Percutaneous mitral valve therapies

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Evanston Hospital

Angioplasty Summit
TCT Asia Pacific 2009
April 21st-24th, 2009
Disclosures

Grant support: Abbott, Atritech, BSC, Cardiac Dimensions, Edwards, Evalve, Myocor, St Jude
Consultant: Abbott, Cardiac Dimensions, CoAptus, Coherex, Cordis, WL Gore, Myocor, Quantam-Cor
Speaker: Boston Scientific

Off label use of products and investigational devices will be discussed in this presentation
Endovascular CVRS for E2E Mitral Repair
Cardiovascular Valve Repair System
# EVEREST I & II Enrollment


<table>
<thead>
<tr>
<th>Enrollment</th>
<th>Population</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVEREST I Feasibility (1st patient 7/2/2003)</td>
<td>Registry patients</td>
<td>55</td>
</tr>
<tr>
<td>EVEREST II</td>
<td>Roll-in</td>
<td>60</td>
</tr>
<tr>
<td>Randomized n=279</td>
<td>Randomized Clip</td>
<td>184</td>
</tr>
<tr>
<td></td>
<td>Randomized Surgery</td>
<td>95</td>
</tr>
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<td>High Risk Registry</td>
<td>78</td>
</tr>
<tr>
<td><strong>Total enrolled</strong></td>
<td></td>
<td>472</td>
</tr>
</tbody>
</table>
# EVEREST Preliminary Cohort

<table>
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<tr>
<th>Study</th>
<th>Population</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVEREST I (Feasibility)</td>
<td>All patients enrolled</td>
<td>55</td>
</tr>
<tr>
<td>EVEREST II (Pivotal)</td>
<td>Non-randomized patients (Excluding High Risk Registry)</td>
<td>52</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>107</td>
</tr>
</tbody>
</table>

- *Preliminary Cohort analysis per EVEREST II definitions*
- *30 North American sites*
- *70% are 1\(^{st}\), 2\(^{nd}\), or 3\(^{rd}\) procedure at a site*
Kaplan-Meier Freedom from Death and MV Surgery

Preliminary Cohort - Per Protocol

Event Free Survival

Freedom From Death
Freedom From MV Surgery

n at risk Death
79 79 73 69 63 56
n at risk Surgery
79 79 72 67 59 51
# EVEREST I & II Enrollment


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**Total enrolled: 472**
**EVEREST HRR**

**Study Algorithm**

**KEY INCLUSION CRITERIA**
- Predicted procedural mortality $\geq 12\%$
  - STS or Surgeon estimated
- Symptomatic 3+ or 4+ MR
- Degenerative or Functional

**KEY EXCLUSION CRITERIA**
- $\text{EF} \leq 20\%$ and/or $\text{LVESD} > 60\text{mm}$
- $\text{MVA} < 4\text{cm}^2$
- Leaflet anatomy unsuitable

78 Enrolled

46 FMR Patients - 59%

36 Concurrent Control

50% met all inc/exclusion criteria
50% met all but clip anatomical criteria
<table>
<thead>
<tr>
<th></th>
<th>HRR, FMR (n=46)</th>
<th>Euro Heart Survey*</th>
<th>STS Database 2007**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Not Operated (n=193)</td>
<td>Operated (n=203)</td>
</tr>
<tr>
<td>Age</td>
<td>73</td>
<td>69</td>
<td>63</td>
</tr>
<tr>
<td>&gt; age75</td>
<td>56%</td>
<td>65% (est)</td>
<td>35% (est)</td>
</tr>
<tr>
<td>Male gender</td>
<td>63%</td>
<td>47%</td>
<td>53%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>52%</td>
<td>21%</td>
<td>10%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>91%</td>
<td>53%</td>
<td>47%</td>
</tr>
<tr>
<td>COPD / Chronic lung disease</td>
<td>35%</td>
<td>21%</td>
<td>11%</td>
</tr>
<tr>
<td>Moderate to Severe Renal Failure</td>
<td>26%</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>History CHF</td>
<td>100%</td>
<td>49%</td>
<td>29%</td>
</tr>
<tr>
<td>History CAD</td>
<td>87%</td>
<td>60%</td>
<td>38%</td>
</tr>
<tr>
<td>History Atrial Fibrillation</td>
<td>77%</td>
<td>36%</td>
<td>32%</td>
</tr>
<tr>
<td>Prior Cardiac Surgery</td>
<td>63%</td>
<td>7% CABG</td>
<td>3% CABG</td>
</tr>
<tr>
<td>STS Score</td>
<td>17%</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>MR Grade (mean)</td>
<td>3.2</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Ejection Fraction</td>
<td>47%</td>
<td>48%</td>
<td>56%</td>
</tr>
<tr>
<td>NYHA III or IV</td>
<td>91%</td>
<td>70%</td>
<td>65%</td>
</tr>
<tr>
<td>LV EDD (mm)</td>
<td>59</td>
<td>57</td>
<td>59</td>
</tr>
<tr>
<td>LV ESD (mm)</td>
<td>44</td>
<td>41</td>
<td>40</td>
</tr>
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**US Data Analyses of the STS National Adult Cardiac Surgery Database, 2007
HRR FMR (ITT)
Reverse LV remodeling
LV End Diastolic & Systolic Volumes

Diastolic
- LVEDV Baseline: 192 ml
- LVEDV 12 Months: 153 ml

Systolic
- LVESV Baseline: 103 ml
- LVESV 12 Months: 87 ml

P=0.001
P=0.002

n=34, Matched Data
HRR FMR (ITT)

Hospitalization for CHF

Baseline Pre-Clip

12 Months Post Clip

# CHF Hosp

# Patients

Annual Rate CHF Hospitalization
European Sites

71 procedures at 10 sites
FMR 66%
EVEREST Conclusions

- Proof of principle for both degenerative & functional MR

- High Risk Registry
  - Unmet need for poor surgical candidates
  - Reverse LV remodeling, Increased Stroke Volume, Decrease in Septal-Lateral Annular Dimension
  - Improved NYHA Class, Reduction in hospitalization for CHF
  - Clinical benefits sustained for at least one year

- Enrollment complete in EVERST II
  - role for patients with surgical option

- Surgical options preserved

- Randomized trial results in 1 year
  - Landmark results with 1st percutaneous repair technology to complete a trial
  - Prospective evaluation of current mitral valve surgery
Percutaneous Mitral Approaches

- **Coronary sinus annuloplasty**
  - Edwards Monarc
  - Cardiac Dimensions Carillon
  - Viacor Shape Changing Rods

- **Direct annuloplasty**
  - Mitralign Suture-Based Plication
  - Guided Delivery Anchor-Cinch Plication
  - Quantum Cor

- **Chamber + annular remodeling**
  - Myocor iCoapsys
  - Ample PS3

- **Leaflet repair**
  - EVAlve Mitraclip

- **Chordal replacement**

- **Mitral valve replacement**
CARILLON Mitral Contour System

The MONARC system
Delayed Release - in situ
59% of patients are responders:

- 44% 1 grade
- 15% 2 grades

n=72

TCT 2008
Six Minute Walk Test - AMADEUS™

![Bar chart showing Meters walked at baseline, 1 month, and 6 months with P < 0.001.]

Baseline: 307 meters for n=30
1 Month: 387 meters for n=26
6 Months: 403 meters for n=23

Caution: Investigational Device: Limited by US Law to European Investigational Use