Mitraclip: step by step

Vlasis Ninios
Conflict of interest

- Abbott proctor for Mitraclip
Spectrum of Mitral Regurgitation

Mitral Regurgitation

Functional Mitral Regurgitation (FMR)
- LV Dysfunction Dilated Annulus
  (Non-ischemic or ischemic dilated cardiomyopathy)
- LA Dysfunction Dilated Annulus
  (Chronic atrial fibrillation, hypertension)

I
- Loss of leaflet coapation due to:
  - annular enlargement
  - Papillary muscle displacement causing leaflet tethering/tenting

Degenerative Mitral Regurgitation (DMR)
- Etiologies:
  - Advanced Barlow’s Disease
  - Fibroelastic deficiency
- Leaflet prolapse due to:
  - Leaflet deformities or lesions
  - Ruptured/elongated chordae
  - Papillary muscle rupture

II

IIIb/IIla
Overview of mitral regurgitation and time impacts

MR is a progressive disease that increases in severity over time

As MR becomes more severe, morbidity and mortality risk increases

Earlier treatment improves outcomes

‘a paradigm shift is occurring in the timing of intervention for patients with chronic MR.’


Mitral regurgitation (MR) progresses to Heart Failure

MR initiates a cascade of events progressing to heart failure, then death, if left untreated.\textsuperscript{2,3}

In organic MR, progression of MR occurs over time, at an average rate of 7.4 ml/year, 2.9%/year and 5.9 mm$^2$/year for RVol, RF and ERO, respectively.\textsuperscript{4}

4 Enriquez-Sarano – Progression of Mitral regurgitation – JACC 1999: Vol. 34, No4
RVol : Regurgitant volume - RF: Regurgitant Fraction – ERO: Effective Regurgitant Orifice
As mitral regurgitation becomes more severe, morbidity and mortality risk increases.

**Event – free survival decreases with increasing MR severity**

![Graph showing event-free survival decreases with increasing MR severity]

**Risk of mortality increases with increasing NYHA class**

![Graph showing cumulative risk of all-cause mortality increases with increasing NYHA class]


Ahmed A et al. - Higher NYHA Classes and increased mortality and hospitalisation in HF patients with preserved LV function - Am Heart J. 2006 151: 444–50
Early surgical intervention improves outcomes

10-year overall survival of asymptomatic MR patients was significantly greater with early surgery vs. medical management.

“early intervention to prevent left ventricular systolic dysfunction or pulmonary hypertension provides optimal clinical outcomes”.

Otto, C. Heart 2003

Mild regurgitation needs echocardiographic examinations, about every 5 years.¹

Moderate MR and normal LV size should be examined every 1–2 years.¹

Severe or if “moderate” regurgitation is accompanied by left ventricular dilation should be examined annually.¹

Surgical Options for MR Treatment

- Annuloplasty ($n = 13$)
- Papillary muscle fenestration ($n = 8$)
- Open bilateral commissurotomy ($n = 5$)
- Quadrangular posterior leaflet valve resection ($n = 4$)
- Cleft closure ($n = 4$)
- Mitral supravalvular membrane resection ($n = 3$)
- Anterior mitral valve leaflet repair ($n = 3$)

(aortic valve, pulmonary artery, left atrium, left ventricle, healthy mitral valve, healthy tricuspid valve, right ventricle, muscle wall of heart, replacement mechanical valve, replacement biological valve)
Primary MR-DMR: Repair better than Replacement


- The operative mortality was lower in the MV repair group (0.2% vs. 4.4%, P< 0.001) and 20-year survival was better (41% vs. 24%, P< 0.001).
Relative Sizes of Clinical Needs
Primary vs Functional MR

Expected WW Ann. Incidence

Degenerative MR
~650,000

Functional MR
~2,570,000

Cardiac Dimensions
Guided Delivery Systems
- Mitralign
- Myocor
- Viacor
- Ample
- Edwards
- e-Valve
- others
Management of patients with severe MR

- FMR Medical Rx: 47.5%
- DMR Medical Rx: 3.3%
- Other Medical Rx: 1.9%
- FMR MV Surgery: 26.8%
- DMR MV Surgery: 17.4%
- Other MV Surgery: 3.1%

(Goel et al. J Am Coll Cardiol 2014;63:185–90.)
Surgery may be high risk

Mitral valve replacement in elderly patients

Hemodynamic Instability?

No

Renal Failure?

No

NYHA Class IV?

No

Concomitant CABG?

