

Percutaneous Mitral Interventions

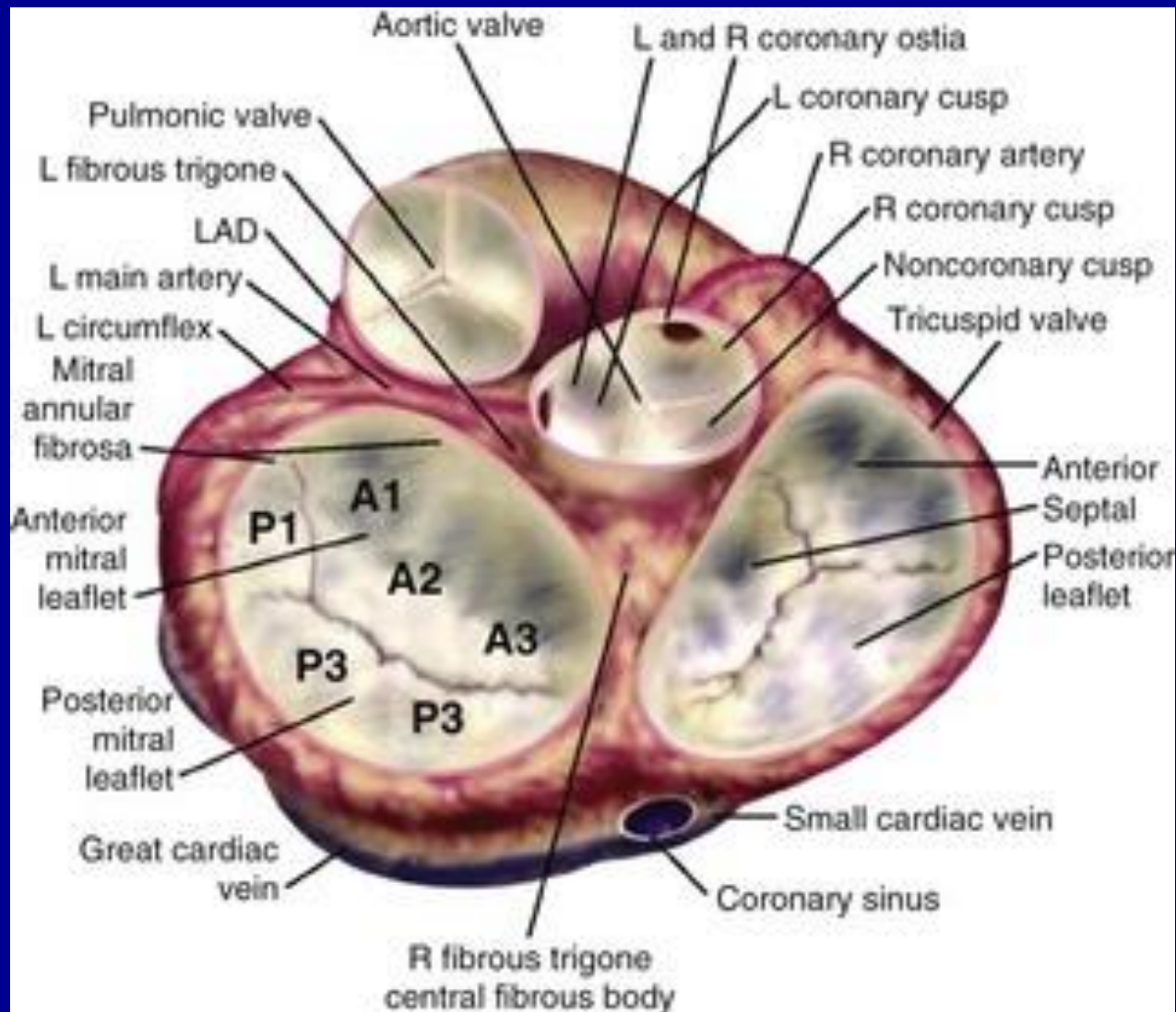
Yousef Bader

December 8 2017

Mitral Clip

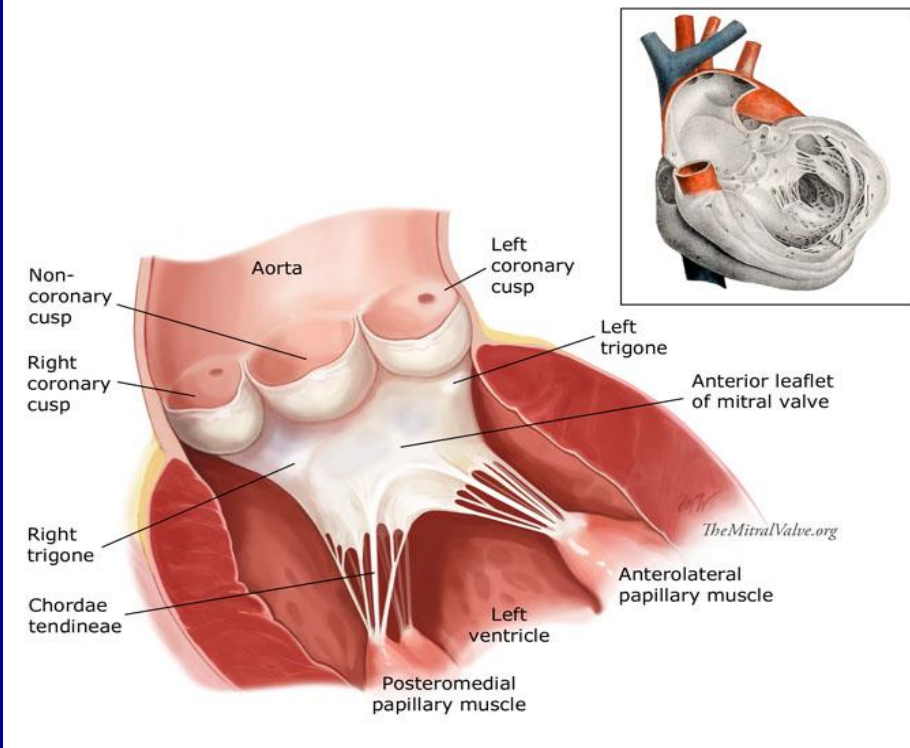
- What is the Mitral clip (Alfieri technique)
- Indications for mitral clip
- Multidisciplinary team approach
- Data supporting Mitral Clip (EVEREST trial)
- Future directions for percutaneous mitral valve repair

