Percutaneous Valve in Native With and Without Mitral Valve Calcification: When To Go Hybrid

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Disclosures

None
Percutaneous Valve With Mitral Valve Calcification

• Severe mitral annular calcification can dramatically affect surgical risk
  • Risk of AV groove disruption
  • Increased operative time (pump/clamp time)
  • Debridement can increase stroke risk
  • Small surgical valve size placed
  • Increased paravalvular leak risk

• Elderly patients with comorbid conditions
Background

- Mitral annular calcification (MAC) has been reported in nearly 10% of patients in large historical autopsy studies.
- CT or echocardiographic determination of MAC has been seen in 8-15% of patients without cardiovascular disease.
- The incidence of MAC may be as high as 42% in elderly patients with known cardiovascular disease.
- It is estimated that MAC may be found in 24% of patients referred for mitral valve surgery.
Epiphany: TAVR in MAC

• TAVR seats into calcified annulus
• Balloon mounted TAVR devices have a relatively low profile
• Case reports of TAVR in v-in-v MVR with good results and safety profiles\(^1\,^2\)
• TAVR in MAC transseptal and transapical with reasonable success in highly selected patients
• Scattered surgical discussion of successful implants.

Imaging: Echo

- Mitral annular calcification
- Mitral stenosis
- Mitral regurgitation
- EF: 60%
Imaging: TEE
Imaging: Gated CTA Heart for screening

- Burden and distribution of MAC
- Mitral annulus sizing
- Mitral valve planimetry
- Septal thickness
- Septal-Mitral annulus plane distance
- THV mannequin embedding (Annulus & LV)
Imaging: Gated CTA Heart for screening
Imaging: Gated CTA Heart for screening

Mean: 248
Area: 4.85 cm²
Min: -27
Max: 1500
SDev: 169
Avg. Diameter: 24.8 mm
Perimeter: 80.0 mm

Mitral Annulus

27.7 mm
23.9 mm
Imaging: Gated CTA Heart for screening

Sub-annulus MV seal
Imaging: Gated CTA Heart for screening
Imaging: Gated CTA Heart for screening

- Septal-Mitral Annulus Distance: 11.4 mm
- Neo-LVOT 26 S3 and 29 S3: 26.0 mm and 29.0 mm
- 13.1 mm
Imaging: Gated CTA Heart for screening
Imaging: Gated CTA Heart for screening
Transcatheter Mitral Valve Replacement in Native Mitral Valve Disease with Severe Mitral Annular Calcification

Results from the First Global Registry

Mayra Guerrero, MD, FACC, FSCAI
Director of Cardiac Structural Interventions
NorthShore University HealthSystem

TVT 2016
Chicago, IL
June 17, 2016
## Procedural Outcomes

<table>
<thead>
<tr>
<th>Event</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success by MVARC criteria</td>
<td>78/104 (75%)</td>
</tr>
<tr>
<td>Need for second valve (migration=6, MR=7)</td>
<td>13/104 (12.5%)</td>
</tr>
<tr>
<td>LVOT obstruction with hemodynamic compromise</td>
<td>11/104 (10.5%)</td>
</tr>
<tr>
<td>Valve embolization</td>
<td>4/104 (3.8%)</td>
</tr>
<tr>
<td>Conversion to open surgery (embolization=2, LV perforation=1, LVOTO=1)</td>
<td>4/104 (3.8%)</td>
</tr>
<tr>
<td>LV perforation (surgery=1, conservative=1)</td>
<td>2/104 (1.9%)</td>
</tr>
<tr>
<td>Pulmonary Vein Perforation</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Condition</td>
<td>n (%)</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td><strong>Cardiovascular</strong></td>
<td>11/104 (10.6%)</td>
</tr>
<tr>
<td>LVOT Obstruction</td>
<td>3 (2.9%)</td>
</tr>
<tr>
<td>LV Perforation</td>
<td>2 (1.9%)</td>
</tr>
<tr>
<td>Complete AV block</td>
<td>1%</td>
</tr>
<tr>
<td>MI due to air emboli / Pulmonary vein perforation</td>
<td>1%</td>
</tr>
<tr>
<td>Stroke</td>
<td>2 (1.9%)</td>
</tr>
<tr>
<td>PEA arrest</td>
<td>1%</td>
</tr>
<tr>
<td>MR</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Non-Cardiac</strong></td>
<td>15/104 (14.4%)</td>
</tr>
<tr>
<td>Multi-organ failure</td>
<td>9 (8.6%)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>3 (2.9%)</td>
</tr>
<tr>
<td>Thoracentesis related bleeding complication</td>
<td>1%</td>
</tr>
<tr>
<td>Infection</td>
<td>2 (1.9%)</td>
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</table>
Concerns for TAVR in MAC

- Device embolization
- LVOT obstruction
  - From device
  - From leaflet
  - From ventricular septal thickness
- Difficulty in determining positioning for deployment
  - 17.2% needing a second valve deployed*
- PVL
- High mortality rate reported
  - All cause 30 day mortality ~30%*

