PERCUTANEOUS MITRAL VALVE THERAPIES

13TH ANNUAL CARDIAC, VASCULAR AND STROKE CARE CONFERENCE
PIEDMONT ATHENS REGIONAL

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I WILL BE DISCUSSING OFF-LABEL USAGE OF DEVICES RELATED TO TMVR
OBJECTIVES

• REVIEW MITRAL VALVE ANATOMY
• DISCUSS TYPES OF MITRAL REGURGITATION
• TREATMENT OPTIONS REVIEWED
• REVIEW PERCUTANEOUS MITRAL VALVE REPAIR
• DISCUSS PERCUTANEOUS TMVR OPTIONS
CASE JH

- 86yo WM severe eccentric MR-prolapse P2, EF-40%
- Exertional Dyspnea (NYHA Class 3)
- Prohibitive Surgical Risk
MITRAL VALVE ANATOMY
CLASSIFICATION OF MR

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

Secondary:
LV dilation; often secondary to ischemic heart disease
- “Tethering” of the chordae and mitral leaflets
- Incomplete coaptation of the mitral valve

The Valve is the Problem
The Ventricle is the Problem

Rev Esp Cardiol. 2011;64(12):1169-1181
PREVALENCE OF VALVE DISEASE

MR: LARGELY UNTREATED

Mitral Regurgitation 2009 U.S. Prevalence

- **Total MR Patients**: 1,200,000
- **Eligible for Treatment** (MR Grade ≥3+): 1,700,000
- **Annual Incidence** (MR Grade ≥3+): 250,000
- **Annual MV Surgery**: 30,000
- **Untreated Large and Growing Clinical Unmet Need**: 1,670,000
- **Only 2% Treated Surgically**

Nearly half of MR patients not considered appropriate for mitral valve surgery ¹

Factors prohibiting surgery include¹:
- Impaired LVEF
- High operative risk
- Multiple comorbidities
- Advanced age

Rankin, et al, J of Thoracic and Cardiovascular Surgery, March 2006
Severity of MR Predictive of HF Survival

Survival of Heart Failure Patients with MR by Degree of MR
Adjusted for demographics and clinical variables at baseline

Note: Adjusted survival estimates are shown.
PRE-OP EF PREDICTS POST-OP SURVIVAL

val, 1.65 to 4.72) for ejection fraction <50% and 1.81 (95% confidence interval, 1.11 to 2.95) for ejection fraction 50% to 60%. The estimated 5-year survival and yearly mortality according to preoperative ejection fraction, symptoms, and presence of coronary artery disease are presented in Table 4. The combination of echocardiographic ejection fraction (globally or subdivided in calculated or estimated) and angiographic end-systolic volume in a single multivariate model showed that no additional survival information was provided by the angiographic variable.

To confirm the predictive value of echocardiographic ejection fraction independent of the type of operation performed, the late survival was compared in subgroups defined according to the level of ejection fraction and separately in patients with mitral valve repair and in patients with mitral valve replacement (Fig. 2). The
NATURAL HISTORY OF FLAIL MITRAL VALVE

EARLY SURGERY IS BETTER

Suri R et al., JAMA 2013;310:609-16
2017 ACC/AHA GUIDELINES
INDICATIONS FOR SURGERY FOR MR

FIGURE 2  Indications for Surgery for MR (Updated Figure 4 From the 2014 VHD guideline)
SURGICAL MV REPAIR
GOLD STANDARD DMR

Figure 1 Common Established Surgical Techniques Used to Correct Mitral Regurgitation
(A) Ring annuloplasty. (B) Quadrangular resection and sliding leaflet plasty. (C) Chordal transfer. (D) Cleft closure. (E) Mitral replacement. Figure illustration by Craig Skaggs.

