MitraClip

Brian Whisenant, MD

December 2015
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant/Speaker’s Bureau</td>
<td>Abbott</td>
</tr>
</tbody>
</table>
MitraClip Key Procedural Steps

1. Transseptal Puncture
2. LA Navigation & CDS Trajectory
3. Arm Angle Orientation
4. Leaflet Grasp
5. Confirmation of Leaflet Insertion
6. Avoid Complications
86 yo woman, 43 KG, O₂ dependent HF
P2 Jet
No Flail

Prolapsing Segment & Small Ruptured Chord
- 3.5 – 4 CM above plane of coaptation
- Posterior in short axis
- Never through PFO

- Mid Fossa (rather than posterior) if necessary to lose height.
Steer in 3D When Possible
Trajectory is Essential
3D Rarely Deceives
+ Knob for “Aorta-Hugger”

Anterior to posterior trajectory

Anterior transseptal puncture

Add “+” knob brings the guide and the CDS away from the anterior wall and optimizes the grasp
Confident Arm Angle
Visualize The Grasp
The Confident Grasp
The Victory Lap
Chordal Entanglement
The Most Important Preventable MitraClip Complication

88 yo man with CAD, IDDM, Creat 1.7, STS 12 \(\rightarrow\) poor surg candidate
Single Clip Result
Single Clip Result: LVOT View
2 Yr FU: Recurrent Medial P2 Prolapse
2012: Second Clip above the valve
Caught in Chordae
P3 Entanglement, Persistent P2 MR
MitraClip

Know When to Say No

1. Small planimetered TTE annulus
   • ~ 3.5 – 4.0 limited to single clip
   • < 3.5 prohibitive
2. Commissural origin
3. Prohibitive leaflet anatomy
   • Large flail (> 1cm)
   • Heavily calcified annulus/leaflet
   • Small posterior leaflet
   • Cleft
   • Rheumatic
4. Poor acoustic windows
Single Leaflet Device Detachment
Clip in posterior chords, no leaflet insertion.
Calcified Posterior Annulus
Vestigial Posterior Leaflet
EVEREST II Randomized Clinical Trial
Study Design

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 and Clinical Follow-Up:
Baseline, 30 days, 6 months, 1 year, 18 months, and annually through 5 years
# Patients experiencing event
<table>
<thead>
<tr>
<th>Event</th>
<th>Device Group (n=136)</th>
<th>Control Group (n=79)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>2 (2.5%)</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0</td>
<td>2 (2.5%)</td>
</tr>
<tr>
<td>Re-operation of Mitral Valve</td>
<td>0</td>
<td>1 (1.3%)</td>
</tr>
<tr>
<td>Urgent / Emergent CV Surgery</td>
<td>0</td>
<td>4 (5.1%)</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Deep Wound Infection</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ventilation &gt;48 hrs</td>
<td>0</td>
<td>4 (5.1%)</td>
</tr>
<tr>
<td>New Onset Permanent Atrial Fib</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Septicemia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>GI Complication Requiring Surgery</td>
<td>1 (0.7%)</td>
<td>0</td>
</tr>
<tr>
<td>All Transfusions ≥2 units*</td>
<td>12 (8.8%)</td>
<td>42 (53.2%)</td>
</tr>
<tr>
<td><strong>TOTAL % of Patients with MAE</strong></td>
<td>9.6%</td>
<td>57.0%</td>
</tr>
</tbody>
</table>

*p<0.0001 if include Major Bleeding only

(95% CI 34.4%, 60.4%)
EVEREST II RCT: MR Reduction
Per Protocol Cohort

Device Group
- Baseline: n=137
  - 3+/4+: 23
  - 2+: 3+/4+: 13.4%
- 12 Months: n=119
  - 3+/4+: 36.1%
  - 2+: 33.6%
  - 1+ - 2+: 11.8%

Control Group
- Baseline: n=80
  - 3+/4+: 23
  - 2+: 3+/4+: 58.2%
- 12 Months: n=67
  - 1+: 58.2%
  - 2+: 13.4%
  - 1+ - 2+: 7.5%

Replacement:
- Device Group: 7.7% (1/13)
- Control Group: 18.4% (7/38)
CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes.
MitraClip Implant Rate
EVEREST Trials

N=710
July 2003 - Nov 2010
“Indicated for percutaneous reduction of significant 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.”
Mitral Regurgitation Etiologies

Degenerative MR
(primary or organic MR)
- Anatomic defect of the mitral valve apparatus – ie. myxomatous leaflet or ruptured chordae tendineae

Functional MR
(secondary MR)
- Results from left ventricular (LV) dysfunction and dilation, which prevents leaflet coaptation
Degenerative Mitral Regurgitation
Repair is the Standard of Care

188 consec pts 2002-2010 at Mt Sinai NY
- bileaflet prolapse 78%
- anterior prolapse 22%