Septal ablation to treat LVOT Obstruction after TMVR

Baseline

After TMVR

Alcohol Septal Ablation

Courtesy of Dr. William O’Neill
MITRAL: Mitral Implantation of Transcatheter Valves

- Investigator initiated, prospective multi-center clinic trial
- 30 high risk surgical patients with symptomatic severe MAC
  - Severe MS
  - Severe MR with moderate MR

92 pts presented

61 pts turned down:
- high risk LVOTO
- high risk of embolization
- both

Geurrero, M. TVT 2017
## MAC Primary Safety Endpoints

<table>
<thead>
<tr>
<th>Event Description</th>
<th>N(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success at exit from Cath Lab</td>
<td>22 (73.3%)</td>
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<tr>
<td>LVOTO (1 TS, 1 TA, 1 Tatrial)</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Need for 2\textsuperscript{nd} valve</td>
<td>1 (3.3%)</td>
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<tr>
<td>&gt;2+ MR</td>
<td>2 (6.6%)</td>
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<tr>
<td>LV perforation (transatrial)</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>VSD (transatrial)</td>
<td>1 (3.3%)</td>
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</table>
### Primary Safety Endpoints

<table>
<thead>
<tr>
<th>Event</th>
<th>N</th>
<th>(%)</th>
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<tbody>
<tr>
<td>Procedural Success at 30 days</td>
<td>15</td>
<td>51.7</td>
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<tr>
<td>Death</td>
<td>5</td>
<td>17.2</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>3</td>
<td>10.3</td>
</tr>
<tr>
<td>Bleed (GIB, hemothorax)</td>
<td>2</td>
<td>6.9</td>
</tr>
<tr>
<td>HF requiring an ASD closure</td>
<td>1</td>
<td>3.4</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>1</td>
<td>3.4</td>
</tr>
<tr>
<td>LV perforation during transatrial TMVR</td>
<td>1</td>
<td>3.4</td>
</tr>
<tr>
<td>3+MR</td>
<td>1</td>
<td>3.4</td>
</tr>
</tbody>
</table>
Trans-septal Valve in MAC

Vinod H. Thourani, MD

AATS Mitral Conclave
April, 2017
Wire Ready to LAMPOON
Snare Wire from Aorta to LA
LAMPOON Loop Made
LAMPOON Burn
Valve Deployment
Post Valve 3D TEE
When To Go Hybrid
Concept for SITRAL

• Surgical Implantation of TRAnscatheter vaLve in native mitral annular calcification

• Potential benefits:
  • Reduce LVOTO risks
  • Reduce risk of embolization
  • Reduce PVL risk
  • Orient the valve into standard surgical configuration (posts at the trigones)
  • Control device depth (re-deploy if necessary)

• Performed in minimally invasive approach to reduce physical recovery
Implantation of Transcatheter Aortic Prosthesis in 3 Patients With Mitral Annular Calcification

Heike Baumgarten, MD, John J. Squiers, BSE, William T. Brinkman, MD, J. Michael DiMaio, MD, Ambarish Gopal, MD, Michael J. Mack, MD, and Robert L. Smith, MD


- This is an off label use of a transcatheter valve
- Approach is right mini thoracotomy via 4th IS
- Utilizes CPB
- Can also address septal thickness with septal myectomy and TR with annuloplasty
Typical case (Off Label)

• 84 Year old female
• MS with MAC
• NYHA IV
• Medical History: HTN, PVD S/P R fem-pop, Brain stem tumor removal 1992 (benign) with right facial droop, subclavian steal syndrome
• Normal coronaries
• STS-PROM MVR 8.1%
Preoperative TTE

MV gradient: 23 mmHg
MVA: 0.8 cm²
RVSP: 68 mmHg
Planning CTA

Severe concentric MAC
Extensive calcification penetrating ventricular wall
Porcelain aorta
Intraoperative TEE
Intraoperative Course

- MI MVR via right mini thoracotomy or robotic approach with femoral bypass and cold fibrillatory arrest
- Resection of A2 and chords, septal myectomy can be performed
- Balloon sizing of the mitral annulus
- Pledged sutures are placed in the trigones and at the annulus on P2 from ventricular to atrial position with possible felt buttress
  - The valve is positioned with the valve skirt at the level of the annulus
  - Thoracoscopic visualization is used to watch full valve deployment
  - The sutures are then placed through the cuff of the valve and secured
Intraoperative Photos

- Septal Myomectomy
- Removed portion of A2
Post Implantation 3D TEE
Postoperative Imaging
POD #1 TTE

- Mean gradient of 4 mmHg across the mitral valve
- Mean gradient of 4 mmHg across the LVOT
- Laminar flow seen through both
Postoperative TTE
Follow Up Imaging at 7 months-TTE

- Mitral valve mean gradient 8mmHg
- LVOT mean gradient 2 mmHg
- Laminar flow through both
- EF: 65%
Follow Up Imaging
Short Axis 4D CTA