Figure 2 Newer Surgical Techniques Used to Repair Regurgitant Mitral Valve
(A) Chordal replacement. (B) Posterior leaflet augmentation. (C) Edge-to-edge Affieri stitch (valve shown in diastole with double orifice). (D) Papillary muscle approximation. (E) Posterior wall resection. Figure illustration by Craig Skaggs.
WHAT IF SURGERY IS NOT AN OPTION?
CASE JH

• MEDICAL THERAPY?
• PERCUTANEOUS OPTIONS?
PERCUTANEOUS REPAIR OR SURGERY FOR MITRAL REGURGITATION
TRANCATHETER MITRAL VALVE REPAIR
UPDATED LAB MR GRADE AT 1 YEAR (MATCHED)
EVEREST II AND CONTINUED ACCESS HIGH SURGICAL RISK PATIENTS

**EVEREST II**
High Surgical Risk Patients
(n=54 matched cases)

- Baseline:
  - 4+ (27%)
  - 3+ (20%)
  - 2+ (19%)
  - 1+ (13%)
  - 3+ (10%)
  - 2+ (10%)

- 1 Year:
  - 4+ (27%)
  - 3+ (20%)
  - 2+ (19%)
  - 1+ (13%)
  - 3+ (10%)
  - 2+ (10%)

**Continued Access**
High Surgical Risk Patients
(n=69 matched cases)

- Baseline:
  - 4+ (33%)
  - 3+ (33%)
  - 2+ (17%)
  - 1+ (13%)
  - 3+ (10%)
  - 2+ (10%)

- 1 Year:
  - 4+ (33%)
  - 3+ (33%)
  - 2+ (17%)
  - 1+ (13%)
  - 3+ (10%)
  - 2+ (10%)

*p < 0.0001*
LV END DIASTOLIC AND SYSTOLIC VOLUMES
EVEREST II AND CONTINUED ACCESS HIGH SURGICAL RISK PATIENTS

**EVEREST II**
High Surgical Risk Patients
(n=54 matched cases)

Baseline 1 Year
LVEDV
172 140
LVESV
82 72

**Continued Access**
High Surgical Risk Patients
(n=63 matched cases)

Baseline 1 Year
LVEDV
158 143
LVESV
89 80

p = 0.0003
p = 0.011

Volume (mL)

p < 0.0001
p = 0.0012

Baseline 1 year
Baseline 1 year
NYHA FUNCTIONAL CLASS AT 1 YEAR
EVEREST II AND CONTINUED ACCESS HIGH SURGICAL RISK PATIENTS

EVEREST II
High Surgical Risk Patients (n=54 matched cases)

Continued Access
High Surgical Risk Patients (n=89 matched cases)

P < 0.0001

Baseline 1 Year

Percent Patients

Baseline 1 Year

74%
84%
HOSPITALIZATION FOR CHF
EVEREST II AND CONTINUED ACCESS HIGH SURGICAL RISK PATIENTS

EVEREST II
High Surgical Risk Patients

Continued Access
High Surgical Risk Patients

1 Year Prior to MitraClip
1 Year Post MitraClip

Annual Rate of CHF Rehop*

0.65
0.36

0.86
0.45

p=0.02
p=0.0002

45% Reduction
48% Reduction

1 Year Prior
N=78
1 Year Post
N=75

1 Year Prior
N=133
1 Year Post
N=128

*CHF hospitalizations per patient-year
EVEREST II TRIAL SUMMARY-1 YEAR
PERCUTANEOUS EDGE TO EDGE REPAIR IN DEGENERATIVE MR WITH PROHIBITIVE SURGICAL RISK

- **Effective reduction in mitral regurgitation**
- **Reduction in LV volume**
- **Improvement in NYHA functional class**
- **Reduction in HF hospitalization**
MITRACLIP IFU

- The MitraClip® NT Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be 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, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.
CASE JH
Eligible Patients

- Symptomatic Functional mitral regurgitation >3+
- Not suitable candidate for surgical MVR
- NYHA Class 2,3, or ambulatory 4, not stage D HF

Primary endpoints

Efficacy
- Recurrent heart failure (HF) hospitalizations

Safety
- Composite of Single Leaflet Device Attachment (SLDA), device embolizations, endocarditis requiring surgery, Echocardiography Core Laboratory confirmed mitral stenosis requiring surgery, and any device related complications requiring non-elective cardiovascular surgery at 12 months

