Catheter Based Valve Interventions

Matthew Caldwell, MD
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Puerto Vallarta, Mexico
Prevalence of Valvular Heart Disease by Age

PREVALENCE OF MODERATE OR SEVERE VALVE DISEASE

AGE (YEARS)

References

Approximately 12.4% of the population over the age of 75 have aortic stenosis.¹²

Exhibit 5. The U.S. Mitral Valve Market Opportunity

4,100,000 Total Moderate to Severe MR Patients

1,670,000 Eligible For Treatment (MR 3/4+)

30,000 Annual MV Surgeries

Relevance to Non-Cardiac Anesthesiologist

• Approx 12% of adults >75 years have mod-severe valve disease
  (80 million adults over age 75 by 2050)

• Similar therapies available for congenital population

• Medical optimization of non-cardiac surgery patients is changing

• Many patients will have these as part of their past surgical history

• These will be (are) a part of mainstream clinical anesthesia practice
Disclosures
Figure 2: Survival after detection of moderate or severe valvular heart disease
(A) Survival in population-based studies. (B) Expected versus observed survival in Olmsted County. The blue line represents survival of 971 residents diagnosed with valve diseases between 1990 and 1995; the yellow line represents the expected survival in the age-matched and sex-matched population of the county.
Natural History of Severe Aortic Stenosis
Figure 2: Overview of the alternative approaches

- Transcarotid
- Transaortic
- Transseptal
- Transcaval
- Iliac artery
- Transapical
- Transsubclavian
- Transfemoral
Society of Thoracic Surgery Risk Calculation

• Multiple variables and online calculator

<table>
<thead>
<tr>
<th>Consensus Risk Characterization</th>
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</thead>
<tbody>
<tr>
<td>Risk Category</td>
</tr>
<tr>
<td>Low</td>
</tr>
<tr>
<td>Intermediate</td>
</tr>
<tr>
<td>High</td>
</tr>
</tbody>
</table>
Extrapolating* Risk of Death from Travel

- Flying from DTW to PVR
- Driving from DTW to PVR
- Bicycle from DTW to PVR
- Motorcycle from DTW to PVR
- Space shuttle from DTW to PVR
- How many trips from DTW to PVR equals the risk from 1 skydive?

1/16M
1/67K
1/4.5K
1/1.9K
1/58 (per journey)
2 for death by car
120 for death by airline

Megamillions 1/300M
Reserve chute 1/548
Heart valve team assessment

Life expectancy >1 year if SAVR or TAVI is performed AND SAVR or TAVI likely to improve the quality of life?

- Yes
  - Transfemoral TAVI feasible?
    - Yes
      - Transfemoral TAVI
      - Individualized risk/benefit assessment of alternative access TAVI versus medical therapy
    - No
      - Transfemoral TAVI
      - Individualized risk/benefit assessment of alternative access TAVI versus SAVR

- No
  - SAVR risk assessment
  - Palliative therapy

High surgical risk (STS-PROM >8 with <50% probability of death)

- Transfemoral TAVI feasible?
  - Yes
    - Transfemoral TAVI
  - No
    - Individualized risk/benefit assessment of alternative access TAVI versus SAVR

Intermediate surgical risk (STS-PROM 4 to 8)

- Transfemoral TAVI feasible?
  - Yes
    - Individualized risk/benefit assessment of transfemoral TAVI versus SAVR
  - No
    - SAVR

Low surgical risk (STS-PROM <4)

- Transfemoral TAVI feasible?
  - Yes
    - Individualized risk/benefit assessment of transfemoral TAVI versus SAVR
  - No
    - SAVR
In 2018

- Severe aortic stenosis

- Inoperable
- High risk
- Intermediate risk
- Low risk

- TAVR
- SAVR
Anesthetic Evolution in Transcatheter Aortic Valve Replacement: Expert Perspectives From High-Volume Academic Centers in Europe and the United States

Prakash A. Patel, MD*, Abraham M. Ackermann, MD†, John G.T. Augoustides, MD, FASE, FAHA*,1, Joerg Ender, MD†, Jacob T. Gutsche, MD*, Jay Giri, MD‡, Prashanth Vallabhajosyula, MD§, Nimesh D. Desai, MD, PhD§, Megan Kostibas, MD§, Mary Beth Brady, MD§, Eun J. Eoh, MD§.

