Use of Echocardiography In Mitral Clip and Mitral Ring.

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Mitral Clip

• MitraClip therapy is based on the surgical edge-to-edge repair first described by Alfieri.
• The first two cases were done in Catania, Italy in 2008.
• Since that time more than 35,000 cases have been done worldwide (including USA)
Indications of Mitral Clip

• **Primary mitral regurgitation:**
  • Patients with *primary* MR, severe LV dysfunction (LV-EF<30%) and relevant co-morbidities.

• **Secondary mitral regurgitation:**
  • Symptomatic patients with severe *secondary* MR, severe LV dysfunction (EF<30%) and no option for revascularization.
  • Symptomatic patients with severe *secondary* MR with mild to moderate LV dysfunction (EF>30%), no option for revascularization and relevant co-morbidities.
Data

- EVEREST I: Feasibility study (n=55)
- EVEREST II: Randomized trial (n=279)
- REALISM: Registry
- ACCESS Europe: Registry
- TRAMI: Registry
- GRASP: Registry
- RESHAPE-HF: Randomized study, clip vs. medical therapy (Halted as patients did not want to be randomized to the medical therapy arm)
- TVT registry (USA)
- COAPT: Randomized study, clip vs. medical therapy for functional mitral regurgitation. (USA)
STS TVT Registry (USA)

- 212 sites
- More than 6300 cases submitted so far
- Only degenerative mitral regurgitation.
- Functional MR only eligible for enrollment in the COAPT trial
- Initial outcomes:

<table>
<thead>
<tr>
<th>At discharge</th>
<th>2014 (n=1,023)</th>
<th>2015 (n=3,362)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral Regurgitation (&lt;=2+)</td>
<td>92.0%</td>
<td>92.0%</td>
</tr>
<tr>
<td>MV Mean Gradient &lt;=8 mmHg</td>
<td>92.3%</td>
<td>93.8%</td>
</tr>
<tr>
<td>Single Leaflet Device Attachment</td>
<td>1.2%</td>
<td>1.6%</td>
</tr>
<tr>
<td>MV Re-intervention</td>
<td>0.4%</td>
<td>0.9%</td>
</tr>
<tr>
<td>ASD requiring closure</td>
<td>1.6%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Event</td>
<td>2013q4-2014q3</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------</td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>20.6%</td>
<td></td>
</tr>
<tr>
<td>Atrial Fib</td>
<td>2.8%</td>
<td></td>
</tr>
<tr>
<td>Stroke (any)</td>
<td>2.4%</td>
<td></td>
</tr>
<tr>
<td>Re-intervention</td>
<td>3.0%</td>
<td></td>
</tr>
<tr>
<td>HF Re-admission</td>
<td>10.0%</td>
<td></td>
</tr>
<tr>
<td>MR (3-4+)</td>
<td>12.1%</td>
<td></td>
</tr>
<tr>
<td>MV mean gradient (\leq 8) mm Hg</td>
<td>94.3%</td>
<td></td>
</tr>
</tbody>
</table>
Data from the EVEREST II, European registries and the STS TVT registry suggest that Mitral Clip therapy is a viable treatment option in daily clinical routine for high surgical risk patients with significant MR.

At the present time the best indication for Mitral Clip therapy is for symptomatic patients with clinically significant functional or degenerative MR who are at high or increased risk for open heart surgery.
Role of Echocardiography in Mitral clip

• Assessment of severity of mitral regurgitation (TTE and TEE)
  • Primary MR

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jet area in relation to LA</td>
<td>20-40%</td>
<td>&gt; 40%</td>
</tr>
<tr>
<td>Timing of jet</td>
<td>Mid or late systolic</td>
<td>Holosystolic</td>
</tr>
<tr>
<td>Vena contracta</td>
<td>&lt;0.7 cm</td>
<td>&gt;0.7 cm</td>
</tr>
<tr>
<td>ERO</td>
<td>&lt;0.4 cm²</td>
<td>&gt;0.4 cm²</td>
</tr>
<tr>
<td>Regurgitant volume</td>
<td>&lt;60 ml</td>
<td>≥60 ml</td>
</tr>
<tr>
<td>Regurgitant fraction</td>
<td>&lt; 50%</td>
<td>≥ 50%</td>
</tr>
</tbody>
</table>

• Secondary MR

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERO</td>
<td>&gt; 0.2 cm²</td>
</tr>
<tr>
<td>Regurgitant volume</td>
<td>≥ 30 ml</td>
</tr>
<tr>
<td>Regurgitant fraction</td>
<td>≥ 50 %</td>
</tr>
</tbody>
</table>
Assessment of Morphology (TEE)

- The current recommendations are based on the EVEREST data:
  - Functional or degenerative MR
  - Coaptation depth < 11 mm
  - Flail gap < 10 mm
  - Flail width < 15 mm
  - Mitral valve area > 4 cm²
  - Absence of significant calcification in the grasping area.

- Other anatomic features to consider:
  - Atrial septal anatomy
  - Posterior leaflet width > 7 mm.
Unsuitable Valve Morphology

• Perforated mitral valve leaflet.
• Cleft mitral valve.
• Severe calcification of grasp zone.
• Mitral valve area < 3 cm$^2$ or mean gradient $\geq$ 5 mmHg.
• Mobile length of the posterior leaflet < 7 mm.
• Rheumatic mitral valve.
• Barlow’s syndrome with multisegment flail leaflets.
Anatomical Exclusion

- Coaptation length < 2 mm
- Coaptation depth > 11 mm
- Flail gap > 10 mm
- Flail width > 15 mm
During the Procedure

• The mitral clip procedure cannot be performed without TEE guidance.
• TEE guidance for Mitral Clip requires considerable expertise of the echocardiographer and the interventionalist.
• Most centers use combined 2-D and 3-D imaging modalities.
• 3D TEE needs more operator experience.
Advantages of 3D TEE

• 3D TEE allows good visualization and excellent spatial orientation of the device system within the left atrium.

