Percutaneous mitral valve repair: current techniques and results

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Disclosure Information

The following relationships exist:

Grant support: Abbott, Atritech, BSC, Cardiac Dimensions, Cordis, Evalve, EV3, St Jude.
Consultant: BSC, Cardiac Dimensions, Cordis, Edwards, Myocor
Speaker: Boston Scientific

Off label use of products and investigational devices will be discussed in this presentation
Percutaneous Mitral Repair Approaches

- **Coronary sinus annuloplasty**
  - Edwards Monarc
  - Cardiac Dimensions Carillon
  - Viacor Shape Changing Rods
  - St. Jude Annulus Reshaping

- **Direct annuloplasty**
  - Mitralign Suture-Based Plication
  - Guided Delivery Anchor-Cinch Plication
  - QuantumCor RF Annulus Remodeling
  - MiCardia variable size ring

- **Leaflet repair**
  - EValve Mitraclip
  - Edwards Mobius stitch

- **Chamber + annular remodeling**
  - Myocor iCoapsys
  - Ample PS3
Percutaneous Mitral Valve Therapies

- Evalve
- Mobius
- Monarc
- Vaicor
- Ample PS3
- Cardiac Dimensions

- Mitralign
- Guided Delivery
- Quantum-Cor

>200

Evalve
CARILLON Mitral Contour System
**Average Exercise Improvement**

**CARILLON Implants**

**Six Minute Walk Test**

<table>
<thead>
<tr>
<th>Baseline</th>
<th>1 Month</th>
<th>6 Months</th>
<th>Six Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>279</td>
<td>412</td>
<td>276</td>
<td>487</td>
</tr>
</tbody>
</table>

**Average improvement:**
- **1 month** (n=12) 133 meters or 48%
- **6 months** (n=6) 211 meters or 77%

Combined data from AMADEUS, PERSEUS, VERITAS Trials
The MONARC system
Delayed Release-\textit{in situ}

EVOLUTION study interim performance data

- Baseline Grade 3-4+
- Baseline Grade 2-4+

**Active Device Foreshortening (6 Weeks)**

<table>
<thead>
<tr>
<th>Time</th>
<th>Baseline Grade 3-4+</th>
<th>Baseline Grade 2-4+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>3.4 (n = 22)</td>
<td>2.7 (n = 42)</td>
</tr>
<tr>
<td>30 Days</td>
<td>2.6 (n = 30)</td>
<td>2.1 (n = 30)</td>
</tr>
<tr>
<td>90 Days</td>
<td>2.3 (n = 27)</td>
<td>2.0 (n = 27)</td>
</tr>
<tr>
<td>180 Days</td>
<td>1.6 (n = 13)</td>
<td>1.4 (n = 13)</td>
</tr>
</tbody>
</table>

Echo Core Lab data
Surgical isolated edge-to-edge mitral repair without annuloplasty

clinical proof of principle for an endovascular approach

Freedom from re-operation and 2+ MR

Maisano F, Vigano G, Blasio A, Columbo A, Calabrese C, Alfieri O

Eurointervention 2:181-186, 2006
Percutaneous Mitral Repair

Caution: Investigational Device. Limited by Federal (US) Law to Investigational Use
Key Eligibility Criteria

- Age 18 years or older
- Moderate to severe (3+) or severe (4+) MR
  - Symptomatic
  - Asymptomatic with $\text{LVEF} < 60\%$ or $\text{LVESD} > 45\text{mm}$
- MR originates from A2-P2 mal-coaptation
- Core lab echo assessment
  - ASE Guideline - JASE 2003;16:777-802
- Candidate for mitral valve surgery including CPB
- Transseptal deemed feasible
- Key Exclusions
  - $\text{EF} < 25\%$ or $\text{LVESD} > 55\text{mm}$
  - Renal insufficiency
  - Endocarditis, rheumatic heart disease
## Clinical Features

(N = 104)

<table>
<thead>
<tr>
<th>Clinical Feature</th>
<th>EVEREST Registry</th>
<th>STS Database 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median Age (range)</strong></td>
<td>71 (26 – 88)</td>
<td>59</td>
</tr>
<tr>
<td>≥ age 65</td>
<td>61 %</td>
<td>37%</td>
</tr>
<tr>
<td><strong>Male gender</strong></td>
<td>63 %</td>
<td>58%</td>
</tr>
<tr>
<td><strong>Diabetes mellitus</strong></td>
<td>19 %</td>
<td>9%</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>68 %</td>
<td>47%</td>
</tr>
<tr>
<td><strong>COPD</strong></td>
<td>11 %</td>
<td>13%</td>
</tr>
<tr>
<td><strong>History CHF</strong></td>
<td>50 %</td>
<td>40%</td>
</tr>
<tr>
<td><strong>Atrial Fibrillation</strong></td>
<td>38 %</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Median EF</strong></td>
<td>63 %</td>
<td>55%</td>
</tr>
<tr>
<td><strong>NYHA III or IV</strong></td>
<td>45 %</td>
<td>43%</td>
</tr>
</tbody>
</table>