Mitral Valve Anatomy

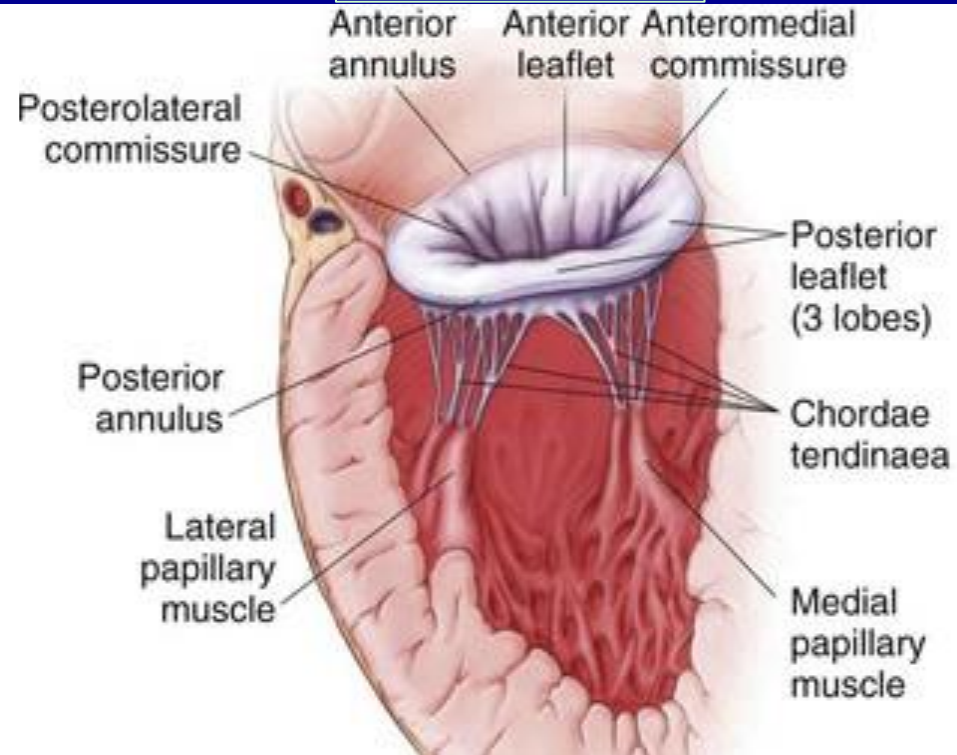


Mitral Valve Anatomy

Aortic Valve



Mitral Valve



Mitral Regurgitation

- Degenerative

- Disease of mitral valve structure

- Prolapse of a mitral leaflet
 - Flail leaflet

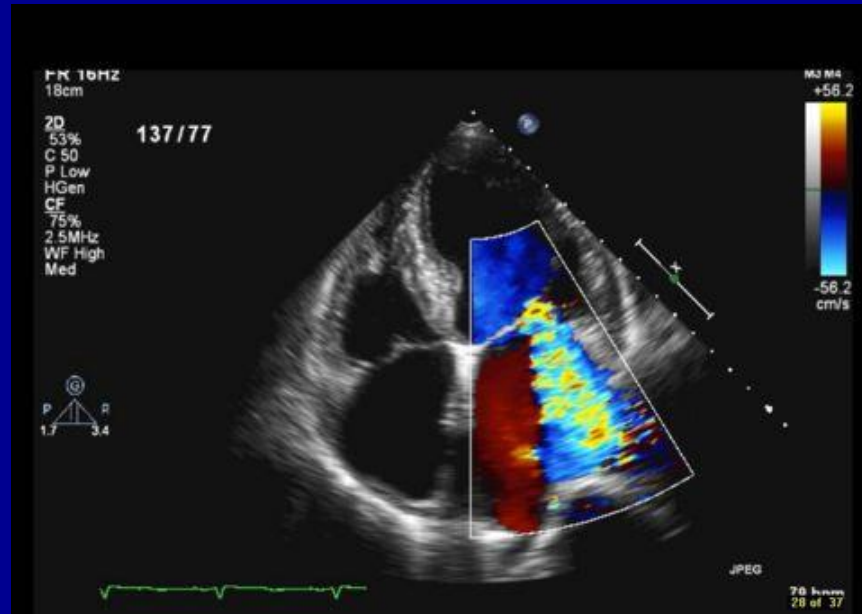
- Functional

- Disease of ventricle
 - Valve structure is normal

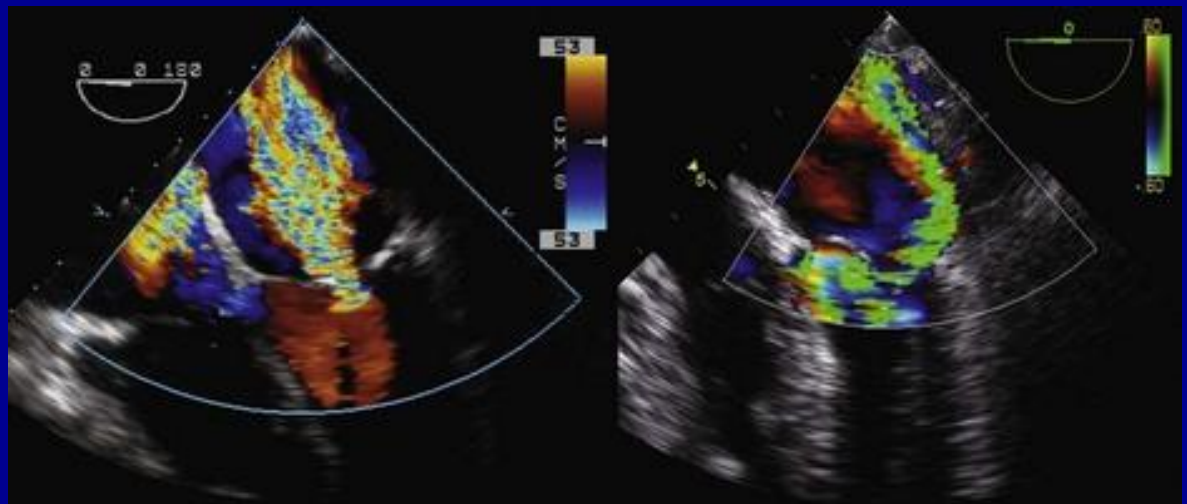
- Annular dilation
 - Papillary muscle dysfunction
 - Leaflet tethering

