PERCUTANEOUS MITRAL VALVE THERAPIES

13TH ANNUAL CARDIAC, VASCULAR AND STROKE CARE CONFERENCE

PIEDMONT ATHENS REGIONAL

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DISCLOSURES

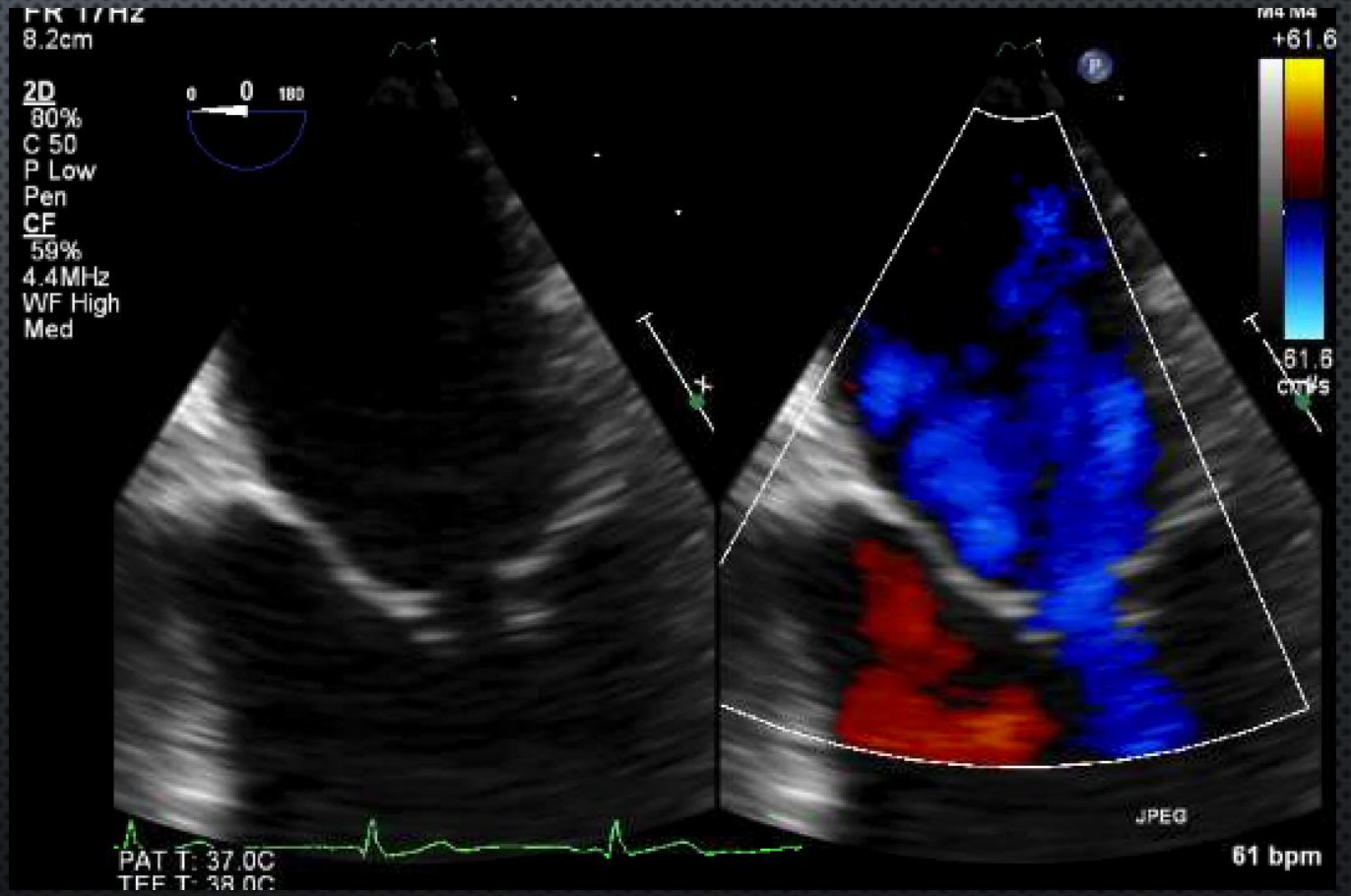
I WILL BE DISCUSSING OFF-LABEL USAGE OF DEVICES RELATED TO TMVR

Objectives

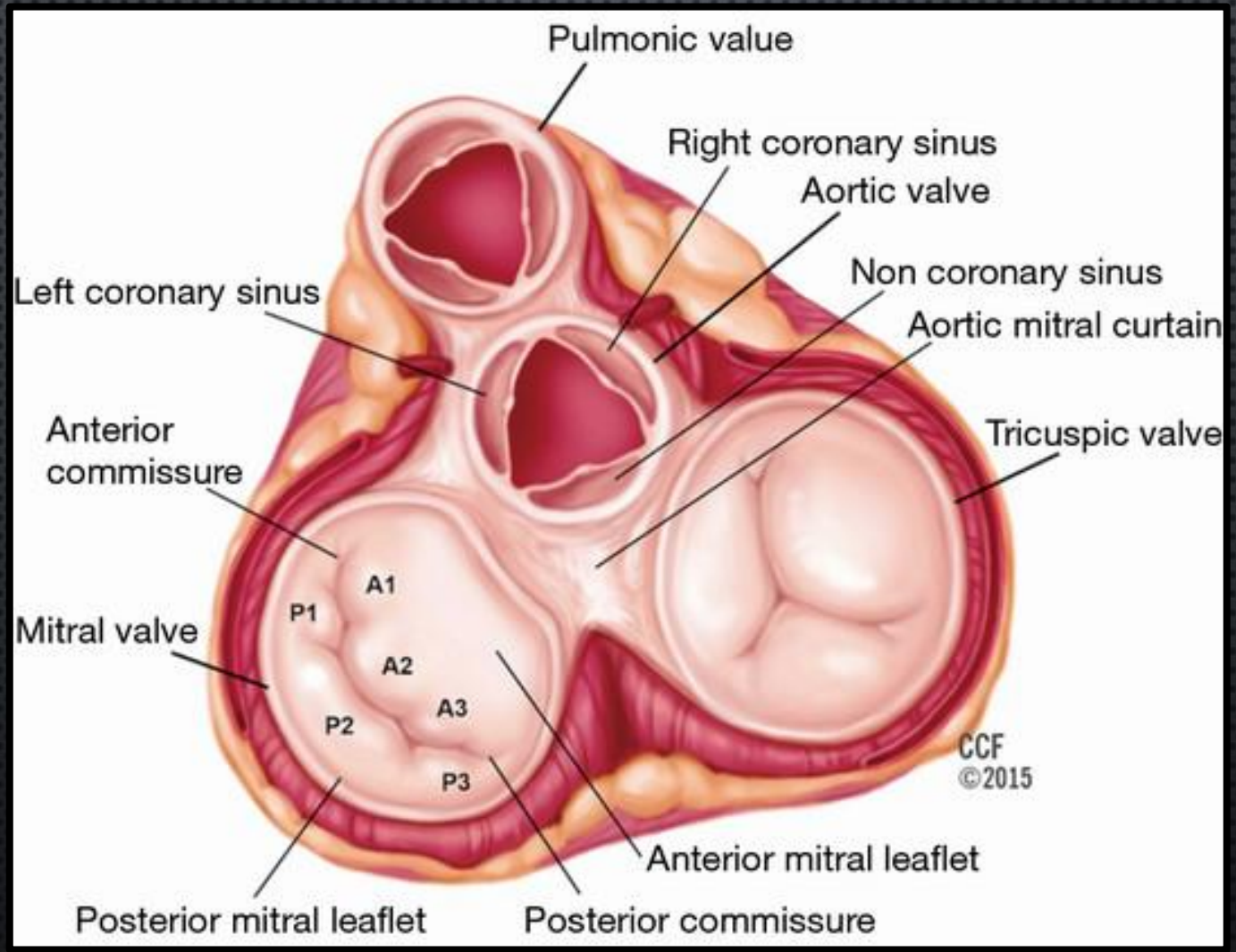
- Review Mitral Valve anatomy
- Discuss types of mitral regurgitation
- Treatment Options Reviewed
- Review Percutaneous Mitral Valve Repair
- Discuss percutaneous TMVR options

CASE JH

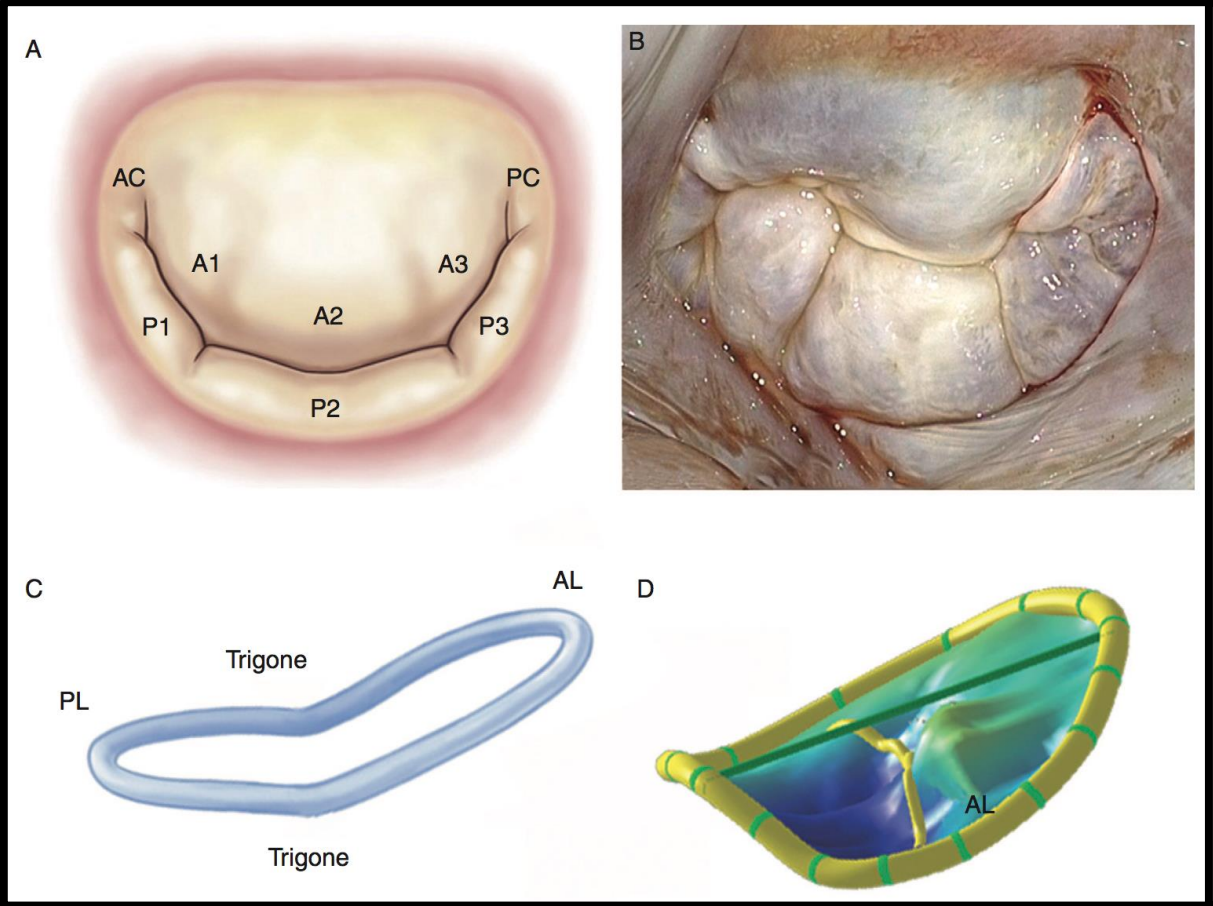
- 86YO WM SEVERE ECCENTRIC MR-PROLAPSE P2, EF-40%
- EXERTIONAL DYSPNEA(NYHA CLASS 3)
- PROHIBITIVE SURGICAL RISK

