STS/ACC TVT Registry™

Mitral Module

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TVT Registry Steering Committee

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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

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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)**

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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

Data collection form

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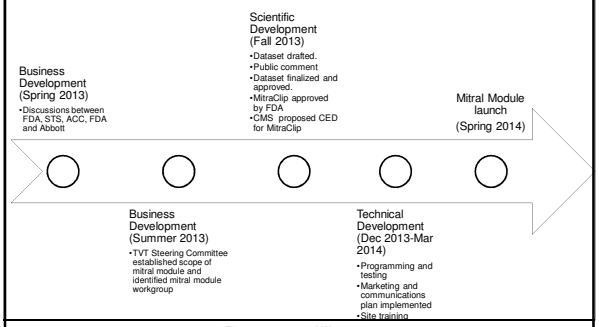
Development of the Mitral Module



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TVT Registry Mitral Module

Workgroup Composition

STS Members
- **Fred Edwards**
- **Patrick McCarthy**
- **Craig Miller**

ACC Members
- **John Carroll - Chair**
- **Samir Kapadia**

Echo Specialists
- **Paul Grayburn**
- **Neil Weissman**

Heart Failure Specialists
- **Maggie Redfield**
- **JoAnn Lindenfeld**

Data Analytic Center (DCRI) – **Matt Brennan**

FDA - **John Laschinger**

STS, DCRI and ACC Staff
- **Cynthia Shewan and Donna McDonald – STS**
- **Michael Booth and Paul Meehan - DCRI**
- **Joan Michaels and Susan Fitzgerald – ACC**

Stakeholders
- ***FDA***
- ***CMS***
- ***Industry***
- ***ACC and STS leadership***
- ***Analytic Centers***
- ***Users (public comment period)***

Abbott Input
Barathi Sethuraman
Bhagya Gurusu
Liz McDermott

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

	TAVR	Mitral Leaflet Clip	Mitral Valv Valve (ViV)
Indication	Aortic stenosis *(>5% of adults over the age of 75 have moderate to severe AS)*	Degenerative mitral regurgitation (DMR) *(>9.6% of adults over the age of 75 have moderate to severe MR)*	Prosthetic mitral valve failure (stenosis or regurgitation)
Patient presentation	Dyspnea, Syncope, Angina	Heart Failure	Heart Failure
Assessment	5 meter walk for frailty	6 minute walk for exercise capacity	6" walk
Vascular access	Transfemoral, Transapical, Other	Venous (trans-septal)	Transapical

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Mitral Regurgitation (MR) Defined

- **Etiology**
- **Classifcation 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**

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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**

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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 <u>versus</u> optimal medical therapy alone**

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Mitral Dataset – What's New?

HOME MEDICATIONS

ACE or ARB

Beta Blocke

Diruretics - A

Diuretics – L
→If Loop D

ECHOCARDIOGRAM FINDINGS

Left Atrial Volume[13000]: ___ml or LA Volume Index[13001]: ____ mL/

Left Ventricular Internal Systolic Dimension[5595]: _____cm Le

Left Ventricular

Aortic Regurgita

Aortic Stenosis

Mitral Regurgita

Note: According

→If Prior MV F

→If Prior MV F

Effective Orifice

LEAFLET CLIP PROCEDURE: REASONS/INDICATIONS (CHECK A

☐ Frailty[5900] *(assessed by*

☐ Severe Liver Disease

☐ Predicted STS MV Rep

☐ Predicted STS MV Rep

☐ Unusual Extenuating C

→If Unusual Extenuating (

Steerable Guide Model ID[26100]: _____	Steerable Gu
Counter[26200]	Leaflet Clip #1
Delivery System Lot Serial #[26205]	
UDI[26209]	
UDI Expiration Date[26305]:	mm / dd / yyyy
Location[26275]:	O A1P1 O A2P2 O A3P3
Clip Deployed[26275]	O No O Yes
→If No, Reason[26280]:	O Inability to Grasp Leaflets O Inability to Reduce MR O Mitral Stenosis O MV Injury O Device Malfunction O Adverse Event O Other

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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**

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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**

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Mitral Module
Pre-Procedure and Follow-up Assessment

