Mitral Module

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TVT Registry Steering Committee

STS-ACC TVT Registry

Three Modules in 2.0 Release

Transcatheter Aortic Valve Replacement
- Types
  - Native
  - Valve-in-Valve
- Technologies
  - Sapien™
  - CoreValve™

Transcatheter Mitral Valve Repair
- Types
  - Direct Leaflet
- Technologies
  - MitraClip™
  - Future Additions
  - Annular Reduction

Transcatheter Mitral Valve Replacement
- Types
  - Native
  - Valve-in-Valve
  - Valve-in-Ring
- Technologies
  - Sapien™

Relevant Issues
- Commercially approved Melody™ valve in separate NCDR® Registry
- Potential Areas of Expansion in TVT Arena?
  - Mitral balloon commissurotomy
  - Para-prosthetic valve regurgitation repair with transcatheter plugs
  - Annular Reduction

Objective of the Mitral Module

- To capture and report patient safety and real-world outcomes related to the transcatheter mitral valve interventional (leaflet clip and valve-in-valve) procedures for
  - quality improvement
  - post-market surveillance
  - public policy (CMS and FDA monitoring of safety, effectiveness and value)
Data Elements and Definitions

- Aligned with “Valve Academic Research Consortium 2 (VARC2)” endpoints
- Harmonized with STS and ACC-NCDR data elements where possible
- Reviewed by all stakeholders in public comment period.
- Reviewed and approved by Industry, CMS and FDA

Development of the Mitral Module

Workgroup Composition
**ST/S ACC TVT Registry**

**What’s the Difference? TAVR vs Leaflet Clip vs Mitral ViV**

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>Mitral Leaflet Clip</th>
<th>Mitral Valve-in-Valve (ViV)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indication</strong></td>
<td>Aortic stenosis (&gt;5% of adults over the age of 75 have moderate to severe AS)</td>
<td>Degenerative mitral regurgitation (DMR) (&gt;30% of adults over the age of 75 have moderate to severe MR)</td>
<td>Prosthetic mitral valve failure (stenosis or regurgitation)</td>
</tr>
<tr>
<td><strong>Patient presentation</strong></td>
<td>Dyspnea, Syncope, Angina</td>
<td>Heart Failure</td>
<td>Heart Failure</td>
</tr>
<tr>
<td><strong>Assessment</strong></td>
<td>5 minute walk for frailty</td>
<td>6 minute walk for exercise capacity</td>
<td>60” walk</td>
</tr>
<tr>
<td><strong>Vascular access</strong></td>
<td>Transfemoral, Transapical, Other</td>
<td>Venous (trans-septal)</td>
<td>Transapical</td>
</tr>
</tbody>
</table>

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**STS/ACC TVT Registry**

**Mitral Regurgitation (MR) Defined**

- **Etiology**
- **Classification of MR**
  - Acute (e.g. papillary muscle rupture)
  - Chronic
    - Degenerative (primary)
    - Functional (secondary)

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**Degenerative (Primary) Mitral Regurgitation (DMR)**

- **Pathology**
  - At least 1 valve component (leaflets, chordae tendineae, papillary muscles, annulus) causes valve incompetence (leaflet flail and leaflet prolapse most common)
- **Etiologies (Partial list)**
  - Mitral valve prolapse
  - Infectious endocarditis
  - Connective tissue disorders
  - Rheumatic heart disease
- **Result**
  - Myocardial damage, heart failure, atrial fibrillation, pulmonary hypertension, and death
Functional (Secondary) Mitral Regurgitation (FMR)

- Pathology
  - Valve is normal
  - Left ventricular (LV) dysfunction caused by CAD
  - Abnormal and dilated LV causes
    - papillary muscle displacement
    - Leaflet tethering
    - Annular dilation
  - Restoration of valve competence by itself is not curative because LV still is not normal

