Surgical intervention post MitraClip Device: Repair or Replacement

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Objectives

• To review the experience from the
  – EVEREST II randomized trial
  – Published peer-reviewed literature
  – German Heart Center Munich

  with respect to surgery post MitraClip procedure

• To appreciate the types of mitral valve injury that may occur after a MitraClip procedure

• To realize that mitral valve repair may be challenging after a failed MitraClip procedure
Objectives

To highlight the importance of a multidisciplinary team approach for proper patient and mitral valve pathology selection

successful MitraClip procedure
EVEREST II Randomized Clinical Trial

279 Patients enrolled at 37 sites

Significant MR (3+-4+)
Specific Anatomical Criteria

Randomized 2:1

Device Group
MitraClip System
n=184

Control Group
Surgical Repair or Replacement
n=95

Echocardiography Core Lab
Baseline, 30 days, 6 months, 1 year, 18 months, and annually through 5 years
Inclusion / Exclusion criteria

**Table 1. Major inclusion and exclusion criteria**

**Major inclusion criteria**
- Moderate-severe (3+) or severe (4+) chronic MR and
  Symptomatic with >25% left ventricular ejection fraction and left
  ventricular end-diastolic diameter ≤55 mm or,
  Asymptomatic with one or more of the following:
  i. LVEF 25% to 60%
  ii. LVESD ≥40 mm
  iii. New onset of atrial fibrillation
  iv. Pulmonary hypertension defined as pulmonary artery systolic
     pressure >50 mm Hg at rest or >60 mm Hg with exercise
- Candidate for MV repair or replacement surgery, including
  cardiopulmonary bypass
- The primary regurgitant jet originates from malcoaptation of the
  A2 and P2 scallops of the MV. If a secondary jet exists, it must be
  considered clinically insignificant

**Major exclusion criteria**
- Acute myocardial infarction in the prior 12 weeks of the intended
  treatment
- The need for any other cardiac surgery
- Any endovascular therapeutic interventional or surgical procedure
  performed within 30 days prior
- Ejection fraction <25%, and/or end-systolic dimension >55 mm
- MV orifice area <4.0 cm²
- If leaflet flail is present
  Width of the flail segment ≥15 mm, or
  Flail gap ≥10 mm
- If leaflet tethering is present
  Coaptation depth >11 mm, or
  Vertical coaptation length is <2 mm
- Severe mitral annular calcification
- Leaflet anatomy that may preclude clip implantation, proper clip
  positioning on the leaflets, or sufficient reduction in MR. This may
  include the following:
  Evidence of calcification in the grasping area of the A2 and/or
  P2 scallops
  Presence of a significant cleft of A2 or P2 scallops
  More than 1 anatomic criteria dimensionally near the exclusion limits
  Bileaflet flail or severe bileaflet prolapse
  Lack of both primary and secondary chordal support
- Prior MV surgery or valvuloplasty or any currently implanted mechanical
  prosthetic valve or currently implanted ventricular assist device
- Echocardiographic evidence of intracardiac mass, thrombus, or
  vegetation
- History of or active endocarditis or rheumatic heart disease
- History of atrial septal defect or patent foramen ovale associated with
  clinical symptoms
Need for sufficient leaflet tissue

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.
Repair Rates in EVEREST II

High repair rates in both arms

Device Group
n=178

- No Device Withdrew
  n=3
- MV Repair Device or Surgery
  n=158
  - Device MV Repair
    n=138
  - Surgical MV Repair Post-Device
    n=20
  - Surgical MV Replacement Post-Device
    n=17

Overall repair rate: 89%

Control Group
n=80

- MV Repair
  n=69
- MV Replacement
  n=11

Overall repair rate: 86%

2007 STS repair rate for isolated MV procedures: 59%

*Gammie et al, Circulation, 2007*
Did the surgeon’s previous experience with surgical MV Repair influence the type of surgery in EVEREST II control group?

<table>
<thead>
<tr>
<th>Surgeons’ Prior Year MV repair surgeries</th>
<th>&lt; 25</th>
<th>≥ 25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repair (n=69)</td>
<td>89%</td>
<td>83%</td>
</tr>
<tr>
<td>Replacement (n=11)</td>
<td>11%</td>
<td>17%</td>
</tr>
</tbody>
</table>

P value = 0.52

MV repair experience had no impact on type of surgery
Surgery after MitraClip vs. Surgery in the Control group

Are the results different?
Type of surgery performed within 1 year

Device Group
n=178

- No Device Withdrawn
  n=3

- MV Repair
  Device or Surgery
  n=158

  - Device MV Repair
    n=138

  - Surgical MV Repair Post-Device
    n=20

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Control Group
n=80

- MV Repair
  n=69

- MV Replacement
  n=11

1 out of 5 patients cross-over from device to surgery!