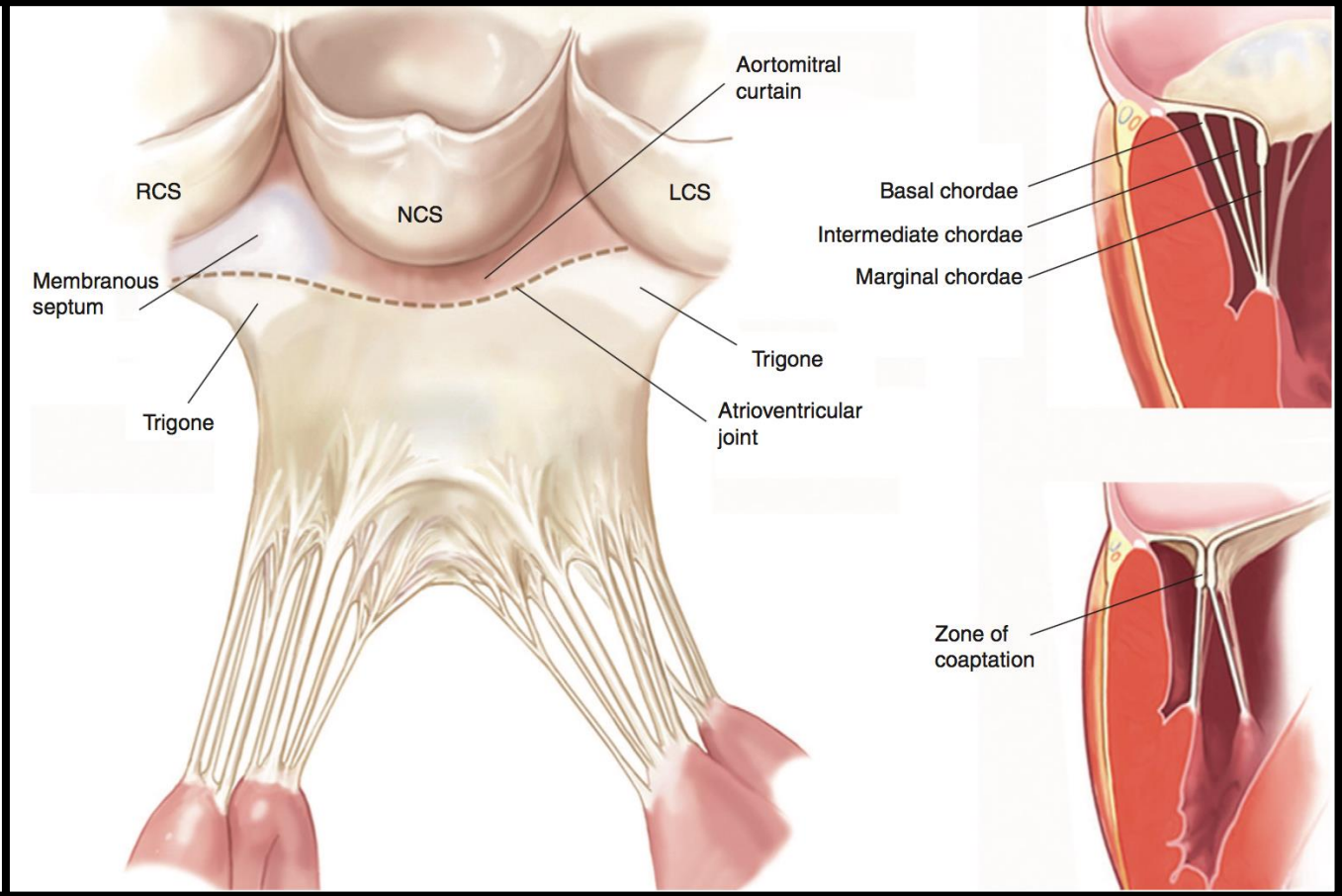


MITRAL VALVE ANATOMY



MITRAL VALVE ANATOMY





CLASSIFICATION OF MR

Primary:
Anatomic abnormality the mitral valve

- Leaflets
- Subvalvular apparatus
- Chordae and papillary muscles

The Valve is the Problem

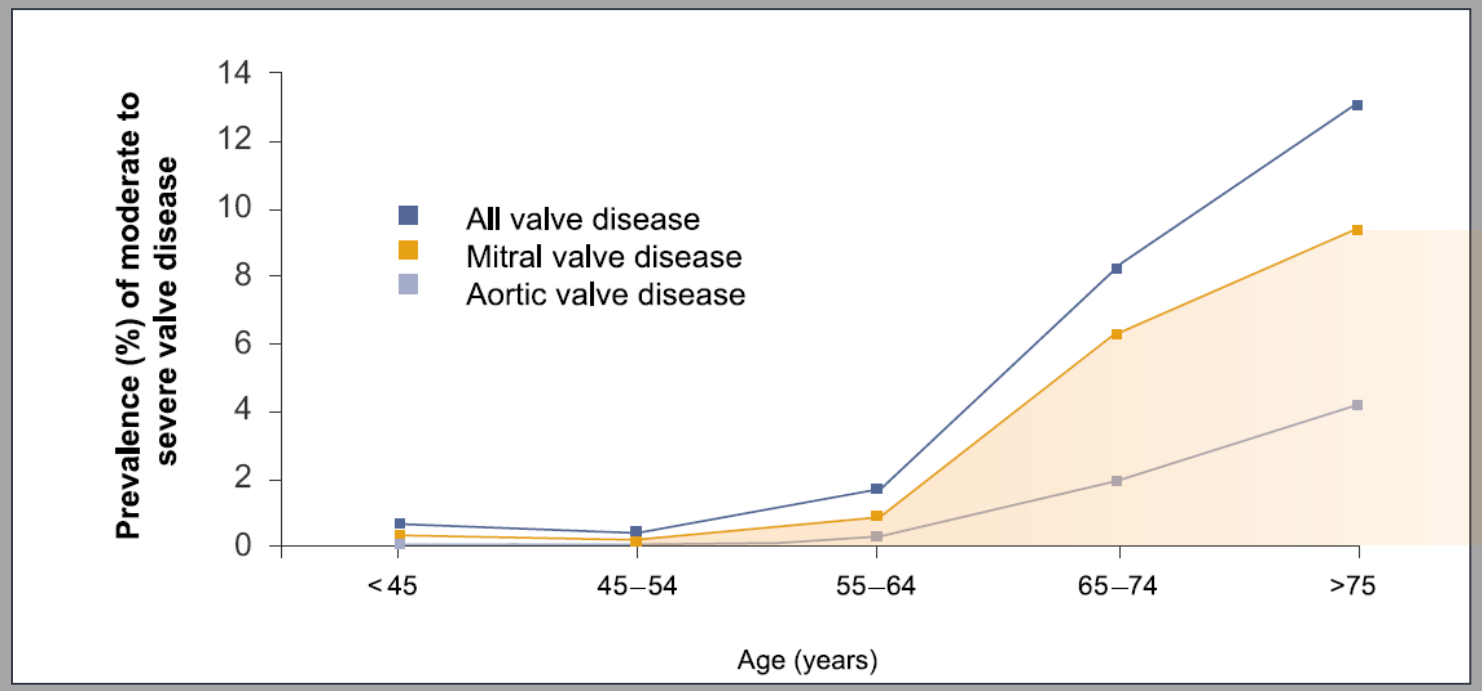
Secondary :
LV dilation; often secondary to ischemic heart disease

- “Tethering” of the chordae and mitral leaflets
- Incomplete coaptation of the mitral valve

The Ventricle is the Problem

Rev Esp Cardiol. 2011;64(12):1169–1181

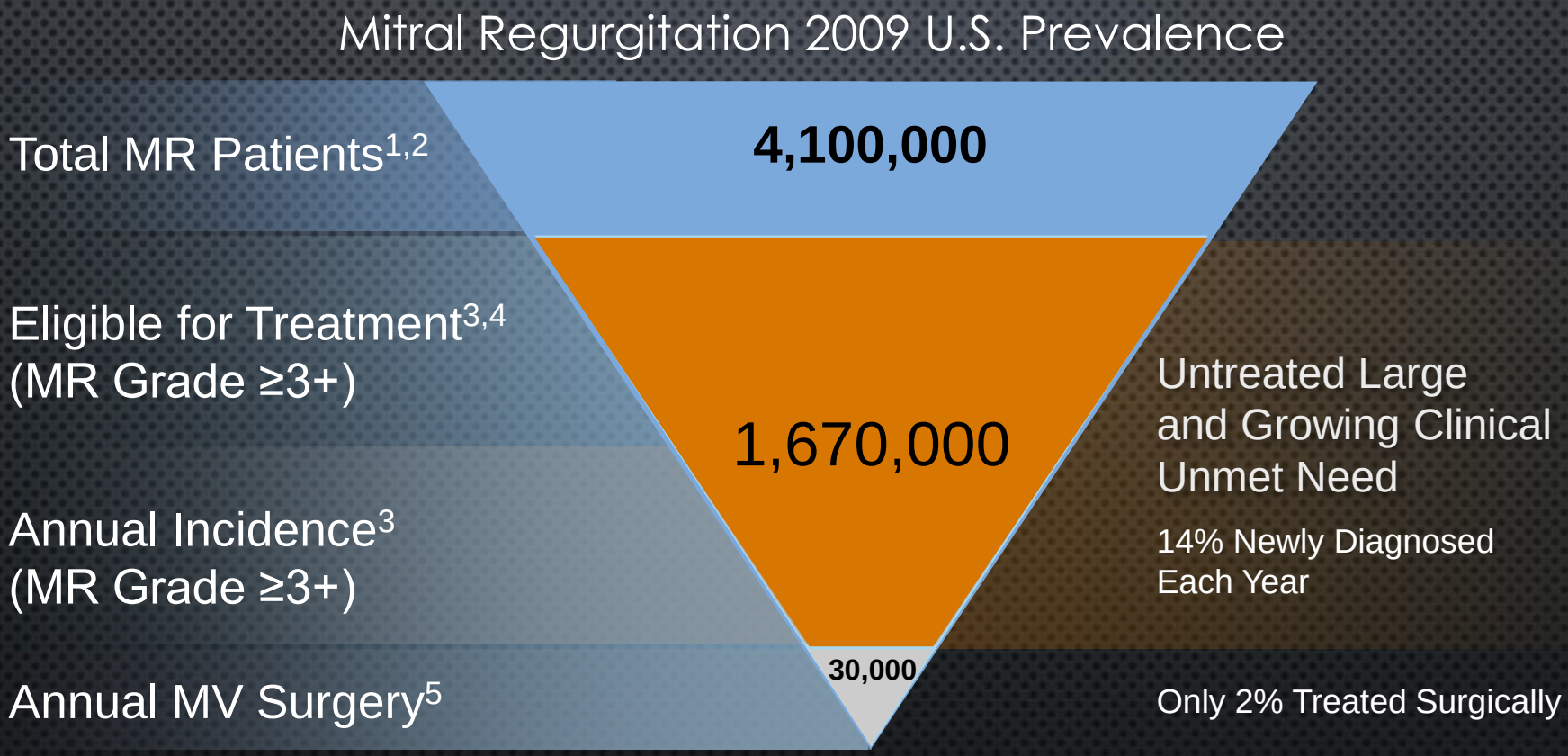
PREVALENCE OF VALVE DISEASE



Prevalence increases from 0.5% for 18-44 year olds to 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.

MR: LARGELY UNTREATED



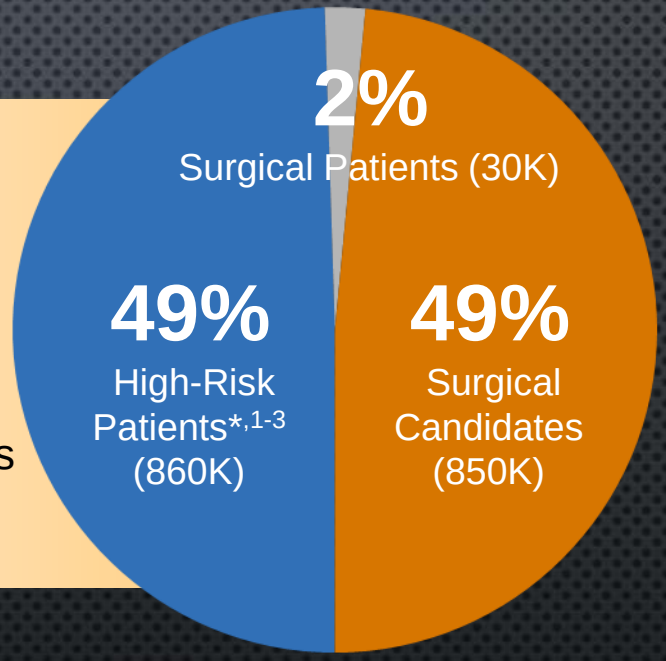
1. US Census Bureau. Statistical Abstract of the US: 2006, Table 12.
2. Nkomo et al. Burden of Valvular Heart Diseases: A Population-based Study, Lancet, 2006; 368: 1005-11.
3. Patel et al. Mitral Regurgitation in Patients with Advanced Systolic Heart Failure, J of Cardiac Failure, 2004.
4. ACC/AHA 2008 Guidelines for the Management of Patients with Valvular Heart Disease, Circulation: 2008
5. Gammie, J et al, Trends in Mitral Valve Surgery in the United States: Results from STS Adult Cardiac Database, Annals of Thoracic Surgery 2010.

HIGH-RISK MR: NOT SURGICAL CANDIDATES

Nearly half of MR patients not considered appropriate for mitral valve surgery [1]

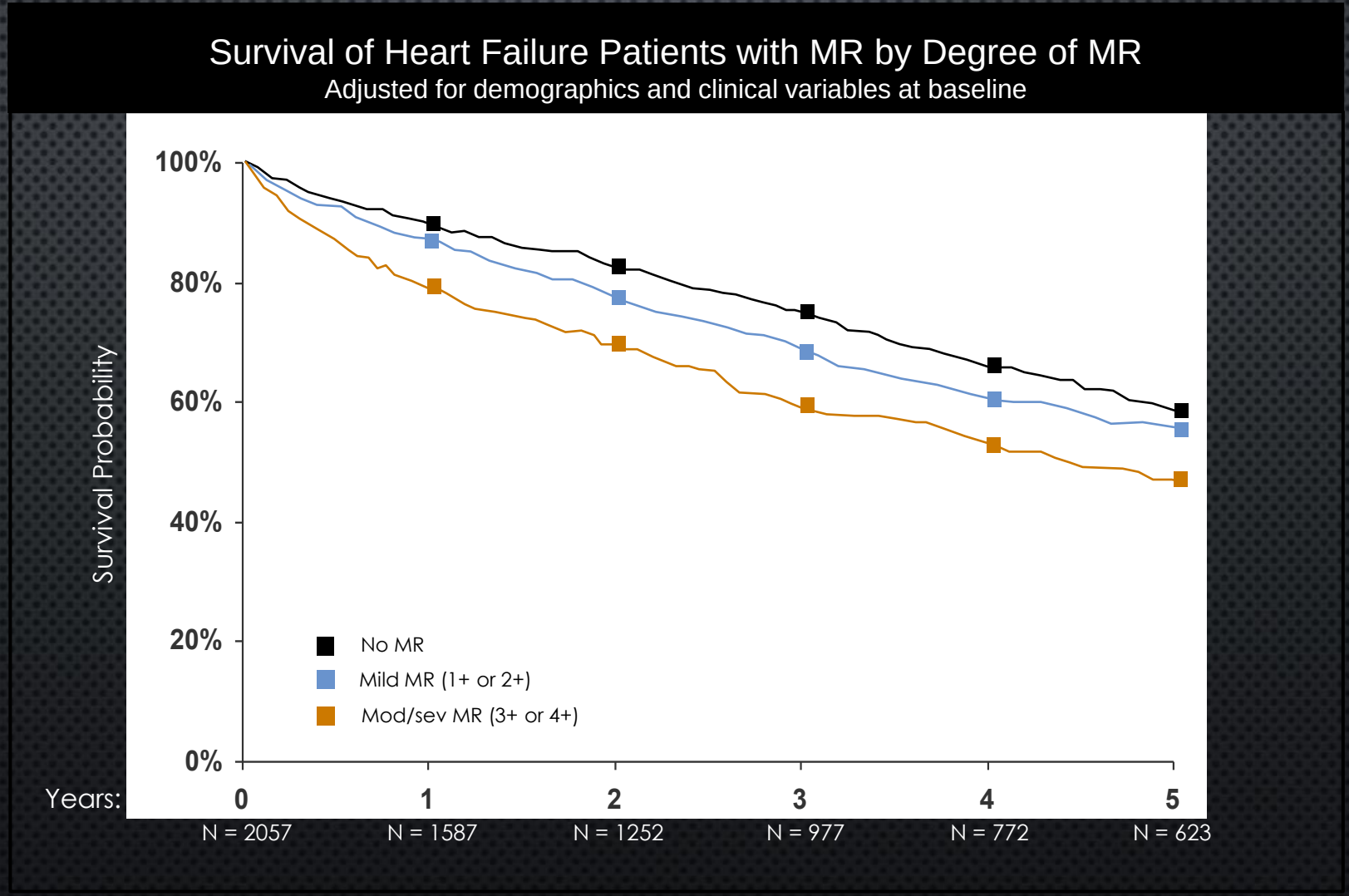
Factors prohibiting surgery include[1]:

- Impaired LVEF
- High operative risk
- Multiple comorbidities
- Advanced age



Rankin, et al, J of Thoracic and Cardiovascular Surgery, March 2006

Severity of MR Predictive of HF Survival



Note: Adjusted survival estimates are shown.
Source: Trichon BH et al. Am J Card. 2003,91:538-43.

