TMVR Transcatheter Valve-in-Valve: Technical Considerations

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Disclosures:

- None relevant to this topic
Outline

- Background
- Pre-Procedural
  - Appropriate THV Sizing
  - Determining Risk of LVOT Obstruction
- Procedural
  - Access Approach
  - Procedural Technical Aspects
- Post-Procedural Issues
- Conclusions/Discussion
Background

Rates of bioprosthetic valve use for MVR have dramatically increased over the last 15 years in the US.

Fig 5. Mitral valve replacement type, mechanical (white bars) or bioprosthetic (gray bars), for the years 2000 to 2007 (p < 0.0001).

Mitral valve bioprosthesis failure requiring reoperation is more common than mechanical MVR
- Within 10 years, 20-35% of patients require reoperation
Re-operation in many of these patients is high risk
- Mortality ranges from 5-12%
Valve-in-Valve using a transcatheter heart valve (THV) has been shown to be safe and effective in patients with aortic and mitral valve bioprosthetic failure

FDA Okays Sapien 3 for Mitral, Aortic Valve-in-Valve Replacement

Steve Stiles
June 05, 2017

WASHINGTON, DC — The US Food and Drug Administration has expanded the Sapien 3 THV (Edwards Lifesciences) approval indication to include transcatheter "replacement" of failed bioprosthetic valves in either the aortic or mitral valve positions in high-surgical-risk patients[1].

The FDA says the new expanded indication represents the first approval of any transcatheter valve for so-called "valve-in-valve" procedures on not only aortic prostheses, but also mitral prostheses that have failed. The expanded indication is limited to patients deemed "at high or greater risk of death or
Mitral Valve-in-Valve Patient Demographics and Characteristics

- 608 patients in United States for 1/1/17-12/31/17
- Mean Age 72 y/o; 60% Female
- 61% with STS risk >8% (High Risk)
- NYHA Class III/IV 88%; Mean LVEF 54%
- Previous CABG 39%; prior CVA 16%
- Moderate or severe MR 45%
Procedural Features of Mitral Valve-in-Valve

- CPB used in 5.5%
- GETA in 99.5% of cases
- Procedural Time 141 min
- Fluoro Time 28 min
- Successful Implant in 95%
- Median LOS 5.5 days
- Median ICU Stay 27 hours
- Pre-implant balloon inflation 45%; Post 23%

2017 TVT Data

STS ACC TVT Registry Data Q42017 Data Report
## TMVR Procedures
### Outcomes & Adverse Events at Discharge

<table>
<thead>
<tr>
<th>Post Procedure Events (at discharge)</th>
<th>2015 R4Q</th>
<th>2016 R4Q</th>
<th>2017 R4Q</th>
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<tr>
<td>Myocardial Infarction</td>
<td>0%</td>
<td>.4%</td>
<td>1.0%</td>
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<tr>
<td>Acute Kidney Injury (stage 3)</td>
<td>4.4%</td>
<td>4.2%</td>
<td>4.2%</td>
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<tr>
<td>Bleeding (major)</td>
<td>2.4%</td>
<td>4.9%</td>
<td>3.1%</td>
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<tr>
<td>Bleeding (life threatening)</td>
<td>6.1%</td>
<td>7.0%</td>
<td>7.7%</td>
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<tr>
<td>In hospital mortality</td>
<td>7.9%</td>
<td>6.7%</td>
<td>9.9%</td>
</tr>
</tbody>
</table>

- **Patients with >1 valve 5.2%**
- **Stroke/TIA 1%**
- **LVOT Obstruction 2.1%**
- **Perforation 1.1%**
- **Moderate to Severe-Severe MR 2.2%**

STS/ACC TVT Registry Outcomes Report 2017
Technical Considerations—Pre-Procedural Planning

- Appropriate THV Sizing
- Type of bioprosthetic valve
  - Location of Landmarks
  - Height of BPV
  - Design/length of leaflets
- Determining Risk of LVOT obstruction
Use of Valve in Valve App