*Gammie et al, Circulation, 2007
### Indications for Surgery Post MitraClip within 12 Months

<table>
<thead>
<tr>
<th>Indication</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No MitraClip device implanted</td>
<td>46% (17)</td>
</tr>
<tr>
<td>Single Leaflet Insertion</td>
<td>24% (9)</td>
</tr>
<tr>
<td>Residual MR</td>
<td>14% (5)</td>
</tr>
<tr>
<td>Recurrent MR</td>
<td>8% (3)</td>
</tr>
<tr>
<td>Clinical symptoms despite MR reduction</td>
<td>8% (3)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100% (37)</strong></td>
</tr>
</tbody>
</table>
Did valve injury or difficulty removing the device affect the type of MV surgery (repair or replacement)?

• Individual case observations indicate that surgery post MitraClip can occasionally result in the need for mitral valve replacement

• Valve injury or difficulty removing the device was noted in 11 out of 37 Surgery Post MitraClip patients

• Hypothesis: Was valve injury or difficulty removing the device a predictor of replacement in the surgery post MitraClip group?
Did valve injury or difficulty removing the device affect the type of MV surgery (repair or replacement)?

Of the 37 patients who required surgery post MitraClip . . .

<table>
<thead>
<tr>
<th>Valve injury or difficulty removing the device</th>
<th>NO Valve injury or difficulty removing the device</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 patients</td>
<td>26 patients</td>
</tr>
<tr>
<td>Repair rate 45%</td>
<td>58%</td>
</tr>
<tr>
<td>P=0.72</td>
<td></td>
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</table>

Valve injury or difficulty removing the device did not influence the repair rate
Did the duration of implant influence the ability of MV repair?

- Repair rate ≤ 90 days = 52% (14/27)
- Repair rate >90 days = 60% (6/10)

Successful MV repair surgery performed up to 5 years post MitraClip implant*

Duration of implant did not impact ability to repair

30 Day Modified* MAE Rate

*Modified MAE: Major bleeding requiring transfusion ≥ 2U, or surgical intervention

Surgery post-MitraClip not associated with higher MAE
Clinical Success* Rate at 1 year

Surgery Post-MitraClip vs. Control

* Clinical Success defined as freedom from death, reoperation and MR > 2+

86.2% 87.8%

Surgery Post-MitraClip (n=29) Control Group (n=80)

Similar 1 year clinical success in patients who underwent surgery post-MitraClip compared to Control
Predictors of Mitral Valve Repair or Replacement

Summary

• Analyses were performed to determine predictors of mitral valve repair or replacement in the EVEREST II trial.

• Mitral valve replacement in the EVEREST II RCT was associated with bileaflet/anterior flail/prolapse.

• Surgeon experience and duration of implant did not appear to impact the repair/replacement rate.

• The repair rate in patients who had an operative note of valve injury or difficulty removing the device is not different from patients who did not have the operative note.
Predictors of Mitral Valve Repair or Replacement

Summary

• No evidence that treatment type (device or surgery) affects the probability of mitral valve repair or replacement

• Mitral valve surgery following the MitraClip procedure can be performed safely, and results are similar to the control group at 30 day and 12 month
Surgical Revision After Percutaneous Mitral Valve Repair With a Clip: Initial Multicenter Experience

Nicholas C. Dang, MD, Michael S. Aboodi, Taichi Sakaguchi, MD, Hal S. Wasserman, MD, Michael Argenziano, MD, Delos M. Cosgrove, MD, Todd K. Rosengart, MD, Ted Feldman, MD, Peter C. Block, MD, and Mehmet C. Oz, MD

Description. We describe 6 patients from three centers with mitral regurgitation after percutaneous repair who underwent reintervention. During open surgical revision, the clips were uneventfully removed in all patients with no limitation in surgical options. Five patients underwent repair and 1 underwent replacement.

- 5 patients underwent MV repair
- 1 patient underwent MV replacement

Was the “stage” set wrongly back in 2005?