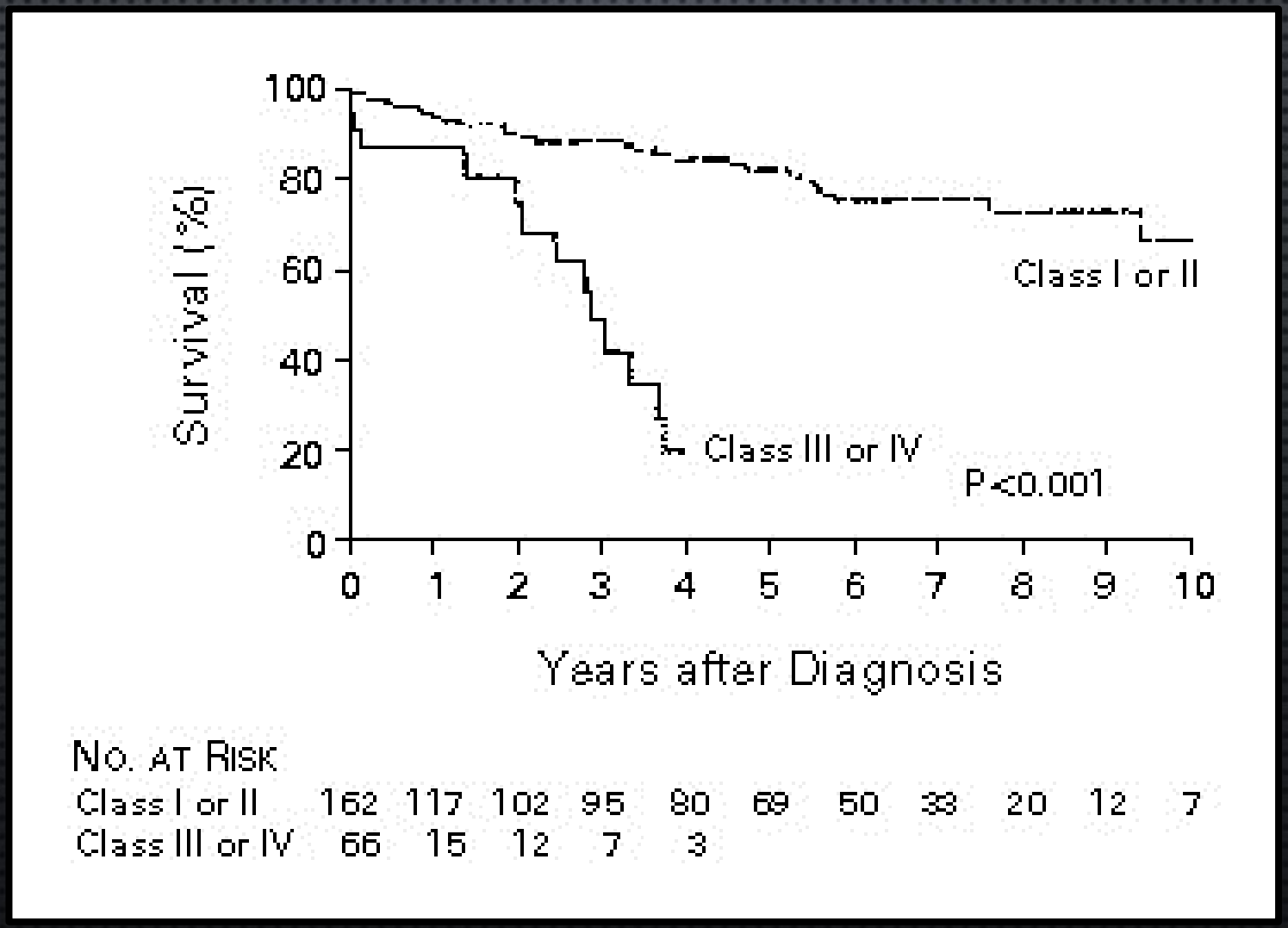
PRE-OP EF PREDICTS POST-OP SURVIVAL

val, 1.65 to 4.72) for ejection fraction <50% and 1.81 (95% confidence interval, 1.11 to 2.95) for ejection fraction 50% to 60%. The estimated 5-year survival and yearly mortality according to preoperative ejection fraction, symptoms, and presence of coronary artery disease are presented in Table 4. The combination of echocardiographic ejection fraction (globally or subdivided in calculated or estimated) and angiographic end-systolic volume in a single multivariate model showed that no additional survival information was provided by the angiographic variable.

To confirm the predictive value of echocardiographic ejection fraction independent of the type of operation performed, the late survival was compared in subgroups defined according to the level of ejection fraction and separately in patients with mitral valve repair and in patients with mitral valve replacement (Fig 3). The

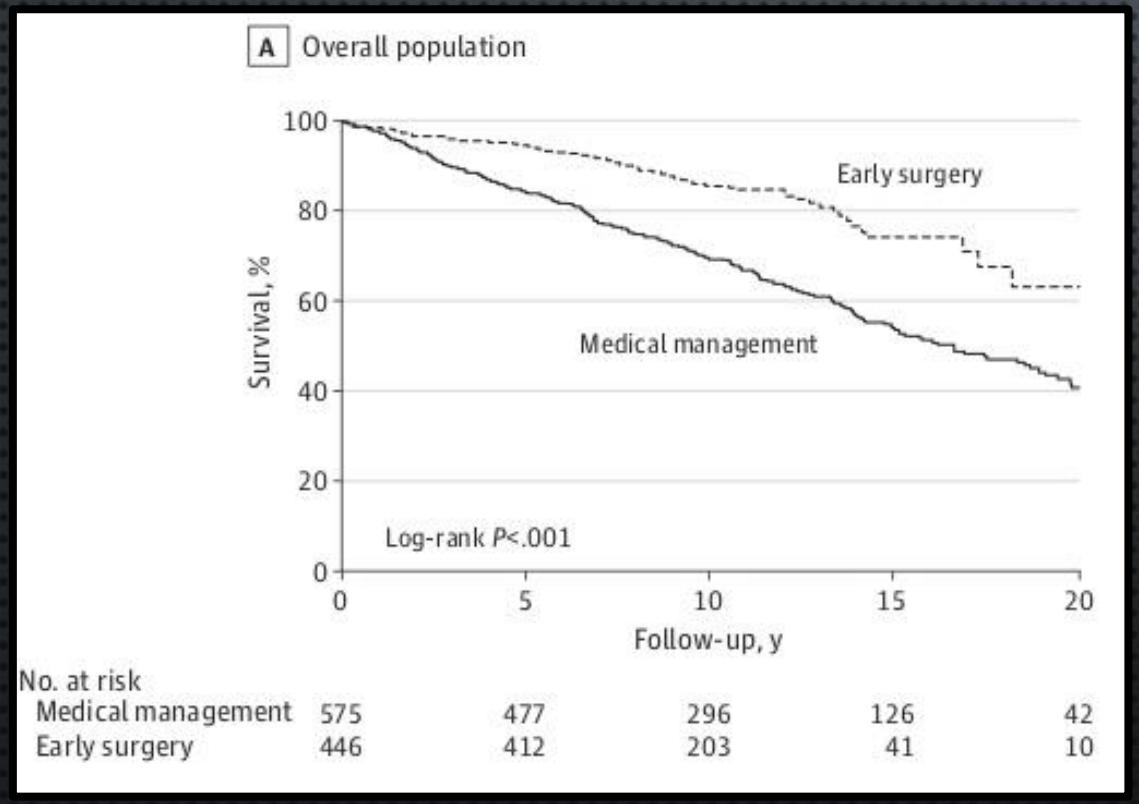
Enriquez-Sarano M, et al., Circulation 1994;90:830-837

NATURAL HISTORY OF FLAIL MITRAL VALVE



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

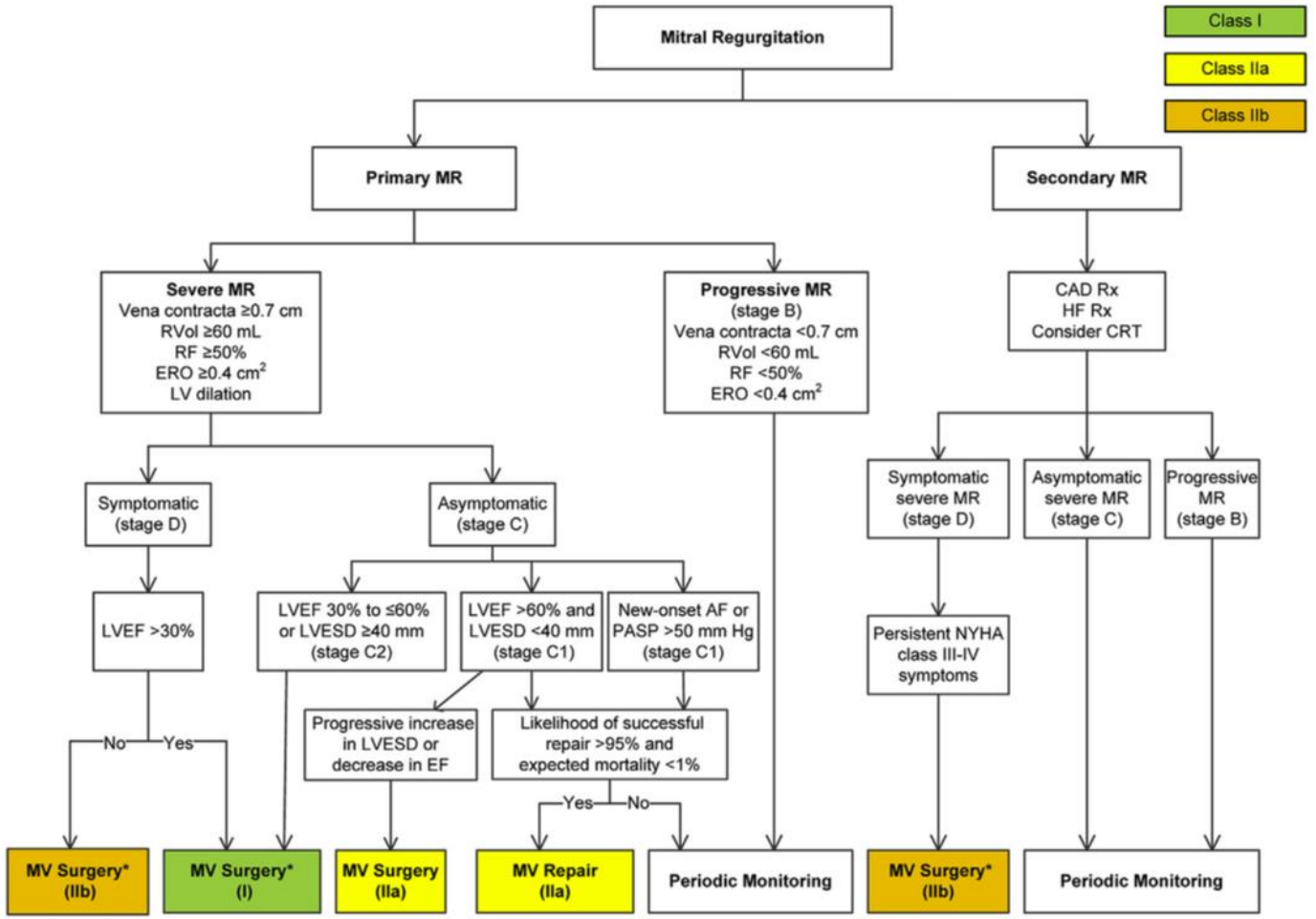
EARLY SURGERY IS BETTER



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

2017 ACC/AHA GUIDELINES INDICATIONS FOR SURGERY FOR MR

FIGURE 2 Indications for Surgery for MR (Updated Figure 4 From the 2014 VHD guideline)



JACC 2017;70:252-289

SURGICAL MV REPAIR
GOLD STANDARD DMR

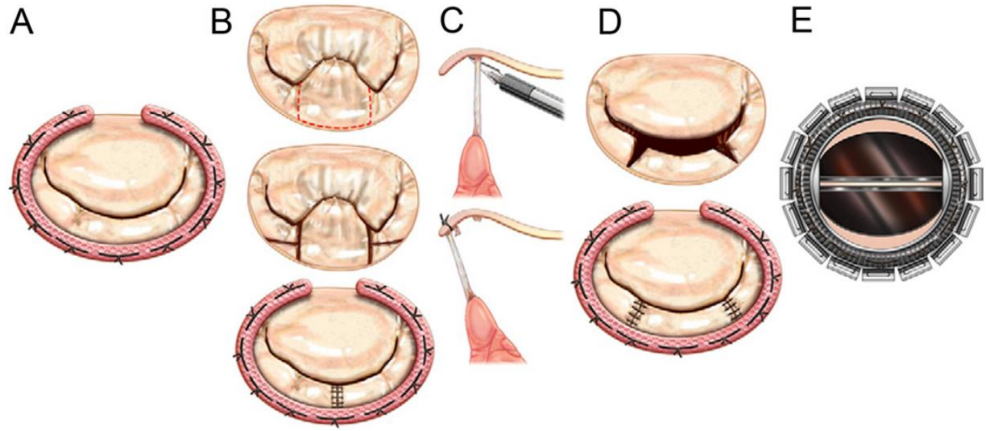


Figure 1 **Common Established Surgical Techniques Used to Correct Mitral Regurgitation**

(A) Ring annuloplasty. **(B)** Quadrangular resection and sliding leaflet plasty. **(C)** Chordal transfer. **(D)** Cleft closure. **(E)** Mitral replacement. Figure illustration by Craig Skaggs.

