Mitral Valve Repair
Does Hospital Volume Matter?

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Disclosures

• Edwards Lifesciences – Consultant
• Abbott Mitraclip – Royalties
• Johnson & Johnson - Proctor
The **BIG** Picture

Why Do We Need To Talk About This?

- Noncommunicable diseases account for 38 million deaths/year
- 17.5 million due to cardiovascular disease
- 75% of those occur in low- to middle-income countries

Are there enough centers/doctors to care for this growing population?

The Volume-Outcome Relationship “From Luft to Leapfrog”

- 1979 Luft *et al.*: Empirical correlation between surgical volume and mortality
- Birkmeyer – Review of MEDPAR files from 1994 to 1999 (>900,000 patients)
  - Real differences between high volume vs. low-volume programs in cardiovascular procedures
  - High volume vs. low-volume centers: 20% reduction in 30-day mortality

Hospital Volume vs. Mortality

Do Hospitals and Surgeons With Higher Coronary Artery Bypass Graft Surgery Volumes Still Have Lower Risk-Adjusted Mortality Rates?

Edward L. Hannan, PhD; Chuntao Wu, PhD; Thomas J. Ryan, MD; Edward Bennett, MD; Alfred T. Culliford, MD; Jeffrey P. Gold, MD; Alan Hartman, MD; O. Wayne Isom, MD; Robert H. Jones, MD; Barbara McNeil, MD, PhD; Eric A. Rose, MD; Valavanur A. Subramanian, MD

*(Circulation. 2003;108:795-801.)*

(NNT=118). The risk-adjusted mortality rate (RAMR) for patients undergoing surgery performed by surgeons with volumes of $\geq 125$ in hospitals with volumes of $\geq 600$ was 1.89%. The RAMR was significantly higher (2.67%) for patients undergoing surgery performed by surgeons with volumes of $<125$ in hospitals with volumes of $<600$. 
Surgeon Volume
The “Team Effect”

Surgeon Volume
The “Team Effect”

- Surgeon to hospital case volume relationship is important
- Hospital processes and team stability are critical determinants in CT surgery outcomes

Aortic Valve Operations
The Hospital Volume Effect

- 277,928 Medicare patients undergoing AVR between 1999-2009 at 1,255 hospitals
- 5 categories: <10; >10-20; >20-40; >40-70; >70 cases/year
- 32% of hospitals (>40 cases/year) performed 62.5% of all AVRs

Aortic Valve Operations
The Volume Effect
Use Of Mechanical Prosthesis

Table 2. Percent (95% CI) of Patients Receiving a Mechanical Valve by Age and Annual Hospital Medicare Aortic Valve Replacement Volumes

<table>
<thead>
<tr>
<th>Volume</th>
<th>Overall</th>
<th>65–69</th>
<th>70–74</th>
<th>75–79</th>
<th>80–84</th>
<th>85+</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤10</td>
<td>64.5 (63.6–65.5)</td>
<td>68.1 (65.8–70.4)</td>
<td>66.8 (65.0–68.7)</td>
<td>65.0 (63.3–66.7)</td>
<td>60.6 (58.6–62.6)</td>
<td>60.6 (57.6–63.7)</td>
</tr>
<tr>
<td>11–20</td>
<td>55.0 (54.5–55.6)</td>
<td>62.7 (61.2–64.2)</td>
<td>57.6 (56.5–58.8)</td>
<td>54.5 (53.5–55.6)</td>
<td>51.2 (50.0–52.3)</td>
<td>48.6 (46.8–50.4)</td>
</tr>
<tr>
<td>21–40</td>
<td>45.0 (44.6–45.4)</td>
<td>52.8 (51.7–53.9)</td>
<td>47.8 (47.0–48.6)</td>
<td>44.2 (43.4–44.9)</td>
<td>41.7 (40.9–42.5)</td>
<td>39.1 (38.0–40.3)</td>
</tr>
<tr>
<td>41–70</td>
<td>37.6 (37.2–38.0)</td>
<td>47.1 (46.0–48.2)</td>
<td>40.7 (39.9–41.4)</td>
<td>36.2 (35.6–36.9)</td>
<td>33.5 (32.8–34.3)</td>
<td>32.6 (31.5–33.7)</td>
</tr>
<tr>
<td>&gt;70</td>
<td>25.4 (25.2–25.7)</td>
<td>34.2 (33.3–35.0)</td>
<td>28.1 (27.6–28.7)</td>
<td>24.8 (24.3–25.3)</td>
<td>22.0 (21.5–22.5)</td>
<td>20.3 (19.6–21.0)</td>
</tr>
<tr>
<td>Overall</td>
<td>37.5 (37.3–37.7)</td>
<td>46.3 (45.8–46.9)</td>
<td>40.6 (40.2–41.0)</td>
<td>36.7 (36.4–37.0)</td>
<td>33.6 (33.2–34.0)</td>
<td>31.2 (30.7–31.7)</td>
</tr>
</tbody>
</table>

CI = confidence interval.