<table>
<thead>
<tr>
<th>Past</th>
<th>Present</th>
<th>Future</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radial arterial catheter</td>
<td>± Radial arterial catheter</td>
<td>Noninvasive blood pressure monitoring?</td>
</tr>
<tr>
<td>Central catheter and pulmonary artery catheter</td>
<td>± Central catheter</td>
<td>No central catheter?</td>
</tr>
<tr>
<td>GA with endotracheal intubation</td>
<td>MAC (with anesthesia provider)</td>
<td>MA (with no anesthesiologist)?</td>
</tr>
<tr>
<td>TEE</td>
<td>TTE only, ± physician echocardiographer</td>
<td>No echocardiography?</td>
</tr>
<tr>
<td>Intensive care unit</td>
<td>PACU</td>
<td>Same-day discharge?</td>
</tr>
</tbody>
</table>

*Cardiothoracic Surgery, Department of Surgery, School of Medicine, Duke University, Durham, NC
†Cardiothoracic Anesthesiology, Department of Anesthesiology, School of Medicine, Duke University, Durham, NC
‡Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital School of Medicine, Harvard University, Boston, MA
Major complications possible

- Conduction anomalies
- Arrhythmias
- Rupture of aortic root
- Aortic regurgitation
- Mitral valve interference
- Coronary occlusion
- Embolisation
- Cardiac tamponade

Cardiac complications
<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GA</strong></td>
<td>• May prolong need for intensive care unit</td>
</tr>
<tr>
<td>• Protected airway</td>
<td>• Increased need for pressors/inotropes</td>
</tr>
<tr>
<td>• Ease of TEE use</td>
<td></td>
</tr>
<tr>
<td>• Lack of patient movement</td>
<td></td>
</tr>
<tr>
<td>• Ability to provide apnea</td>
<td></td>
</tr>
<tr>
<td><strong>Sedation</strong></td>
<td></td>
</tr>
<tr>
<td>• Improved hemodynamic stability</td>
<td>• Risk of emergency conversion to GA</td>
</tr>
<tr>
<td>• Improved preload</td>
<td>• Less likely to have TEE support</td>
</tr>
<tr>
<td>• Shorter procedure time</td>
<td>• Patient movement</td>
</tr>
<tr>
<td>• Monitoring of mental status</td>
<td></td>
</tr>
</tbody>
</table>
## Intraoperative Complications: Drive Anesthesia Plan

| Complications (decreased incidence with new devices and operator experience) | 
|---|---|
| Access site hemorrhage/dissection (11%→4.5%) | AKI (dialysis 1.8%) |
| Permanent pacemaker (8-25%) | Coronary ischemia (↑ valve in valve) |
| Myocardial stunning/arrest (95% ↑ troponin) | Mitral valve disruption (rare) |
| Stroke (2-5%) | Death (1.1-4.2%) |
| Paravalvular leak (1.5-25%) ↓ with newer designs | Conversion to CPB (1.4%, mortality 46%) Aortic root disruption, perforation, Valve malposition |
Michigan Medicine Experience

• Initial patients were inoperable or extreme risk (or special populations)
  • GA with PAC/TEE multi vasoactive infusions
  • ICU postop

• Currently intermediate to extreme risk
  • Screen for high BMI and OSA and ability to lay flat in clinic
  • ASA standard monitors plus 7fr RIJ sheath for transvenous pacing
  • Sedation with dexmedetomidine and/or propofol
  • Minimize benzodiazepines and opiates
  • Surface TTE by ultrasound tech
  • Right radial embolic protection device (used for continuous arterial monitor)
  • Step down unit for 24 hours
  • Remove transvenous pacer if no conduction concerns on POD1
  • LOS ~3-4 days
**TriGuard™**
- Deflector
- 9F
- Femoral
- 130 μ pore

**POINT-GUARD™**
- Deflector
- 8F
- Femoral
- 105 μ pore

**Sentinel®**
- Capture
- 6F
- Radial or Brachial
- 140 μ pore

**Emblok™**
- Capture
- 12F
- Femoral
- 125 μ pore

**Emboline™**
- Capture
- 9F
- Femoral
- n/a
# Enhanced Recovery for TAVR

<table>
<thead>
<tr>
<th>Preoperative</th>
<th>Intraoperative</th>
<th>Postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient education</strong></td>
<td>No benzodiazepines</td>
<td>Protocol driven</td>
</tr>
<tr>
<td>Frailty assessment</td>
<td>No opiates</td>
<td>Out of bed early</td>
</tr>
<tr>
<td>Cognitive assessment</td>
<td>Long acting local anesth</td>
<td>Walk halls early</td>
</tr>
<tr>
<td>Incentive Spirometry</td>
<td>Cerebral protection</td>
<td>Conduction abnl protocol</td>
</tr>
<tr>
<td>Exercise</td>
<td>Vascular closure device</td>
<td>Discharge planning</td>
</tr>
<tr>
<td>Carbohydrate drink</td>
<td>No foley</td>
<td><strong>Follow up process</strong></td>
</tr>
</tbody>
</table>

