Percutaneous Therapy for Calcific Mitral Valve Disease

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Disclosures

Speakers Bureau (Philips, Medtronic)
Advisory Board (Siemens)
Calcific Mitral Valve Disease

- **Mitral annular calcification (MAC)** is the primary form of calcific nonrheumatic mitral valve disease
- Calcifications often extend to **other parts of the mitral apparatus**
- Unlike rheumatic stenosis, MAC-associated stenosis has **no commissural fusion**
- May lead to **mitral stenosis** and/or **mitral regurgitation**
- **Degenerative disease** associated with aging, atherosclerosis, aortic stenosis and renal disease

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**PRACTICE GUIDELINE**

**2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease**

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

*Developed in Collaboration With the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons*
Nonrheumatic Calcific Mitral Disease

**Natural History**
- Data are relatively sparse on the natural history of senile calcific mitral stenosis.

**Mitral Stenosis Diagnosis**
- **Mean pressure gradient** from Doppler echocardiography is accurate
- However, mitral valve area calculation by **pressure half-time** is uncertain in this population

**Treatment**
- Patients with calcification are often elderly and debilitated, have multiple comorbidities, and are at **high risk** for percutaneous or surgical intervention
- Intervention should be **delayed** until symptoms are severely limiting and cannot be managed with diuresis and heart rate control

TTE
TTE: Nonrheumatic Calcific MV Disease
TTE: Nonrheumatic Calcific MV Disease

MEAN MITRAL DIASTOLIC GRADIENT

16 mm Hg at HR 81 bpm
TTE: Nonrheumatic Calcific MV Disease

PRESSURE HALF-TIME METHOD
Should NOT be used for this form of mitral stenosis!

2D & 3D TEE
2D TEE: Nonrheumatic Calcific MV Disease

3D TEE: Nonrheumatic Calcific MV Disease
3D TEE: Nonrheumatic Calcific MV Disease

CT
CT: Nonrheumatic Calcific MV Disease

Tissue
AVR

MAC

Pacemaker Leads

CT: Nonrheumatic Calcific MV Disease
Nonmedical Treatment Options

- **DEFINITELY NOT CANDIDATE FOR**
  - Percutaneous mitral balloon valvuloplasty (PMBV)

- **LIKELY NOT CANDIDATE FOR**
  - Transcatheter mitral valve replacement (TMVR)

- **POSSIBLY CANDIDATE FOR**
  - Mitral valve surgery
  - Percutaneous valve-in-MAC procedure

Not An Option: Balloon Valvuloplasty
**Dwight Harken**
(1910 – 1993)
Iowa-born
Cardiac Surgeon

**Charles Bailey**
(1910 – 1993)
New Jersey-born
Cardiac Surgeon

Coined the term
Mitral Valvuloplasty

Coined the term
Mitral Commissuromy

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**Normal MV vs. Rheumatic Mitral Stenosis**

Normal mitral valve

Severe rheumatic mitral stenosis
Commissural fusion is hallmark of RHEUMATIC mitral stenosis
Mitral Balloon Valvuloplasty

*Inoue balloon* is reinforced with a nylon micromesh. Its shape changes in 3 stages, depending on the extent of inflation.

Rheumatic Mitral Stenosis: Balloon Valvuloplasty

*Before Valvuloplasty*  
*After Valvuloplasty*
Question

Balloon valvuloplasty is NOT indicated for calcific nonrheumatic valve disease. Why?

Answer

• Valvuloplasty (commissurotomy) works by disrupting commissural fusion.

• Commissural fusion is NOT a feature of calcific nonrheumatic mitral valve disease.

• Thus, commissurotomy does NOT work for calcific nonrheumatic mitral valve disease.
Likely Not an Option: Transcatheter MV Replacement

Caisson TMVR

Transvenous / Transseptal Implantation
3D TEE & Angio Fusion Guidance

Precise Diagnosis of MV Disease

Accurate Procedural Guidance
3D TEE & Angio Fusion Guidance

Precise TMVR Anchor Placement Guidance  Successful TMVR Deployment

Intrepid TMVR

Transapical Implantation
Intrepid TMVR

Step 1. Advance across valve
Step 2. Deploy brim
Step 3. Retract to desired position
Step 4. Expand fixation ring
Step 5. Release
Question

Patients with calcific nonrheumatic valve disease are typically excluded from TMVR trials. Why?

