Minimally Invasive Mitral Valve Surgery

Robotic or Thoracoscopic?

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Disclosures

- Consultant - Edwards Lifesciences
- Patent/Royalties - MitraClip
Mitral Valve Repair
“The Gold Standard”

Nishimura, RA et al.
2014 AHA/ACC Valvular Heart Disease Guideline

Class I
Mitral valve repair is recommended in preference to mitral valve replacement (MVR) when surgical treatment is indicated for patients with chronic severe primary MR limited to the posterior leaflet (155, 183-198). (Level of Evidence: B)

Class IIa
Mitral valve repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR involving the anterior leaflet or both leaflets when a successful and durable repair can be accomplished (195-197, 199-203). (Level of Evidence: B)

Mitral valve repair is reasonable in asymptomatic patients with chronic severe primary MR (stage C1) with preserved LV function (LVEF >60% and LVESD <40 mm) in whom the likelihood of a successful and durable repair without residual MR is greater than 95% with an expected mortality rate of less than 1% when performed at a Heart Valve Center of Excellence.
Early Mitral Valve Repair

Clear Benefit

Survival Benefit

Risk of CHF

Suri RM et al, Association Between Early Surgical Intervention vs Watchful Waiting and Outcomes for Mitral Regurgitation Due to Flail Mitral Valve Leaflets. JAMA 2013; 310(6):609
Isolated MV repair (n=28,140) operative mortality was 1.2%.

For asymptomatic patients, operative mortality was 0.6%.
World Trends in MIVS

Aortic CAGR: 16%*
Mitral CAGR: 17%

*Without Transapical aortic valves
Source: Internal market research
Trends in MIVS
Society of Thoracic Surgeons (USA)

Minimally Invasive Valve Surgery

Benefits to the Patient

▫ Less pain
▫ Shorter hospital stay
▫ Lower blood loss
▫ Faster recovery and return to normal activity
▫ Greater satisfaction

Minimally Invasive Valve Surgery

Benefits to the Surgeon

• Excellent visualization of structures
• Clear sterile field perception
• More direct access to the mitral valve
The Law of Conservation of Pain
(As applied to Minimally Invasive Surgery)

Pain is neither created nor destroyed, it is transferred from the Patient to the Surgeon

Michael Argenziano, M.D.
Initial Concerns

Less-Invasive Mitral Valve Operations: Trends and Outcomes from the STS Adult Cardiac Surgery Database

• Equivalent mortality
• Longer CPB and cross-clamp times
• Higher repair rates in MIS group
• Lower blood transfusions

• Significantly higher stroke rate

• Similar mortality between MIVS and conventional
• MIVS has higher incidence of:
  – Aortic Dissection, CVA & Phrenic paralysis
• MIVS is superior in:
  – POP AF
  – Mediastinal drainage
  – Patient’s satisfaction and pain

Neurologic Events
Sünderman et al. 2014

<table>
<thead>
<tr>
<th>Study</th>
<th>MIV Events</th>
<th>Conv. Events</th>
<th>Risk Ratio</th>
<th>RR</th>
<th>95%–CI</th>
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<td>Stevens (2012)</td>
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<td>Stevens (2012Rob)</td>
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Fixed effect model: 7235 / 7155
Random effects model: 1.06 [0.82; 1.36] 100% --
Heterogeneity: I-squared=59.8%, tau-squared=0.6206, p=0.0012

Minimally Invasive vs Conventional Mitral Valve Repair

2010 Gammie
Significantly Higher Stroke Rate

2011 Cheng
Higher Ao. Diss and Stroke Risk

2013 Cao
NO DIFFERENCE

2014 Sünderman
No difference in neurologic events
More vascular complications
The Challenge...

✧ AVOID TRANSFERRING THE LEARNING CURVE TO THE PATIENT
✧ Minimize neurologic complications
✧ Avoid vascular complications
Minimally Invasive Mitral Valve Repair Learning Curves

75-125 Surgeries to overcome Learning Curve

>50 Surgeries/Year to maintain competence

Average Surgeon

Overperforming Surgeon

MIVS Team?

