Clinical experience with Edwards Cardioband system for mitral regurgitation

Francesco Maisano
Potential conflicts of interest

Speaker's name: Francesco Maisano

- Consultant for Edwards
Outcome of Unoperated Patients with Severe MR and Heart Failure†

- **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.](chart.png)

- Year 1:
  - Mortality: 20%
  - Hospitalized: 41%

- Year 2:
  - Mortality: 29%
  - Hospitalized: 50%

- Year 3:
  - Mortality: 37%
  - Hospitalized: 58%

- Year 4:
  - Mortality: 46%
  - Hospitalized: 68%

- Year 5:
  - Mortality: 50%
  - Hospitalized: 90%

*Sachin S. Goel, JACC Volume 63, Issue 2, January 2014*
How are Patients with Isolated FMR Treated?

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

N=1538
N=440
N=298
N=313
N=479
Edwards Cardioband Mitral Repair System

Edwards Cardioband Delivery System

Stand

Edwards Cardioband Implant
Edwards Cardioband Mitral Repair Procedure
Edwards Cardioband Mitral Repair System  Key Advantages

- Transseptal access
  - designed for safety

- Supraannular fixation
  - preserves subvalvular apparatus

- Significant reduction of annular dimensions
  - improves coaptation

- Keeps future options open
  - maintains native anatomy
Edwards Cardioband
Transcatheter Mitral Repair System

EUROPEAN CE MARK TRIAL
Edwards Cardioband Mitral Repair System – CE Mark Trial

Single arm, multicenter, prospective study with intra-subject comparisons to evaluate the performance and safety of the Edwards Cardioband Mitral Repair System for repair of functional mitral regurgitation
Major Inclusions

- **Age > 18 years**
- **Symptomatic patients** (NYHA Class II-IV) despite optimal medical therapy, including CRT if indicated
- **LVEF ≥ 25%, LVEDD ≤ 70mm**
- **Moderate to severe functional MR**
- **Subject is high risk to undergo MV surgery**
  (as assessed by a cardiac surgeon and a cardiologist, at the site and according to ESC/EACTS guidelines on the management of valvular heart disease)
Major Exclusions

- Untreated clinically significant CAD requiring revascularization
- **Pulmonary hypertension >70mmHg at rest**
- Renal insufficiency requiring dialysis
- Right-sided congestive heart failure with echocardiographic evidence of **severe right ventricular dysfunction and severe tricuspid regurgitation**
- **Heavily calcified annulus or leaflets**
- Any recent cardiovascular intervention
- CVA or TIA within 6 months or severe carotid stenosis (>70% by ultrasound)
- **Mitral valve anatomy which may preclude proper device treatment**
### Primary Endpoints

#### Safety

- **Overall rate of Major Serious Adverse Events (SAEs) and Serious Adverse Device Effects (SADE) until hospital discharge and at post-operative 30 days**

- **Major SAEs:** Death, myocardial infarction, cardiac tamponade, device related cardiac surgery, stroke

*Events defined according to VARC II guidelines*

#### Performance

- **Technical success** rate of the implantation of the Edwards Cardioband system
- **Technical feasibility** of Edwards Cardioband system adjustment
- **Edwards Cardioband system ability to reduce mitral valve regurgitation (MR) intra-procedure, at hospital discharge and at 30 days**
## Secondary Endpoints

### Safety
- Overall rate of **Major Serious Adverse Events** (SAEs) and Serious Adverse Device Effects (SADE) up to 24 months

### Performance
- **MR severity at 6, 12 and 24 months**
- **Change in 6 MWT** in 6, 12 and 24 months
- **Change in quality of life** (MLWHFQ) at 6, 12 and 24 months
Participating Sites

Bichat Hospital (N=13)

HSR, Milan (N=10)

Asklepios, St. Georg, Hamburg (N=10)

Medizinische Klinik Universitätsklinikum Bonn (N=16)

St. Antonius Ziekenhuis, NL (N=1)

Heart Center University of Köln (N=4)

Presidio Ospedaliero Ferrarotto, Catania (N=1)

Zurich University Hospital (N=4)

Rambam Health Care Campus (N=1)

LMU Klinikum der Universität München, Campus Großhadern (N=1)

Universitätsmedizin der Johannes Gutenberg Universität Mainz (N=1)
Patient Flow

**Intention To Treat (ITT)**
- **N=62**
  - Compassionate use of Edwards Cardioband system in a patient out of the device indication