Techniques
PTFE neochordoplasty 49%
Chordal transfer 46%
Posterior leaflet flip 11%
MV replacement – n=1
In-hosp mortality 1%
Table 17. Summary of Recommendations for **Chronic Primary MR**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>MV surgery is recommended for <strong>symptomatic patients</strong> with chronic severe primary MR (stage D) and LVEF &gt;30%</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>MV surgery is recommended for asymptomatic patients with chronic severe primary MR and LV dysfunction (LVEF 30%-60% and/or LVESD &gt;40 mm, stage C2)</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>MV repair is reasonable for asymptomatic patients with chronic severe nonrheumatic primary MR (stage C1) and preserved LV function in whom there is a high likelihood of a successful and durable repair with 1) new onset of AF or 2) resting pulmonary hypertension (PA systolic arterial pressure &gt;50 mm Hg)</td>
<td>IIa</td>
<td>B</td>
</tr>
</tbody>
</table>
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities.
# 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Rick A. Nishimura, Catherine M. Otto, Robert O. Bonow, Blase A. Carabello, John P. Erwin III, Robert A. Guyton, Patrick T. O'Gara, Carlos E. Ruiz, Nikolaos J. Skubas, Paul Sorajja, Thoralf M. Sundt III and James D. Thomas

*Circulation.* published online March 3, 2014;

## Table 18. Summary of Recommendations for Chronic Severe Secondary MR

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>MV surgery is reasonable for patients with chronic severe secondary MR (stages C and D) who are undergoing CABG or AVR</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>MV surgery may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe secondary MR (stage D)</td>
<td>IIb</td>
<td>B</td>
</tr>
</tbody>
</table>
COAPT: Trial design

~420 patients enrolled at up to 75 US sites

Significant FMR (≥3+ by core lab)
High risk for mitral valve surgery

Randomize 1:1

MitraClip
N=210

Control group
Standard of care
N=210

Clinical and TTE follow-up:
1, 6, 12, 18, 24, 36, 48, 60 months
Initial HF Clinic Evaluation

Date of Service: 08/08/2009

HISTORY OF PRESENT ILLNESS: Mr. K. is a 64-year-old male referred to heart failure clinic with increasing short of breath, nausea and dry heaves. The patient had his first MI with a stent placed in Indiana at age 42. He had done well until June 2, 2009 when he had burning sensation in his stomach, along with severe chest pain starting at 7:00 p.m. He was transferred to the IMC at 5:00 AM the next day. He had 2 bare metal stents placed in the LAD and distal circumflex. The patient required an intra-aortic balloon pump. His initial troponin was 812. Since that time he has been hospitalized twice for decompensated heart failure. He has PND, dry heaves, right upper quadrant pain and constipation. He is short of breath at rest with orthopnea and class 4 CHF. Metoprolol and lisinopril were discontinued secondary to hypotension. Current medications are carvedilol 3.125 mg twice daily, lasix 20 mg once a day and Aldactone.
IMPRESSION AND RECOMMENDATIONS: Ischemic cardiomyopathy. The patient has an ischemic cardiomyopathy. Given his narrow QRS complex, he does not meet the criteria for a biventricular ICD. He had his myocardial infarction in June; now after 2.5 months of therapy his ejection fraction has worsened; I do not think that is going to get better. We should look towards an ICD implant. He is being considered for possible mitral valve treatment for his severe mitral regurgitation and possible heart transplant down the line if he does not get better.

Thanks for the interesting consultation.
Baseline Echo
Qualifying Echo 10/09

PHILIPS
TDK, PROTECT II
57011420091013
10/13/2009  14:14:22  TIS2.3  MI 1.1
S5-1/Adult

FR 12Hz
16cm

2D
75%
C 50
P Low
HPen
CF
66%
2.3MHz
VW High
Low

M3 M4
+56.2
-56.2
1.4
2.8

81 bpm
MitraClip 1/2010
Summary: 68HR: AO 92/59/68 PA 64/28/42

Summary: 76HR: AO 122/70/89 LA 27/31/23
Jet isolated laterally
RHC 9/2010

Summary: 60HR: PA 20/6/11

Summary: 60HR: PCW 6/3/2
Most Recent HF Clinic

Here today for routine follow up. Pt reports feeling well. Denies dyspnea on exertion/SOB and fatigue. No complaints of chest pain, orthopnea, pnd, peripheral edema, nausea, bloating. No c/o palpitations, lightheadedness. Weight is stable. Activity tolerance is unchanged since last clinic visit.

NYHA Classification: I
1. HF:Ischemic CM/valvular- s/p Mitral clip. Last EF 25-30% today (REALSIM protocol) by Echo. Pt Euvolemic on exam and exercising (walking) and "doing whatever I want to".
MitraClip
Conclusions

1. MitraClip is a powerful option for patients with symptomatic mitral regurgitation and significant risks of surgical repair.
   - SOC for DMR
   - COAPT is Pivotal Trial for FMR

2. Committed & experienced team with outstanding echo imaging is essential.
Thank You