Sola: *Am J Cardiol*. 2016 Aug 1;118(3):418-23
TAVR Summary

• First line therapy for intermediate → extreme risk if femoral access used
• National trend towards MAC vs. GA (minimal sedation common in EU)
• MAC considerations
  • ERAS
  • Embolic prevention
  • Transvenous pacing plan
  • Imaging plan (Flouro and TTE)
  • Rehearse rescue plans with teams regularly
• Low risk patients still SAVR until durability established
• SAVR in patients who require other procedures (MVR, CABG)
Mitral Valve Disease in 2019

![Graph showing prevalence of valvular heart disease by age](image)

References
Primary vs Secondary Mitral regurgitation
Everest II 5 year data

3-4+ MR
Primary and secondary MR

sMVR: reduced reoperation for MR compared to tMVR

Comparable outcomes after adjusting for residual MR in first 6 months in tMVR group.
Coapt Trial: Secondary MR

A Hospitalization for Heart Failure

Control group

Device group

Hazard ratio, 0.53 (95% CI, 0.40–0.70)

P<0.001

No. at Risk

Control group: 312 294 271 245 219 176 145 121 88

Device group: 302 286 269 253 236 191 178 161 124

67.9%

35.8%

NNT=3.1

Coapt Trial: Secondary MR

C Death from Any Cause

Hazard ratio, 0.62 (95% CI, 0.46–0.82)  
P<0.001

Control group
Device group

No. at Risk
Control group
Device group

<table>
<thead>
<tr>
<th>Months since Randomization</th>
<th>Control group</th>
<th>Device group</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>312</td>
<td>302</td>
</tr>
<tr>
<td>3</td>
<td>294</td>
<td>286</td>
</tr>
<tr>
<td>6</td>
<td>271</td>
<td>269</td>
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<tr>
<td>9</td>
<td>245</td>
<td>253</td>
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<td>12</td>
<td>219</td>
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<td>15</td>
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<td>191</td>
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<td>18</td>
<td>145</td>
<td>178</td>
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<tr>
<td>21</td>
<td>121</td>
<td>161</td>
</tr>
<tr>
<td>24</td>
<td>88</td>
<td>124</td>
</tr>
</tbody>
</table>

NNT=5.9

Coapt vs MitralFR: Need Further Trials

- **MitralFR**: Death or HF hospitalization: 54.6% in tMVR vs. 51.3% medical therapy
  - Multiple smaller centers, less rigorous inclusion/exclusion criteria

- **Coapt**: NNT 6 to prevent 1 death of 2 years
  - High volume, expert centers
  - High screened to enrolled

- **Reshape-HF2**:

  **Study Design**
  - Study Type: Interventional (Clinical Trial)
  - Estimated Enrollment: 420 participants
  - Allocation: Randomized
  - Intervention Model: Parallel Assignment
  - Masking: None (Open Label)
  - Primary Purpose: Treatment
  - Official Title: A Randomized Study of the MitraClip Device in Heart Failure Patients With Clinically Significant Functional Mitral Regurgitation
  - Study Start Date: March 2015
  - Estimated Primary Completion Date: March 2021
  - Estimated Study Completion Date: March 2021
Heart Failure Maximal Medical Therapy

- Fluid/sodium restriction
- ACE or ARBs
- Beta blockers
- Aldosterone antagonists
- Diuretics
- Vasodilators
- Digoxin
- **Cardiac Resynchronization Therapy (CRT)** = Biventricular pacemaker
Deep Sedation Vs. General Anesthesia in 232 Patients Undergoing Percutaneous Mitral Valve Repair Using the MitraClip® System

Patrick Horn, MD, Katharina Hellhammer, MD, Michael Minier, MD, Monika A. Stenzel, MD, Verena Veulemans, MD, Tienush Rassaf, MD, Peter Luédike, MD, Julia Pohl, MD, Jan Balzer, MD, Tobias Zeus, MD, Malte Kelm, MD, and Ralf Westenfeld, MD

Objectives: To investigate in a series of 232 patients whether the MitraClip® procedure can be performed safely using deep sedation (DS) without general anesthesia (GA).

Background: Transcatheter mitral valve repair using the MitraClip® system is a safe and effective therapy for severe mitral regurgitation (MR) in patients who are at high operative risk or areunsuitable for surgery. For these patients, avoidance of GA might be beneficial.

Methods: Between 2011 and 2015, we performed 232 MitraClip® procedures for the treatment of severe MR. Of those, 78 procedures were performed using GA, while the remaining 156 procedures were performed using DS. Results: Age, logistic EuroScore, severity of MR, left and right ventricular function, and renal function did not differ between the groups. The primary combined safety endpoint, which was defined as the occurrence of major adverse cardiac and cerebrovascular events, conversion to surgery, major vascular complications or pneumonia, did not differ between MitraClip® procedures performed using GA and MitraClip® procedures performed using DS. Intraprocedural conversion to GA was required in 2% of the patients in the DS group.