*Median Age (range) ≥ age 65*

**EVEREST Registry**

| **Median Age (range)**           | 71 (26 – 88)     | 59                |
| ≥ age 65                         | 61 %             | 37%               |

**STS Database 2002**

| **Median Age (range)**           | 71 (26 – 88)     | 59                |
| ≥ age 65                         | 61 %             | 37%               |
Procedural Results
(N = 104)

Clip Procedure Attempted
N = 104 (100%)

61% ≤ 1+

Clip Implanted
n=92 (89%)
Event Free Clinical Success Kaplan-Meier
Patients with Acute Procedural Success
n = 79

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>Freedom From Death</th>
<th>Freedom From Surgery</th>
<th>Freedom From Death, Surgery or MR &gt;2+</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>6</td>
<td>99%</td>
<td>97%</td>
<td>97%</td>
</tr>
<tr>
<td>12</td>
<td>97%</td>
<td>97%</td>
<td>97%</td>
</tr>
<tr>
<td>18</td>
<td>97%</td>
<td>97%</td>
<td>97%</td>
</tr>
<tr>
<td>24</td>
<td>97%</td>
<td>97%</td>
<td>97%</td>
</tr>
<tr>
<td>30</td>
<td>100%</td>
<td>97%</td>
<td>97%</td>
</tr>
<tr>
<td>36</td>
<td>90%</td>
<td>87%</td>
<td>86%</td>
</tr>
<tr>
<td>42</td>
<td>85%</td>
<td>86%</td>
<td>86%</td>
</tr>
<tr>
<td>48</td>
<td>86%</td>
<td>86%</td>
<td>85%</td>
</tr>
<tr>
<td>54</td>
<td>67%</td>
<td>68%</td>
<td>68%</td>
</tr>
<tr>
<td>n = Reached Endpoint</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Freedom from death, mitral valve surgery, & MR>2
Reverse LV Remodeling
Matched Data, Acute Procedural Success Patients
n = 46

LV End Diastolic & Systolic Dimensions

<table>
<thead>
<tr>
<th>Dimension (cm)</th>
<th>Baseline</th>
<th>12-Month</th>
<th>Baseline</th>
<th>12-Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diastolic</td>
<td>5.5</td>
<td>5.2</td>
<td>3.5</td>
<td>3.3</td>
</tr>
<tr>
<td>Systolic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p < 0.001
p = 0.04

LV End Diastolic & Systolic Volumes

<table>
<thead>
<tr>
<th>Volume (ml)</th>
<th>Baseline</th>
<th>12-Month</th>
<th>Baseline</th>
<th>12-Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diastolic</td>
<td>172</td>
<td>146</td>
<td>72</td>
<td>63</td>
</tr>
<tr>
<td>Systolic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p < 0.001
p = 0.002
Surgery Following Clip Procedure (N = 104)

Surgery After Clip Implanted (n = 20)
- 15 (75%) Repairs (0 - 562 days)
- 5 (25%) Replacements

Surgery After No Clip (n = 8)
- 5 (63%) Repairs
- 3 (37%) Replacements

71% Repaired

SURGERY FREE
73%

76/104
EVEREST II Study Design

- Prospective, randomized, multi-center study
  - Control: surgical mitral valve repair or replacement
  - Patients randomized 2:1

- Primary Effectiveness Endpoint: non-inferiority
  - Freedom from surgery for Valve Dysfunction, death, and moderate to severe (3+) or severe (4+) mitral regurgitation at 12 months

- Primary Safety Endpoint: superiority
  - Freedom from MAE at one month
High Risk : Inclusion Criteria

- STS surgical risk calculator $\geq 12\%$
- or judgment of surgeon investigator the patient is considered high risk due to one of the following:
  - Porcelain aorta or mobile ascending aortic atheroma
  - Post-radiation mediastinum
  - Previous mediastinitis
  - Functional MR with EF<40
  - Over 75 years old with EF<40
  - Re-operation with patent grafts
  - Two or more prior chest surgeries
  - Hepatic cirrhosis
  - Three or more of the following STS high risk factors:
    - Creatinine $>2.5$ mg/dL
    - Prior chest surgery
    - Age over 75
    - EF<35
# EVEREST I & II Enrollment (4/23/07)

<table>
<thead>
<tr>
<th>Enrollment</th>
<th>Population</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVEREST I Feasibility (completed)</td>
<td>Registry patients</td>
<td>55</td>
</tr>
<tr>
<td>EVEREST II</td>
<td>Roll-in</td>
<td>50</td>
</tr>
<tr>
<td>Randomized n=97</td>
<td>Randomized Clip</td>
<td>65</td>
</tr>
<tr>
<td></td>
<td>Randomized Surgery</td>
<td>32</td>
</tr>
<tr>
<td>EVEREST II High Risk Registry</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Total enrolled</td>
<td></td>
<td>208</td>
</tr>
</tbody>
</table>

- 30 sites
“You will spend many years in a luxurious mansion sprawled in front of a warm fireplace.”