## Aortic Valve Operations

### Operative Mortality

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10</td>
<td>9.9 (8.0–11.8)</td>
<td>9.5 (7.8–11.3)</td>
<td>10.1 (8.4–11.9)</td>
<td>10.0 (8.3–11.8)</td>
</tr>
<tr>
<td>11–20</td>
<td>9.0 (7.9–10.2)</td>
<td>9.2 (8.2–10.3)</td>
<td>7.7 (6.8–8.6)</td>
<td>7.9 (7.0–8.9)</td>
</tr>
<tr>
<td>21–40</td>
<td>8.4 (7.7–9.2)</td>
<td>8.8 (8.1–9.5)</td>
<td>7.4 (6.8–8.0)</td>
<td>6.2 (5.7–6.8)</td>
</tr>
<tr>
<td>41–70</td>
<td>8.1 (7.4–8.8)</td>
<td>8.2 (7.6–8.9)</td>
<td>7.0 (6.4–7.7)</td>
<td>6.0 (5.5–6.6)</td>
</tr>
<tr>
<td>&gt;70</td>
<td>7.7 (7.2–8.2)</td>
<td>7.3 (6.8–7.8)</td>
<td>6.5 (6.0–6.9)</td>
<td>5.2 (4.8–5.6)</td>
</tr>
<tr>
<td>Overall</td>
<td>8.2 (7.8–8.5)</td>
<td>8.2 (7.8–8.5)</td>
<td>7.1 (6.8–7.4)</td>
<td>6.1 (5.8–6.4)</td>
</tr>
</tbody>
</table>

CI = confidence interval.

The Volume Effect on Aortic Valve Operations

- No change in mortality or practice patterns over time in *Low Volume* hospitals

- Lack of quality improvement processes leading to inability to learn as Organization?

Mitral Valve Surgery Outcomes
Surgeon and Hospital Effect

- 50,152 patients undergoing MV surgery from 2003 to 2008
- Hospital volume (by tertiles): low 1-41; intermediate 42-94; high >95 cases/year
- Surgeon volume: low 1-6; intermediate 6-21; high >21 cases/year
Mitral Valve Surgery Outcomes: Surgeon and Hospital Effect


* p<0.05
Mitral Valve Surgery Outcomes: Surgeon and Hospital Effect

Operative Mortality Rate (%)

Low Surg Vol
Low Hosp Vol: 5.6
Low Surg Vol
High Hosp Vol: 3.3
High Surg Vol
Low Hosp Vol: 2.3
High Surg Vol
High Hosp Vol: 2.0

p-value < 0.001 for decreasing trend in operative mortality

Mitral Valve Repair Rates
Surgeon Effect

Mitral Valve Surgery Outcomes
Surgeon and Hospital Effect On Cost


*p<0.05
Mitral Valve Surgery Outcomes
Surgeon and Hospital Effect

• Surgeon volume affects mortality, repair rates, and cost
• Contrary to CABG, hospital processes don’t seem to mitigate the surgeon-volume effect
• What makes high volume surgeons better and how can we teach it?
The Volume-Outcome Relationship

1979 Luft
Corelation between surgical volume and mortality

2002 Birkmeyer
Hospital volume and surgical mortality

2008 Carey
Surgeon volume per hospital and risk-adjusted mortality

2016 McNeely
Effect of hospital volume on AVR mortality

2016 Adams
Mitral Valve Centers of Excellence
The LatAm Reality

- Referral centers are not widespread
- Patient volumes are not readily available to flatten learning curves

How can we break the paradigm and achieve better results with less patients, to then become a referral center?

Minimally Invasive Mitral Valve Repair Learning Curves

75-125 Surgeries to overcome Learning Curve

>50 Surgeries/Year to maintain competence
The FCI Experience

- Dedicated Mitral Valve Surgery Team since 2004
  - Team training and continuing education
  - Established Clinical Pathways
  - Continued improvement processes
The FCI Experience

Methods

- Mitral valve repairs performed at a single institution from January of 2004 to June 2017
- Patients were identified through an institutional cardiac surgery database
- Prospective harvest from July 2008
- Follow up was performed by telephone or in person (clinic visits)
  - End points were recurrent Mitral Regurgitation, reoperation or death
  - Echocardiograms were performed postoperatively before discharge, 30 to 90 days after surgery, and annually thereafter
## The FCI Experience