VIV Aortic
VIV Mitral

App Store
Google market

Bapat, V. EuroIntervention. 2014 Sep;10 Suppl U:U44-51
Surgical Bioprosthesis Sizing Nomenclature

Label Size: Variable and rarely indicates ID of valve

S-ID: Inner diameter of valve struts and frame

True-ID: Inner diameter with leaflets and sutures (VIV App)

CT-ID: CT-Inner diameter including pannus/calcification of leaflets/valve

Shivaraju A et al. J Am Heart Assoc 2018;7:e007767
Concept of True ID

**Types**

*Porcine Valves*

```
True ID = Stent ID - 2mm
```

**Examples:**
- Biocor / Epic
- CE SAV
- CE Standard
- Hancock II
- Mosaic

```
True ID = Stent ID - 1mm
```

**Examples:**
- Magna
- Pericarbon More
- Perimount
### Table 2. Dimensions of Various Bioprostheses and Recommended THV Sizes Based on True ID Measurements

<table>
<thead>
<tr>
<th>Valve Name</th>
<th>Size (mm)</th>
<th>Stent ID</th>
<th>True ID</th>
<th>Sapien XT</th>
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</table>

- **H Hancock II Valve Size**
  - **Stent Internal Diameter**: 24
  - **True ID**: 22
  - **Height**: 19
  - **Suggested TAVI Valve Size**: 26

Bapat VN et al J Am Coll Cardiol Intv 2014;7:115–
Deployment and Sizing in Mitral VIV

Flaring is important

Mitral Bioprostheses range from 19-35 mm!

Parallel vs Conical deployment
Proposed Algorithm for Determining Choice of S3 THV Size

Pre-select S3 size based on T-ID (Min. 1mm oversizing*)

THV size concordance based on CT-ID & T-ID

Use pre-selected S3 size

CT-ID-guided balloon sizing and tug test

Balloon does not fit securely

Balloon fits securely

Use smaller S3 size based on CT-ID (Min. 1mm oversizing*)

*In borderline cases (oversizing 0-1mm) the smaller S3 THV can be used as an alternative and over-deployed in order to achieve a minimum of 1mm oversizing.

N.B. Consider bioprosthetic ring fracture and implantation of a larger size S3 in small bioprosthetic valves (label size ≤21).

Shivaraju A et al. J Am Heart Assoc 2018;7:e007767
THV Size Selection for MVIV

- Consider True ID size and CT ID size
- Type of valve pathology
  - Smaller valve for stenosis
  - Larger valve for regurgitation
- Risk of LVOT obstruction
  - Potentially smaller (shorter) THV
Technical Considerations—Pre-Procedural Planning

- Appropriate THV Sizing
- Type of bioprosthetic valve
  - Location of Landmarks
  - Height of BPV
  - Design/length of leaflets
- Determining Risk of LVOT obstruction
Varying Landmarks To Guide Implant

Carpentier-Edwards Porcine Valve
Edwards Lifesciences

Mosaic Tissue Valve
Medtronic

Epic Tissue Valve
St. Jude Medical
Stent Design Issues: Leaflet Coverage and Profile

Valve Height ranges from 16-26 mm!
Case Examples of Oversizing

**26 mm S3 in 27 mm Mosaic**

- True ID: 22 mm
- CT ID: 22 mm
- VIV App Rec: 23 or 26 mm S3

**26 mm S3 in 27 mm Magna**

- True ID: 26 mm
- CT ID: 23 mm
- VIV App Rec: 29 mm S3
Central Regurgitation After Extensive Oversizing

26-mm S3 THV within a St. Jude Epic 27-mm bioprosthesis in the mitral position

Shivaraju A et al. J Am Heart Assoc 2018;7:e007767
Technical Considerations—Pre-Procedural Planning