• 3D TEE is valuable to determine that the orientation of the clip arms is perpendicular to the line of MV coaptation and that the clip is positioned between the middle scallops.

• 3-D imaging obviates the need for transgastric imaging.

• X-plane imaging is useful to assess the leaflet insertion in the device.
Advantages of 3DTEE

• 3D TEE can be used to assess proper leaflet insertion using full volume data set and cropping
• Can shorten the procedural time especially with experienced operators.
• 3D TEE is not to be use alone during the procedure.
• Does not effect the outcome of the procedure
Utility of Combined Two-Dimensional and Three-Dimensional Transesophageal Imaging for Catheter-Based Mitral Valve Clip Repair of Mitral Regurgitation

Simon Biner, MD, Gila Perk, MD, FASE, Saibal Kar, MD, Asim M. Rafique, MD, James Slater, MD, Takahiro Shiota, MD, FASE, Asma Hussaini, MS, PAC, Stanley Chou, MD, Itzhak Kronzon, MD, FASE, and Robert J. Siegel, MD, FASE, Los Angeles, California; New York, New York; Tel Aviv, Israel
Table 2  Procedural outcomes of CBMCR patients guided by 2D TEE and combined 2D and 3D TEE

<table>
<thead>
<tr>
<th>Variable</th>
<th>2D TEE only (n = 23)</th>
<th>Combined 2D and 3D TEE (n = 36)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline MR grade</td>
<td>3.8 ± 0.4</td>
<td>3.8 ± 0.4</td>
<td>NS</td>
</tr>
<tr>
<td>Acute procedural success</td>
<td>95%</td>
<td>94%</td>
<td>NS</td>
</tr>
<tr>
<td>Final MR grade</td>
<td>1.3 ± 0.6</td>
<td>1.3 ± 0.5</td>
<td>NS</td>
</tr>
<tr>
<td>Procedural time (min)</td>
<td>241 ± 58</td>
<td>201 ± 68</td>
<td>.035</td>
</tr>
<tr>
<td>Time to first clip (min)</td>
<td>134 ± 47</td>
<td>96 ± 37</td>
<td>.005</td>
</tr>
<tr>
<td>Time from first to second clip (min)</td>
<td>46 ± 15</td>
<td>54 ± 28</td>
<td>NS</td>
</tr>
</tbody>
</table>

Data are expressed as mean ± SD or as percentage.
Procedural Guidance
Baseline mitral regurgitation
Septal puncture

• Location should be in the posterior and superior part of the septum
• If PFO present → do not cross it
• Use bicaval view to view superior and inferior part
• Use short axis view to view anterior/posterior part
• Height of the puncture is measured in mid-esophageal 4 chamber
• Should be 3.5 cm - 4.5 cm from the coaptation of the mitral leaflets.
• A relatively low puncture is preferred in tented valves (IIIb) and higher in prolapsing/degenerative valves
3-D showing the guiding catheter position (surgical view)
Maneuvering the clip into the A2/P2 region with live 3-D zoom view
Clip in ideal position
Checking clip arms orientation (should be perpendicular to the line of coaptation). View from the LA (surgical view)
Checking the clip arms orientation from the LV side
Clip position relative to the jet
Capturing the leaflets in the LVOT view
Grasping of the leaflets and closing the clip
Post capture (clip still attached to the delivery system) in the X-plane view
3D view showing double orifice
Trace residual mitral regurgitation
Significant lateral jet after 1st clip
2nd clip maneuvered into place in X-plane view
2\textsuperscript{nd} clip in live 3D zoom view
2nd clip post grasping (still attached to delivery system)
Final result
Patient with two clips with resultant triple orifice valve
3D color showing flow in the 3 separate orifices (mean gradient was 4 mmHg)
Post Deployment of the Clip

• Check for residual MR
• Check the MV gradients
• Check of ASD:
  • If large then may need to be closed
• Check for complications:
  • Partial leaflet detachment
  • Pericardial effusion
After 1st Clip
After 2nd Clip
After 3rd Clip
After Releasing 3\textsuperscript{rd} Clip
What to do now?

Leave it alone
Carillon Mitral Contour System (CMCS) Mitral Ring

• Why Carillon?
  • Easy Access to the Coronary Sinus
  • Wrap and squeeze to reduce the Annulus Diameter
  • Fast procedure
  • Done under fluoroscopy guidance
For Whom is Carillon?

- Functional mitral regurgitation grade III-IV with EF (EF < 40%)
- Carpentier type 1 MR (normal leaflet motion and annular dilatation)
- Symptomatic patients with NYHA ≥ II despite optimal medical therapy
- No option for revascularization.
General Exclusion Criteria

- Structural abnormalities of the mitral leaflets
- Ischemic heart disease requiring revascularization
- Previous CRT therapy
- MI or CABG in past 3 months
- Right atrial thrombi
- Serum creatinine > 195 mmol/l
Limitations of Carillon
• A significantly high rate of device fatigue fracture, up to 25% in the TITAN trial
• Use of contrast during the procedure can worsen renal function
• Reduction of MR may not be significant immediately after procedure
• Only one device fracture was noted due to damage during implantation
• No fatigue fractures
Color Doppler Assessment

Baseline
Pre-Procedure

Post-Procedure
M-mode Assessment

Pre-procedure M-mode

Post-procedure M-mode
Pre-procedure M-mode

Post-procedure M-mode
Patient with DCM and Severe Functional MR
Post Carillon Implantation
TEE Assessment
Mean gradient = 5 mmHg