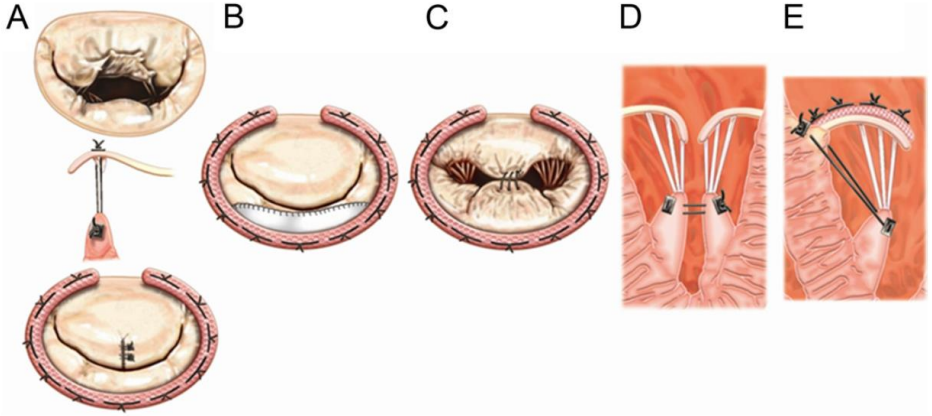


Figure 2 **Newer Surgical Techniques Used to Repair Regurgitant Mitral Valve**

(A) chordal replacement. **(B)** Posterior leaflet augmentation. **(C)** Edge-to-edge Alfieri stitch (valve shown in diastole with double orifice). **(D)** Papillary muscle approximation. **(E)** Posterior wall reduction. Figure illustration by Craig Skaggs.

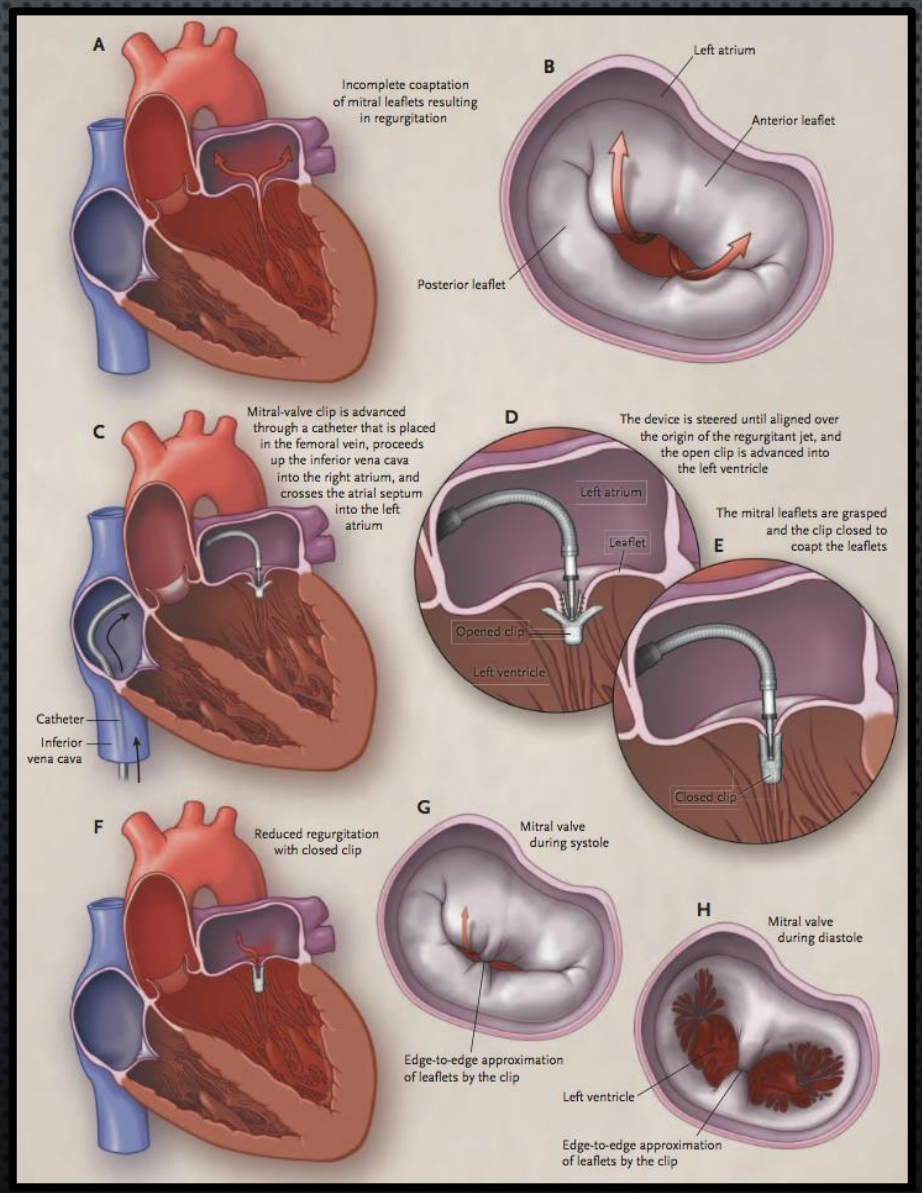
J Am Coll Cardiol 2012;60:1315–22

What if surgery is not an option?
Case JH

- Medical therapy?
- Percutaneous options?

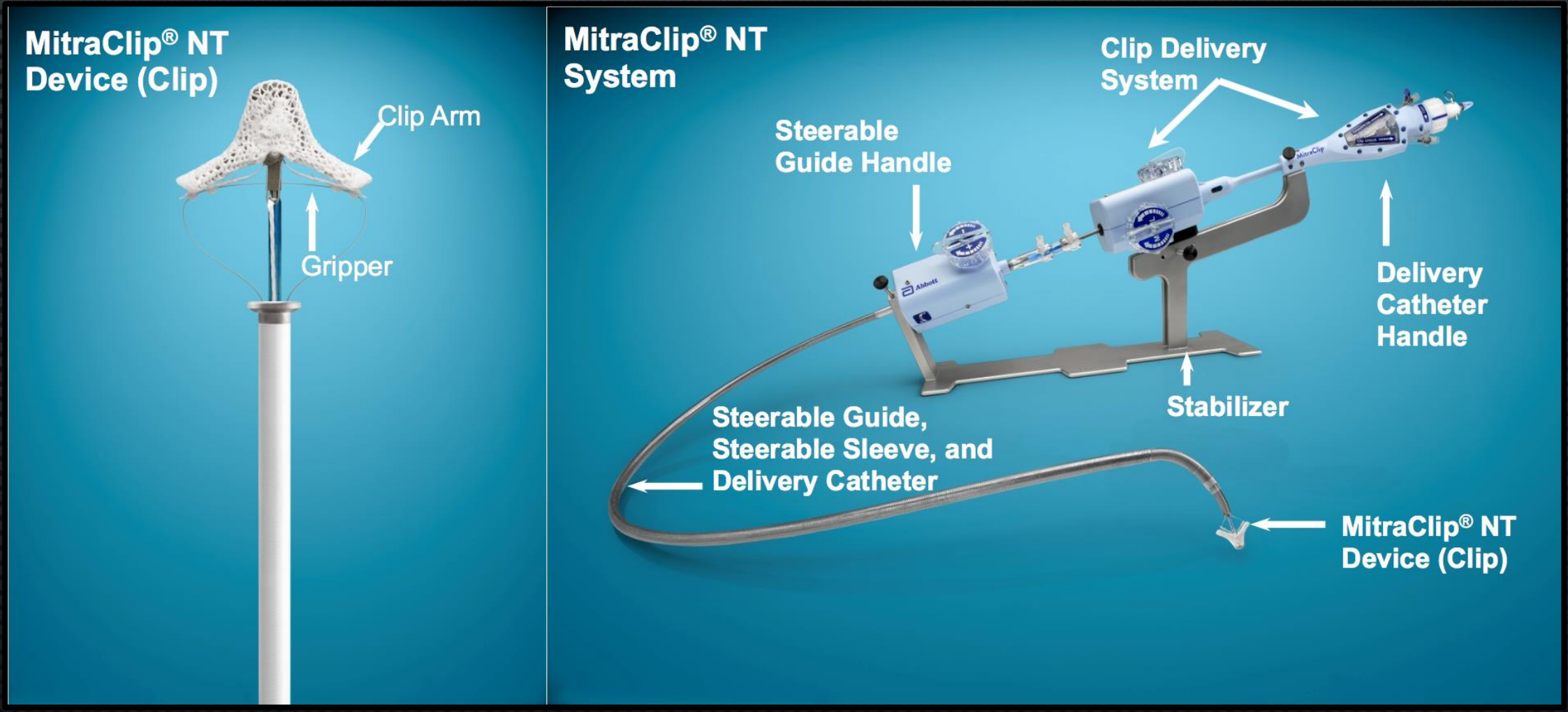
PERCUTANEOUS REPAIR OR SURGERY FOR MITRAL REGURGITATION

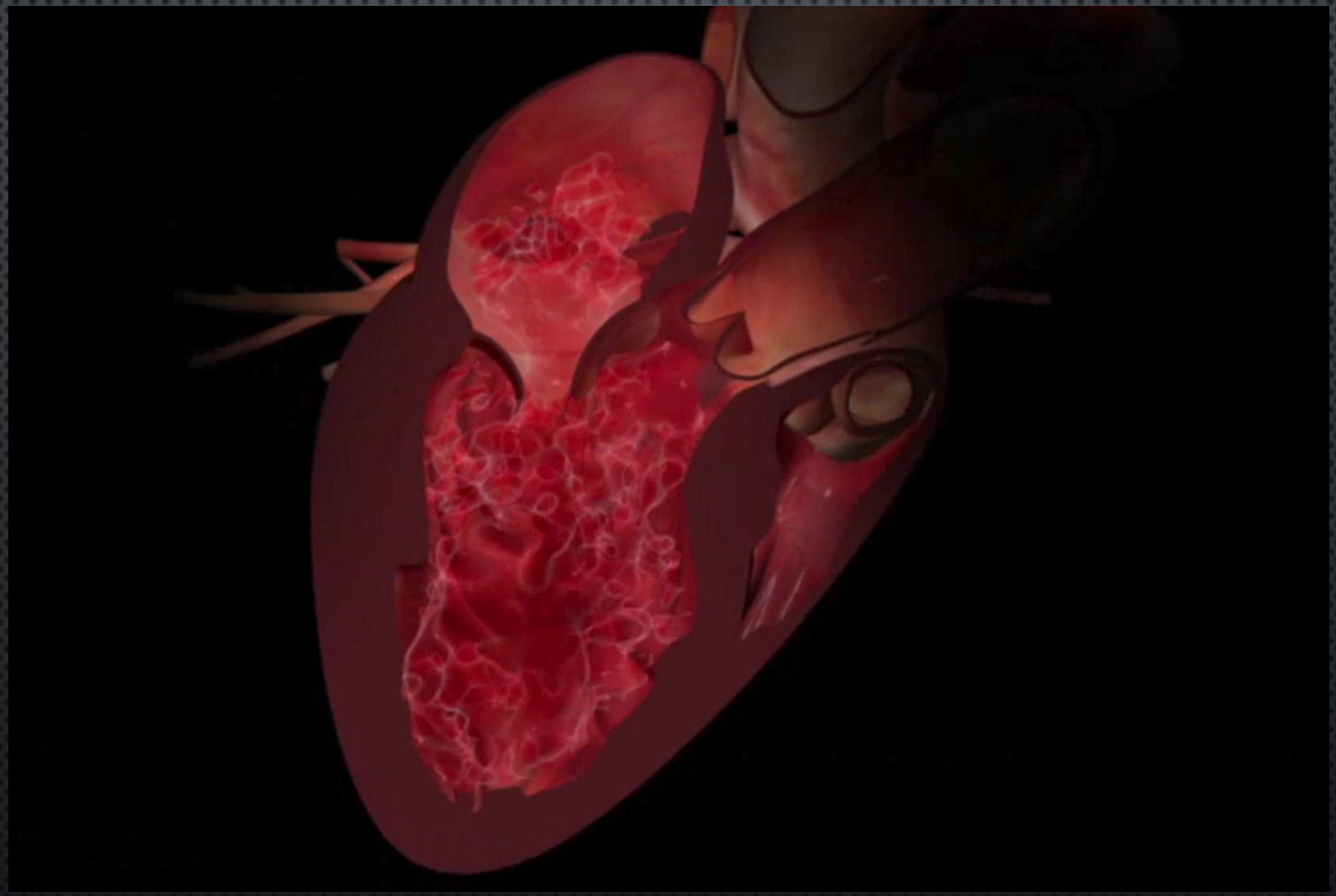
FELDMAN ET AL. EVEREST II. N ENGL J MED 2011;364:1395-406.



