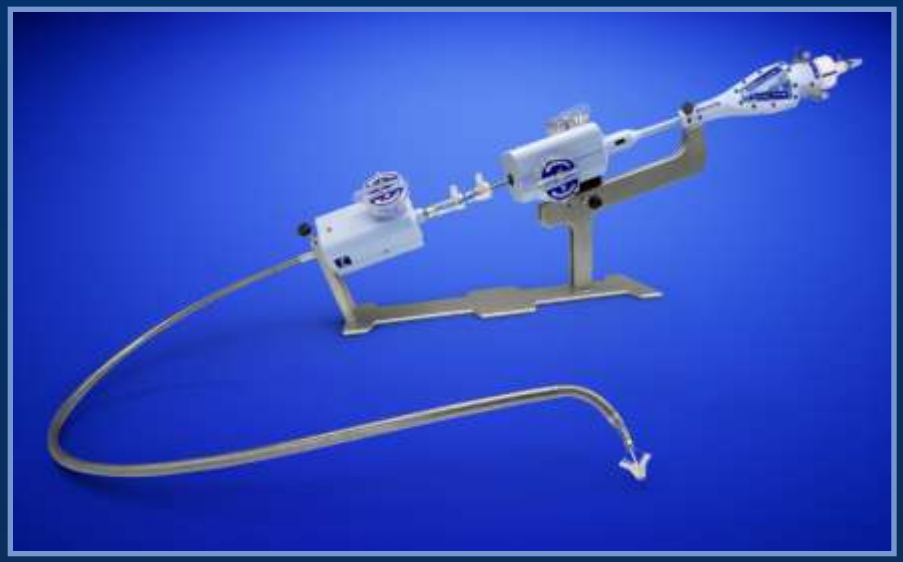
1,095 pts with severe MR and CHF



5-yr mortality for medically managed = 50%

Goel SS, et al. J Am Coll Cardiol 2014;63:185-90

MitraClip® System



Important Safety Information
referenced within

MitraClip® Indications

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus **[degenerative MR]** in patients who have been determined to be at **prohibitive risk for mitral valve surgery by a heart team,** which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

Important Safety Information referenced within

Transcatheter Mitral Repair

ACC/AHA Guidelines –Degenerative MR

May be considered for prohibitive risk patients with primary MR and severe symptoms despite GDMT (class IIb)

Prohibitive Surgical Risk DMR Cohort (n=127)

Age: 82 ±9 years

Prior MI: 24%

Prior stroke: 10%

Diabetes: 30%

COPD: 32%

Renal disease: 28%

Mean STS Risk

13.2%

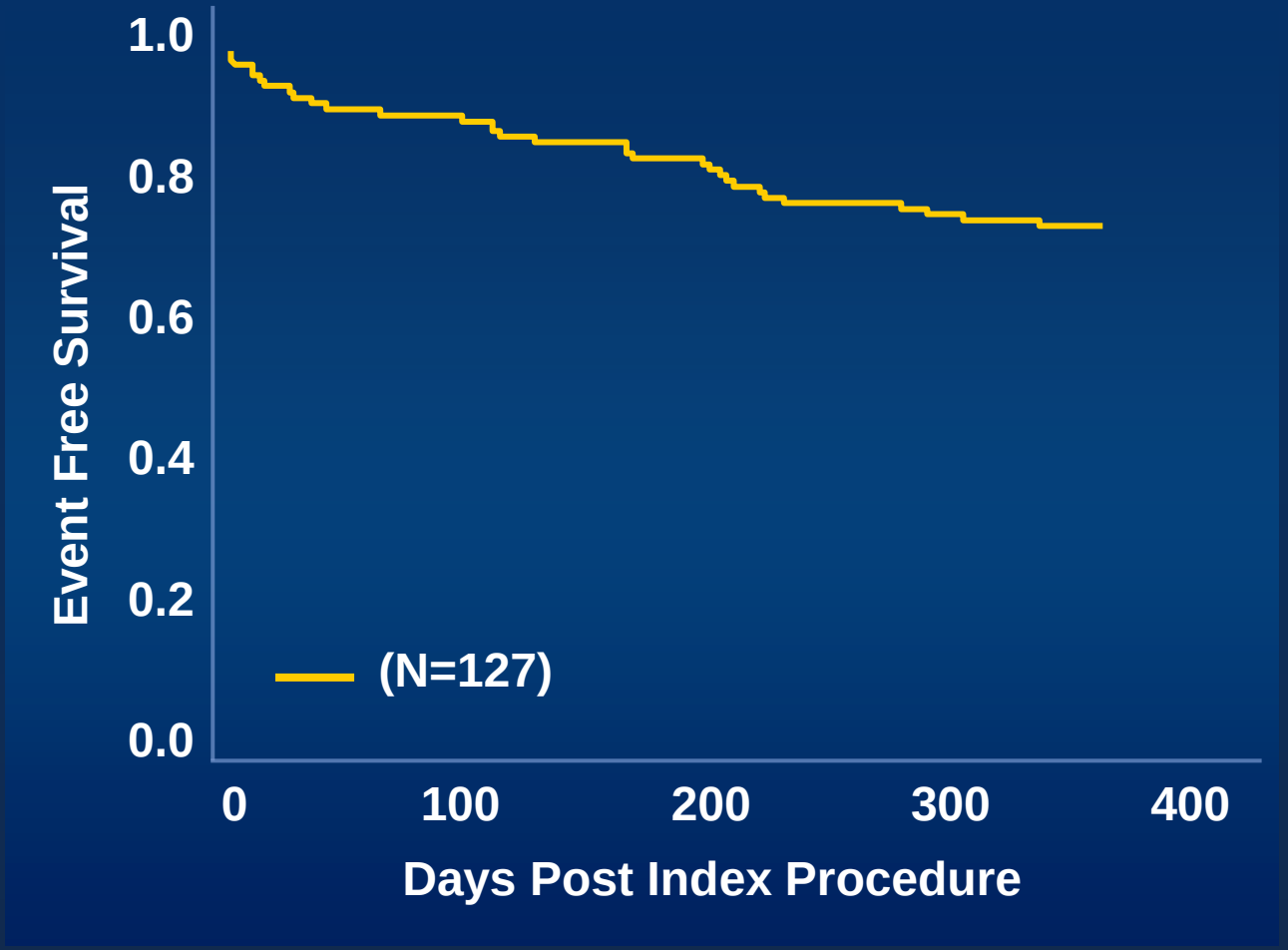
Lim et al. Improved functional status and quality of life in prohibitive surgical risk patients with degenerative mitral regurgitation after transcatheter mitral valve repair, JACC 2014;64:182-192.