MR Characterization

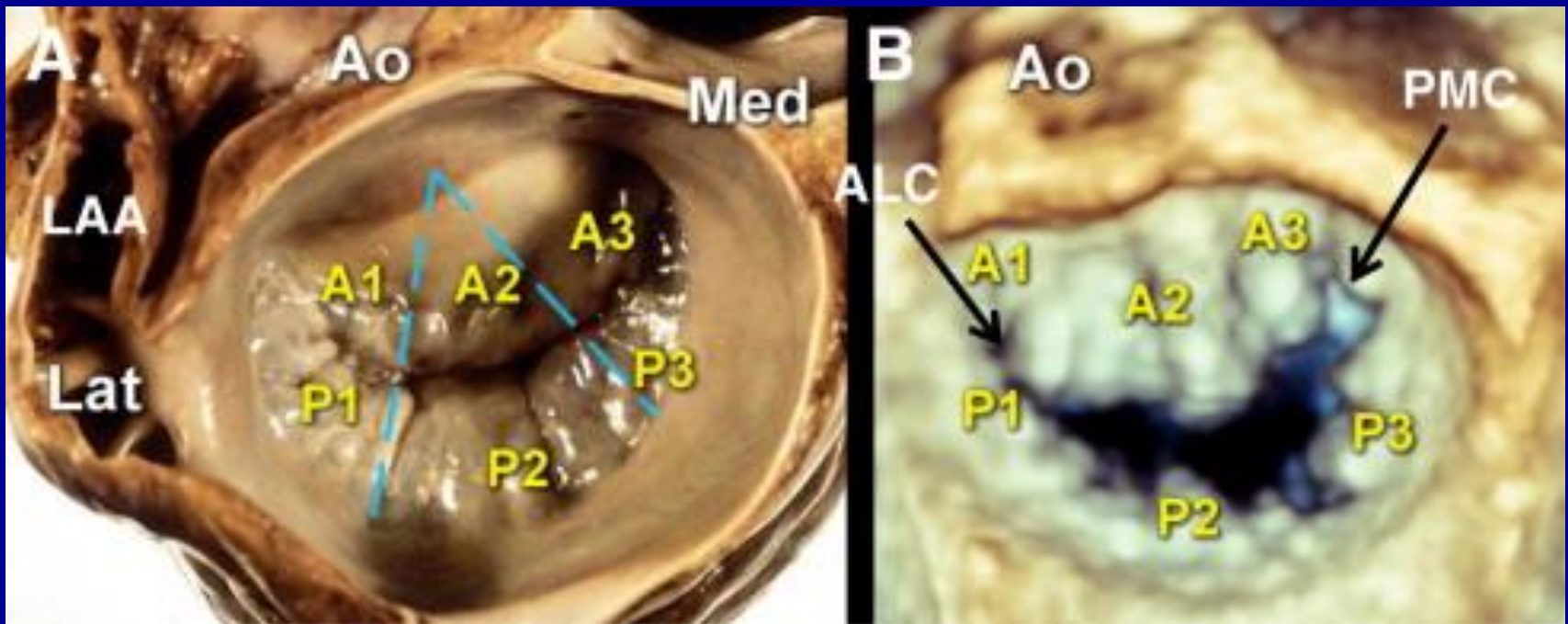
Diagnosis



Characterization



3D - Transesophageal Echo



Mitral Valve Management

1 Medical Therapy

Afterload Reduction: 1. ACE/ARB 2. Nitrates 3. Hydralazine

Management of CHF with diuretics

➤ Must be optimized on MT prior to other options

2 Mitral Valve Repair

3



3



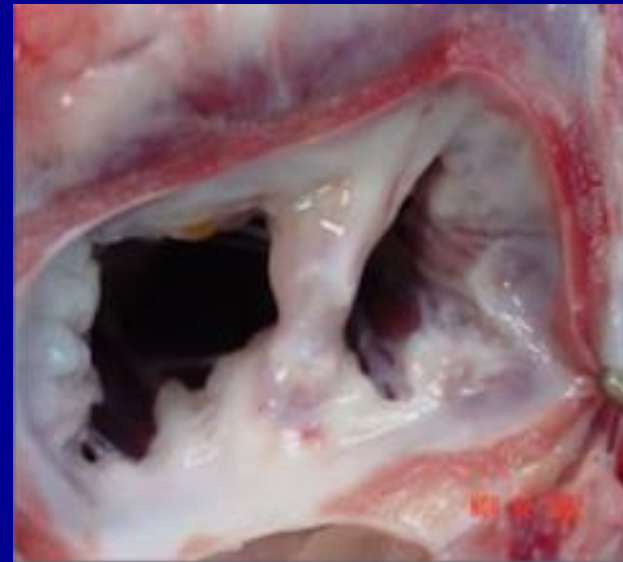
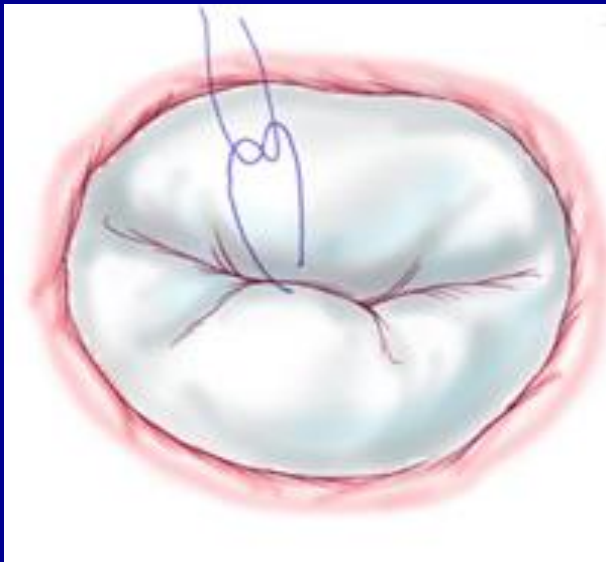
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Edge to Edge Mitral Repair

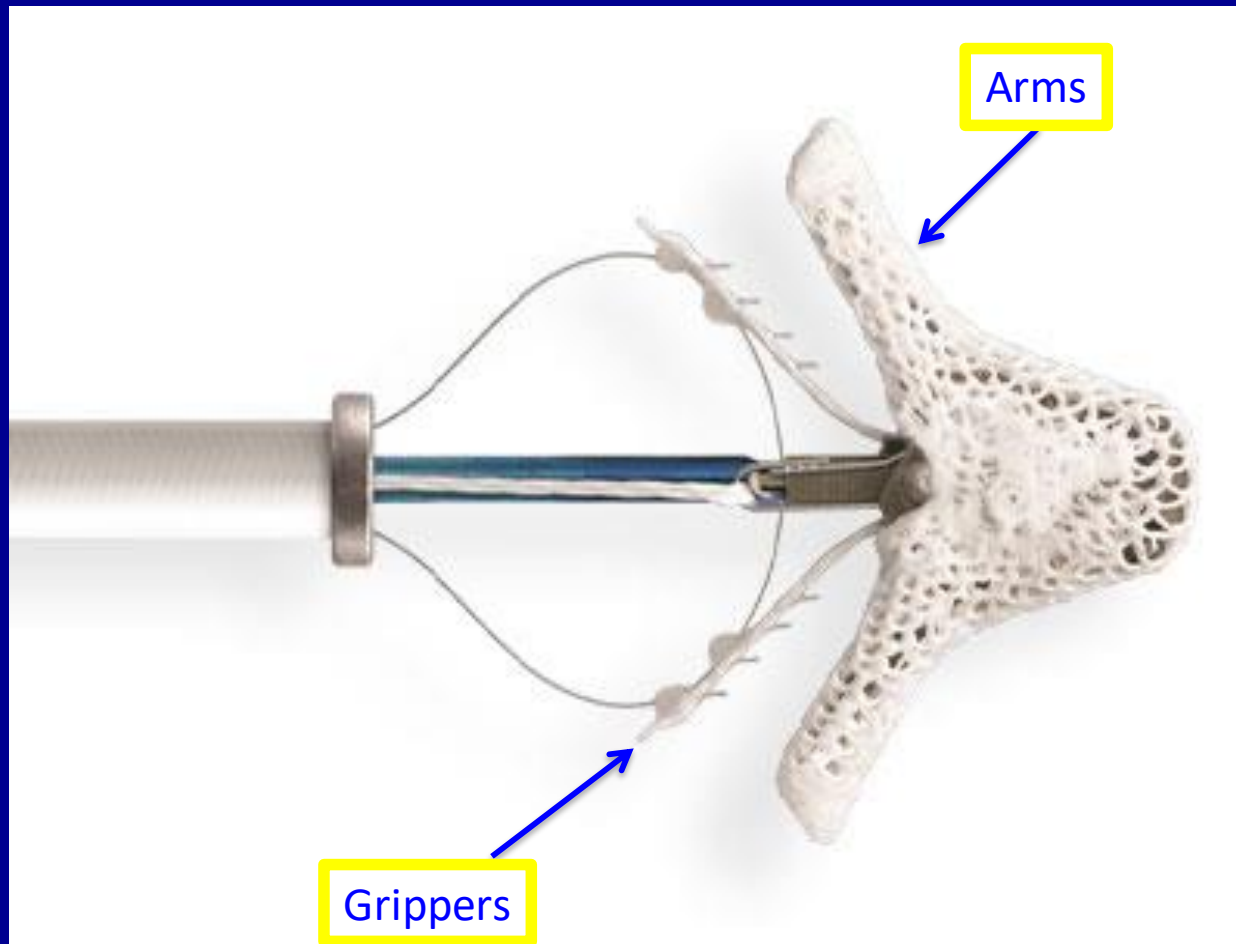
Alfieri technique

- Surgical technique developed in the early 1990s
- A suture between A2 and P2 segments

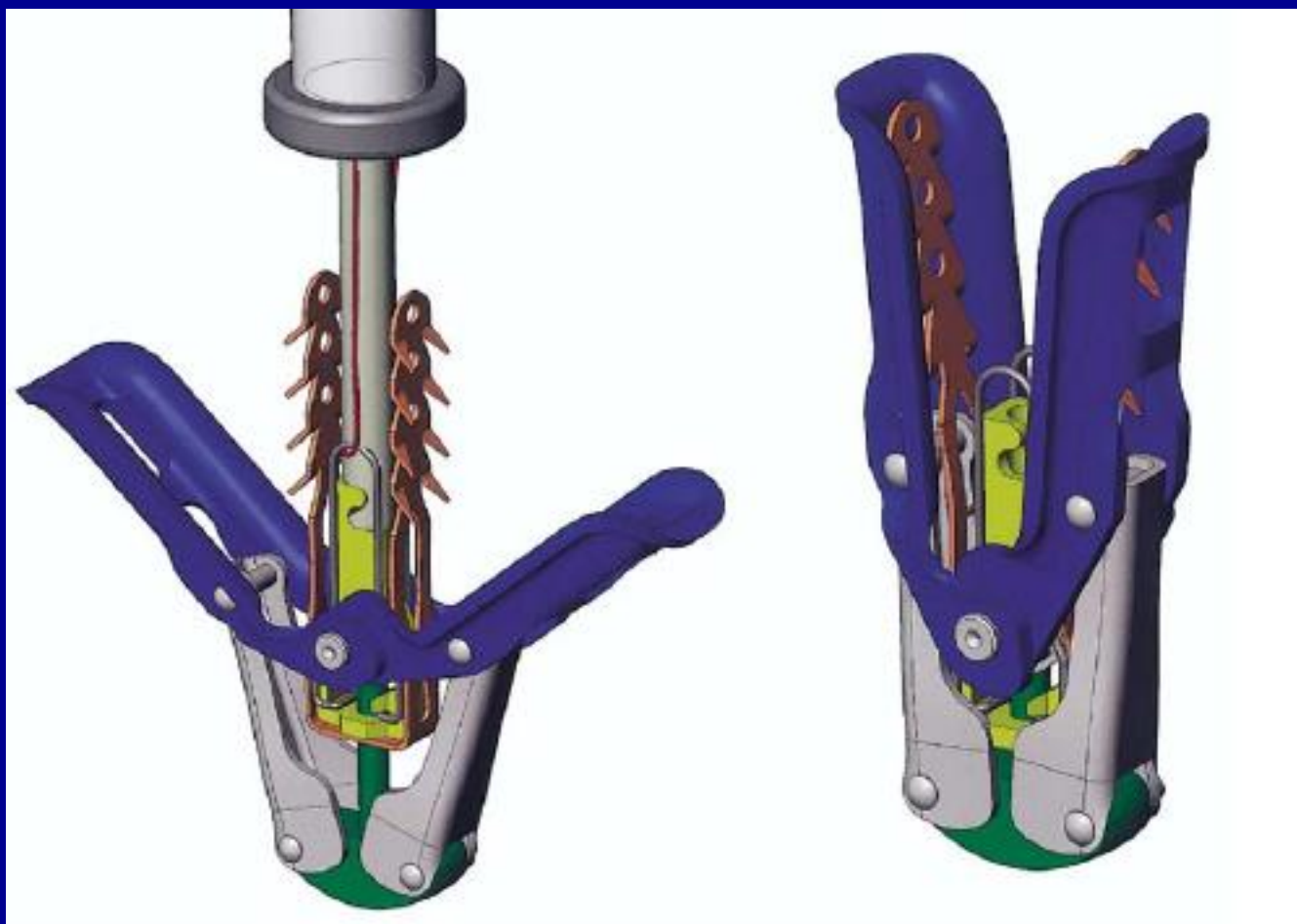


MitraClip: Percutaneous Edge to Edge

Percutaneous approach to Alfieri technique



MitraClip: Percutaneous Edge to Edge



MitraClip: Percutaneous Edge to Edge



Indications for Mitral Clip

1. The patient must have significant symptoms, NYHA class III or IV
2. The patient must be inoperable/prohibitive risk from a surgical standpoint
3. The patient must be optimized on medical therapy

IIb

B

Transcatheter mitral valve repair may be considered for severely symptomatic patients (NYHA class III to IV) with chronic severe primary MR (stage D) who have favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal GDMT for heart failure (HF) (124).