No thrombus is seen on the leaflets and the valve is fully expanded with complete leaflet excursion.
Follow Up Imaging
Long Axis 4D CTA
90 yo Female Severe AS and MS
Even can add a TAVR same day
<table>
<thead>
<tr>
<th>STS-PROM</th>
<th>Indication</th>
<th>Concomitant Procedure</th>
<th>Age</th>
<th>Sex</th>
<th>Preop Mean MV Gradient</th>
<th>Preop Mean LVOT Gradient</th>
<th>Valve Type</th>
<th>Valve Size</th>
<th>LOS</th>
<th>Disposition</th>
<th>Postop Mean MV Gradient</th>
<th>Postop Mean LVOT Gradient</th>
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<tbody>
<tr>
<td>17.3</td>
<td>Stenosis</td>
<td>None</td>
<td>87</td>
<td>F</td>
<td>11</td>
<td>2</td>
<td>Sapien XT</td>
<td>26</td>
<td>5</td>
<td>Rehab</td>
<td>10</td>
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<tr>
<td>8.1</td>
<td>Mixed</td>
<td>Myomectomy</td>
<td>84</td>
<td>F</td>
<td>23</td>
<td>1</td>
<td>Sapien 3</td>
<td>26</td>
<td>8</td>
<td>Rehab</td>
<td>4</td>
<td>4</td>
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<tr>
<td>9.3</td>
<td>Mixed</td>
<td>Tricuspid Annuloplasty</td>
<td>86</td>
<td>F</td>
<td>9</td>
<td>1</td>
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<td>29</td>
<td>24</td>
<td>LTAC</td>
<td>4</td>
<td>6</td>
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<tr>
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<td>Mixed</td>
<td>Tricuspid Annuloplasty</td>
<td>78</td>
<td>F</td>
<td>13</td>
<td>4.2</td>
<td>Sapien 3</td>
<td>29</td>
<td>11</td>
<td>Home</td>
<td>4</td>
<td>7</td>
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<td>6.5</td>
<td>Stenosis</td>
<td>Myomectomy</td>
<td>77</td>
<td>F</td>
<td>12</td>
<td>5</td>
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<td>26</td>
<td>11</td>
<td>Rehab</td>
<td>6</td>
<td>2</td>
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<tr>
<td>4.0</td>
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<td>Myomectomy</td>
<td>71</td>
<td>F</td>
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<td>32</td>
<td>Death</td>
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<td>9</td>
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<td>12.6</td>
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<td>76</td>
<td>F</td>
<td>15</td>
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<td>26</td>
<td>8</td>
<td>Home</td>
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<td>3</td>
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<tr>
<td>6.1</td>
<td>Stenosis</td>
<td>Myomectomy</td>
<td>70</td>
<td>F</td>
<td>17</td>
<td>4</td>
<td>Sapien XT</td>
<td>26</td>
<td>11</td>
<td>Home</td>
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<td>2</td>
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<tr>
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<td>Myomectomy</td>
<td>83</td>
<td>F</td>
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<td>3</td>
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<td>8</td>
<td>Rehab</td>
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<td>1.5</td>
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<tr>
<td>9.5</td>
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<td>AVR, TVR, Myomectomy</td>
<td>80</td>
<td>F</td>
<td>5</td>
<td>5</td>
<td>Sapien XT</td>
<td>29</td>
<td>13</td>
<td>Rehab</td>
<td>6</td>
<td>3</td>
</tr>
</tbody>
</table>
Case Series-THHBP

• 14 off-label procedures have been completed at The Heart Hospital Baylor Plano, additional procedures have been completed as part of the SITRAL study

• Nine cases were performed via right thoracotomy

• Two cases were done through sternotomy due to concomitant AVR and TVR

• Three cases were done robotically

• Technical and hemodynamic success was achieved in all patients
  • 2 In-hospital death (salvage patients, 1 died of ascending cholangitis & 1 from multi system organ failure)
  • 1 Acute kidney injury (stage 2)
Case Series

• More than 20 procedures have been completed at 3 institutions
  • Technical and hemodynamic success was achieved in all patients
  • 2 Deaths (salvage patients, 1 died of ascending cholangitis & 1 died of multi system organ failure)
  • 2 Postoperative pacemaker
  • 1 Stroke
  • 1 Acute kidney injury (stage 2)
Transcatheter Mitral Valve Options Without MAC
Transcatheter Mitral Valve Options Without MAC

Summary

• Transcatheter approaches for addressing high risk patients with mitral valve disease are advancing

• Transcatheter approaches for addressing mitral valve disease complicated by MAC are allowing treatment in otherwise often untreatable patients

• The results thus far are relatively safe and effective though there needs to be improvement

• Surgical assistance in delivery does contribute to greater control in device delivery, reducing the post-placement Ivoto, and stabilizing the device after placement
Anticipation

• With time, we will identify patients who are suitable candidates for a completely percutaneous, transseptal approach for valve replacement in the native mitral annulus and others who require a more invasive procedure due to structural hindrances that require additional intervention