There were no differences in procedural success or complications at the 3-month follow-up. Preparation time and intensive care unit (ICU) stay were shorter in the DS group. Conclusion: The MitraClip® implantation performed using DS is as effective as MitraClip® implantation performed using GA.

Key words: mitral regurgitation; analgesedation; interventional cardiology

Transcatheter mitral valve repair with the MitraClip® can be performed without general anesthesia and without conscious sedation

Jakob Ledwoch¹ · Predrag Matic¹ · Jennifer Franke¹ · Sameer Gafoor¹ · Stefan Bertog¹ · Markus Reinartz¹ · Laura Vaskelyte¹ · Ilona Hofmann¹ · Horst Sievert¹
UofM approach to MitraClip

- General anesthesia with ETT
- Anesthesia performed TEE for procedural guidance
- Standard ASA monitors plus radial arterial line
- PIV +/- Right IJ central line (individualized plan)
- Hybrid OR with CPB standby
- Extubation at conclusion of procedure
- Overnight in step down unit (non-ICU: takes art lines and vasoactive gtts)
- Typical LOS 3 days
## Transcatheter Mitral Replacement Trials

<table>
<thead>
<tr>
<th>Device</th>
<th>Enrollment Criteria</th>
<th>Intended Enrollment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caissong transcatheter MVR system (Caissong Interventional LLC; Maple Grove, MN)</td>
<td>18 years and older • Severe MR • High risk for surgery</td>
<td>20</td>
</tr>
<tr>
<td>CardioAQ-Edwards™ Transcatheter Mitral Valve (Edwards Lifesciences; Irvine, CA)</td>
<td>18 years and older • New York Heart Association (NYHA) ≥II • Moderate to severe/severe MR • Prohibitive risk for open-heart surgery</td>
<td>200</td>
</tr>
<tr>
<td>CardioAQ-Edwards™ Transcatheter Mitral Valve (Edwards Lifesciences; Irvine, CA)</td>
<td>18 years and older • Clinically significant symptomatic MR • High risk for open-heart surgery</td>
<td>28</td>
</tr>
<tr>
<td>Tiara™ valve and transapical delivery system transcatheter MVR (Neovasc Inc; Richmond, B.C. Canada)</td>
<td>18 years and older • NYHA ≥III • High risk for open mitral valve surgery</td>
<td>30</td>
</tr>
<tr>
<td>Tiara™ valve and transapical delivery system transcatheter MVR (Neovasc Inc; Richmond, B.C. Canada)</td>
<td>18 years and older • Severe MR • High risk for open mitral surgery</td>
<td>115</td>
</tr>
<tr>
<td>Twelve transcatheter MVR (Twelve, Inc; Redwood City, CA)</td>
<td>18 years and older • NYHA ≥II • Severe MR</td>
<td>10</td>
</tr>
<tr>
<td>Tendyne™ Mitral Valve System (Tendyne Holdings, LLC, a subsidiary of Abbott Vascular; Roseville, MN)</td>
<td>18 years and older • NYHA ≥II • Not suitable for traditional surgical treatment</td>
<td>110</td>
</tr>
<tr>
<td>Edwards SAPIEN XT and SAPIEN 3 transcatheter heart valve (Edwards Lifesciences; Irvine, CA)</td>
<td>22 years and older • NYHA ≥II • Severe MAC • Severe mitral stenosis or severe MR with at least moderate mitral stenosis • Extremely high risk for standard mitral surgery</td>
<td>30</td>
</tr>
<tr>
<td>Edwards SAPIEN 3 transcatheter heart valve (Edwards Lifesciences; Irvine, CA)</td>
<td>22 years and older • Severe MAC with mitral stenosis or MR • NYHA ≥II • High-risk or Inoperable</td>
<td>30</td>
</tr>
<tr>
<td>Edwards SAPIEN 3 transcatheter heart valve (Edwards Lifesciences; Irvine, CA)</td>
<td>21 years and older • Severe mitral valve failure after mitral annuloplasty repair or related to MAC • High or prohibitive risk for surgical MVR • High or prohibitive risk of LVOT obstruction or transcatheter heart valve dysfunction from long/anterior mitral valve leaflet</td>
<td>60</td>
</tr>
</tbody>
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Opportunities for Anesthesia in Catheter Based Valve Interventions

• Integration into structural heart team for patient evaluation and planning
• Leadership in enhanced recovery planning
• Continued evolution to safest and most cost effective anesthetic
• Imaging expertise in cardiac OR/hybrid OR/cath labs
  • Point of Care Ultrasound including TTE
  • Procedural guidance via TEE
• Leaders in team training for emergent rescue