2014 recommendation remains current.

Patient Selection

After a patient is identified to have moderate to severe mitral regurgitation refractory to medical therapy



Referral for *Heart Team* evaluation

- Imaging Cardiologist
- Interventional Cardiologist
- Cardiac Surgeon
- Valve Coordinator

1. Is the patient symptomatic and optimized on medical therapy?
2. What is the patient's risk for open heart surgery?
3. If the patient were to go for surgery, are they likely to undergo mitral valve repair or are they likely to get a mitral valve replacement?
4. Is their anatomy suitable for mitral clip (Degenerative)?

Optimal Medical Therapy

1. Diuretics

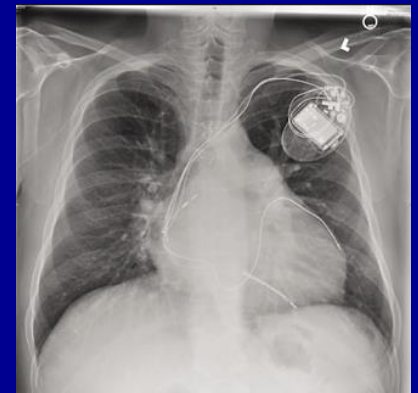
1. Afterload reduction

- ACE Inhibitors
- Nitrates
- Hydralazine

How do we know the patient is on maximal tolerated medical therapy?

→ Blood pressure should be low 100s systolic

3. Cardiac Resynchronization Therapy



Operative Risk

Frailty Metrics:

- 5 Meter walk test
- ADLs
- Albumin
- Grip Strength

Other Factors:

- Advanced dementia
- Severe liver disease
- Malignancy
- Life expectancy
- Anemia
- Debility

- Left ventricular ejection fraction
- THE EYEBALL TEST

Operative Risk

Surgical MV Repair

<input type="radio"/> CAB Only	RISK SCORES <small>About the STS Risk Calculator</small> Procedure: MV Repair
<input type="radio"/> AV Replacement	
<input type="radio"/> MV Replacement Only	
<input checked="" type="radio"/> MV Repair	
<input type="radio"/> AV Replacement + CAB	
<input type="radio"/> MV Replacement + CAB	
<input type="radio"/> MV Repair + CAB	
Patient Age 82	
Sex <input type="radio"/> Male <input checked="" type="radio"/> Female	
Risk of Mortality: 1.926%	
Morbidity or Mortality: 14.349%	
Long Length of Stay: 7.562%	
Short Length of Stay: 24.302%	
Permanent Stroke: 1.686%	
Prolonged Ventilation: 7.084%	
DSW Infection: 0.192%	
Renal Failure: 2.809%	
Reoperation: 7.262%	

MV Replacement

<input type="radio"/> CAB Only	RISK SCORES <small>About the STS Risk Calculator</small> Procedure: MV Replacement Only
<input type="radio"/> AV Replacement	
<input checked="" type="radio"/> MV Replacement Only	
<input type="radio"/> MV Repair	
<input type="radio"/> AV Replacement + CAB	
<input type="radio"/> MV Replacement + CAB	
<input type="radio"/> MV Repair + CAB	
Patient Age 82	
Sex <input type="radio"/> Male <input checked="" type="radio"/> Female	
Risk of Mortality: 3.488%	
Morbidity or Mortality: 20.315%	
Long Length of Stay: 9.461%	
Short Length of Stay: 16.834%	
Permanent Stroke: 1.686%	
Prolonged Ventilation: 11.114%	
DSW Infection: 0.192%	
Renal Failure: 3.351%	
Reoperation: 9.988%	

Mitral Valve Repair or Replacement

Surgery:

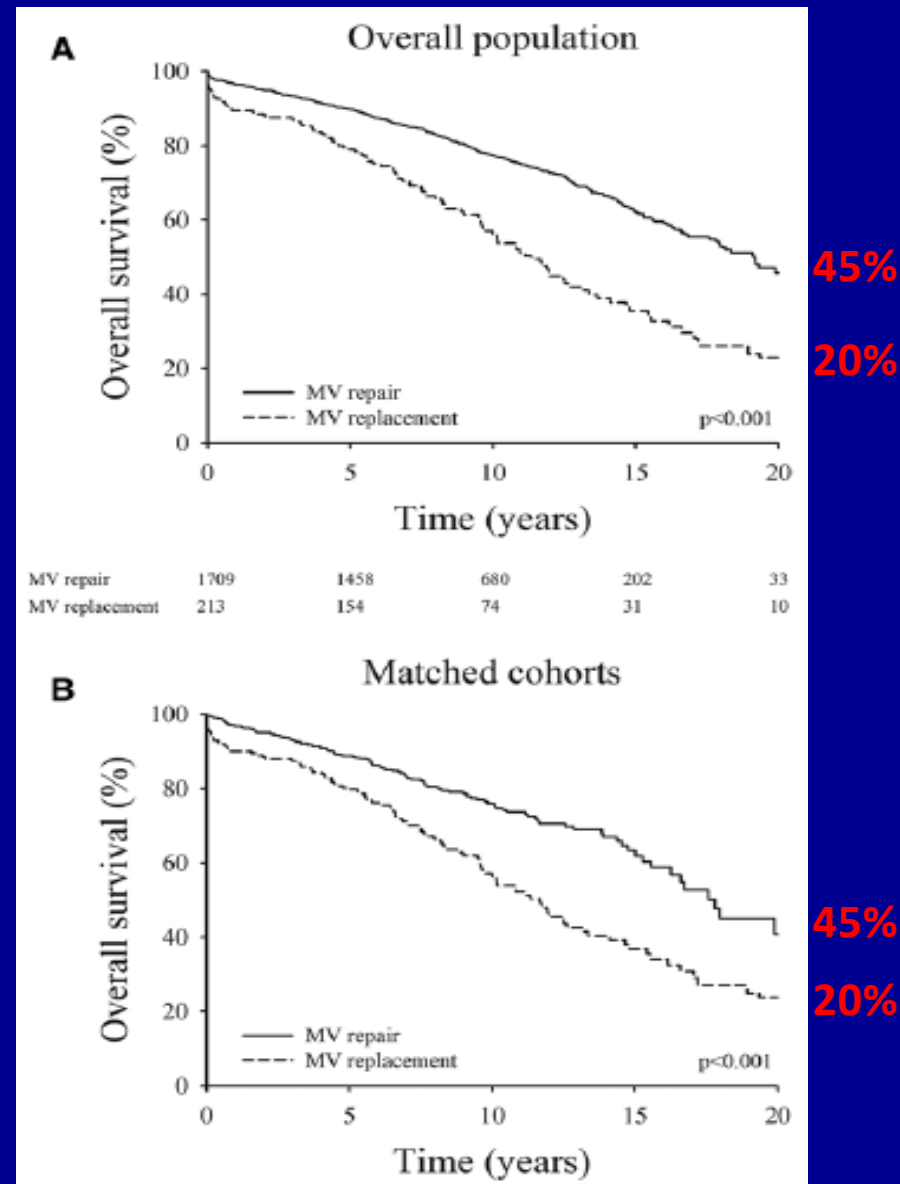
- Posterior leaflet pathology is usually successfully treated with surgical repair, anterior leaflet pathology often ends in replacement

Advantages of mitral valve repair:

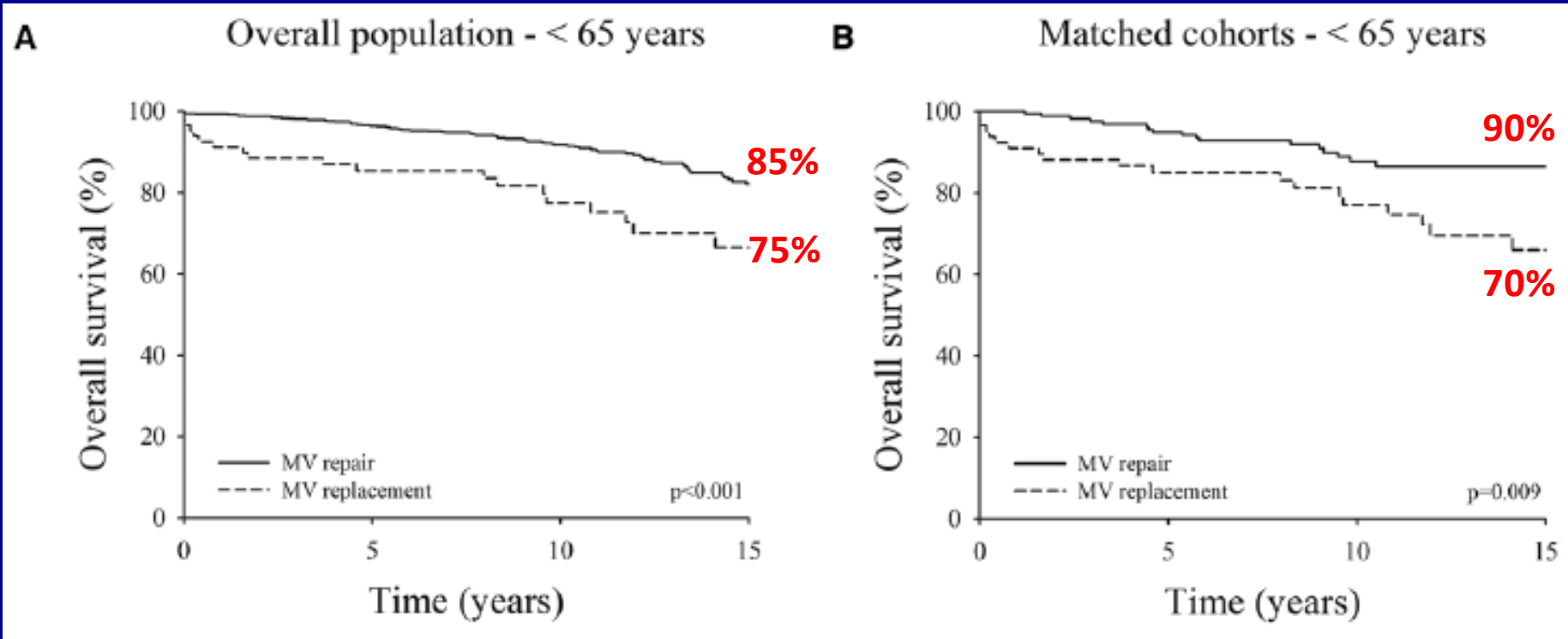
1. Lower operative mortality
2. Improved preservation of left ventricular function
3. Greater freedoms from prosthetic valve-related complications:
 - thromboembolism
 - anticoagulant-related hemorrhage
 - Endocarditis

Mitral Valve Repair or Replacement

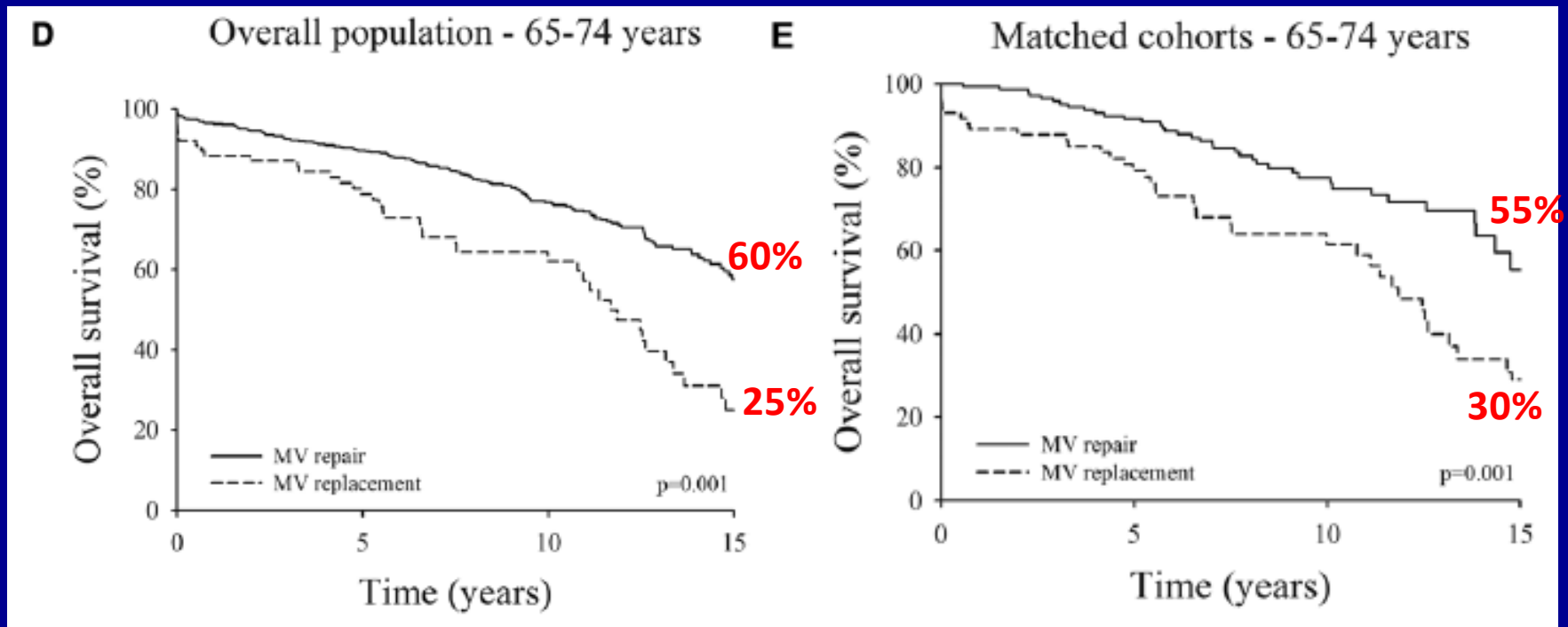
- Prospective multicenter registry data
- 2000 patients
- Followed for 20 years