- **Kansas City Cardiomyopathy Questionnaire**
- **Baseline echo**
- **Six Minute Walk**

Six Minute Walk Test[5061]:
O Performed
O Not pe
O Not pe
O Not pe
O Not pe

KCCQ-12 Performed[5165]: O No O Yes

→**If Yes, KCCQ-12**[5166]: Q1a: _____ Q1b: _____ Q1c:

ECHOCARDIOGRAM FINDINGS

→If Perfo (See s

Note: According to American Society of Echocardiography Guidelines integrated approach

Mitral Regurgitation[906]: O None O Trace/Trivial O 1+/mild O 2+/moderate O 3+/moderate-severe O 4+/severe

Total Distance[506]

Effective Orifice Area (EOA) or EROA/[5xx]: _____ cm^2

Method of Assessment: O 3D Planimetry O PISA O Quantitative Doppler O Other

MV Area[5710]: _____ cm^2

MV Mean Gradient[5715]: _____ mmHg

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Pre-Procedure Echocardiogram Assessment

According to ASE Guidelines integrated approach

Echocardiogram Findings (Preprocedure)

LVEF[3005]: _____ % ☐ LVEF Not Assessed[3006]	**Left Atrial Volume:** ___ml or **LA Volume Index:** ___ml/m2
Left Ventricular Internal Systolic Dimension[3035]: _____ cm	**Left Ventricular End Systolic Volume**[3]: ___ml ☐ Not Evaluated
Left Ventricular Internal Diastolic Dimension[3050]: _____ cm	**Left Ventricular End Diastolic Volume**[3]: ___ml ☐ Not Evaluated

Aortic Regurgitation[3036]: ○ None ○ Trace/Trivial ○ 1+/mild ○ 2+/moderate ○ 3-4+/severe

Aortic Stenosis[3085]: ○ No ○ Yes

Mitral Regurgitation[3046]: ○ None ○ Trace/Trivial ○ 1+/mild ○ 2+/moderate ○ 3+/moderate-severe ○ 4+/severe

Note: According to American Society of Echocardiography Guidelines integrated approach

Effective Orifice Area (EOA) or EROA[3xx]: _____ cm^2 **Method of Assessment:** ○ 3D Planimetry ○ PISA ○ Quantitative Doppler ○ Other

MV Area[3210]: _____ cm^2

MV Mean Gradient[4731]: _____ mmHg

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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.

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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"**

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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)***

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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.**

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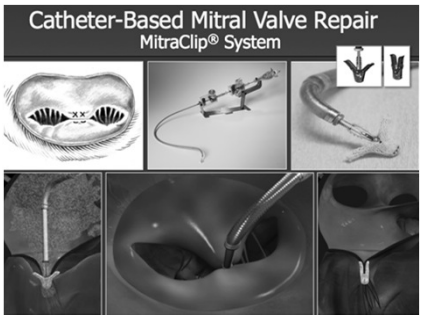

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Adverse Events Unique to Mitral Leaflet Clip Procedures

- 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

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

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Valve-in-Valve International Data VIVID

Data Collection Form- Mitral Valve-in-Valve Procedures
Valve-in-Valve International Data (VIVID)
Version 3.0

Danny Dvir
St. Paul's Hospital, Vancouver, B.C

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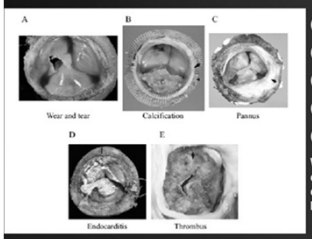
Most Common Reasons for Bioprosthetic Valve Failure [1]



(A) Wear and tear

(B) Calcific degeneration

(C) Pannus

(D) Endocarditis

(E) Thrombus

Wear and tear (A) and calcification (B) are the most common reasons for bioprosthetic valve failure

1. Piazza, N, et al. *JACC Cardio Interventions*. 2011;4:721-32.

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Valve-in-Valve and Valve-in-Ring

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.**

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Data Elements Unique to Mitral Valve-in-Valve Procedure

- **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**

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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

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Mitral Module and CMS

- CMS held an open comment period for a "National Coverage Decision" for MitraClip procedures
- NCD expected soon

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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

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QUESTIONS?