Prohibitive Surgical Risk DMR Cohort (n=127)

95% implant success

No procedural deaths

LOS = 2.9 days



Lim et al. Improved functional status and quality of life in prohibitive surgical risk patients with degenerative mitral regurgitation after transcatheter mitral valve repair, JACC 2014;64:182-192.

CLINICAL TRIALS

COAPT TRIAL: OVERVIEW

Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation

Clinical Investigational Plan 11-512; Version 6.0, September 8, 2014, Approved by FDA October 15, 2014
CAUTION: Investigational device. Limited by Federal (U.S.) law to investigational use only.

Purpose

- COAPT is a landmark trial to further study the MitraClip device in symptomatic FMR patients with heart failure
- The study will generate important clinical and economic data to support reimbursement and evidence to support the development of treatment guidelines
- COAPT is the first randomized controlled clinical trial to compare non-surgical (medical) standard of care treatment to a percutaneous intervention to reduce MR

Clinical Investigational Plan 11-512; Version 6.0, September 8, 2014, Approved by FDA October 15, 2014
CAUTION: Investigational device. Limited by Federal (U.S.) law to investigational use only.

Objective

To evaluate the safety and effectiveness of the MitraClip System for treatment of functional mitral regurgitation (FMR ≥3+) in symptomatic heart failure subjects who are treated per standard of care and who have been determined by the site's local heart team as not appropriate for mitral valve surgery

Clinical Investigational Plan 11-512; Version 6.0, September 8, 2014, Approved by FDA October 15, 2014

CAUTION: Investigational device. Limited by Federal (U.S.) law to investigational use only.

Trial Design

430 patients enrolled at up to 85 US sites

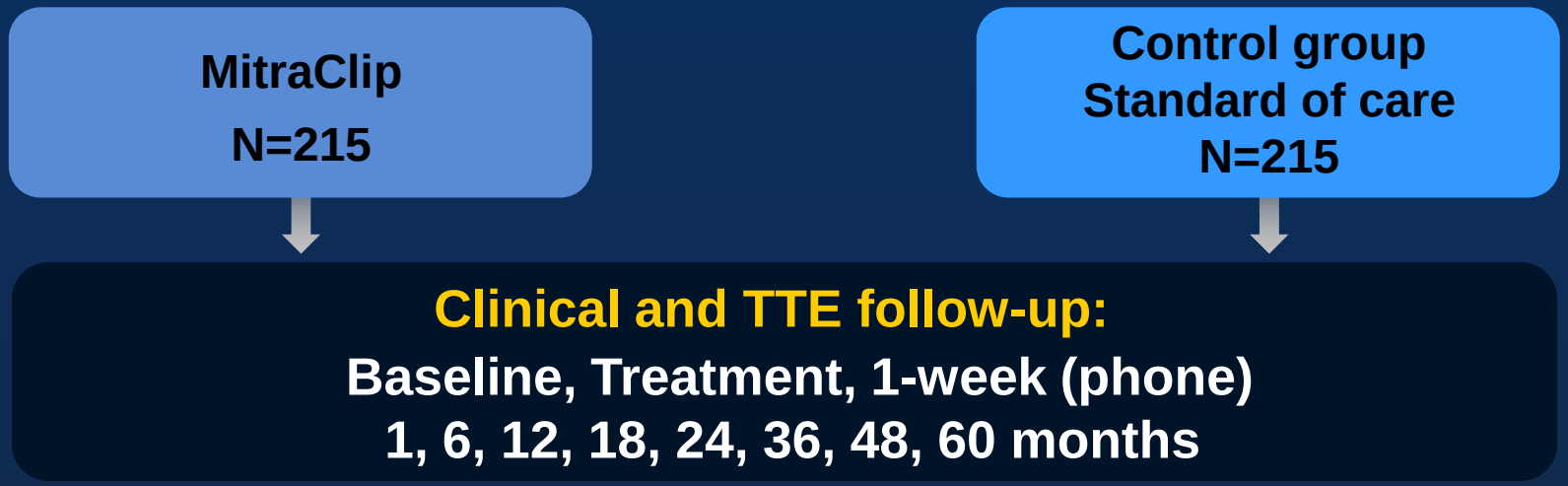
Significant FMR (≥3+ by core lab)

Symptomatic heart failure subjects who are treated per standard of care

Determined by the site's local heart team as not appropriate for mitral valve surgery

Specific valve anatomic criteria

Randomize 1:1



2013 ACCF/AHA Guideline for the Management of Heart Failure: Circulation 2013; 128:e240-327.

Clinical Investigational Plan 11-512; Version 6.0, September 8, 2014, Approved by FDA October 15, 2014

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