- Appropriate THV Sizing
- Type of bioprosthetic valve
  - Location of Landmarks
  - Height of BPV
  - Design/length of leaflets
- Determining Risk of LVOT obstruction
LVOT Obstruction
Evaluation of Aortic/Mitral Annular Angle
LVOT obstruction: Echo Imaging

Acute angle:
Higher chance of obstruction

Obtuse angle:
Less chance of obstruction
RISK OF OBSTRUCTION INCREASES

a. Depth of Sapien implant
b. Flaring of device
c. More acute AMA angle
d. Septal hypertrophy
e. Tall AML/bioprosthetic valve
Predicting LVOT Obstruction in Transcatheter Mitral Valve Implantation


Image Post-Processing Steps to Determine Neo-LVOT
Predicting LVOT Obstruction After TMVR

Use of 3Mensio Mitral Valve Software for Procedural Planning: Determination of Neo-LVOT

- Neo-LVOT >250 mm predicts low risk of LVOT obstruction
- Effective Neo-LVOT area may be underestimated with short leaflets (Hancock, Mosaic and Epic porcine valves)

CT Pre-Procedure Case Plan

NeoLVOT 375 sq cm with 26 S3

<table>
<thead>
<tr>
<th>ID Type</th>
<th>Label</th>
<th>Value</th>
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<tbody>
<tr>
<td>2</td>
<td>Distance</td>
<td>9.6 mm</td>
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</table>
Outline

- Procedural
  - Access Approach
  - Procedural Technical Aspects
Transapical Approach

- Many programs comfortable with TA Approach
- Direct Access
- Co-Axial Valve Deployment
- More Stablity/Control

- More Invasive
- Higher Rate of Complications
- Potential Impact on LV function
- Longer Recovery Time
Transvenous Transseptal Approach

- Less Invasive
- Less Access Site Complications
- Potential for monitored anesthesia
- No LV function impact

- Technically challenging
- Less co-axial/stable
- Positioning more difficult
- Residual septal defect
Non-Coaxial Implant with a Transeptal Approach
Transfemoral Transeptal Procedural Technique

- Bilateral Femoral Access
- Pacing Wire via LCFV
- Transeptal puncture
- Mullins Transeptal Sheath Placed
- Heparin with ACT 250-300 sec
- Toray Wire in LA
- Edwards E-sheath placed
- 8.5F Agilis small curve catheter placed
- Pigtail used to cross valve and Extra Small Safari wire placed in LV Apex
- Septum dilated with 12-14 mm balloon
- Sapien 3 with skirt towards left atrium
- Mounted in IVC
- Turn delivery system with Edwards logo down
- Advanced across septum with flex as needed
- Slow inflation with rapid RV pacing

UCH Approach

- SL1 Transseptal Catheter
- BRK transseptal needle
- Bovie for crossing
- Inferior and Posterior Approach
- Agilis Medium Curve Catheter
- Extra-Small Safari Wire
- Charger Balloon 12 x 20 mm x 75 cm shaft
TF Case

- 58 y/o female with NYHA Class IV CHF
- Hx of prior MVR with a 27 mm Magna in 2010
- STS PROM 6.8%
  - Cirrhosis on Liver Tx List
- MS with mean gradient of 23 mm Hg
TF Procedure

Medium Curve Agilis with 6F Pigtail

Extra Small Curve Safari Wire
12 x 20 mm Charger Balloon
Trajectory Across Valve and Mounting of S3

12 x 20 mm Charger Balloon
Positioning and Implant of Sapien 3 Valve
Final Valve Imaging
Post Procedural Issues
  - LVOT Obstruction
  - Late Valve Migration
  - Late Valve Thrombosis
Mitral Valve-in-Valve

74 y/o female with failing Carpentier-Edwards mitral bioprosthesis and CHF NYHA Class III, with LE edema, bilateral pleural effusions

