Edwards’ solution for patients suffering from mitral regurgitation with annular dilatation

Azeem Latib MD
EMO-GVM Centro Cuore Columbus and San Raffaele Scientific Institute, Milan, Italy
Speaker's name: Azeem Latib

☑ I have the following potential conflicts of interest to report:

Consultant/SAB: InnovHeart, Medtronic, Mitralign, Cardiovalve, Millipede, Shockwave, Abbott

Grants/research support: Edwards Lifesciences, Medtronic, Mitralign
Prevalence of Moderate or Severe Mitral Valve Disease in the US = ~4.2M Patients*


*Nkomo: 1.7% prevalence (population based studies); US Census Bureau 2016: 248M adults
Types of Mitral Regurgitation

Mitral Regurgitation

Functional Mitral Regurgitation (FMR)

- LV Dysfunction
  - Dilated Annulus
    (Non-ischemic or ischemic dilated cardiomyopathy)

  - Loss of leaflet coaptation due to:
    - Annular dilatation
    - Papillary muscle displacement causing leaflet tethering/tenting

Degenerative Mitral Regurgitation (DMR)

- LA Dysfunction
  - Dilated Annulus (Chronic atrial fibrillation, hypertension)

Etiologies:
- Advanced Barlow’s Disease
- Fibroelastic deficiency

Leaflet prolapse due to:
- Leaflet deformities or lesions
- Ruptured/ elongated chordae
- Papillary muscle rupture

50% of MR patients are treated medically

Goel et al. JACC 2014;63:185-186

The more severe the LV dysfunction, the more likely to be treated conservatively.\(^1\)

<table>
<thead>
<tr>
<th>LVEF</th>
<th>Conservative management</th>
<th>Isolated MV surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>All pts</td>
<td>88.6%</td>
<td>11.4%</td>
</tr>
<tr>
<td>20%-30%</td>
<td>94.1%</td>
<td>5.9%</td>
</tr>
<tr>
<td>30%-40%</td>
<td>91.6%</td>
<td>8.4%</td>
</tr>
<tr>
<td>40%-50%</td>
<td>88.2%</td>
<td>11.8%</td>
</tr>
<tr>
<td>50%-60%</td>
<td>81.6%</td>
<td>18.4%</td>
</tr>
</tbody>
</table>

\(^1\) Duke Databank: 1,538 pts with echocardiographic 3+ to 4+ FMR and LVEF ≥20% between 2000 and 2010 not undergoing CABG

Courtesy of M. Mack MD, FACC, Baylor Scott & White Health
Medically Managed Patients with Severe MR Have Poor Outcomes

- **20%**
  - One year mortality rate
- **50%**
  - Five year mortality rate
- **Very high**
  - Rate of heart failure hospitalization

![Bar chart showing mortality and hospitalization rates over five years.]

- **Year 1**: 20% mortality, 41% hospitalization
- **Year 2**: 29% mortality, 50% hospitalization
- **Year 3**: 37% mortality, 58% hospitalization
- **Year 4**: 46% mortality, 68% hospitalization
- **Year 5**: 50% mortality, 90% hospitalization

*Data from Sachin S. Goel, JACC Volume 63, Issue 2, January 2014*
Edwards Cardioband Mitral Valve Reconstruction System

- Trans-femoral venous access (transeptal)
- Designed to reduce MR by annular reduction
- Supra-annular fixation like in surgery
- Preserves the native anatomy – *keeps future options open*

Access
1. Transseptal Puncture & System Insertion

Implant
2. Deployment

Implant Size
3. Adjustment
## Edwards Cardioband Mitral System
### Key Advantages

<table>
<thead>
<tr>
<th>Annular Reduction</th>
<th>Adjustable Implantation</th>
<th>Real-Time Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restores valve to a more functional state, facilitating leaflet coaptation - reducing MR</td>
<td>Enables annular reduction based on each patient’s anatomy</td>
<td>Allows real-time adjustment and confirmation of MR reduction</td>
</tr>
</tbody>
</table>
Single arm, multicenter, prospective study with intra-subject comparisons to evaluate the performance and safety of the Cardioband Mitral System for reconstruction of pathological mitral valves
Edwards Cardioband Mitral System CE Mark Trial

Patient Flow

Intent to treat (ITT)
N=62

Patient out of the device indication n=1

Full analysis set (FA)
N=61

No implantation n=1

Per protocol (PP)
N=60

Death n=7
Incomplete follow-up n=8
Secondary intervention n=6

12-month follow up
63% (39/62)

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\(^a\) 2/7 patients died due to complications of elective open heart surgery

\(^b\) 39 patients completed echo follow-up at 12 months. 38 patients completed clinical follow-up at 12 months
Edwards Cardioband Mitral System CE Mark Trial

95% MR reduction sustained at 1 year in paired analysis by core lab\(^1\)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Discharge</th>
<th>30 days</th>
<th>6 Months</th>
<th>12 Months</th>
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</thead>
<tbody>
<tr>
<td>3-4+</td>
<td>60%</td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>2+</td>
<td>40%</td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>0-1+</td>
<td>0%</td>
<td>40%</td>
<td>40%</td>
<td>40%</td>
<td>40%</td>
</tr>
</tbody>
</table>

\(n=39\)

\(^1\) Dr. Paul Grayburn – Baylor University
Edwards Cardioband Mitral System CE Mark Trial

Septolateral reduction maintained at 1 year in paired analysis

n=25

1 Dr. Paul Grayburn – Baylor University
Edwards Cardioband Mitral System CE Mark Trial

Significant functional improvement at 1 year in paired analysis

**NYHA Class**

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>III</td>
<td>15%</td>
<td>20%</td>
</tr>
<tr>
<td>II</td>
<td>79%</td>
<td>75%</td>
</tr>
<tr>
<td>I</td>
<td>0%</td>
<td>4%</td>
</tr>
</tbody>
</table>

**P<0.01**

79% NYHA I/II

**MLHFQ Score**

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>42</td>
<td>21</td>
</tr>
</tbody>
</table>

**P<0.01**

Δ = -21

**6MWT**

<table>
<thead>
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<th></th>
<th>Baseline</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>309</td>
<td>367</td>
</tr>
</tbody>
</table>

**P<0.01**

Δ = 58

6MWT – Six-minute Walk Test; MLHFQ - Minnesota Living with Heart Failure Questionnaire; NYHA Class - New York Heart Association (NYHA) Functional Classification
Baseline patient characteristics

Clinical Background
- 75 year-old male
- Ischemic Cardiomyopathy
  - Prev. CABG (LIMA-LAD; RIMA-RI; SVG-OM)
  - Prev. PCI on PL, Ramus
- Permanent AF
- VVI pacemaker
- NYHA III

Baseline Echo
- Moderate-to-severe MR
- Annular dilatation & dysfunction
  - AP Diameter = 33 mm
  - IC Diameter = 41 mm
  - Coaptation depth = 4 mm
- EF=45%
At 2-year follow-up:
- MR remains mild
- NYHA reduced from III to I
- No admissions for Heart Failure
- LVEF stable at 40%
Direct annuloplasty with Cardioband has become a standardized procedure
Favorable safety profile while preserving patients’ native anatomy – keeping future options open
Provides significant and stable reduction in mitral regurgitation through annular reduction
Results are clinically and statistically significant at 1-year
Core lab evaluable patients demonstrate:
  • Stability of 95% MR ≤ 2+ at 1 year
  • No mitral stenosis

Email: alatib@gmail.com