TRANCATHETER MITRAL VALVE REPAIR

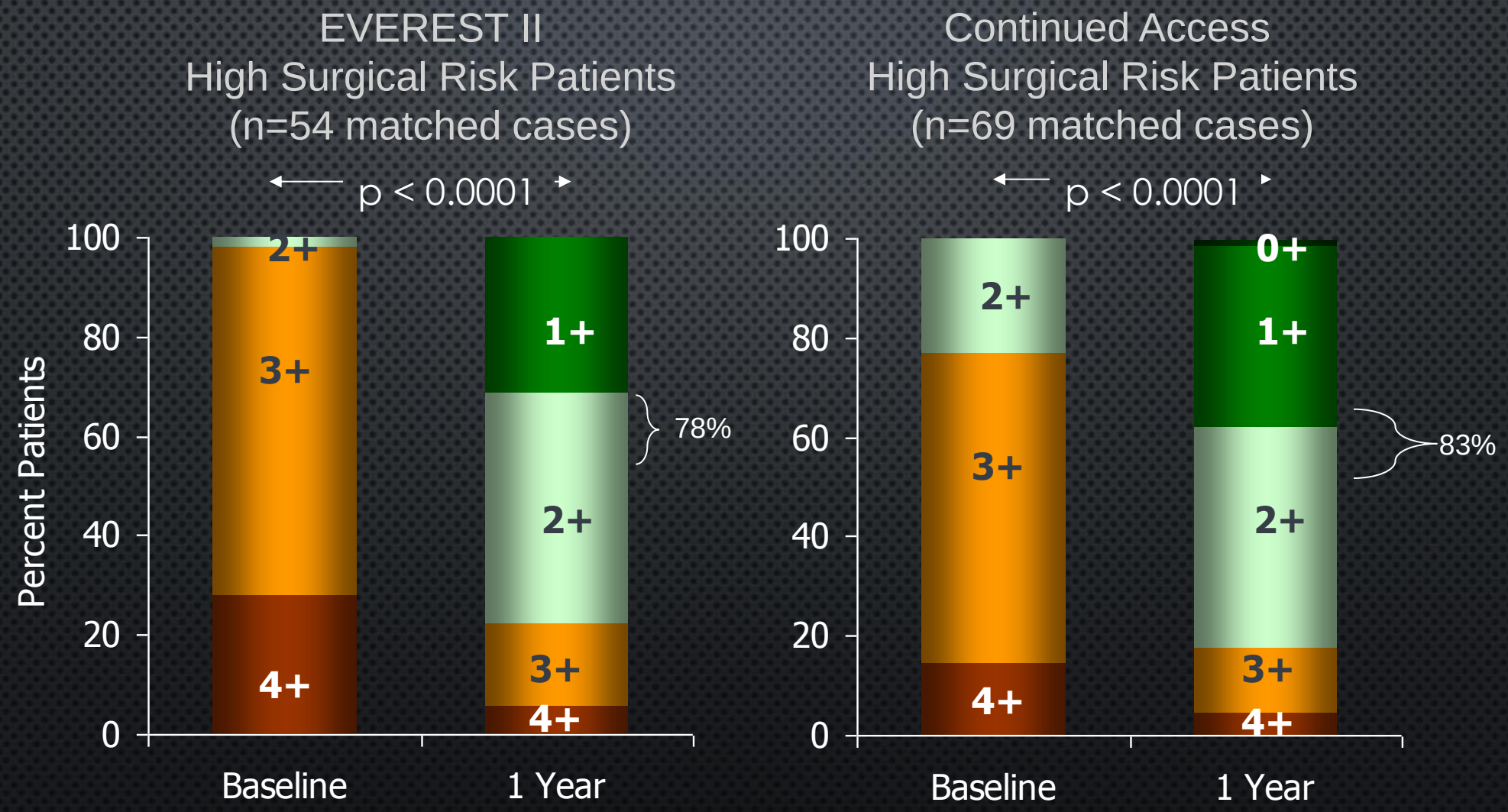
MITRACLIP NT





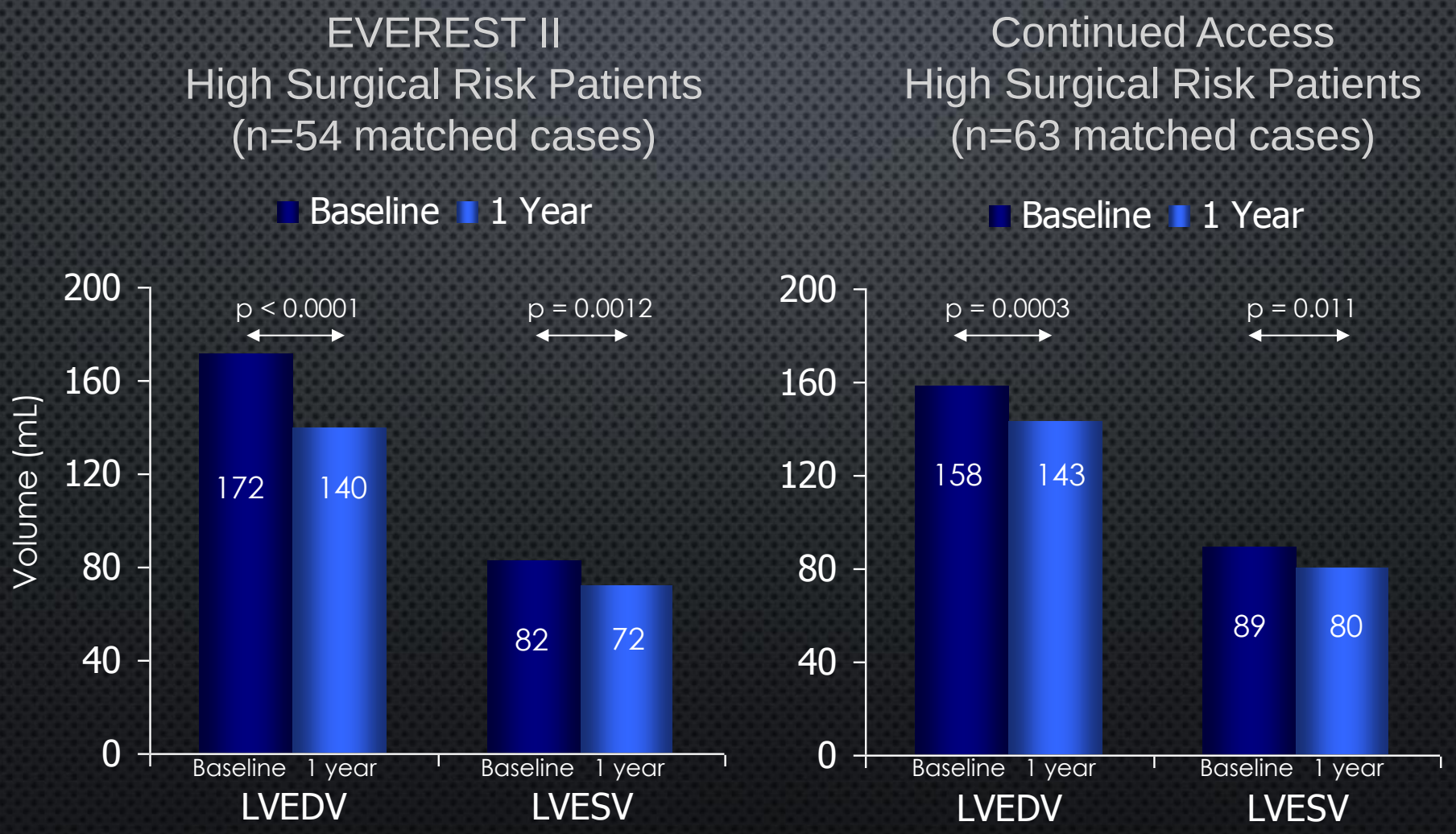
CORE LAB MR GRADE AT 1 YEAR (MATCHED)

