Transcatheter innovations to treat mitral and tricuspid regurgitation, what milestones have we reached?

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

Receipt of grants / research supports: JenaValve
Receipt of honoraria or consultation fees: Biotronik, Boston Scientific, Edwards Lifesciences, Medtronic, TriCares
Transcatheter solutions addressing Mitral and Tricuspid valve disease

**Etiology**

**Mitral**
- Annular repair
- Leaflet repair
- Chordal repair
- Replacement

**Tricuspid**
- Annular repair
- Leaflet repair
Types of mitral regurgitation

**Functional Mitral Regurgitation (FMR)**

- **Etiologies**
  - LV dysfunction dilated annulus: Non-ischemic or ischemic dilated cardiomyopathy
  - LA dysfunction dilated annulus: Chronic atrial fibrillation, hypertension.

**Degenerative Mitral Regurgitation (DMR)**

- **Etiologies**
  - Advanced Barlow’s Disease
  - Fibroelastic deficiency

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

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

Most patients with isolated FMR are conservatively managed today\(^1\)

\(^1\) 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

† Sachin S. Goel, JACC Volume 63, Issue 2, January 2014
Edwards’ solutions addressing mitral regurgitation

MR due to annular dilatation
Cardioband Mitral System

DMR due to ruptured/elongated chordae
HARPOON Beating Heart Mitral Valve Repair System
Edwards Cardioband Mitral System
Key Advantages

- **Annular Reduction**
  - Restores valve to a more functional state, facilitating leaflet coaptation - reducing MR

- **Adjustable Implantation**
  - Enables annular reduction based on each patient's anatomy

- **Real-Time Confirmation**
  - Allows real-time adjustment and confirmation of MR reduction

Advantage compared to surgery
95% MR reduction sustained at 1 year in paired analysis by core lab\textsuperscript{1}

<table>
<thead>
<tr>
<th>Time</th>
<th>3-4+</th>
<th>2+</th>
<th>0-1+</th>
<th>(92% \text{ MR} \leq 2+) at 30 Days</th>
<th>95% MR (\leq 2+) at 6 Months</th>
<th>95% MR (\leq 2+) at 12 Months</th>
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<tbody>
<tr>
<td>Baseline</td>
<td>3-4+</td>
<td>2+</td>
<td>0-1+</td>
<td>3-4+</td>
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<td>Discharge</td>
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<td>30 days</td>
<td>3-4+</td>
<td>2+</td>
<td>0-1+</td>
<td>3-4+</td>
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<td>3-4+</td>
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<tr>
<td>6 Months</td>
<td>3-4+</td>
<td>2+</td>
<td>0-1+</td>
<td>3-4+</td>
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<tr>
<td>12 Months</td>
<td>3-4+</td>
<td>2+</td>
<td>0-1+</td>
<td>3-4+</td>
<td>3-4+</td>
<td>3-4+</td>
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n=39

Echo Core Lab: Dr. Paul Grayburn – Baylor University
Septolateral reduction maintained at 1 year in paired analysis

Dr. Paul Grayburn – Baylor University

n=25
Significant functional improvement at 1 year in paired analysis

**NYHA Class**

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<thead>
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<th>Baseline</th>
<th>12 Months</th>
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<tr>
<td>IV</td>
<td>100%</td>
<td>20%</td>
</tr>
<tr>
<td>III</td>
<td>80%</td>
<td>40%</td>
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<tr>
<td>II</td>
<td>40%</td>
<td>80%</td>
</tr>
<tr>
<td>I</td>
<td>20%</td>
<td>100%</td>
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79% NYHA I/II

**MLHFQ Score**

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<th>Baseline</th>
<th>12 Months</th>
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<tr>
<td></td>
<td>42</td>
<td>21</td>
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$P<0.01$ \( \Delta = -21 \)

**6MWT**

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<th>Baseline</th>
<th>12 Months</th>
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<td></td>
<td>309</td>
<td>367</td>
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$P<0.01$ \( \Delta = 58 \)

6MWT – Six-minute Walk Test; MLHFQ - Minnesota Living with Heart Failure Questionnaire; NYHA Class - New York Heart Association (NYHA) Functional Classification
Cardioband: solutions addressing tricuspid regurgitation

TR due to annular dilatation

Cardioband Tricuspid System
1. Functional (secondary) TR = 80 – 90%
   - (morphological normal leaflets; annular dilatation, leaflets tethering)
     - Left-sided heart failure (LV dysfunction / valve disease)
     - primary or secondary pulmonary hypertension
     - right ventricular dysfunction (myocardial disease, ischemic heart disease)
     - atrial fibrillation
     - cardiac tumors

2. Degenerative (primary) TR = 10 – 20%
   - (structural abnormality of TV apparatus)
     - Endocarditis
     - Traumatic chordal rupture
     - iatrogenic
       (pacemaker lead interference)
Dilatation of the annulus occurs primarily in anterior/posterior aspect, resulting in more circular, planar shape. Annuloplasty as best solution.
Limits of Tricuspid Annuloplasty

- leaflet tethering (>1cm)
- risk factor for long-term failure

Prevalence of TR in the US

Significant undertreatment of TR

- TR is a frequent problem!
- High Surgical Mortality: ca. 20%
- Medical therapy: poor prognoses
- TR affects > 50% of MR patients
- Severe TR of all TR cases: 36.1%

TR causes large reduction in quality of life and a significantly reduced survival.

Impact of Tricuspid Regurgitation on Long-Term Survival
Jayant Nath, MD,* Elyse Foster, MD, FACC,† Paul A. Heidenreich, MD*
Palo Alto and San Francisco, California

**Figure 1.** Kaplan–Meier survival curves for all patients with tricuspid regurgitation (TR). Survival is significantly worse in patients with moderate and severe TR.

1-year survival rate:
- Moderate TR: 79%
- Severe TR: 64%

4-year survival rate:
- Moderate TR: 48%
- Severe TR: 39%

Edwards Cardioband™ Tricuspid Valve Reconstruction System

- Tricuspid annular reduction via transfemoral access
  - Dedicated technology to treat tricuspid regurgitation
  - Same concept and similar implant technique to the Cardioband Mitral System
- Shortened learning curve from Cardioband Mitral System users
Sustained echo improvement at 6 months in paired analysis by core lab¹

- **PISA EROA**
  - 48% Reduction
  - Baseline: 0.73 ± 0.5
  - 6 Months: 0.38 ± 0.2
  - N = 14

- **Vena Contracta**
  - 27% Reduction
  - Baseline: 1.1 ± 0.3
  - 6 Months: 0.8 ± 0.3
  - N = 18

- **LV Stroke Volume**
  - 4% Improvement
  - Baseline: 61.2 ± 17.6
  - 6 Months: 63.8 ± 12.4
  - N = 13

¹ Dr. Rebecca T. Hahn – Cardiovascular Research Foundation
Sustained functional improvement at 6 months in paired analysis

6MWT - 6 Minute Walk Test, KCCQ - Kansas City Cardiomyopathy Questionnaire, NYHA Class - New York Heart Association, Functional Classification
Cardioband Mitral System

- Is a safe and feasible transcatheter mitral repair option
- Results are clinically and statistically significant at 1 year
- Core lab evaluable patients demonstrate stability of 95% MR ≤ 2+ at 1 year

Cardioband Tricuspid System

- Delivers a safe, significant and consistent reduction in tricuspid regurgitation
- Provides significant reduction in EROA through annular reduction
- Outcomes show clinically and statistically significant improvements in functional status, quality of life and exercise capacity at 6 months