Percutaneous mitral valve repair: leaflet & annuloplasty approaches

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Disclosure Information

The following relationships exist:

Grant support: Abbott, Atritech, BSC, Cardiac Dimensions, Edwards, Evolve, Myocor, St Jude
Consultant: Abbott, Cardiac Dimensions, Coherex, Cordis, 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
Surgical Correction of Pure Mitral Insufficiency by Annuloplasty Under Direct Vision

C. WALTON LILLEHEI, Ph.D., M.D., VINCENT L. GOTT, M.D., RICHARD A. DE WALL, M.D., and RICHARD L. VARCO, Ph.D., M.D.

Minneapolis, Minnesota

In recent years, effective surgical measures for treating stenotic lesions of the pulmonary mitral, and aortic valves have been described. The previously described techniques have been carried out under direct vision. The development and routine clinical use of such instruments for working inside of the body have made possible direct vision by use of a pump-oxygenator which has removed the barrier to the development of cardiac surgery and has made possible the repair of defects in the treatment of congenital heart disease. In 1955, the rapidly increasing use of the pump-oxygenator for congenital cardiac malformations had resulted in confidence concerning the well-being of the patient during the operation. Since then, many patients have been operated on under direct vision with those obtained by blind methods. However, with the increasing number of surgical appliance repairs of valvular regurgitation, the benefits of open cardiac surgery have been carried out by closed or blind methods, and none has found general acceptance.

Lancet 1957
<table>
<thead>
<tr>
<th>Condition</th>
<th>Annuloplasty</th>
<th>Leaflet Repair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional CHF</td>
<td></td>
<td>✔️</td>
</tr>
<tr>
<td>Functional Ischemic</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Degenerative Prolapse</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>
Percutaneous Mitral Valve Therapies

- CS annuloplasty
- Evalesce leaflet repair
- Monarc
- Vaicor
- Cardiac Dimensions
- Ample PS3
- >375
CARILLON Mitral Contour System

The MONARC system
Delayed Release-\textit{in situ}
# Cumulative MACE events

<table>
<thead>
<tr>
<th>Event</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Probable Cause: Use of non-J-Tip Guidewire *</td>
</tr>
<tr>
<td>Day 6</td>
<td>Probable Cause: Use of non-J-Tip Guidewire *</td>
</tr>
<tr>
<td><strong>MI (3)</strong></td>
<td></td>
</tr>
<tr>
<td>Day 16</td>
<td>Distal Anchor Positioned at first Diagonal Branch *</td>
</tr>
<tr>
<td>Day 19</td>
<td>LCx occlusion, pre-existing disease *</td>
</tr>
<tr>
<td>Day 551</td>
<td>OM1 Occlusion &amp;</td>
</tr>
<tr>
<td><strong>Death (9)</strong></td>
<td></td>
</tr>
<tr>
<td>Day 22</td>
<td>Arrhythmia</td>
</tr>
<tr>
<td>Day 24</td>
<td>Heart failure</td>
</tr>
<tr>
<td>Day 51</td>
<td>Bacterial infection</td>
</tr>
<tr>
<td>Day 52</td>
<td>Fall Leading to Cranial Hemorrhage &amp;</td>
</tr>
<tr>
<td>Day 61</td>
<td>Pulmonary Embolism</td>
</tr>
<tr>
<td>Day 96</td>
<td>Multi-Organ System Failure – Post MV Surgery</td>
</tr>
<tr>
<td>Day 141</td>
<td>Heart Failure</td>
</tr>
<tr>
<td>Day 280</td>
<td>Worsening for Cardiopulmonary Disease</td>
</tr>
<tr>
<td>Day 552</td>
<td>Left Heart Failure due to MI &amp;</td>
</tr>
</tbody>
</table>

N=59 implants

TCT 2007
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
**EVEREST Preliminary Cohort**

**Surgery Following Clip Procedure**

N = 107

- **Surgery After Clip Implanted** (n = 23)
  - 16 (70%) Repairs (0 - 562 days)
  - 7 (30%) Replacements

- **Surgery After No Clip** (n = 9)
  - 5 (56%) Repairs
  - 4 (44%) Replacements

- **Surgery** (32/104)
  - 66% Repaired
  - 22%
  - 8%

- **SURGERY FREE**
  - 75/107
  - Median Follow-up 386 Days

84% (21/25) attempted repairs successful
64% (7/11) replacements planned (complex disease, age, co-morbidity)
EVEREST Preliminary Cohort

Event Free Clinical Success Kaplan-Meier

Acute Procedure Success Patients  \( n = 81 \)

- Freedom From Death
- Freedom From Surgery
- Freedom From Death, Surgery and MR > 2+

Freedom from death, mitral valve surgery, & MR>2
EVEREST Preliminary FMR Cohort:
Event Free Clinical Success Kaplan-Meier

Acute Procedure Success Patients  n=19

Freedom from death, mitral valve surgery, & MR > 2+
Surgery for Mitral Valve Disease

- Intention to treat reporting
  - Frequency of conversion to MVR highly variable
- Severity of MR
  - Results better in moderate MR
  - Trials include more severe grades than usual practice
- Core lab MR assessment
  - Challenges for MR grading substantial
  - Post-operative vs pre discharge vs 1 month
- Endpoints
  - Recurrent MR not well characterized
  - Functional status difficult to characterize
  - Results not so great for functional MR
Mitral valve surgery in heart failure

Insights from the Acorn Clinical Trial

Baseline MR grade

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 atheoroma
  - 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$<35$
Medical Decision Making

<table>
<thead>
<tr>
<th>Technique</th>
<th>Metric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eminence-based</td>
<td>white hair</td>
</tr>
<tr>
<td>Vehemence-based</td>
<td>level of stridency</td>
</tr>
<tr>
<td>Eloquence-based</td>
<td>smoothness of tongue</td>
</tr>
<tr>
<td>Providence-based</td>
<td>religious fervor</td>
</tr>
<tr>
<td>Nervousness-based</td>
<td>risk of litigation</td>
</tr>
<tr>
<td>Confidence-based</td>
<td>bravado (surgeons only)</td>
</tr>
<tr>
<td>Evidence-based</td>
<td>Statistically-valid inferences from well-designed RCTs</td>
</tr>
</tbody>
</table>
# EVEREST I & II Enrollment (3/20/08)

<table>
<thead>
<tr>
<th>Enrollment</th>
<th>Population</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EVEREST I</strong></td>
<td>Registry patients</td>
<td>55</td>
</tr>
<tr>
<td>Feasibility (completed)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>EVEREST II</strong></td>
<td>Roll-in</td>
<td>59</td>
</tr>
<tr>
<td>Randomized n=131</td>
<td>Randomized Clip</td>
<td>129</td>
</tr>
<tr>
<td></td>
<td>Randomized Surgery</td>
<td>61</td>
</tr>
<tr>
<td><strong>EVEREST II</strong></td>
<td>High Risk Registry (completed)</td>
<td>78</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total enrolled</strong></td>
<td></td>
<td>382</td>
</tr>
<tr>
<td></td>
<td>38 sites</td>
<td></td>
</tr>
</tbody>
</table>
Retrograde-LV Direct Suture Annuloplasty
The Myocor Surgical Coapsys System
iCoapsys
Interventionalist meets Valve Surgeon
1970-2000

Circa 2010