Underperforming Surgeon
The Question

✧ Are these results reproducible in smaller centers?
✧ What about LatAm?
✧ How to do it?
FCI - IC Results
A LatAm Team Experience
Patients & Methods

- Historical cohort of patients undergoing mitral valve repair between January 2004 and February 2015
  - Prospective harvest from July 2008

- Inclusion criteria:
  - First-time isolated mitral valve repairs
    - Conventional or minimally invasive
  - Single surgical team

- Exclusion criteria
  - History of preoperative arrhythmias
Methods - Sampling

- Conventional and minimally invasive mitral valve repair patients were matched by:
  - Date of surgery
  - Gender
  - Age range
  - Random patient selection
Mitral Procedures
n= 1275

Replacement
N=757

Repair
N= 518

Single Surgeon
N=285

CONVENTIONAL
N= 248

VA – MIVR
N= 37

Exclusion Criteria - Matching

CONVENTIONAL
N= 61

VA – MIVR
N= 25
# Results – Preoperative Variables

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>CONVENTIONAL</th>
<th>VA-MIVR</th>
<th>P VALUE</th>
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<tbody>
<tr>
<td>Body mass index Median (IQR)</td>
<td>24 (22-27)</td>
<td>24 (22-25)</td>
<td>0,35</td>
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<tr>
<td>Diabetes mellitus n (%)</td>
<td>1 (1,6)</td>
<td>1 (4)</td>
<td>0,51</td>
</tr>
<tr>
<td>Hypertension n (%)</td>
<td>28 (46)</td>
<td>10 (40)</td>
<td>0,65</td>
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<tr>
<td>Previous myocardial infarction n (%)</td>
<td>1 (1,6)</td>
<td>1 (4)</td>
<td>0,51</td>
</tr>
<tr>
<td>Previous stroke n (%)</td>
<td>2 (3,3)</td>
<td>0</td>
<td>0,36</td>
</tr>
<tr>
<td>COPD n (%)</td>
<td>5 (8,3)</td>
<td>3 (12)</td>
<td>0,55</td>
</tr>
<tr>
<td>Preoperative Blocker n (%)</td>
<td>25 (40,9)</td>
<td>12 (48)</td>
<td>0,49</td>
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<tr>
<td>Preoperative creatinine Median (IQR)</td>
<td>0,9 (0,8-1)</td>
<td>1 (1-1,1)</td>
<td>0,02</td>
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<tr>
<td>Ejection fraction Median (IQR)</td>
<td>59 (50-65)</td>
<td>60 (52-60)</td>
<td>0,84</td>
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</tbody>
</table>
Preoperative Euroscore II

Graphs by mininva

P = 0.01
### Variables Affecting Euroscore II

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>CONVENTIONAL</th>
<th>VA-MIVR</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal Impairment; n (%)</td>
<td>6 (10)</td>
<td>3 (12)</td>
<td>0.67</td>
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<tr>
<td>NYHA &gt; II; n (%)</td>
<td>12 (20)</td>
<td>3 (12)</td>
<td>0.43</td>
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<tr>
<td>Pulmonary hypertension; n (%)</td>
<td>11 (18)</td>
<td>2 (8)</td>
<td>0.23</td>
</tr>
<tr>
<td>Elective; n (%)</td>
<td>41 (67)</td>
<td>18 (72)</td>
<td>0.65</td>
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</tbody>
</table>
Intraoperative Results

Conventional       VA-MIVR

Minutes Median (IQR)

P = 0.05

105 (90-118)  135 (115-148)
84 (69-95)    95 (90-107)