Complex Surgical Valve Repair After Failed Percutaneous Mitral Intervention Using the MitraClip Device

Stephan Geidel, MD, Jörg Ostermeyer, MD, Michael Lass, MD, and Michael Schmoeckel, MD

62 year old male with P2 prolapse and chordal rupture

Pre-operative grade 3-4 mitral regurgitation

2 MitraClip devices

Post-operative grade 4 mitral regurgitation

Clip explantation by opening arms and grippers of clip with explantation catheter and forceps
Surgical procedure on day 32

1. Posterior sliding plasty
2. Neochord implantation with 4- Goretex sutures
3. Ring annuloplasty CE Physio ring #34
4. ASD repair
5. Tricuspid valve repair

Surgical Revision After Percutaneous Mitral Repair With the MitraClip Device

Michael Argenziano, MD, Eric Skipper, MD, David Heimansohn, MD, George V. Letsou, MD, Y. Joseph Woo, MD, Irving Kron, MD, John Alexander, MD, Joseph Cleveland, MD, Bobby Kong, MD, Michael Davidson, MD, Thomas Vassiliades, MD, Karl Krieger, MD, Ed Sako, MD, Pierre Tibi, MD, Aubrey Galloway, MD, Elyse Foster, MD, Ted Feldman, MD, and Donald Glower, MD; for the EVEREST Investigators

107 patients from EVEREST I and EVEREST II (roll-in)

32 patients (30%) required surgical intervention at a median follow-up of 386 days

Indications for surgery

- No clip implanted/procedure failure (n=9)
- Clips implanted (n=23)
  - Partial clip detachment (n=10)
  - Residual or recurrent MR (n=9)
  - ASD (n=2)
  - Device malfunction (n=1)
  - Mitral stenosis (n=1)

32 patients underwent MV surgery

11 had MV replacement
- 34%

21 had MV repair
- 64%

German Heart Center Experience
MV surgery post MitraClip

7 patients

↓

Age 54-83 (average 71 yrs)

↓

Pre-operative MR grade 3-4

↓

Post MitraClip MR grade 3-4

↓

1 MV repair 6 MV replacement

Surgery performed on day 1-365 days post clip (median 33 days)
Clip entangled in chordae

Leaflet injury

Chordal rupture

Types of injuries observed during surgery post MitraClip Device

Atrial septal defect 1-4 cm

Clip-induced mitral stenosis
Patient History

75 year old female

• Severe mitral regurgitation from P2 prolapse
• Moderate to severe tricuspid regurgitation
• Pulmonary hypertension (mean 50 mmHg)
• Severe right ventricular dysfunction
• Paroxysmal atrial fibrillation
• Cerebral vascular disease (stroke June 2009)
• Logistic EuroScore 17%
Treatment History

February 8, 2010
• Stenting right coronary artery

February 11, 2010
• “Successful” MitraClip procedure (2 Clip devices) with “reduction of MR from grade 3 to 2”
• Large ASD from 26 F MitraClip delivery catheter

February 11, 2010
• Unsuccessful closure attempt with 2 (!) ASD Amplatz closure devices “34mm”

March 3, 2010
• Discharged home
Treatment History

April 11, 2010

• Readmitted for heart failure due to iatrogenic ASD and MR grade 3

April 12, 2010

• Unsuccessful closure attempt with 3 (!) ASD Amplatz closure devices

April 13, 2010

• Discharged home

NO SURGICAL CONSULTATION
Treatment History

September 21, 2010

• Readmitted in severe heart failure, NYHA IV

Echocardiogram

• Severe mitral regurgitation and moderate mitral stenosis (mean pressure gradient 7 mmHg)
• Severe tricuspid regurgitation
• Severe right ventricular dysfunction
• ASD (diameter 2 x 3 cm)

NOW SURGICAL CONSULTATION
Surgical Procedure

- Mitral valve replacement (Medtronic-Hancock II #33)
- Tricuspid valve repair (Edwards MC 3 Ring #30)
- ASD closure

- Cross-clamp time 64 min
- Successful weaning from cardiopulmonary bypass (CPB)
- 60 min later → worsening right > left ventricular function
- CPB re-instituted
- Inability to wean from CPB
- Intraaortic balloon pump (IABP)
- Extracorporeal membrane oxygenation (EMCO)
Intraoperative findings

Rupture of fossa ovalis with consequent ASD
Perforation between clips
Restriction of the posterior leaflet due severe posterior ring calcification
Explanted Mitral Valve

Perforation of leaflets between MitralClips due to severe tension
Explanted Mitral Valve

MitraClips
Post-operative course

16 hours post-op

- Continuous major bleeding on ECMO
- Severe right heart failure + multi organ failure
- Death
Case #2

56 year old male 1 year after MitraClip with recurrent grade 4 MR
Conclusion

German Heart Center Munich experience suggests

- Importance of respecting the clinical guidelines for implantation of MitraClip procedures

- After a prolonged implantation time reconstruction may become a challenge

- Due to hemodynamic deterioration the decision for surgery should be made early after a failed MitraClip procedure

- The initial treatment decision should be made by the “Heart Team”