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
- Cardiac Dimensions
- Ample PS3
- Mitralign
- Guided Delivery
- Quantum-Cor

>200

Evalve
CARILLON Mitral Contour System
Average Exercise Improvement
CARILLON Implants

Six Minute Walk Test

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
Carillon Experience
5/1/2007

- 30 implanted patients to date

2007 Experience

- MR reduction in ~ 80% of patients
  - 2 had compromised coronary artery requiring device removal
  - not all crossed arteries resulted in compression
  - overall implant rate is 70’s%

- more than a 50% MR reduction intraprocedure

- 6 minute walk data positive

- 75% have 1 grade improvement in NYHA class

- QOL Kansas City Cardiomyopathy Questionnaire
  - 25 point improvement in the overall summary score
  - correlates with one grade reduction in NYHA class
The MONARC system
Delayed Release-\textit{in situ}

EVOLUTION study interim performance data

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

Mean MR Value over time:
- Baseline:
  - Grade 3-4+: 3.4 (n = 22)
  - Grade 2-4+: 2.7 (n = 42)
- 30 Days:
  - Grade 3-4+: 2.6
  - Grade 2-4+: 2.1 (n = 30)
- 90 Days:
  - Grade 3-4+: 2.3
  - Grade 2-4+: 2.0 (n = 27)
- 180 Days:
  - Grade 3-4+: 1.6 (n = 13)
  - Grade 2-4+: 1.4

Echo Core Lab data

Active Device Foreshortening (6 Weeks)
Sustained Device Tension
Five-year experience with a suture annuloplasty for mitral valve repair

93.4% freedom from re-operation

n=130

Fig. 1. The modified mitral plication suture. A double semicircular suture is placed in the mitral annulus around the posterior leaflet. The suture is reinforced with pledgets at each commissure and at the centre point of the posterior leaflet. When tying the suture, the mitral annulus can be tightened to appropriate size.

Seven years’ experience with suture annuloplasty for mitral valve repair

FREEDOM From

% at 77 Months

n=222

Significant MR 82
Reoperation 95
Death 87

Aybek et al J Thor CV Surgery 2006
Surgical isolated edge-to-edge mitral repair without annuloplasty

clinical proof of principle for an endovascular approach

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.
2 Clip Case

Post Clip MR

Double orifice inflow

Lossy compression - not intended for diagnosis
Key Eligibility Criteria

- Age 18 years or older
- Moderate to severe (3+) or severe (4+) MR
  - Symptomatic
  - Asymptomatic with LVEF < 60% or LVESD > 45mm
- 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
  - EF < 25% or LVESD > 55 mm
  - Renal insufficiency
  - Endocarditis, rheumatic heart disease
## Clinical Features

(N = 104)

<table>
<thead>
<tr>
<th></th>
<th>EVEREST Registry</th>
<th>STS Database 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Repair</td>
</tr>
<tr>
<td>Median Age (range) ≥ age 65</td>
<td>71 (26 – 88)</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td><em>61 %</em></td>
<td><em>37%</em></td>
</tr>
<tr>
<td>Male gender</td>
<td>63 %</td>
<td>58%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>19 %</td>
<td>9%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>68 %</td>
<td>47%</td>
</tr>
<tr>
<td>COPD</td>
<td>11 %</td>
<td>13%</td>
</tr>
<tr>
<td>History CHF</td>
<td>50 %</td>
<td>40%</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>38 %</td>
<td>n/a</td>
</tr>
<tr>
<td>Median EF</td>
<td>63 %</td>
<td>55%</td>
</tr>
<tr>
<td>NYHA III or IV</td>
<td>45 %</td>
<td>43%</td>
</tr>
</tbody>
</table>
Procedural Results
(N = 104)

Clip Procedure Attempted
N = 104 (100%)

- Clip Implanted
  n=93 (89%)
  Acute Procedural Success
  MR ≤ 2+
  n=79/93 (85%)

- No Clip Implanted
  n=11 (11%)
  No APS
  MR 4+ to 3+
  n=7/93 (7.5%)
  No APS
  No MR Reduction
  n=7/93 (7.5%)

61% ≤1+
Other Clip Related Events

N = 104

Freedom from Clip Embolization 100%

Partial Clip Detachment 9 (8.7%)
- during clip placement 3 (2.9%)
- pre-discharge 1 (1.0%)
- post discharge to 30 days 5 (4.8%)
- > 30 days 0 (0.0%)
Event Free Clinical Success Kaplan-Meier

Patients with Acute Procedural Success

n = 79

Freedom from death, mitral valve surgery, & MR >2
## Registry MR Etiology

N = 104

<table>
<thead>
<tr>
<th>Etiology</th>
<th>Count (Percentage)</th>
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<tbody>
<tr>
<td>Degenerative/Mixed</td>
<td>81 (78%)</td>
</tr>
<tr>
<td>Posterior Prolapse/Flail</td>
<td>56 (69%)</td>
</tr>
<tr>
<td>Anterior/Bi-leaflet Prolapse/Flail</td>
<td>25 (31%)</td>
</tr>
<tr>
<td>Functional</td>
<td>23 (22%)</td>
</tr>
</tbody>
</table>
Event Free Clinical Success Kaplan-Meier
Patients with Acute Procedural Success
n = 79

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

\[ n = 46 \]

LV End Diastolic & Systolic Dimensions

**LV End Diastolic & Systolic Volumes**

- **Diastolic:** Baseline: 172, 12-Month: 146, \[ p < 0.001 \]
- **Systolic:** Baseline: 72, 12-Month: 63, \[ p = 0.002 \]

\[ p < 0.001 \]

\[ p = 0.04 \]
Surgery Following Clip Procedure
(N = 104)

71% Repaired

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

SURGERY FREE
76/104
73%
19%
8%
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 ≥ 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>
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<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>
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<tr>
<td>Randomized n=97</td>
<td>Randomized Clip</td>
<td>65</td>
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<tr>
<td></td>
<td>Randomized Surgery</td>
<td>32</td>
</tr>
<tr>
<td>EVEREST II High Risk Registry</td>
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<td>6</td>
</tr>
<tr>
<td><strong>Total enrolled</strong></td>
<td></td>
<td><strong>208</strong></td>
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</tbody>
</table>

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