Significant Mitral Regurgitation (EF, LVEdD, PH or AF): Five Challenges

Two Etiologies (Primary, Secondary), Three Approaches (Medical, Clipping, Surgical)

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COI: No relationship to disclose for this presentation
A Largely Untreated Patient Population

Mitral Regurgitation 2009 U.S. Prevalence

Total MR Patients\(^1,2\)  
4,100,000

Eligible for Treatment\(^3,4\)  
(MR Grade \(\geq 3+\))  
1,670,000

Annual Incidence\(^3\)  
(MR Grade \(\geq 3+\))  
30,000

Untreated Large and Growing Clinical Unmet Need

Only 2% Treated Surgically

Annual MV Surgery\(^5\)

14% Newly Diagnosed Each Year

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Untreated Severe MR is Associated with Increased Morbidity and Mortality

Increasing Mitral Regurgitation

Dilation of Left Ventricle

Increase Load/Stress

Dysfunction of Left Ventricle

Muscle Damage/Loss

1 year mortality up to 57%¹

MR and Heart Failure
Prevalence in CHF

Moderate or severe MR present in \( \sim 40\% \)

\~5 million people with heart failure in U.S.

Classification of MR – 2 Types

Incompetent mitral valve closure
Systolic retrograde blood flow from the LV into the LA

Primary:
Anatomic abnormality the mitral valve
• Leaflets
• Subvalvular apparatus
• Chordae and papillary muscles

Secondary:
LV dilation; often secondary to ischemic heart disease
• Leads to mitral annular dilation
• Incomplete coaptation of the mitral valve
Prognostic Determinants of Mitral Regurgitation (MR)

- Severity
- Left Ventricular Function
- Symptoms
EVEREST II Randomized Clinical Trial

Surgical and Percutaneous Therapy for Mitral Regurgitation

Mitral Valve Surgery Repair/Replacement or Catheter Based Mitral Valve Repair MitraClip System
EVEREST II Trial: 5-Year Clinical Outcomes – Percutaneous Repair and Surgery for Mitral Regurgitation

Freedom from Death, MV Surgery or Reoperation

Landmark Analysis of Freedom from Death, MV Surgery or Reoperation Beyond 6 Months

Feldman et al., J Am Coll Cardiol 2015;66:2844
Prohibitive Surgical Risk
DMR Cohort (n=127)

- 95% implant success
- No procedural deaths
  - LOS = 2.9 days

Event Free Survival

Days Post Index Procedure

Lim et al, J Am Coll Cardiol 2014;64:182
Acute Procedure Success Rate

MitraClip(s) implanted & MR ≤2+

Percent

0  20  40  60  80  100

EVEREST I
n=55
2004

EVEREST I
n=107

EVEREST II
n=178

ACCESS EU
n=567

TRAMI
n=861

GRASP-It
n=171

2015
# Worldwide Experience Using the MitraClip

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<td><strong>TOTAL</strong></td>
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Clinical Outcomes at 1-year after Commercial Transcatheter Mitral Valve Repair in the United States

Paul Sorajja, MD, Sreekanth Vemulapalli MD, Ted Feldman, MD, Michael Mack, MD, David R. Holmes, Jr. MD, Amanda Stebbins, MS, Saibal Kar, MD, Vinod Thourani, MD, and Gorav Ailawadi, MD

ACC – Washington, DC, USA – March 18, 2017*

* This slide deck has been modified from that presented to include the following required information: Indications for Use, Safety Information, and an internal Abbott document number for identification. In addition, the coding appendix (in German) has been deleted.
Acute Procedural Results

92.8% with post-procedural MR ≤2
SLDA, 1.5%
In-hospital mortality = 2.7%
85.9% discharged home
Median LOS, 2 days (1, 5 days)

Acute procedure success = 91.8%
Post-Procedural MR and Survival

Cumulative incidence of death

- Grade III/IV: 48.9%
- Grade II: 29.2%
- Grade 0/I: 21.7%

Follow-up (months)

No. at risk

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AP2943953-US Rev A
Mitral Valve Replacement Devices
Active Clinical Programs

Intrepid Twelve
Tendyne
Neovasc
CardiAQ
FORTIS
Highlife
Conclusion

- **MitraClip** results in clinically significant MR reduction in a majority of patients. TEE is essential for procedural optimization.

- **MitraClip** is safer than surgery with shorter time to recovery but is less effective than surgery for MR.

- **MitraClip** results in similar patient centered outcomes to surgery including improvement in HF class and QOL and reduction in readmission.

- Therefore **MitraClip** is ideally suited for poor surgical candidates with appropriate anatomy.
Conclusion Contd.

- **MitraClip therapy is now FDA approved** for symptomatic patients with severe MR of degenerative etiology who are poor surgical candidates.

- For patients with **symptomatic functional MR** MitraClip will be available when COAPT trial results will be presented.

- **TMVR devices for native MV disease** have potential but are a long way off

- **TMVR using Sapien valve** has recently been approved by FDA for use in Bio-prosthetic Mitral valve degeneration