How Cardioband Tricuspid System can benefit my patients

R. S. Von Bardeleben, MD
Tricuspid Regurgitation is Frequent but Rarely Treated

1.6M
TR prevalence

<10k
Surgical procedures annually

Tricuspid Regurgitation is Associated with Increased Mortality

5,223 patients
Study shows that moderate to severe TR increases mortality*

Functional Tricuspid Regurgitation
Consequence of RV and Annular Dilatation
Surgical Repair leading to percutaneous procedures

Surgical Annuloplasty = Edwards Cardioband TR

De-Vega Repair
Clover technique E2E = TricuClip or PASCAL
Hetzer Repair = NIH use of pledges
Kay Repair = Trialign
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
Edwards Cardioband Tricuspid System Procedure

1. Femoral Access & System Insertion
2. Implant Deployment
3. Implant Size Adjustment
Cardioband Tricuspid Valve Reconstruction System for treatment of TR
Baseline patient characteristics

80 yo male in NYHA III-IV

Isolated TR III-IV
No CAD
Hx of Afib
Mixed lung disease

Dilated RV and RA, dilated annulus
SL diameter 49 to 55 mm

Invasive sPAP 60 to 65 mmHg
PCWP 18 mmHg
Edwards Cardioband™ Tricuspid Valve Reconstruction System

1st in EU TV Transcatheter Procedure

3D TOE & real-time MPR Guiding of direct annuloplasty (Cardioband®) in a Patient with severe functional TR due to annulus dilatation

Images: Ralph Stephan von Bardeleben, MD, Alexander Tamm, MD, Heart Center University Medicine of Mainz, Germany
Cardioband Tricuspid System implant size reduction by fluoroscopy

Implant original size

Implant final size
Imaging Transcatheter Procedures

Coronary Angiography & Final CT of direct annuloplasty (Cardioband®) in a Patient with severe functional TR due to annulus dilatation

Images: Ralph Stephan von Bardeleben, MD, Alexander Tamm, MD, Heart Center University Medicine of Mainz, Germany
Cardioband Tricuspid System
final result procedural
Cardioband Tricuspid System
pre versus 12 mo and 18 mo follow up
Single arm, multi-center, prospective study to evaluate the performance and safety of the Edwards Cardioband System for repair of tricuspid regurgitation
Edwards Cardioband TRI-REPAIR Study
Participating sites

* Site activation pending approval.
Edwards TRI-REPAIR Study

Patient Flow

Baseline
N=30

Death n=2 (1 device related)

30 day follow up
N=28

Death n=1 (not device or procedure related)
Missed visit n=1
6 month visit pending n=4

6 month follow up
N=22
Successful access, deployment and positioning of the Cardioband device | 100% (30/30)
## Adjudicated 30 Day Events

<table>
<thead>
<tr>
<th>Event</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Death</strong></td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Right ventricular failure</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Bleeding unrelated to the device†</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td>1 (3.3)</td>
</tr>
<tr>
<td><strong>Bleeding complications</strong>*</td>
<td>3 (10.0)</td>
</tr>
<tr>
<td>Life-threatening†</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Extensive</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td><strong>Device related cardiac surgery</strong></td>
<td>0</td>
</tr>
<tr>
<td>Renal failure</td>
<td>1 (3.3)</td>
</tr>
</tbody>
</table>

* MVARC Guidelines (Stone et al, 2015)
† One patient had two life-threatening bleeding complications (cardiac tamponade, intracranial hemorrhage) and died
Edwards TRI-REPAIR Study

16% average annular reduction by core lab\textsuperscript{1} (paired analysis)

Paired difference = 7.34
Paired t-test P<0.0001

N = 26

\textsuperscript{1} Rebecca T. Hahn, MD – Cardiovascular Research Foundation
Sustained annular reduction at 6 months in paired analysis by core lab¹

¹ Dr. Rebecca T. Hahn – Cardiovascular Research Foundation
Edwards TRI-REPAIR Study

Sustained echo improvement at 6 months in paired analysis by core lab

PISA EROA
48% Reduction

Vena Contracta
27% Reduction

LV Stroke Volume
4% Improvement

P<0.01

P<0.01

P=0.4

N=14

N=18

N=13

0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9

PISA EROA (cm²)

0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9

0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9

Baseline 6 Months

1.1±0.3

0.8±0.3

61.2±17.6

63.8±12.4

1.4

1.2

1

0.8

0.6

0.4

0.2

0

Baseline 6 Months

Baseline 6 Months

Baseline 6 Months

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

**6MWT**
- Baseline: 278 meters
- 6 Months: 327 meters
- **P<0.05 Δ49**

**KCCQ Score**
- Baseline: 44
- 6 Months: 68
- **P<0.01 Δ24**

**NYHA Class**
- Baseline: 86%
- 6 Months: 86%
- **P<0.01**

**Edema**
- Baseline: Absent
- 6 Months: Absent
- **P=0.058**

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6MWT - 6 Minute Walk Test, KCCQ - Kansas City Cardiomyopathy Questionnaire, NYHA Class - New York Heart Association, Functional Classification
Patients with functional tricuspid regurgitation have a large unmet need with limited treatment options.

Use of Edwards Cardioband System for tricuspid regurgitation is safe and feasible.

Provides significant reduction in EROA by about 50% through annular reduction.

Clinically significant improvements in functional status, quality of life and exercise capacity at 30 days and sustained at 6 months.

Further studies are warranted to validate these initial promising results, FIRST TC ce mark Tricuspid device.
Thank you

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