ACCUCINCH at IMC

Care of Mitral Valve Disease at Intermountain Healthcare

Heart Team Excellence

Brian Whisenant, MD

2017
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>Consultant, Proctor, Speaker</td>
<td>Edwards Lifesciences</td>
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<tr>
<td>Proctor, Speaker</td>
<td>Boston Scientific</td>
</tr>
<tr>
<td></td>
<td>(not heart valve related)</td>
</tr>
<tr>
<td>Equity, Consulting</td>
<td>JNJ</td>
</tr>
<tr>
<td></td>
<td>(not heart valve related)</td>
</tr>
</tbody>
</table>
Accucinch “Ventriculoplasty”

Transcatheter Therapy of Heart Failure & Mitral Regurgitation

- Access
  Transcatheter Delivery

- Deployment
  Anchors & Band

- Therapy
  TEE Guided Cinch

- Human experience with predecessor device was unsuccessful.
- Spacer added to distribute force.
- IMC invited to participate in early feasibility study.
Annular Therapy of Mitral Regurgitation First Published in 1956

MITRAL INSUFFICIENCY: TREATMENT BY POLAR CROSS-FUSION OF THE MITRAL ANNULUS FIBROSUS

Fig. 4. — The suture is tied down as described in the text after the pericardial sheath has been separated from the Dacron in the region of the knot. At this point competence is restored to the valve in most instances.

Fig. 5. — In some individuals a second such plicating suture is necessary in order to overcome the entire insufficiency.

From the Department of Thoracic Surgery, Hahnemann Medical College and Hospital of Philadelphia, and The Bailey Thoracic Clinic, Philadelphia, Pa.

Read at the Thirty-sixth Annual Meeting of The American Association for Thoracic Surgery at Miami Beach, Fla., May 7 to 9, 1956.
Mitral Repair Including an Annular Ring Standard of Care - - 61 years later
Mitral Valve Repair

<table>
<thead>
<tr>
<th>Center</th>
<th>Patients</th>
<th>Repair</th>
<th>In Hospital Mortality</th>
<th>Freedom from severe MR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mt. Sinai¹</td>
<td>744</td>
<td>99.9%</td>
<td>0.8%</td>
<td>96% - 7 yrs</td>
</tr>
<tr>
<td>U Penn²</td>
<td>525</td>
<td>99%</td>
<td>0.2%</td>
<td>97% - 8 yrs</td>
</tr>
<tr>
<td>Mayo³*</td>
<td>487</td>
<td>100%</td>
<td>0.2%</td>
<td>95% &lt; mod 5 yrs</td>
</tr>
</tbody>
</table>

*Robotic MV repair

Where is the unmet need?

A Largely Untreated Population

Mitral Regurgitation 2009 U.S. Prevalence

Total MR Patients\(^1,2\)

MR Grade ≥3\(^3,4\)

Annual Incidence\(^3\)
(MR Grade ≥3+)

Annual MV Surgery\(^5\)

4,100,000

1,670,000

30,000

Untreated Large and Growing Clinical Unmet Need

Only 2% Treated Surgically

5. Gammie, J et al, Trends in Mitral Valve Surgery in the United States: Results from the STS Adult Cardiac Database, Annals of Thoracic Surgery
Valvular Heart Disease
Who does and does not receive valve surgery?

- Palliation Candidate
- Technically Extreme
- Healthy but elderly

1,239 Hospitals; 125,079 Patients

<table>
<thead>
<tr>
<th>Range</th>
<th>No of Hospitals</th>
<th>%</th>
<th>Repair Rate %</th>
<th>Range</th>
<th>No of Hospitals</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>&lt;5</td>
<td>354</td>
<td>28.6</td>
<td>30.5%</td>
<td>0-1</td>
<td>281</td>
<td>22.7</td>
</tr>
<tr>
<td>6-10</td>
<td>276</td>
<td>22.3</td>
<td>32.9</td>
<td>2-5</td>
<td>525</td>
<td>42.4</td>
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<tr>
<td>11-20</td>
<td>313</td>
<td>25.3</td>
<td>34.9</td>
<td>6-10</td>
<td>233</td>
<td>18.8</td>
</tr>
<tr>
<td>21-40</td>
<td>188</td>
<td>15.2</td>
<td>38.8</td>
<td>11-20</td>
<td>130</td>
<td>10.5</td>
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<tr>
<td>&gt;40</td>
<td>108</td>
<td>8.7</td>
<td>42.0</td>
<td>&gt;20</td>
<td>70</td>
<td>5.6</td>
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</table>