- s/p MVR with 27 mm CE valve
- CAD, s/p CABG x 3 with LIMA and two SVG’s 2006
- Severe pulmonary hypertension with RV dysfunction
- s/p Permanent pacer placement
- Prior pericardietectomy
- Claudication with multiple prior LE revascularization procedures
- STS Risk of 10.5% for repeat MVR

26 mm Sapien 3 via Transseptal Route
Complicated Course

- Patient became hypotensive and was given epinephrine, vasopressin and inhaled NO for worsening PA pressures
- Echo interrogation performed revealing:
Acute LVOT Obstruction
LVOTO Management

- Patient switched from epinephrine to phenylephrine
  - Rapid improvement in BP
  - Started on esmolol once stabilized
- Slowly improved and was extubated on POD#2
- Peak LVOT gradient at discharge was 30 mmHg on metoprolol
Bail-Out Alcohol Septal Ablation for Acute LVOTO

Guerrero M et al  Cathet Cardiovasc Interv  90:1220-1226;2017
Late Malposition—Mitral Valve-in-Valve

- Incorrect sizing
- Incorrect position
- Non-flared deployment
- High LV/LA pressure gradient
Migration of an Edwards-SAPIEN XT Mitral Valve-in-Valve

23 mm Sapien XT in 25 mm CE Edwards Valve

Post procedure

3 weeks post procedure

Mick Sl et al  Ann Thoracic Surg 101(3); 2016,1182-1185
Bioprosthetic Valves: Medical Treatment

<table>
<thead>
<tr>
<th>Grade</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>IIa</td>
<td>B</td>
<td>Aspirin 75 mg to 100 mg per day is reasonable in all patients with a bioprosthetic aortic or mitral valve (178,191–194). 2014 recommendation remains current.</td>
</tr>
<tr>
<td>IIa</td>
<td>B-NR</td>
<td>Anticoagulation with a VKA to achieve an INR of 2.5 is reasonable for at least 3 months and for as long as 6 months after surgical bioprosthetic MVR or AVR in patients at low risk of bleeding (195–197). MODIFIED: LOE updated from C to B-NR. Anticoagulation for all surgical tissue prostheses was combined into 1 recommendation, with extension of the duration of anticoagulation up to 6 months. Stroke risk and mortality rate are lower in patients who receive anticoagulation for up to 6 months after implantation of a tissue prosthesis than in those who have do not have anticoagulation. Anticoagulation for a tissue prosthesis is also supported by reports of valve thrombosis for patients undergoing bioprosthetic surgical AVR or MVR, a phenomenon that may be warfarin responsive.</td>
</tr>
</tbody>
</table>

See Online Data Supplement 6.
Subclinical Valve Leaflet Thrombosis of a Sapien Valve in Mitral VIV

- 70 patients with MVIV, median follow up 14 months
- All with 3 months OAC, 27 pts (39%) stopped
- 3/27 patients with valve leaflet thrombosis (2 asymptomatic)

Capretti G et al. JACC VOL. 68, NO. 16, 2016
Conclusions

- The FDA has now approved the Sapien 3 Valve for Mitral Valve-in-Valve for High Risk/Inoperable Patients
- Mitral Valve-in-Valve requires different pre-procedural planning than Aortic VIV
  - TEE and CT both have challenges with identifying the True ID of surgical mitral valves
  - Determination of Neo-LVOT needed
  - MVIV Application can be helpful but not followed at times
  - Route of access shifting to transseptal, determined by local expertise
Conclusions (Continued)

- Mitral Valve-in-valve has unique complications
  - Valve embolization (especially delayed)
  - LVOT obstruction
  - Development of atrial/valve thrombi=>durability?
- Optimal post procedure medical management and follow up not entirely clear
  - Long term OAC
  - Follow up with TTE/TEE or CT?
- Techniques and lessons learned will have applicability with percutaneous mitral valve replacement going forward
Discussion

Glacier National Park

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