CPB          X-CLAMP
## Primary Outcomes

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>CONVENTIONAL</th>
<th>VA-MIVR</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding requiring reoperation; n (%)</td>
<td>2 (3,3)</td>
<td>1 (0,04)</td>
<td>0,81</td>
</tr>
<tr>
<td>Deep wound infection; n (%)</td>
<td>1 (1,6)</td>
<td>0</td>
<td>0,52</td>
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<tr>
<td>Stroke; n (%)</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Mortality (%)</td>
<td>0</td>
<td>0</td>
<td>-</td>
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<tr>
<td>Postoperative AF; n (%)</td>
<td>9 (14,8)</td>
<td>0</td>
<td>0,04</td>
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## Secondary Outcomes

<table>
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<tr>
<th>VARIABLES</th>
<th>CONVENTIONAL</th>
<th>VA-MIVR</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical ventilation (hours); Median (IQR)</td>
<td>14 (11-24)</td>
<td>11 (7-18)</td>
<td>0,01</td>
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<tr>
<td>ICU stay (hours); Median (IQR)</td>
<td>24 (24-72)</td>
<td>19 (18-24)</td>
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<tr>
<td>RBC Transfusion; n (%)</td>
<td>27 (44)</td>
<td>1 (4)</td>
<td>0,003</td>
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<tr>
<td>Hospital stay (days); Median (IQR)</td>
<td>6,5 (5-11)</td>
<td>5 (4-7)</td>
<td>0,08</td>
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</table>
Freedom from Reoperation

Kaplan-Meier survival estimates, by mininv a1

- 94% [CI 95% (65-99)]

Follow-up 97% complete
Thoracoscopic MV Repair

- Safe and reproducible
- Comparable results to conventional
- Cost-effective in LatAm
- Easy to implement
<table>
<thead>
<tr>
<th>Robotic</th>
<th>vs</th>
<th>Thoracoscopic</th>
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<tbody>
<tr>
<td>High resolution 3D visualization</td>
<td></td>
<td>High definition 2D image</td>
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<tr>
<td>“Endowrist” instruments</td>
<td></td>
<td>Long-shafted rigid instruments</td>
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<tr>
<td>Movement scaling</td>
<td></td>
<td>Fulcrum effect</td>
</tr>
<tr>
<td>Dynamic LA retractor</td>
<td></td>
<td>Fixed LA retractor</td>
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<tr>
<td>Lack of tactile sensation</td>
<td></td>
<td>Tactile sensation</td>
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</tbody>
</table>
Robotic MV Repair

- Least invasive method to treat MV disease
- Comparable success to conventional approach
- Steep Learning Curve
- High Investment & Operational Costs
Midterm Echocardiographic Robotic Outcomes

- 100% repair rate (Complex and simple)
- 5-year freedom from MR ≥ moderate 94.6%
- 5-year freedom from reoperation 97.7%
- 0.2% early mortality
- 0.8% stroke risk
Midterm Echocardiographic Robotic Outcomes

Cumulative Risk of Mitral Regurgitation Recurrence by Complexity

Complexity
- Simple repair
- Complex repair

Moderate or greater mitral regurgitation (%)

Follow-up time (year)

289 153 75 44 24 9
198 110 57 37 21 10

P=0.67

How to Flatten the Learning Curve?

FIGURE 1. Learning curve analysis of total operative time.

Cost of Robotic MV Repair

Direct Operative Costs

- 36,9% > CST
- 37,1% > PST
- 19,6% > ANT

Case Volume : Cost Relationship
Robotic vs Anterolateral Thoracotomy

Yearly Case Volume 55 - 100
It’s The COST...

- Main Barrier for implementation (especially in LatAm)
- High volume centers may offset cost >100 cases/year
- Avg cost of MV repair in the USA $34,000
- Avg cost of MV repair in Colombia $20,000
  - US$2,800 disposables/case
Conclusions

- Comparable results to conventional sternotomy
- Thoracoscopic easier to implement
- Robotic less painful, but more costly
- Robotic may be cost-effective only in large volume centers
Considerations

- MIVS should be performed by surgeons who have already mastered conventional repair techniques, performing >40 cases
- Heart Team Approach Flattens Learning Curve
- Establish Heart Valve Centers of Excellence to Increase Case Volume