Yes

N Mortality

997
31.9

589
25.3

1597
15.7

2207
11.4

2535
7.7

(Mehta, Ann Thorac Surg 2002)
Surgical Repair for Functional MR: Annuloplasty
IMR Recurrence After Surgical Annuloplasty
n=585

68% Cosgrove band, 21% Carpentier ring, 11% Peri-Guard

McGee et al. CVS 2004.
Annuloplasty Does Not Add To Survival In Ischemic MR

Propensity matched survival

Recurrent 3-4+ MR

- 390 patients undergoing surgical revascularization at CCF treated with (N=290) or without (N=100) annuloplasty:
- No difference in survival or symptoms
- Recurrent severe MR lower with annuloplasty, but still 20% at 5 years

Mihaljevic et al, JACC 2007;49:2191
Mitral-Valve Repair versus Replacement for Severe Ischemic Mitral Regurgitation

Edge-to-Edge repair with the MitraClip (Abbott Vascular)
Figure 3  Key Anatomic Eligibility Criteria

The coaptation length must be at least 2 mm. Coaptation depth must be <11 mm. If a flail leaflet exists, the flail gap must be ≤10 mm, and the flail width must be ≤15 mm. These anatomic characteristics are necessary for sufficient leaflet tissue for mechanical coaptation when the MitraClip device is used.
# Mitral Valve Suitability 3D TEE

German Society Cardiology Manual and Guidelines 2013

<table>
<thead>
<tr>
<th>Optimal</th>
<th>Easy</th>
<th>Limited suitable</th>
<th>Inappropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathology in segment 2</td>
<td>Pathology in segment 1 or 3</td>
<td>Leaflet perforation or cleft</td>
<td></td>
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<tr>
<td>No calcification</td>
<td>- Slight calcification outside the grasping area</td>
<td>Severe calcification</td>
<td></td>
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<tr>
<td>- Ring calcification</td>
<td>- Anuloplasty with ring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valve area &gt;4cm²</td>
<td>Valve area &gt;3 cm² &amp; good leaflet mobility</td>
<td>Mitral stenosis (&lt; 3cm², gradient &gt;5mmHg)</td>
<td></td>
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<tr>
<td>Length of the posterior leaflet &gt; 10mm</td>
<td>Length of the posterior leaflet 7-10mm</td>
<td>Length of the posterior leaflet &lt; 7mm</td>
<td></td>
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<tr>
<td>Coaptation depth &lt; 11mm</td>
<td>Coaptation depth &gt;11mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal thickness and mobility of the leaflets</td>
<td>Restriction (Carpentier IIIB)</td>
<td>Rheumatic thickening and restriction (Carpentier IIIA)</td>
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</tr>
<tr>
<td>MR with prolaps</td>
<td>Flail size &gt;15mm only with large mitral anulus and option for more than one clip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flail size &lt; 15mm</td>
<td>Flail gap &lt; 10mm</td>
<td></td>
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</tr>
</tbody>
</table>

MitraClip in Specific Patient Populations

Patient groups in which significant clinical benefits have been reported:

- Degenerative MR, declined for surgery\(^1\)
- Severe LV dysfunction refractory to medical therapy\(^2\)
- Severe Heart Failure, despite optimal medical therapy\(^3\)
- CRT non-responders\(^4\)
- Bivalvular Disease: Severe Aortic Stenosis and Mitral Regurgitation\(^5\)

\(^{1}\) data on file at Abbott Vascular

\(^{2}\) data on file at Abbott Vascular

\(^{3}\) data on file at Abbott Vascular

\(^{4}\) data on file at Abbott Vascular

\(^{5}\) data on file at Abbott Vascular
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Cohort</th>
<th>Age (years)</th>
<th>LV EF</th>
<th>Etiology</th>
<th>MR grade</th>
<th>NYHA</th>
<th>Logistic EuroSCORE</th>
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</thead>
<tbody>
<tr>
<td>DMR declined for Surgery(^1)</td>
<td>117</td>
<td>75±12.1</td>
<td>&gt;40%</td>
<td>DMR</td>
<td>3+4+</td>
<td>III-IV(74%)</td>
<td>15.5±13.3</td>
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<tr>
<td>Severe LV dysfunction refractory to medical therapy(^2)</td>
<td>51</td>
<td>74±10</td>
<td>34±19</td>
<td>69%FMR</td>
<td>3+4+</td>
<td>III-IV</td>
<td>33±23</td>
</tr>
<tr>
<td>Severe Heart Failure, despite optimal medical therapy(^3)</td>
<td>50</td>
<td>70±11</td>
<td>19±5</td>
<td>FMR</td>
<td>3+4+</td>
<td>III - IV</td>
<td>34%</td>
</tr>
<tr>
<td>CRT Non-responders(^4)</td>
<td>51</td>
<td>70.26±9.1</td>
<td>27.1±8.7</td>
<td>73%FMR</td>
<td>3+4+</td>
<td>III - IV</td>
<td>29.7±19.6</td>
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<td>Bivalvular disease(^5)</td>
<td>11</td>
<td>78±6</td>
<td>36±13</td>
<td>45%FMR</td>
<td>3+4+</td>
<td>III-IV(91%)</td>
<td>25</td>
</tr>
</tbody>
</table>