EVEREST II AND CONTINUED ACCESS HIGH SURGICAL RISK PATIENTS



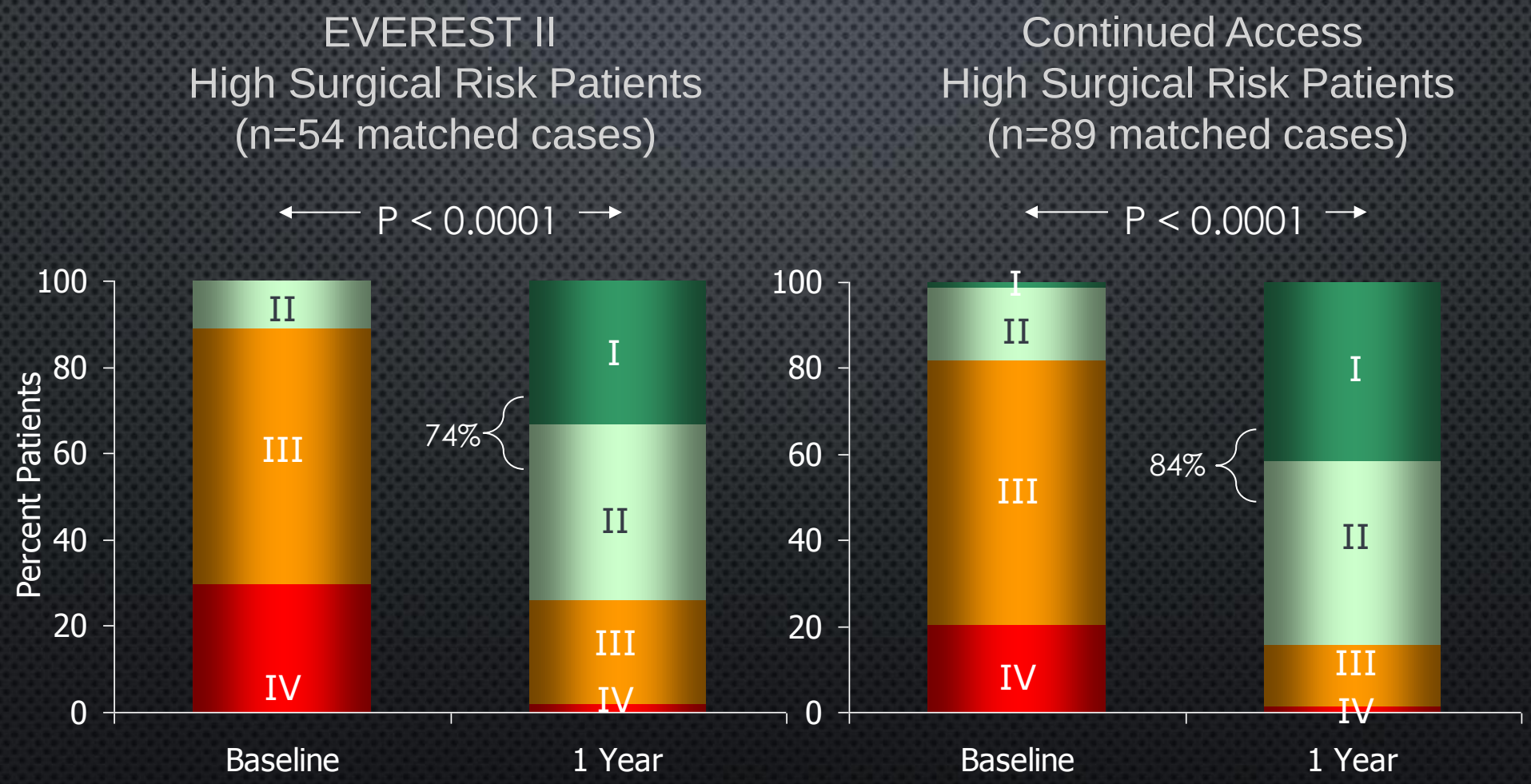
LV END DIASTOLIC AND SYSTOLIC VOLUMES

EVEREST II AND CONTINUED ACCESS HIGH SURGICAL RISK PATIENTS



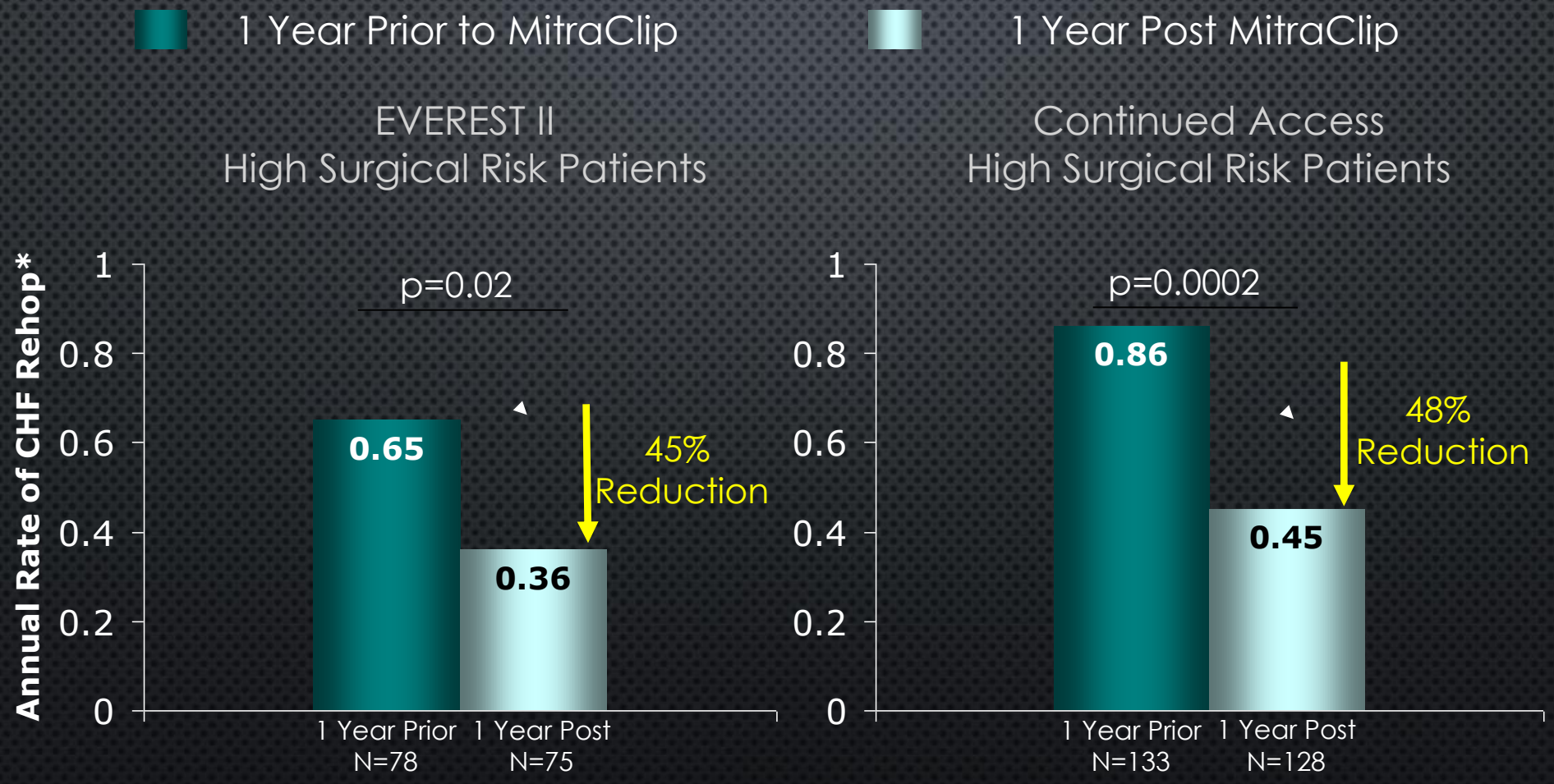
NYHA FUNCTIONAL CLASS AT 1 YEAR

EVEREST II AND CONTINUED ACCESS HIGH SURGICAL RISK PATIENTS



HOSPITALIZATION FOR CHF

EVEREST II AND CONTINUED ACCESS HIGH SURGICAL RISK PATIENTS



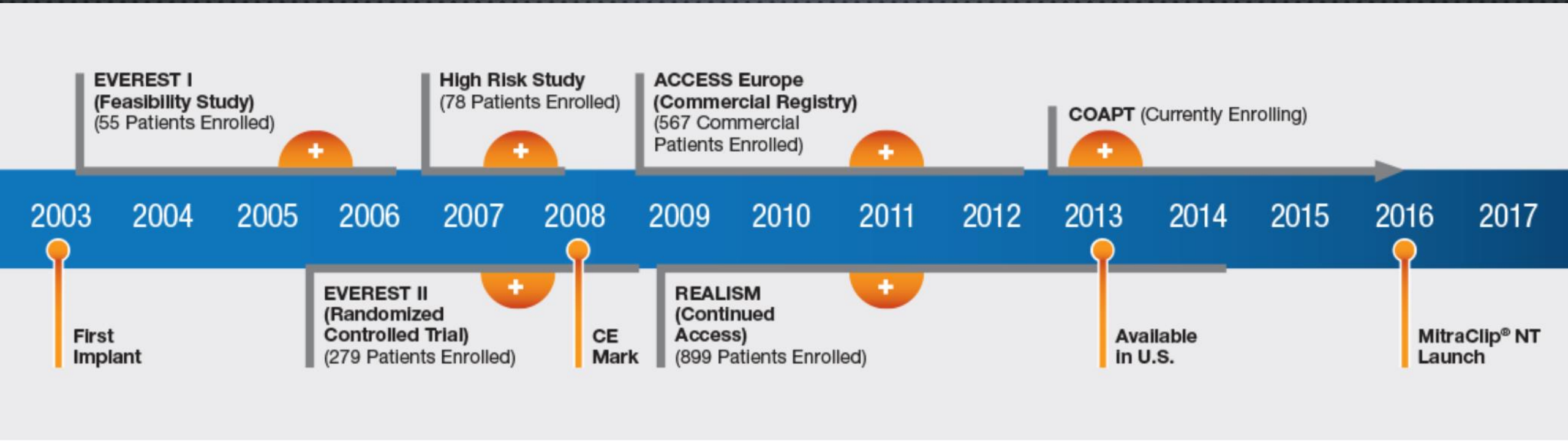
*CHF hospitalizations per patient-year

EVEREST II TRIAL SUMMARY-1 YEAR

PERCUTANEOUS EDGE TO EDGE REPAIR IN DEGENERATIVE MR WITH PROHIBITIVE SURGICAL RISK

- Effective reduction in mitral regurgitation
- Reduction in lv volume
- Improvement in nyha functional class
- Reduction in HF hospitalization

FDA APPROVAL

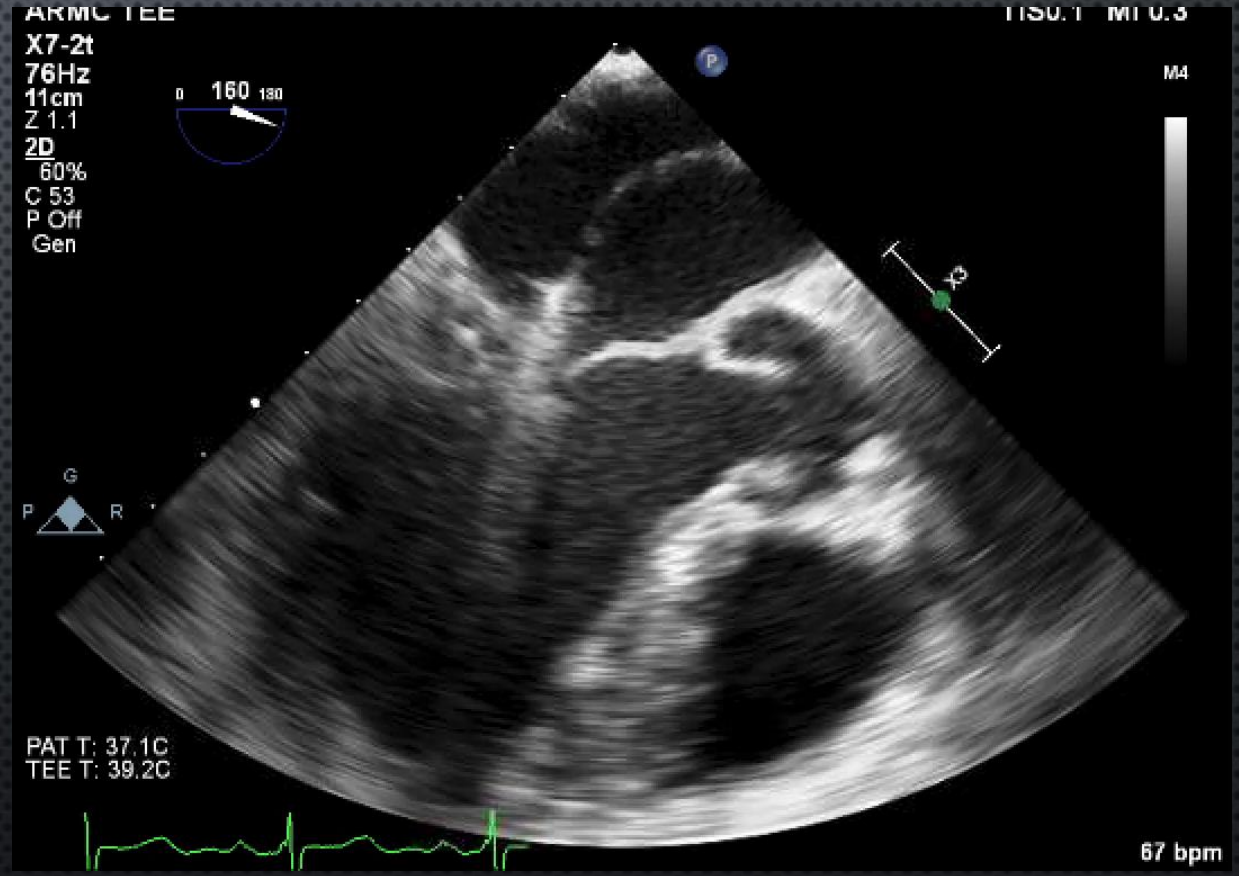


MITRACLIP IFU

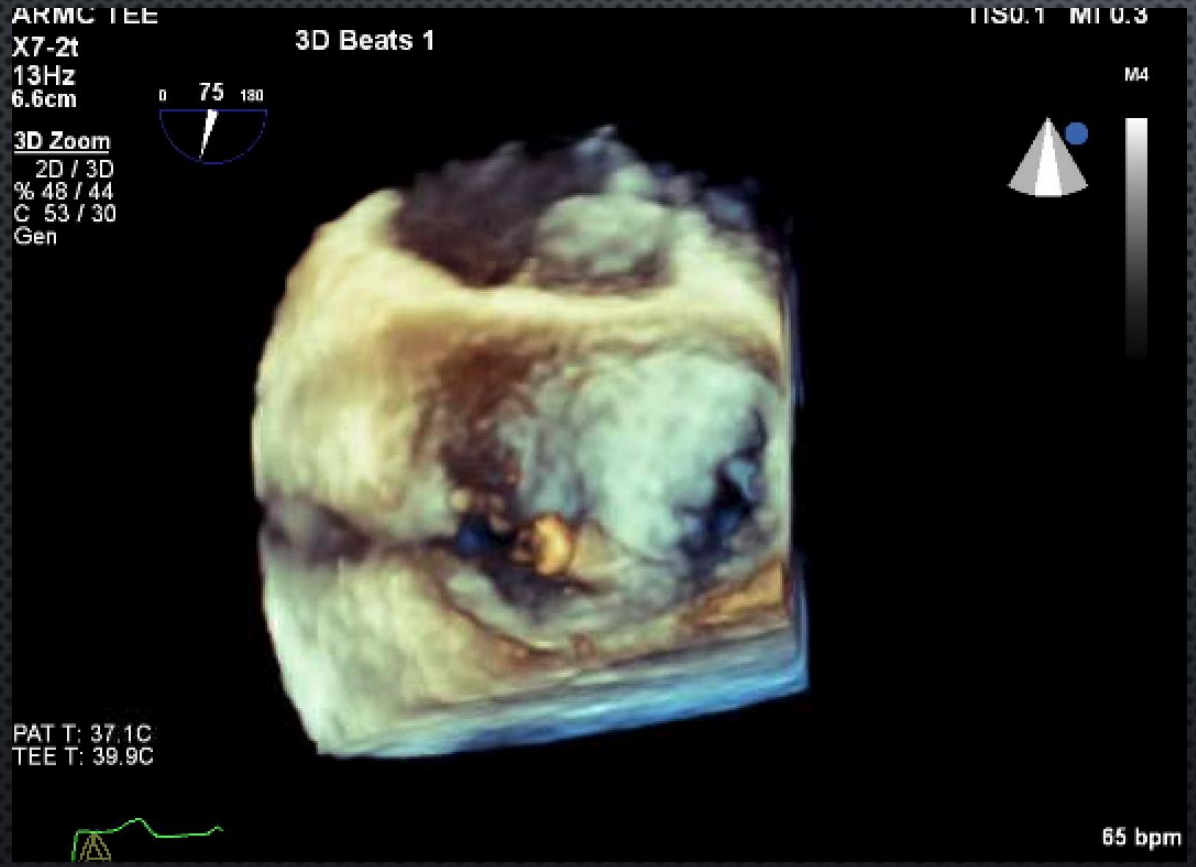
- The MitraClip® NT Clip Delivery System is indicated for the percutaneous reduction of significant **symptomatic mitral regurgitation (MR ≥ 3+)** due to primary abnormality of the mitral apparatus [**degenerative MR**] in patients who have been determined to be at **prohibitive risk** for mitral valve 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.

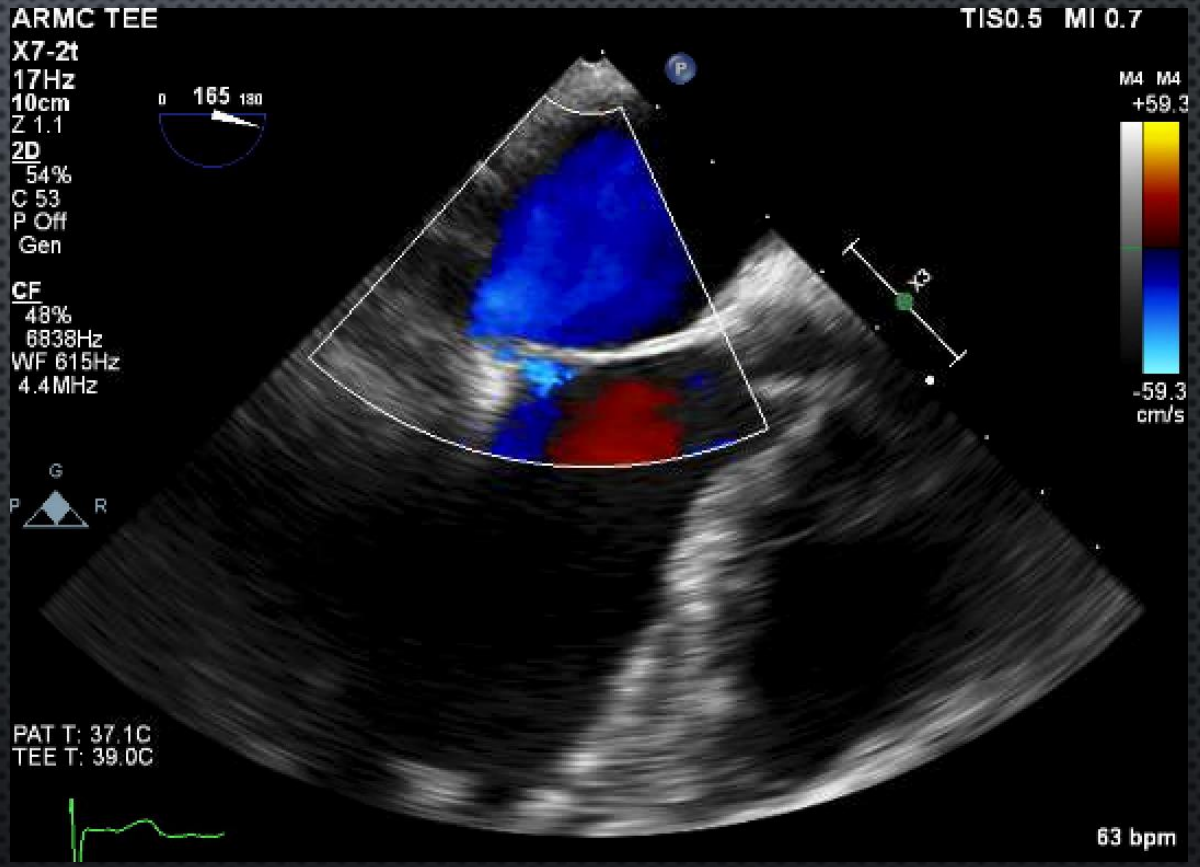
CASE JH

ARMC TEE
X7-2t
10Hz
6.9cm
3D Zoom
2D / 3D
% 43 / 44
C 53 / 30
Gen
3D Beats 1
TIS0.1 MI 0.2
M4
PAT T: 37.1C
TEE T: 39.6C
67 bpm