- > 65% of hospitals perform < 5 Medicare mitral repairs per year
- Overall Replacement = 61.7%
- Overall hospital mortality = 10.7%
Transcatheter Mitral Valve Repair with the MitraClip System

- First LDS Hospital Implant 2007
- FDA Approved for DMR 2013
- 24 Patients enrolled in FMR COAPT Trial (#3 of 94 sites)
- Multidisciplinary cooperation with surgery and HF
- Serve our regional patients with procedural expertise
Transcatheter Mitral Valve Replacement

Transseptal Delivery and Balloon Inflation of THV Valve

THV within Mosaic valve
## TMVR Executive Summary

### Detail Lines

**Intermountain Medical Center (407533)**

<table>
<thead>
<tr>
<th>Line#</th>
<th>Description</th>
<th>My Hospital R4Q</th>
<th>US Registry Pts R4Q</th>
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</thead>
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<tr>
<td></td>
<td></td>
<td>Num</td>
<td>Den</td>
</tr>
<tr>
<td>1955</td>
<td>Volume Metrics</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>1956</td>
<td>Patients with TMVR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1958</td>
<td>Outcome Metrics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1959</td>
<td>Mortality</td>
<td></td>
<td></td>
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<tr>
<td>1960</td>
<td>Mortality – unadjusted</td>
<td>0</td>
<td>11</td>
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<tr>
<td>Line#</td>
<td>Description</td>
<td>My Hospital R4Q</td>
<td>US Registry Pts R4Q</td>
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<tr>
<td></td>
<td></td>
<td>Num</td>
<td>Den</td>
</tr>
<tr>
<td>1964</td>
<td>Neurologic</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>1965</td>
<td>TIA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1966</td>
<td>Stroke (any)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1967</td>
<td>Renal</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>1968</td>
<td>Acute kidney injury (stage 3)</td>
<td>0</td>
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</tr>
<tr>
<td>1969</td>
<td>Bleeding/Vascular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1970</td>
<td>Disabling or life threatening bleed</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>1971</td>
<td>Major vascular complications</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>1976</td>
<td>Valve Performance Metrics</td>
<td></td>
<td></td>
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<tr>
<td>1977</td>
<td>Mitral Regurgitation (&gt;=2+)</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>1979</td>
<td>Process Metrics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1980</td>
<td>Median Fluoro Time (min)</td>
<td>14.5</td>
<td></td>
</tr>
<tr>
<td>1981</td>
<td>Utilization Metrics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1982</td>
<td>Length of Stay – median post procedure</td>
<td>2.0</td>
<td></td>
</tr>
</tbody>
</table>
KG: 35 YO woman
MVR age 15 with rheumatic heart disease
2 Years progressive dypnea
Mean MV Gradient 25 mmHg, PA systolic pressure ~ 100 mmHg

RV Displacing Sternum
Intermountain TMVR Program

CardiaQ
Early Feasibility

Cardioband
US IDE Anticipated
December 2017 Negev Desert
Accucincher Discussion at Intermountain

Characterized by support for our program balanced with concern for patient safety and institutional liability.

Patient Selection
- Identify patients in whom Accucincher represented our best idea to help that individual patient live the healthiest life possible.

Informed Consent
- Full disclosure including risks, limited worldwide experience and lack of local experience

Procedural Execution
- Procedure and contingency preparation
Accucinch Experience at Intermountain

- Five patients identified and approached.
- Three patients declined participation.
- Two patients consented.
  1. CT with thin, infarcted posterior wall representing an increased risk for LV perforation.
  2. Approved for COAPT & Accucinch (CT ineligible for CardiaQ). Visit today to discuss options.
- No procedures to date.
TAVR had significantly better valve performance over SAVR at all follow-up visits.

*Core lab adjudicated
Balloon Expandable Surgical Valve

Innovation Breeds Innovation

Rapid Deployment & TAVR-like Hemodynamics
Intermountain Heart Institute Mission Statement

Our doctors work as a team to provide state-of-the-art, specialized care that saves lives, promotes health, and improves life for patients with heart conditions.

Intermountain Heart Institute
Structural Heart Disease

- Participation in international cardiovascular research elevates the care provided to our community and helps us achieve our goals of:
  • Resource for the multistate intermountain region
  • Delivering the best care for each unique patient
5121 S. Cottonwood Street
Salt Lake City, UT 84157-7000
801-507-4795

intermountainheartinstitute.org