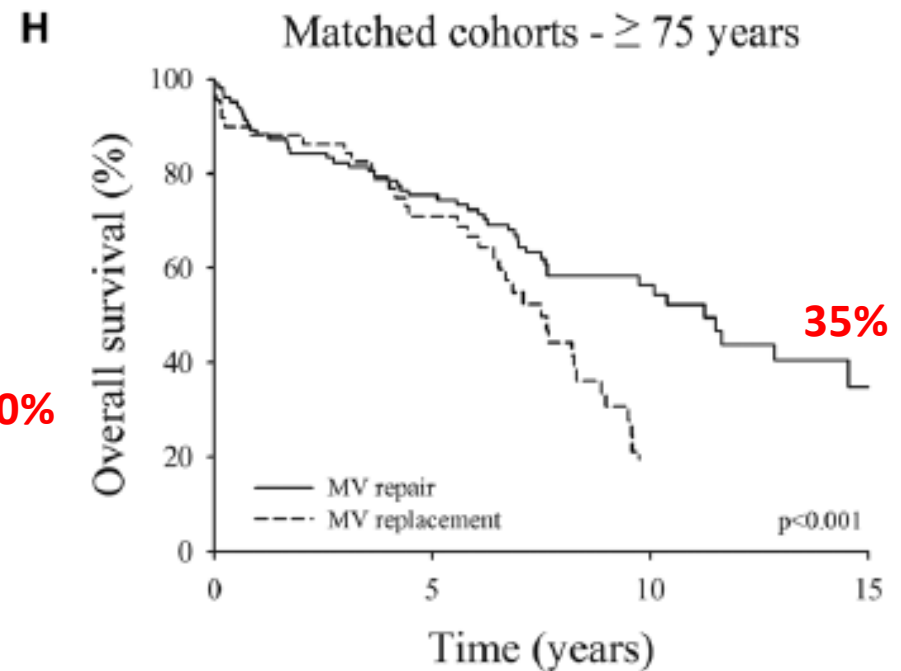
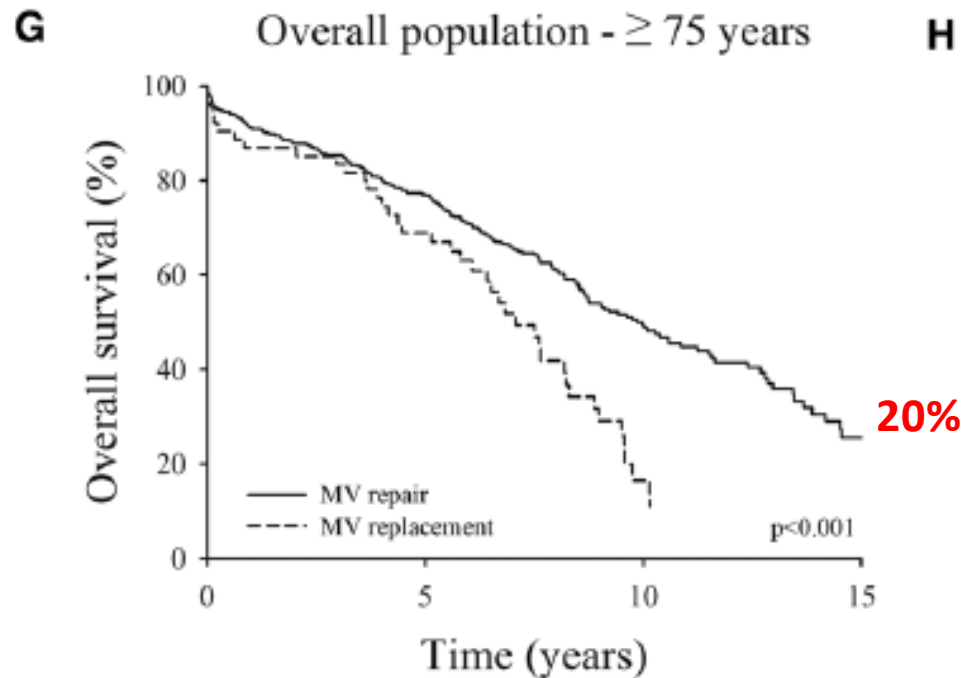
Mitral Valve Repair or Replacement



Mitral Valve Repair or Replacement



Mitral Valve Repair or Replacement



Guidelines

I

B

Mitral valve repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR limited to the posterior leaflet (83-99).

2014 recommendation remains current.

I

B

Mitral valve repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR involving the anterior leaflet or both leaflets when a successful and durable repair can be accomplished (84,89,95,100-104).

2014 recommendation remains current.

Suitability for Mitral Clip

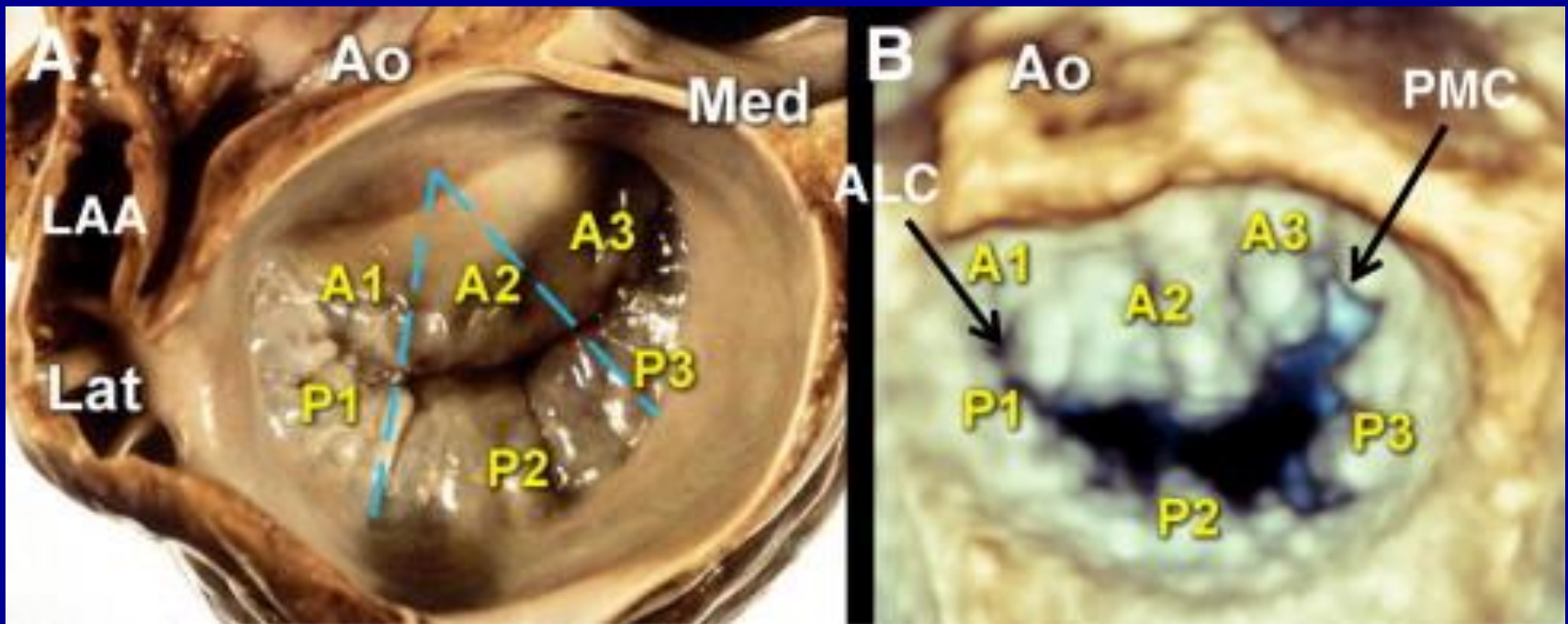
Good Mitral Clip Candidates:

- Central, relatively narrow prolapse or flail segments
- Effective for anterior and posterior leaflet pathology

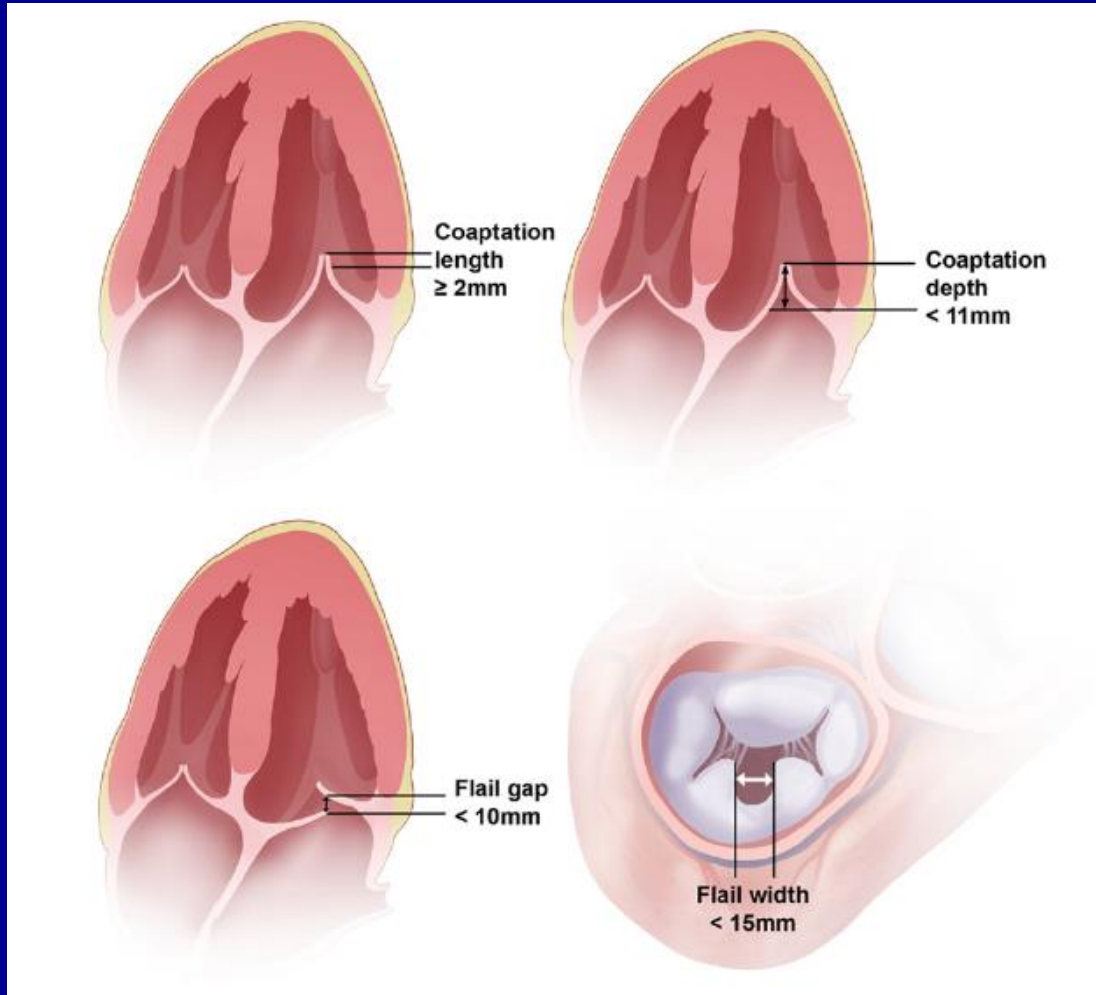
More Difficult Mitral Clip Candidates:

- Very wide flails
 - Calcification at the leaflet tip
 - Very short anterior or posterior mitral leaflet
 - Commissural flail segment
-
- Baseline mitral valve area of $< 4 \text{ cm}^2$ are at risk of developing significant mitral stenosis post clip

3D - Transesophageal Echo

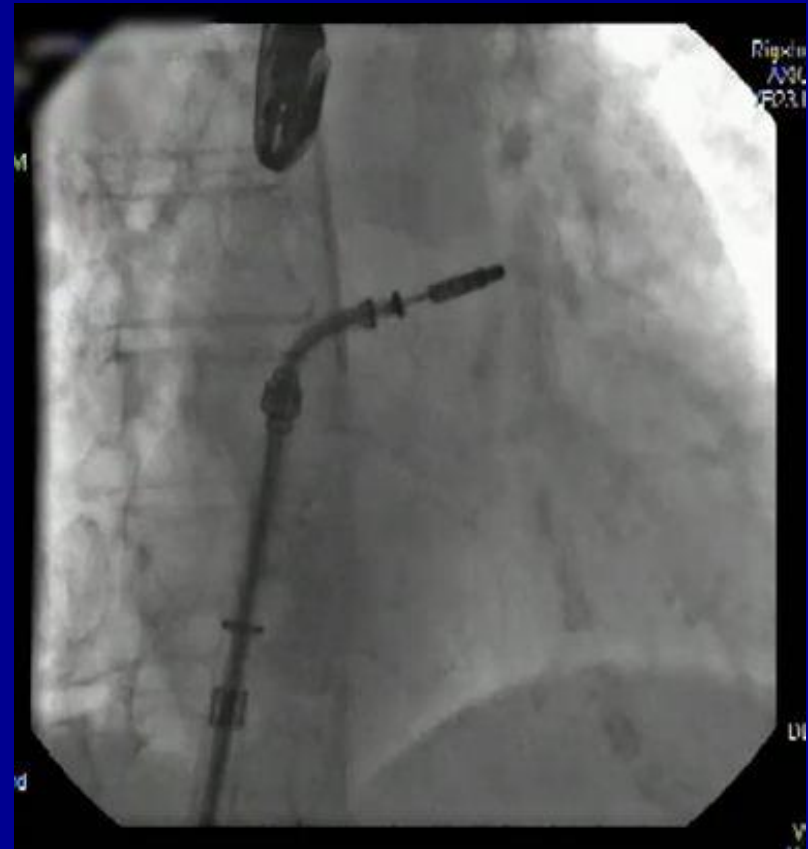
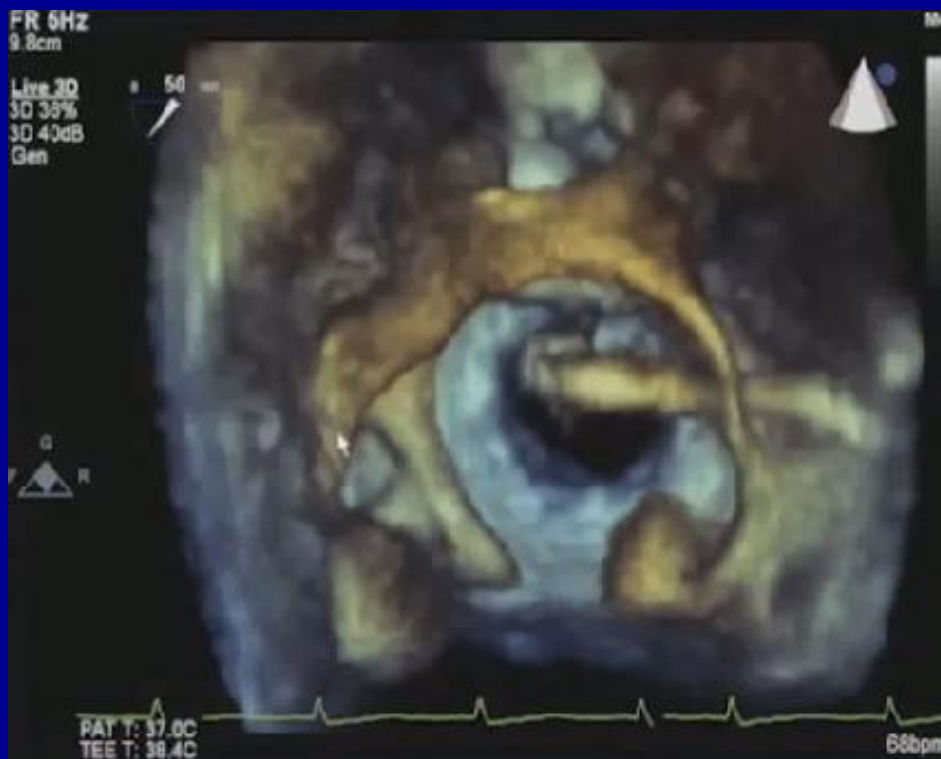


Anatomic Eligibility



- Coaptation length must be $\geq 2\text{mm}$
- Coaptation depth $< 11\text{mm}$
- Flail gap $< 10\text{mm}$
- Flail width $< 15\text{mm}$
- We can work around the above because now we know we can safely place two clips

MitraClip Case



EVEREST I Trial

(Endovascular Valve Edge-to-edge Repair Study)

- Goal was to demonstrate safety and efficacy in 107 pts

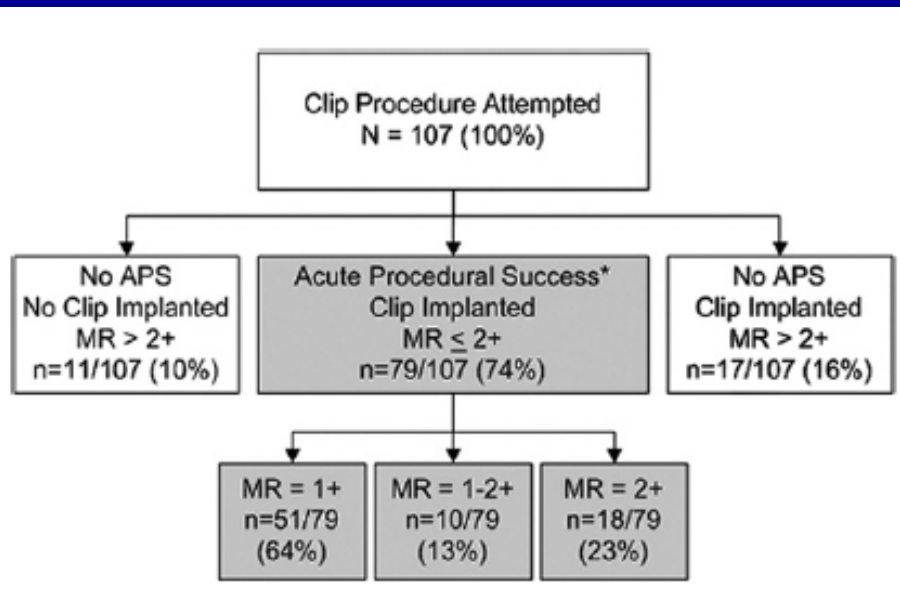


Table 4 In-Hospital Outcomes

In-Hospital Outcomes*	Incidence (n = 107)
Death unrelated to MitraClip device	1 (0.9)†
Mechanical ventilation >48 h	2 (1.8)†‡
Bleeding requiring transfusion ≥2 U (procedural)	4 (3.7)‡
Bleeding requiring transfusion ≥2 U (post-MV surgery)	1 (0.9)
Transseptal complications	3 (2.8)‡
Renal failure or dialysis	0 (0)
Length of hospital stay, days	3.2 ± 3.9
Discharge home (without home health care)	104 (98)