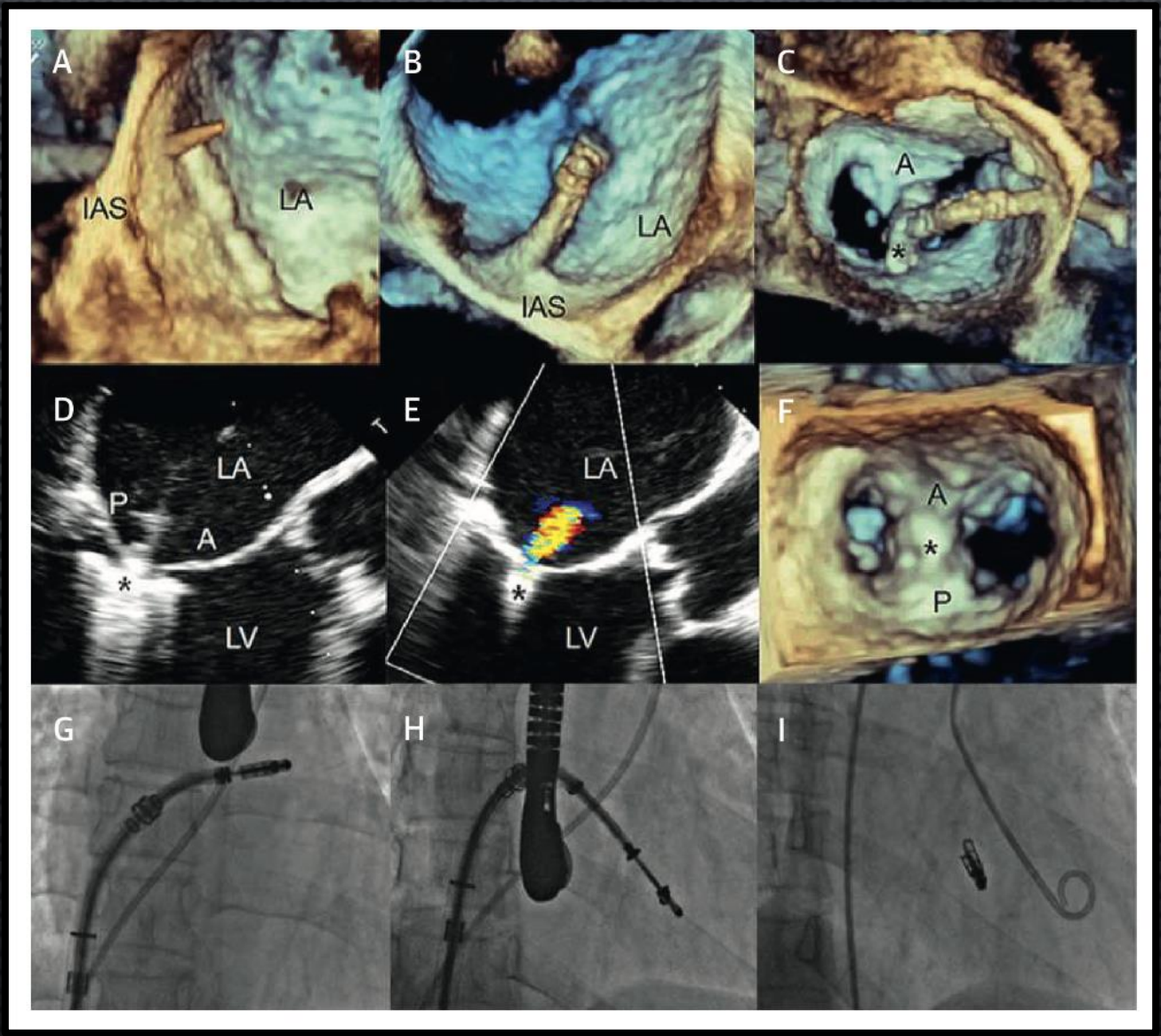

X7-2t
76Hz
11cm
Z 1.1
2D
60%
C 53
P Off
Gen
M4
PAT T: 37.1C
TEE T: 39.2C
67 bpm

CASE JH


ARMC TEE
X7-2t
13Hz
6.6cm
3D Beats 1
TIS0.1 MI 0.3
M4
0 75 180
3D Zoom
2D / 3D
% 48 / 44
C 53 / 30
Gen
PAT T: 37.1C
TEE T: 39.9C
65 bpm


ARMC TEE
X7-2t
17Hz
10cm
Z 1.1
TIS0.5 MI 0.7
0 165 180
2D
54%
C 53
P Off
Gen
CF
48%
6838Hz
WF 615Hz
4.4MHz
M4 M4
+59.3
-59.3
cm/s
G
P R
PAT T: 37.1C
TEE T: 39.0C
63 bpm

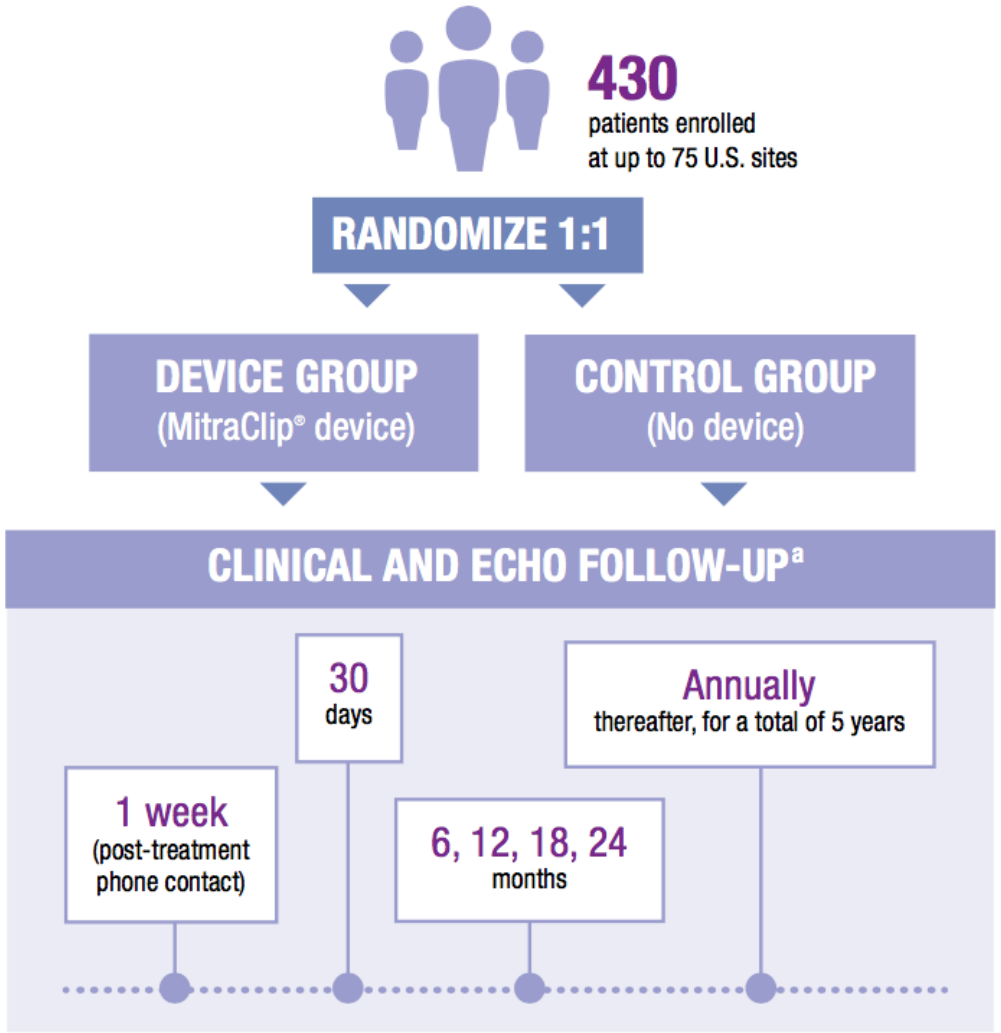
MITRACLIP DEPLOYMENT



Eligible Patients

- Symptomatic **Functional** mitral regurgitation >3+
- Not suitable candidate for surgical MVR
- NYHA Class 2,3, or ambulatory 4, not stage D HF

COAPT Trial design overview†



[a]TEST: 6MWT, QoL, NYHA functional class, TTE, BNP/nT-pro BNP level, modified Rankin Scale

† For COAPT Protocol Rev. 5.1

Primary endpoints

Efficacy

- Recurrent heart failure (HF) hospitalizations

Safety

- Composite of Single Leaflet Device Attachment (SLDA), device embolizations, endocarditis requiring surgery, Echocardiography Core Laboratory confirmed mitral stenosis requiring surgery, and any device related complications requiring non-elective cardiovascular surgery at 12 months

Secondary endpoints

Efficacy

- Mitral regurgitation severity at 12 months
- Change in 6-minute walk test at 12 months
- Change in quality of life at 12 months
- Change in Left Ventricular end-diastolic volume at 12 months
- NYHA functional class I/II at 12 months
- Hierarchical composite of death and recurrent HF hospitalization
- Recurrent hospitalizations — all-cause

Safety

- Composite of all-cause death, stroke, MI, or non-elective cardiovascular surgery for device related complications at 30 days post-procedure in the MitraClip group

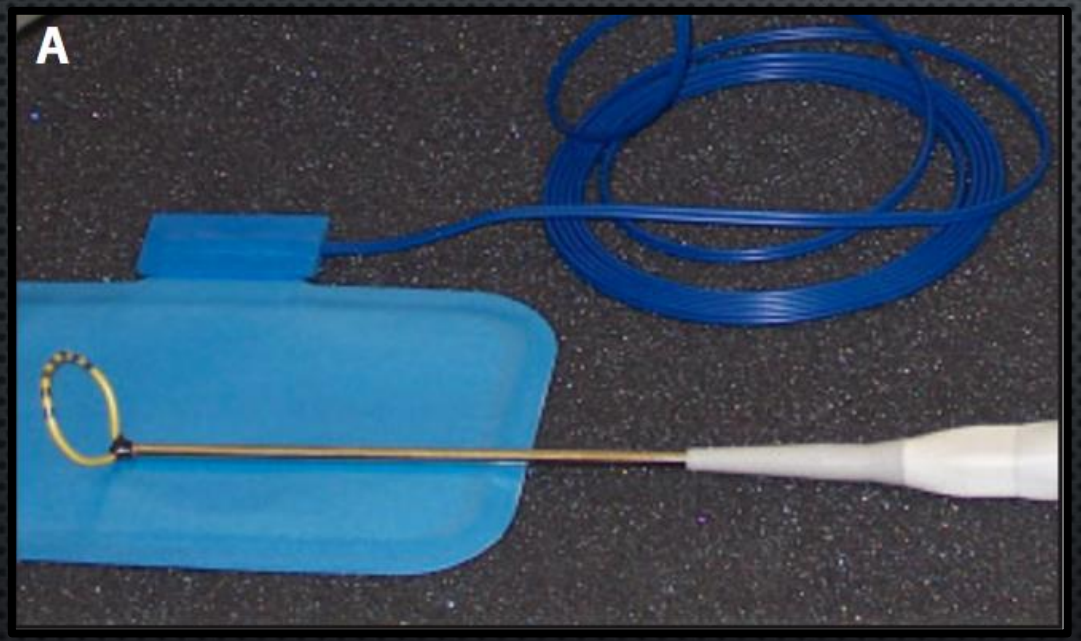
ONE SIZE DOES NOT FIT ALL

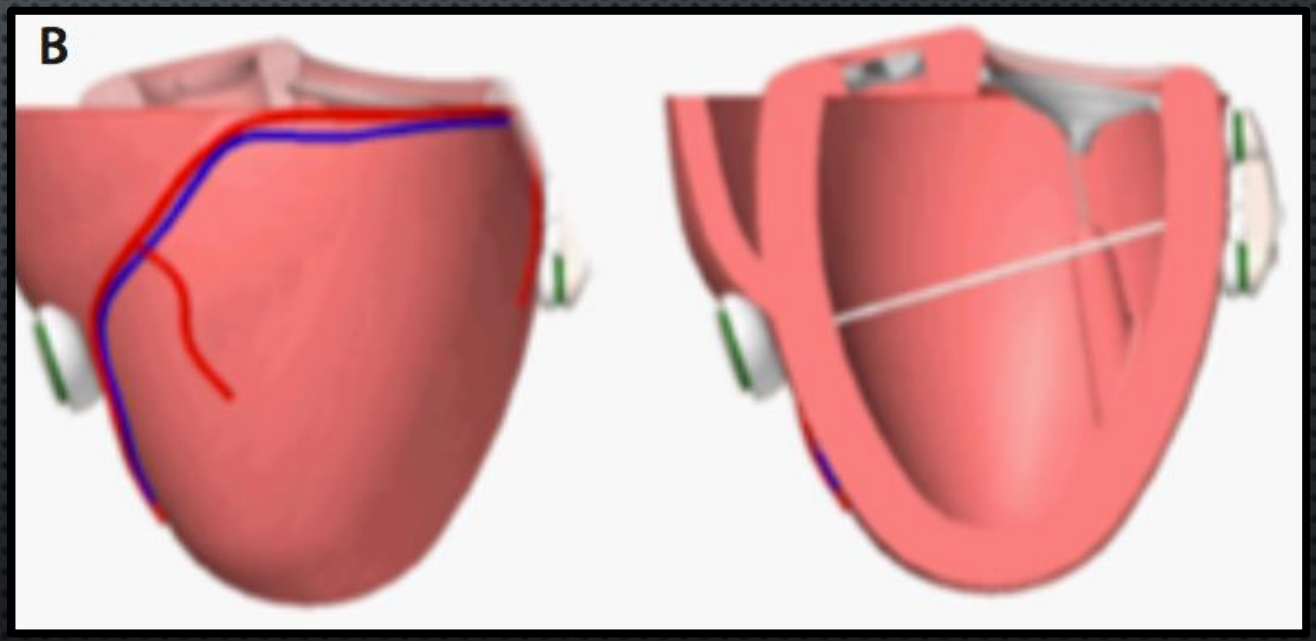
TABLE 1 Echocardiographic Morphological Characteristics for Determining Patient Eligibility for Percutaneous Valve Repair Therapy