MitraClip

- FDA Approved for use in patients with degenerative MR in whom surgery is to high risk – details to follow.
- Not Approved for use in patients with functional MR
  - COAPT is current clinical trial studying MitraClip with optimal medical therapy versus optimal medical therapy alone

Mitral Dataset – What’s New?
Mitral Module
Pre-Procedure Assessment of Heart Failure

- Residence (pre and post procedure)
- Heart failure hospitalizations (pre and post procedure)
- Cardiomyopathy
- CRT or CRT-D

Mitral Module
Pre-Procedure Assessment of Heart Failure

- Medications (at home and post procedure)
  - Diuretics (aldosterone antagonists and loop diuretics)
    - Dose of loop diuretic is a prognostic indicator of heart failure
  - Beta blockers
  - ACE or ARB
- BNP

Mitral Module
Pre-Procedure and Follow-up Assessment

- Kansas City Cardiomyopathy Questionnaire
- Baseline echo
- Six Minute Walk
Pre-Procedure Echocardiogram Assessment

According to ASE Guidelines integrated approach

MitraClip Procedure – Indication for Use

MitraClip was approved by the FDA for percutaneous reduction of significant symptomatic degenerative mitral regurgitation (>=3+) in patients

- At prohibitive risk for mitral valve surgery by a heart team (which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease)
- In whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

MitraClip Procedure Indications

- Risk assessment – STS Risk Score
  - Mitral valve repair (>=6% predicted risk of mortality)
  - Mitral valve replacement (>= 8% predicted risk of mortality)
- Patient population considered “prohibitive risk”
MitraClip Procedure Indications

- Porcelain aorta (or extensively calcified ascending aorta)
- Frailty (assessed by in-person cardiac surgeon)
- Severe liver disease (MELD score >12)
- Other extenuating circumstances (e.g. AIDS or chemotherapy for malignancy)

MitraClip Procedure Description

- Mitral valve accessed via femoral vein and transseptal puncture
- Guided by transesophageal echocardiogram
- Two Components
  - Steerable Guide Catheter
  - Clip Delivery System
- One to two Mitraclips are deployed to hold together the central portion of the anterior and posterior mitral valve leaflets.
Adverse Events Unique to Mitral Leaflet Clip Procedures

- Valve/device
  - Valve injury - leaflet or subvalvular
  - Single leaflet device attachment
  - Mitral regurgitation

- Septum
  - Transseptal complication
  - Atrial-septal defect closure

- Mitral valve re-intervention
- Readmission for heart failure

Mitral Module

Mitral Valve-in-valve or valve-in-ring procedures

Danny Dvir
St. Paul's Hospital, Vancouver, B.C
1. Standard of care is repeat surgery for patients with bioprosthetic valve degeneration or recurrent MR despite placement of an annular rings.
2. Those patients who have prohibitive risk for repeat surgery have had no options for treatment.
3. Currently no FDA approved devices for transcatheter mitral valve replacement.
4. TVT Registry wants to capture these “off-label” cases using commercially approved valves, specifically Sapien.

Prior prosthetic mitral valve or ring model name/size

Etiology
- primary/degenerative bioprosthetic valve failure
- pannus formation
- thrombus Formation

Presence of paravalvular and valvular MR

Carpentier’s Functional Class of MR
Adverse Events Unique to Mitral Valve-in-Valve Procedure
• Systolic anterior motion
• Left ventricular outflow tract gradients
• Mitral valve re-intervention
• Readmission for heart failure

Mitral Module and CMS
• CMS held an open comment period for a “National Coverage Decision” for MitraClip procedures
• NCD expected soon

Mitral Module and Abbott Vascular Post Approval Studies
• Abbott has proposed using the TVT Registry for two MitraClip post approval studies that
  – Define
    • long term safety and effectiveness
    • patient and procedure characteristics that lead to maximum benefit from the MitraClip device
  – Study how “prohibitive risk” is interpreted in real world use of the MitraClip device
QUESTIONS?