Answer

Marked mitral annular calcification is typically an exclusion criterion for TMVR trials.
Not a Great Option: Mitral Valve Surgery

Surgery for Calcific Nonrheumatic MV Disease

- **2014 ACC/AHA Valvular Disease Guidelines**

  - Severe mitral annular calcification causes **problems in securely attaching the prosthetic valve**

  - **Supra-annular insertion** and other innovative techniques can be used, such as placement of a **felt patch around the valve orifice to anchor the prosthesis**; however, this only works if the mitral orifice is adequate. If the annular calcification narrows the orifice, it has to be debrided.

  - The other alternative is **left atrial to ventricular bypass with a valved conduit** in extreme cases of calcification both of the leaflet and the annulus.

  - Patients with calcification are often elderly and debilitated, have multiple comorbidities, and are at **high risk for surgery**.
Possible Option: Valve-in-MAC

Valve-in-MAC Concept

Placement of a TAVR valve (typically a Sapien valve) in a fashion similar to mitral valve-in-valve procedure.

MAC conceptually plays the same role as the surgical bioprosthetic sewing ring in standard mitral valve-in-valve procedure.
Mitral Valve-in-Valve Procedure
Valve-in-MAC

Step #1
Transseptal Puncture

Step #2
Prosthetic Valve Positioning

Step #3
Valve Deployed in MAC

Prior to Valve-in-MAC
After Valve-in-MAC

Transcatheter Mitral Valve Replacement in Native Mitral Valve Disease With Severe Mitral Annular Calcification

Results From the First Multicenter Global Registry
ABSTRACT

OBJECTIVES This study sought to evaluate the outcomes of the early experience of transcatheter mitral valve replacement (TMVR) with balloon-expandable valves in patients with severe mitral annular calcification (MAC) and reports the first large series from a multicenter global registry.

BACKGROUND The risk of surgical mitral valve replacement in patients with severe MAC is high. There are isolated reports of successful TMVR with balloon-expandable valves in this patient population.

METHODS We performed a multicenter retrospective review of clinical outcomes of patients with severe MAC undergoing TMVR.

RESULTS From September 2012 to July of 2015, 64 patients in 32 centers underwent TMVR with compassionate use of balloon-expandable valves. Mean age was 73 ± 13 years, 66% were female, and mean Society of Thoracic Surgeons score was 14.4 ± 9.5%. The mean mitral gradient was 11.45 ± 4.4 mm Hg and the mean mitral area was 1.18 ± 0.5 cm². SAPIEN valves (Edwards Lifesciences, Irvine, California) were used in 7.8%, SAPIEN XT in 59.4%, SAPIEN 3 in 28.1%, and Inovare (Braile Biomedica, Brazil) in 4.7%. Access was transatrial in 15.6%, transapical in 43.8%, and transseptal in 40.6%. Technical success according to Mitral Valve Academic Research Consortium criteria was achieved in 46 (72%) patients, primarily limited by the need for a second valve in 11 (17.2%). Six (9.3%) had left ventricular tract obstruction with hemodynamic compromise. Mean mitral gradient post-procedure was 4 ± 2.2 mm Hg, paravalvular regurgitation was mild or absent in all. Thirty-day all-cause mortality was 29.7% (cardiovascular = 12.5% and noncardiac = 17.2%); 84% of the survivors with follow-up data available were in New York Heart Association functional class I or II at 30 days (n = 25).

CONCLUSIONS TMVR with balloon-expandable valves in patients with severe MAC is feasible but may be associated with significant adverse events. This strategy might be an alternative for selected high-risk patients with limited treatment options. (J Am Coll Cardiol Intv 2016;9:1361-71) © 2016 by the American College of Cardiology Foundation.

Valve-in-MAC Challenges

Paravalvular Leak
Valve-in-MAC: Paravalvular Leak

Valve-in-MAC Challenges

Valve Dislodgment
Valve-in-MAC: Valve Dislodgement

Surgical Retrieval of Dislodged Valve-in-MAC
Thank You!

New York University Langone Medical Center