EVEREST II Trial

- Randomizing 279 patients to surgery vs Mitral Clip
- Endpoints:
 - Freedom from death
 - Freedom from 3+ or 4+ MR
 - MACE
- Conclusions
 - Slightly more 3+/4+ MR in mitral clip group
 - Clinical outcomes were comparable

EVEREST II Trial

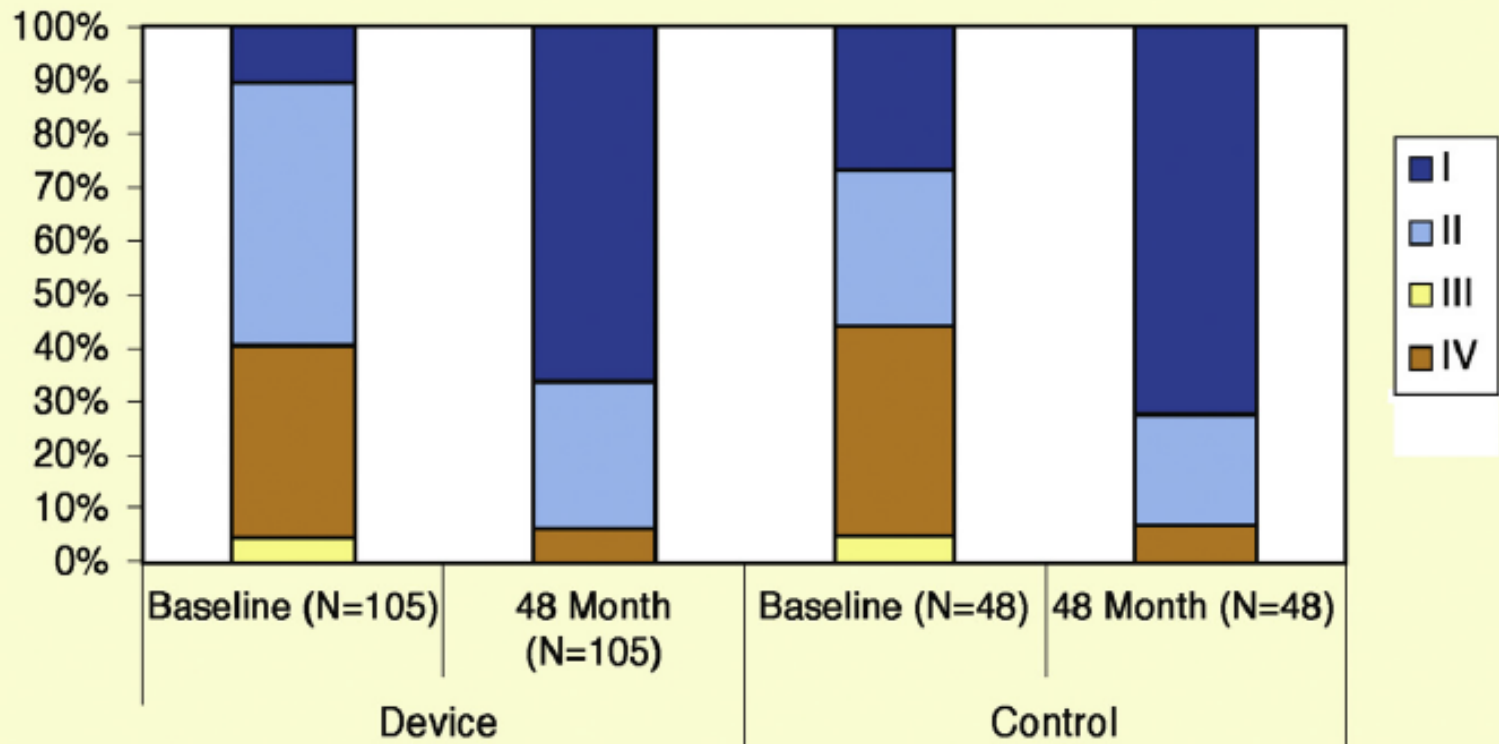
Table 2. Primary Efficacy End Point at 12 Months and Major Adverse Events at 30 Days in the Intention-to-Treat Population.*

Event	Percutaneous Repair no. (%)	Surgery	P Value
Primary efficacy end point			
Freedom from death, from surgery for mitral-valve dysfunction, and from grade 3+ or 4+ mitral regurgitation†	100 (55)	65 (73)	0.007
Death	11 (6)	5 (6)	1.00
Surgery for mitral-valve dysfunction‡	37 (20)	2 (2)	<0.001
Grade 3+ or 4+ mitral regurgitation	38 (21)	18 (20)	1.00
Major adverse event at 30 days§			
Any major adverse event	27 (15)	45 (48)	<0.001¶
Any major adverse event excluding transfusion	9 (5)	9 (10)	0.23
Death	2 (1)	2 (2)	0.89
Myocardial infarction	0	0	NA
Reoperation for failed surgical repair or replacement	0	1 (1)	0.74
Urgent or emergency cardiovascular surgery for adverse event	4 (2)	4 (4)	0.57
Major stroke	2 (1)	2 (2)	0.89
Renal failure	1 (<1)	0	1.00
Deep wound infection	0	0	NA
Mechanical ventilation for >48 hr	0	4 (4)	0.02
Gastrointestinal complication requiring surgery	2 (1)	0	0.78
New onset of permanent atrial fibrillation	2 (1)	0	0.78
Septicemia	0	0	NA
Transfusion of ≥2 units of blood	24 (13)	42 (45)	<0.001

EVEREST II Trial: 4 yr f/u

B

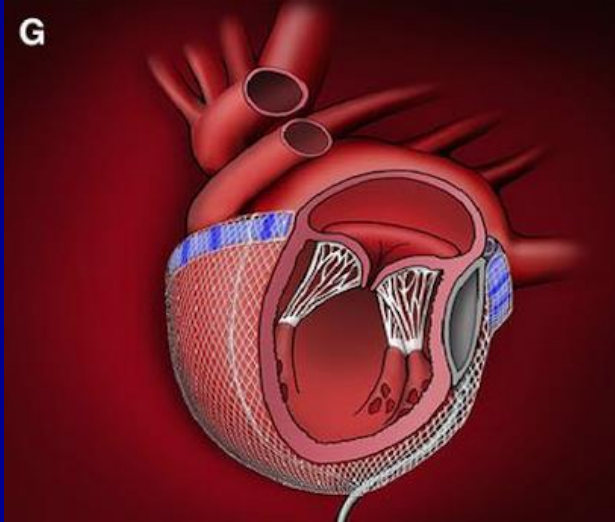
NYHA Functional Class at Baseline and 48 Months



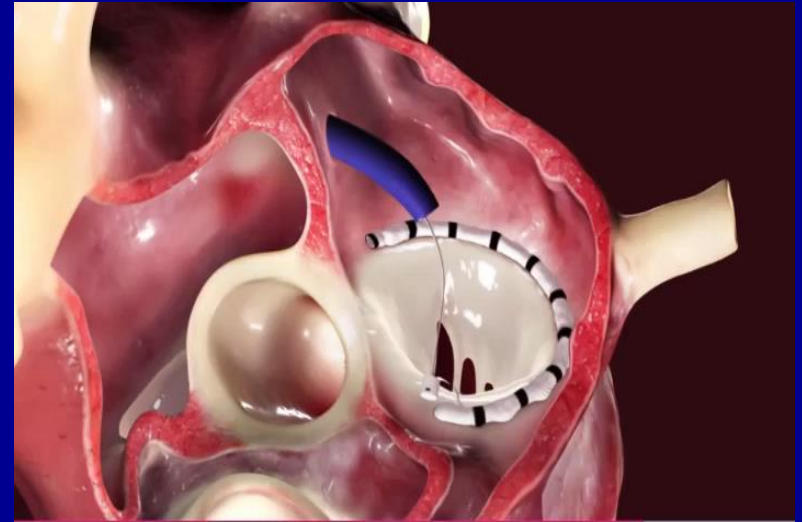
Expected Real World Results

1. Multiple clips can be used
2. Expect some residual mitral regurgitation
3. Interpretation of post procedural imaging is not easy

Future Directions



Ancora mitral valve repair



Percutaneous Mitral Band Edwards



Millipede direct annuloplasty



Ventouch system

Thank you

- I am always available:
 - Pager: 929-1401
 - Cell phone: 202-258-8309
 - Direct office line: 989-894-6913