Secondary endpoints

Efficacy
- Mitral regurgitation severity at 12 months
- Change in 6-minute walk test at 12 months
- Change in quality of life at 12 months
- Change in Left Ventricular end-diastolic volume at 12 months
- NYHA functional class I/II at 12 months
- Hierarchical composite of death and recurrent HF hospitalization
- Recurrent hospitalizations — all-cause

Safety
- Composite of all-cause death, stroke, MI, or non-elective cardiovascular surgery for device related complications at 30 days post-procedure in the MitraClip group
# One Size Does Not Fit All

<table>
<thead>
<tr>
<th>Criteria Suggesting Patient Suitability</th>
<th>Criteria Suggesting Patient Might Not Be Suitable</th>
</tr>
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<tbody>
<tr>
<td>Nonrheumatic etiology</td>
<td>Rheumatic etiology, endocarditis-related valve disease, or prior MV surgery</td>
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<tr>
<td>Central mitral regurgitation jet</td>
<td>Cleft or perforated mitral leaflets</td>
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<tr>
<td>MV orifice area ≥ 40 mm²</td>
<td>Lack of secondary chordal support</td>
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<tr>
<td>If a flail leaflet is present</td>
<td>Posterior leaflet length &lt; 7 mm</td>
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<tr>
<td>Flail gap* &lt; 10 mm</td>
<td></td>
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<tr>
<td>Flail width* &lt; 15 mm</td>
<td></td>
</tr>
<tr>
<td>Posterior leaflet length ≥ 10 mm</td>
<td>Leaflet gap &gt; 2 mm</td>
</tr>
<tr>
<td>If leaflet tethering present</td>
<td>Presence of severe calcifications in the grasping area</td>
</tr>
<tr>
<td>Coaptation depth &lt; 11 mm</td>
<td></td>
</tr>
<tr>
<td>Coaptation length† &lt; 10 mm</td>
<td></td>
</tr>
<tr>
<td>Absence of calcifications in the grasping area</td>
<td>Transmirtal pressure gradient ≥ 4 mm Hg‡</td>
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<td>Effective regurgitant orifice area &gt; 70.8 mm²‡</td>
</tr>
<tr>
<td></td>
<td>MV orifice area &lt; 30 mm²‡</td>
</tr>
<tr>
<td></td>
<td>Evidence of intracardiac mass, thrombus, or vegetation, or evidence of an inferior vena cava or femoral venous thrombus</td>
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PERCUTANEOUS MITRAL ANNULOPLASTY
QUANTUMCOR (A) & ICOAPSY (B)
RESHAPING MITRAL ANNULUS AND VENTRICLE
PERCUTANEOUS MITRAL ANNULOPLASTY
CARILLON
ANNULOPLASTY VIA CORONARY SINUS
PERCUTANEOUS MITRAL ANNULOPLASTY
CARDIOBAND (A) & MITRALIGN (B)
PERCUTANEOUS MITRAL ANNULOPLASTY
Referrals to Valve Team: 706-475-1793
SUMMARY

• **Mitral Regurgitation** is prevalent
• **Significant under-treatment** exists
• **Refer Early**
• **Treatment options** for high risk patients are limited
• **Development of trans-catheter mitral valve replacement** is in its infancy
QUESTIONS??

THANK YOU

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CME QUESTIONS

1. HOW PREVALENT IS MITRAL VALVE DISEASE?

A. 9%
B. 20%
C. 1%
D. 50%
2. WHAT IS THE GOLD STANDARD OF MITRAL VALVE REGURGITATION TREATMENT?

**A. Medical therapy with diuretics**

**B. Surgical repair**

**C. Percutaneous repair**
3. IS HEART FAILURE READMISSION REDUCED WITH EARLY MITRAL VALVE REPAIR?

A. Yes
B. No
4. PERCUTANEOUS MITRAL VALVE REPAIR IS AN OPTION IN PATIENTS WITH SEVERE MITRAL REGURGITATION AND PROHIBITIVE SURGICAL RISK.

A. True

B. False