**Full Analysis Set (FA)**
- **N=61**
  - Edwards Cardioband system not implanted due to patient instability

**Per Protocol (PP)**
- **N=60**
<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%) or Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>72 ± 7</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 44 (72%)</td>
</tr>
<tr>
<td></td>
<td>Female 17 (28%)</td>
</tr>
<tr>
<td>Euroscore II (%)</td>
<td>7.1</td>
</tr>
<tr>
<td>Baseline NYHA Class of III or IV</td>
<td>53 (87%)</td>
</tr>
<tr>
<td>Ischemic</td>
<td>36 (59%)</td>
</tr>
<tr>
<td>Non Ischemic</td>
<td>25 (41%)</td>
</tr>
<tr>
<td>LVEDD (mm) Avg±SD</td>
<td>60 ± 6</td>
</tr>
<tr>
<td>EF (%) Avg±SD</td>
<td>33 ± 11</td>
</tr>
<tr>
<td>Prev CABG</td>
<td>19 (31%)</td>
</tr>
<tr>
<td>COPD</td>
<td>13 (21%)</td>
</tr>
<tr>
<td>Moderate to Severe Renal Failure</td>
<td>46 (75%)</td>
</tr>
<tr>
<td>Severe Pulmonary Hypertension</td>
<td>15 (25%)</td>
</tr>
<tr>
<td>Afib</td>
<td>46 (75%)</td>
</tr>
</tbody>
</table>
## Reported Major Safety Events at 30 Days

### 30 Day Events*  
<table>
<thead>
<tr>
<th>Event</th>
<th>Patients Experiencing Event, n (%)</th>
<th>Full Analysis Set N=61</th>
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<tr>
<td>Death</td>
<td>2 (3.3%)</td>
<td></td>
</tr>
<tr>
<td>Hemorrhagic Stroke**</td>
<td>1 (1.6%)</td>
<td></td>
</tr>
<tr>
<td>Need for elective Mitral Operation**</td>
<td>1 (1.6%)</td>
<td></td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>1 (1.6%)</td>
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</tr>
<tr>
<td>Major Bleeding Complications</td>
<td>2 (3.3%)</td>
<td></td>
</tr>
<tr>
<td>Renal Failure</td>
<td>4 (6.6%)</td>
<td></td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Cardiac Tamponade</td>
<td>1 (1.6%)</td>
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** Part of the Death case  
One additional death case per ITT - compassionate
94% patients with MR≤2+ At 12 Months by Core Lab*

- Baseline: N=61
- Discharge: N=58
- 30 days: N=53
- 6 Months: N=43
- 12 Months: N=36

87% MR ≤ 2+ at 30 Days
93% MR ≤ 2+ at 6 Months
94% MR ≤ 2+ at 12 Months

94% patients with MR≤2+ at 12 Months

*Dr. Paul Grayburn – Baylor University
94% patients with MR≤2+ At 12 Months by Core Lab in paired analysis*

*Dr. Paul Grayburn – Baylor University
Significant Reduction in Septo Lateral (S-L) Dimension

28% average reduction in S-L
Septo Lateral (S-L) Dimension (mm) Over Time

- **Baseline**
- **Discharge**
- **30 Days**
- **6 Months**
- **12 Months**

**Septo Lateral (A-P) Dimension (mm)**

- **p<0.01**
- **N.S.**
Functional Improvement at 12 Months

- **6MWT**
  - P<0.01
  - Δ = 63
  - N = 27

- **MLHFQ Score**
  - P<0.01
  - Δ = -21
  - N = 32

- **NYHA Class**
  - P<0.01
  - 79% NYHA I/II
  - N = 38

6MWT – Six-minute Walk Test
MLHFQ - Minnesota Living With Heart Failure Questionnaire
NYHA Class - New York Heart Association (NYHA) Functional Classification
### Spectrum of Mitral Valve Interventions for FMR

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<td>Transcatheter Leaflet Repair</td>
<td>Class IIb recommendation, risk of stenosis, some leaflet lesions possible</td>
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<td>Unclear indications, delayed effect, inconsistent data</td>
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<td>Effective, minimal footprint, can become first-line option in FMR</td>
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  - Effective, minimal footprint, can become first-line option in FMR

- **TMVR**
  - Early stage, limited feasibility, safety improving, long-term consequences to be determined
Summary

- Transcatheter mitral repair using Edwards Cardioband Mitral Repair System is feasible and safe
- Significant and consistent reduction in mitral regurgitation
- Significant and consistent reduction in septo lateral dimension
- Preserves the native anatomy keeping options open for future interventions
- Further studies are warranted