Criteria Suggesting Patient Suitability	Criteria Suggesting Patient Might Not Be Suitable
Nonrheumatic etiology	Rheumatic etiology, endocarditis-related valve disease, or prior MV surgery
Central mitral regurgitation jet	Cleft or perforated mitral leaflets
MV orifice area ≥40 mm^2	Lack of secondary chordal support
If a flail leaflet is present	Posterior leaflet length <7 mm
Flail gap* <10 mm	
Flail width* <15 mm	
Posterior leaflet length ≥10 mm	Leaflet gap >2 mm
If leaflet tethering present	Presence of severe calcifications in the grasping area
Coaptation depth <11 mm	
Coaptation length† <10 mm	
Absence of calcifications in the grasping area	Transmitral pressure gradient ≥4 mm Hg‡ Effective regurgitant orifice area >70.8 mm^2‡ MV orifice area <30 mm^2‡
	Evidence of intracardiac mass, thrombus, or vegetation, or evidence of an inferior vena cava or femoral venous thrombus

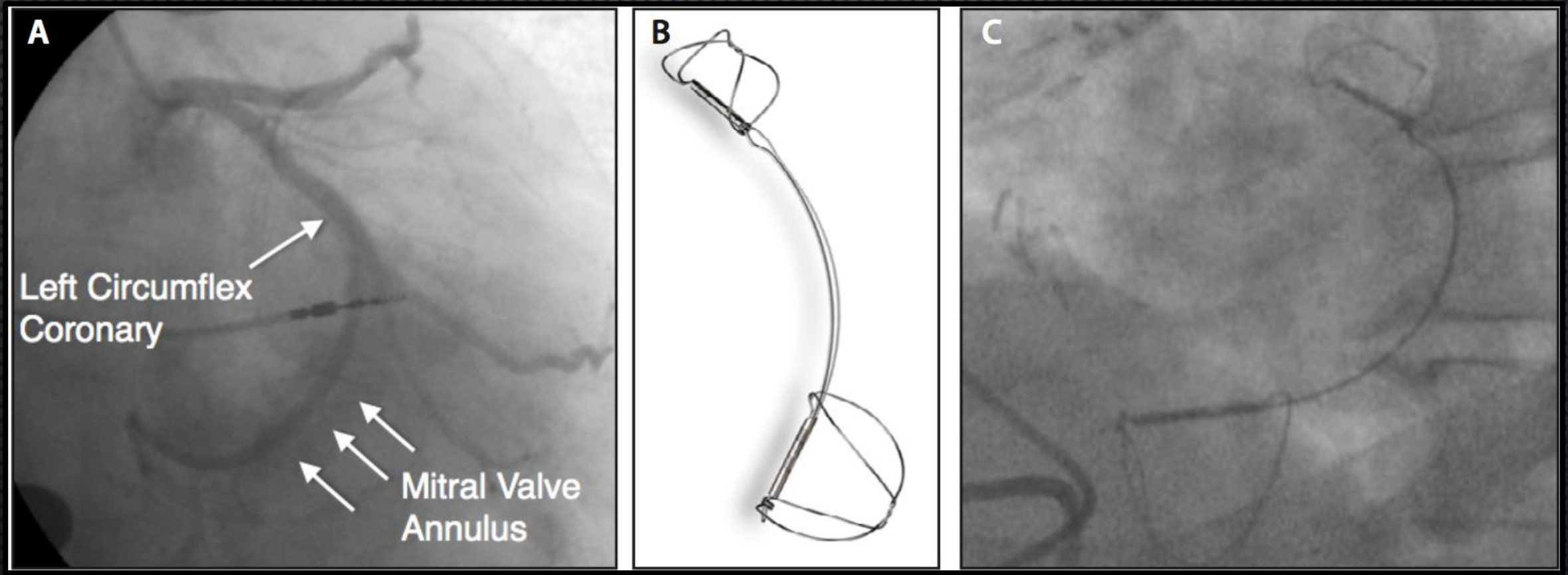
J Am Coll Cardiol 2014;64:2688–700

PERCUTANEOUS MITRAL ANNULOPLASTY
QUANTUMCOR(A) & ICOAPSYS(B)
RESHAPING MITRAL ANNULUS AND VENTRICLE

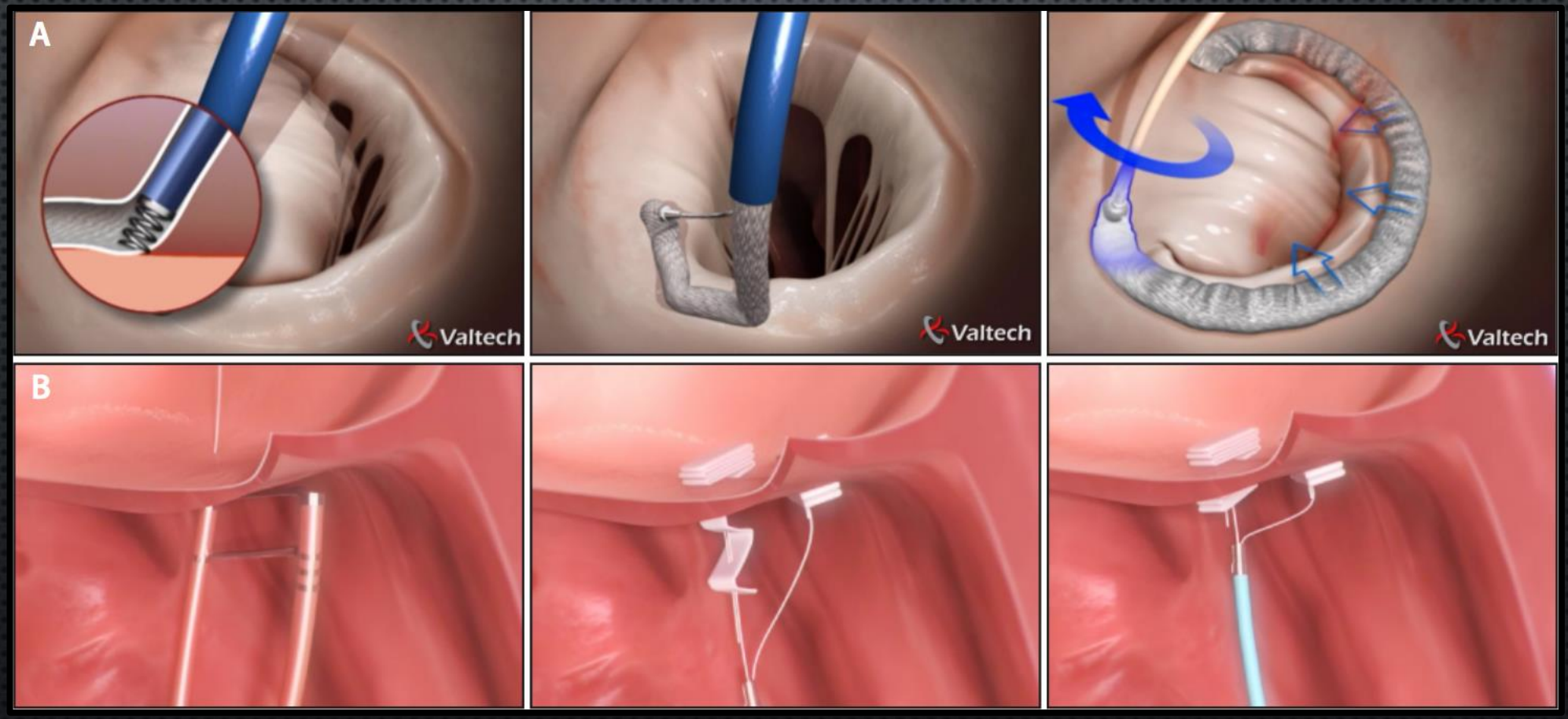




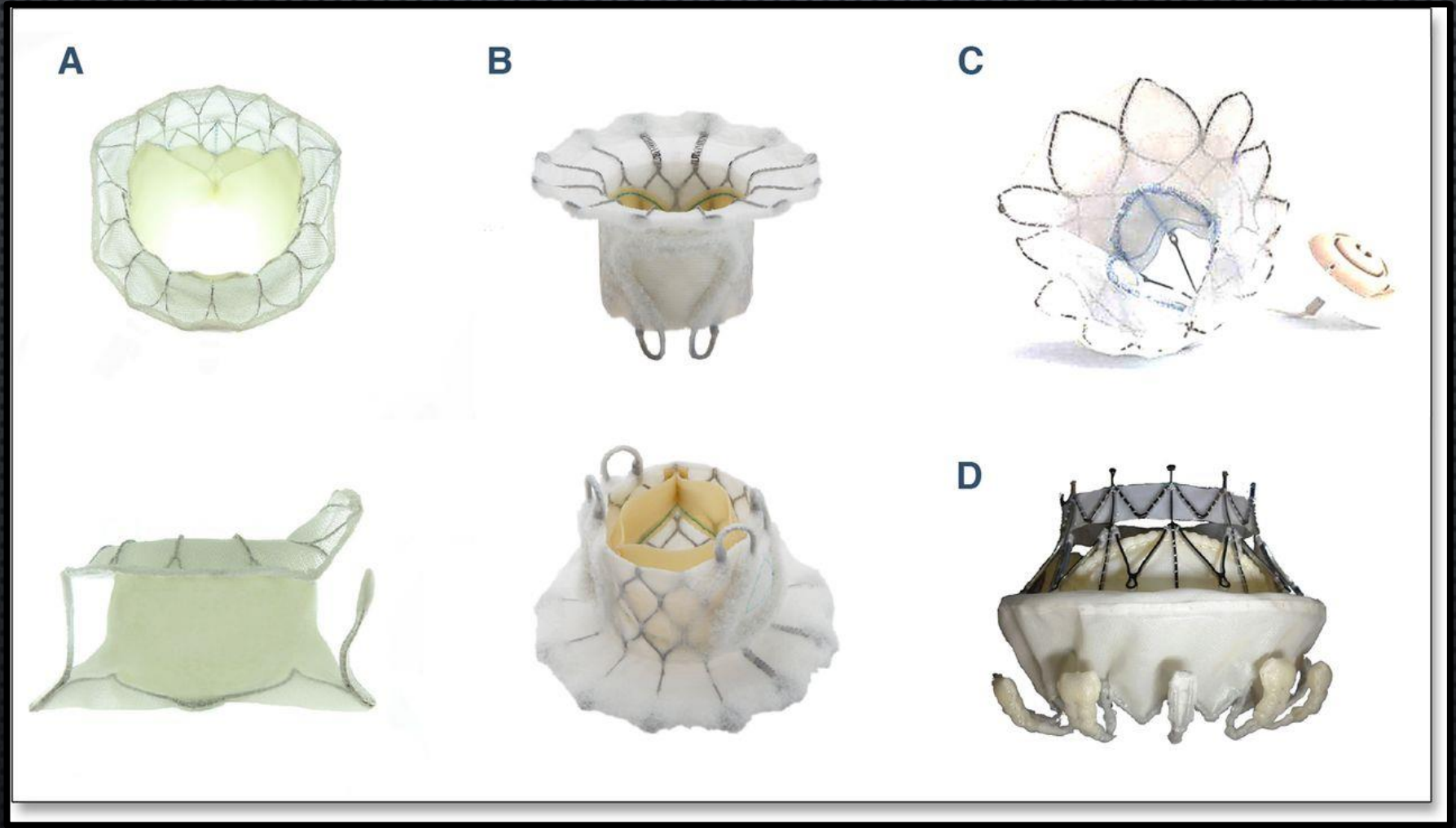
PERCUTANEOUS MITRAL ANNULOPLASTY
CARILLON
ANNULOPLASTY VIA CORONARY SINUS



PERCUTANEOUS MITRAL ANNULOPLASTY
CARDIOBAND(A) & MITRALIGN(B)
PERCUTANEOUS MITRAL ANNULOPLASTY



TRANSCATHETER MITRAL VALVE REPLACEMENT



Philipp Blanke et al. JIMG 2015;8:1191-1208

PIEDMONT ATHENS REGIONAL VALVE TEAM

Referrals to Valve Team: 706-475-1793

Summary

- Mitral Regurgitation is prevalent
- Significant under-treatment exists
- Refer Early
- Treatment options for high risk patients are limited
- Development of trans-catheter mitral valve replacement is in its infancy

QUESTIONS??

THANK YOU

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KHAN.POHLEL@PIEDMONT.ORG

CME QUESTIONS

1. HOW PREVALENT IS MITRAL VALVE DISEASE?

A. 9%
B. 20%
C. 1%
D. 50%

2. WHAT IS THE GOLD STANDARD OF MITRAL VALVE REGURGITATION TREATMENT?

A. Medical therapy with diuretics
B. Surgical repair
C. Percutaneous repair

3. Is heart failure readmission reduced with early mitral valve repair?

A. Yes
B. No

4. Percutaneous mitral valve repair is an option in patients with severe mitral regurgitation and prohibitive surgical risk.

A. True
B. False