### Preoperative Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>No resection (n=142)</th>
<th>Resection (n=58)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>83 (58.4)</td>
<td>39 (67.2)</td>
<td>0.247</td>
</tr>
<tr>
<td>Age years</td>
<td>58 (48-58)</td>
<td>56 (48-56)</td>
<td>0.969</td>
</tr>
<tr>
<td>Diabetes</td>
<td>9 (6.3)</td>
<td>1 (1.7)</td>
<td>0.174</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>18 (12.7)</td>
<td>11 (18.9)</td>
<td>0.252</td>
</tr>
<tr>
<td>Dialysis</td>
<td>2 (1.4)</td>
<td>3 (5.2)</td>
<td>0.122</td>
</tr>
<tr>
<td>Hypertension</td>
<td>59 (41.5)</td>
<td>20 (34.5)</td>
<td>0.354</td>
</tr>
<tr>
<td>COPD</td>
<td>7 (4.9)</td>
<td>4 (6.9)</td>
<td>0.58</td>
</tr>
<tr>
<td>creatininna</td>
<td>1 (0.9-1.08)</td>
<td>0.95 (0.9-1)</td>
<td>0.821</td>
</tr>
<tr>
<td>Previous myocardial infarction</td>
<td>0</td>
<td>3 (5.2)</td>
<td><strong>0.023</strong></td>
</tr>
<tr>
<td>Previous cardiac operation</td>
<td>4 (2.8)</td>
<td>1 (1.7)</td>
<td>0.548</td>
</tr>
<tr>
<td>NYHA functional class</td>
<td></td>
<td></td>
<td><strong>0.217</strong></td>
</tr>
<tr>
<td>I</td>
<td>12 (8.7)</td>
<td>9 (17.3)</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>99 (72.3)</td>
<td>36 (69.2)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>26 (19)</td>
<td>7 (813.5)</td>
<td></td>
</tr>
<tr>
<td>Previous arrhythmia</td>
<td>48 (33.8)</td>
<td>19 (32.8)</td>
<td>0.512</td>
</tr>
<tr>
<td>LVEF</td>
<td>55 (50-60)</td>
<td>60 (51-65)</td>
<td><strong>0.013</strong></td>
</tr>
</tbody>
</table>

Categorical data are expressed as number (%) and continuous data as median (IQR). COPD: Chronic Obstructive Pulmonary Disease, ICU: Intensive Care Unit, IQR: Interquartile Range, LVEF: Left Ventricular Ejection Fraction, NYHA: New York Heart Association.
The FCI Experience
Preoperative EuroScore II

Trends Mitral Valve Repair vs Replacement

Number of Cases per Year

Cases


MVR
MVr
Linear (MVR)
Linear (MVr)

The FCI Experience
Mitral Valve Repair Rates
## The FCI Experience

### Clinical Results

<table>
<thead>
<tr>
<th></th>
<th>No resection n=142</th>
<th>Resection n=58</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reoperation for bleeding</td>
<td>0 (0,0)</td>
<td>2 (3.4)</td>
<td>0.083</td>
</tr>
<tr>
<td>Renal impairment</td>
<td>2 (1.4)</td>
<td>0</td>
<td>0.503</td>
</tr>
<tr>
<td>In-hospital stay (days)</td>
<td>8 (5-15)</td>
<td>8 (5-14)</td>
<td>0.906</td>
</tr>
<tr>
<td>Mortality 30 days</td>
<td>0 (0,0)</td>
<td>0 (0,0)</td>
<td></td>
</tr>
</tbody>
</table>

Categorical data are expressed as number (%) and continuous data as median (Interquartile range)
The FCI Experience
Follow-up

<table>
<thead>
<tr>
<th>NYHA functional class</th>
<th>No resection n=142</th>
<th>Resection n=58</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>109 (81.3)</td>
<td>41 (78.8)</td>
<td>0.797</td>
</tr>
<tr>
<td>II</td>
<td>20 (14.9)</td>
<td>9 (17.3)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>3 (2.2)</td>
<td>2 (3.8)</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>2 (1.5)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mitral valve regurgitation</th>
<th>No resection n=142</th>
<th>Resection n=58</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>None /Trace</td>
<td>76 (56.0)</td>
<td>22 (42.3)</td>
<td>0.267</td>
</tr>
<tr>
<td>Mild</td>
<td>48 (35.3)</td>
<td>22 (42.3)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>9 (6.6)</td>
<td>6 (11.5)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>3 (2.2)</td>
<td>2 (3.8)</td>
<td></td>
</tr>
</tbody>
</table>

Categorical data are expressed as number (%)
The FCI Experience
Freedom from Reoperation

Kaplan-Meier survival estimates

Freedom from Reoperation

No Resection
Resection

Months
0
50
100
150
0.00
0.25
0.50
0.75
1.00
So... Is Bigger Really Better?

- **YES**
- The more you do the better you get
- Earlier flattening of the learning curve
- **BUT**... The “Team Effect” appears to accelerate the process
Why Are High-Volume Centers Better?

- Correlation between program size and resource allocation
- Standardized processes of care
- Quality measures and continuous improvement programs
- Permanently dedicated teams that translate into better rescue options in case of complications

Bigger Is Better

Healthcare Economics

• Costs are reduced in high volume centers through standardization of processes
• New payment models such as bundled-payments encourage the concentration of cardiovascular patients in high volume centers
• “Gentlemen, we will chase perfection, and we will chase it relentlessly, knowing all the while we can never attain it. But along the way, we shall catch excellence”
THANK YOU
How Do We Improve Results And Optimize Access?

• In association with high volume *centres of excellence*:
  – Clinical guidelines
  – Quality improvement projects
  – Provider education
  – Collaborative interactions
  – Consensus referral of high risk patients