Significant clinical benefits have been reported in Degenerative MR, declined for surgery

- 94.9% successful implant rate (117 patients)
- MitraClip therapy reduced symptoms and enhanced quality of life in patients deemed inoperable or at high surgical risk
- Significant clinical benefit in NYHA functional class, and improvement in 6MWT and MLHFQ

**CLINICAL IMPROVEMENTS at 12 months**

- **MR GRADE**: ~75% less than or equal to 2+ (78 patients paired data)
- **NYHA CLASS**: 80.8% in class I or II (78 patients paired data)
- **MLHFQ SCORE**: Mean Improvement of -13 points (44 patients paired data)

**6 MINUTE WALK TEST**

- Median of 324 meters at 12 months
- 78 meters at baseline (2+)
- Median of 246 meters at baseline (P<0.0001) (52 patients paired data)
Significant clinical benefits have been reported in Severe LV dysfunction refractory to medical therapy

- Procedural success achieved in 96% of patients (51 patients)
- Reduction in MR, although moderate in most patients, drove significant clinical improvement

**CLINICAL IMPROVEMENTS at discharge**

94% of patients had MR2+ or less

Significant clinical benefits have been reported in Severe Heart Failure despite optimal medical therapy

- 94% successful implant rate (cohort of 50 patients)
- Improved short-term survival related to NYHA functional class
- Significant improvements in 6-minute walk test, MLHFQ score, and NT-proBNP plasma levels, as well as EF, LV ESV and LVEDV which supports reverse remodeling of the LV

**THERAPY OUTCOMES**

- 94% Success

**CLINICAL IMPROVEMENTS at 6 months**

- **MR GRADE**
  - 87% less than or equal to 2+

- **NYHA CLASS**
  - 72% in class I or II

- **MLHFQ SCORE**
  - Mean improvement of -22 points

**6 MINUTE WALK TEST**

- Median of 311 meters at 6 months
- 81 meters at baseline

Significant clinical benefits have been reported in CRT non-responders

- 95% successful implant rate (Cohort of 51 patients)
- At discharge 73% of the patients had an improved functional NYHA class and even the proportion of NYHA I & II increased over time
- LVEF was nearly unchanged at 3 months but significantly increased at 6 and 12 months
- Reverse remodeling occurred even in the presence of moderate mitral regurgitation (MR 2+)

THERAPY OUTCOMES

95% Success

IMPLANT RATE

IMPROVEMENTS OVER TIME (12 months)

NYHA functional class

Ejection fraction

*Aniscio et al. Correction of Mitral Regurgitation in Nonresponders To Cardiac Resynchronization Therapy By MiraClip Improves Symptoms And Promotes Reverse Remodeling. JACC 2011; 58: 2183-2189.
FMR: ECHO study
Transeptal puncture
Posterior rotation
Needle puncture
Tenting “Superior” Aspect of Fossa

Echo view: 4 Chamber or 5 Chamber, Height 3.5-4.0cm
Sheath placement
TEE
X7-2t
HD Zoom
VR 7Hz

2D
Gen
Gn 50
C 46
4/4/0
50 mm/s

3D Zoom
4/3/0
Zoom 1.9
Clip navigation
Open arms-raise Grippers
Assess trajectory (angle of attack)-perpendicularly
Positioning below the leaflets - Grasping
Assessment of leaflet insertion and MR reduction
Clip deployment
Final result
Guide removal
Extreme DMR case

• 62 y. old male pharmacist
• Extreme kyphoscoliosis
• Paraplegia from old polio, moving around on electric vehicle
• Pulmonary oedema 10 days before, intubated and the tracheotomy
• Known history of Mitral prolapse under ‘watchful waiting’
• On continuous Furosemide and Noradrenaline infusion
• Rejected by the Surgeons
FLAIL A3-P3 RESCUE PROCEDURE
Extreme FMR case

- 79 year old male
- CABG 8 years before
- Previous Inferior MI
- LVEF 35% with known MR (functional) on medical treatment
- Mild Renal Impairment
- 3 Admissions with pulmonary oedema over the last 1 month
- ‘Crushed’ upon arrival- intubated, inotropes
EXTREME FMR- NO COAPTATION
Healed endocarditis

- 83 year old male
- Frailty, cachexia, worsening SOB over the last 3 months (NYHA IV)
- MDS
- Renal failure
- Hep. C, mild Liver cirrhosis
- History of prolonged fever 1 year before, negative investigation
Healed endocarditis
Mitraclip post TAVI
Combined Mitral and Tricuspid repair
2 days later
Combined Mitral and Tricuspid clipping messages

• Mitraclip therapy is safe, effective and versatile used in a broad spectrum of pathologies and patient profiles

• >65000 procedures so far

• Waiting the evidence for FMR (RESHAPE HF-2, COAPT, MITRA-FR)

• ‘One stop shop’ for two atrioventricular valves using a single technology

• Learning curve