THERAPEUTIC DILEMMA

Dr.Deepthi Immadisetty

CASE HISTORY

- A 37 year old female patient X , presented to NIMS with complaint of
- chest pain for 6 hours.
  retrosternal radiating to left arm.
- sudden onset of SOB class IV
  associated with orthopnea.
- known diabetic for approximately 1 yr
- Not a hypertensive/alcoholic/smoker.
- No h/o of CAD in the past and
- No family history of CAD.

- At admission Vitals:

  PR=110/min

  BP=110/70 mmHg

  CVS=S1S2+

  RS= B/L VBS+ basal crepts+.
- ECG at admission: QRBBB, ST elevation in V2-V6.
- Echo at admission: RWMA in LAD territory,

  Moderate LV dysfunction EF=35%.

  Mild MR , Mod TR/mod PAH.

  No PE, No Veg/clot.
- Homocysteine was 65 micro moles/dl
- Lp(A)= 40mg/dl

MANAGEMENT

- Patient was thrombolysed with STK with window period of 6 hrs in outside hospital on 3/7/15.
- CAG was done, PTCA to prox LAD was done with Biomime(3.5*16) stent on 4/7/15 in NIMS
- Patient was discharged in a hemodynamically stable condition with dual antiplatelet regimen with aspirin and prasugrel.

FOLLOW UP

- Echo on 31/07/15 showed
  - RWMA in LAD territory
  - Moderate lv dysfunction EF:35%
  - Moderate MR,
  - Moderate PAH

2ND READMISSION

- August,2015
- Class IV SOB
- Stabilized with diuretics & ionotropes
- ECG:No fresh changes
- Echo:RWMA in LAD territory, Severe LV dysfunction EF:32% Moderate MR,Moderate TR, Severe PAH

3RD READMISSION

- October, 2015
- Class IV SOB
- Stabilized with diuretics & ionotropes
- ECG:No fresh changes
- Echo:moderate to severe MR Severe LV dysfunction

- After stabilisation TEE was done that showed
  - Moderate MR with Jet area of 5.6 cm^2
  - MRVC 6.2mm,mod lv dysfunction with EF=40%
  - A2 scallop is mild flial.
  - Moderate TR and moderate PAH.
- CAG and Cath done showing patent stent in LAD.

PA pressure is 58/22 (37). LVEDP 32.

CATH DATA

- Pressure data:
  - FA-85/50
  - PCWP:32
  - PA:58/22 M:37
  - RV:54/0-5
  - RA:6
  - LV:80/32
  - LV---AORTA:No gradient
- Saturation data:
  - FA-94.9%
  - PA-45.6%
- TPG:5
- PVR:3.73

- Viability scan done showing

  20% viable myocardium in LAD,

  80% viability in LCX & RCA territories,EF=30%,

  Full thickness infarct in apex, anterior wall, anteroseptal, apicoinferior.

- Patient was discharged in stable condition after taking CT surgeon opinion for mitral valve repair.

  CT surgeon deferred surgery in view of high risk.

- Follow up echo on 6/11/15

  Moderate LV dysfunction.

  EDV=108, ESV=60,EF=40%

  Moderate TR and severe PAH

  with RVSP =78 mmHg

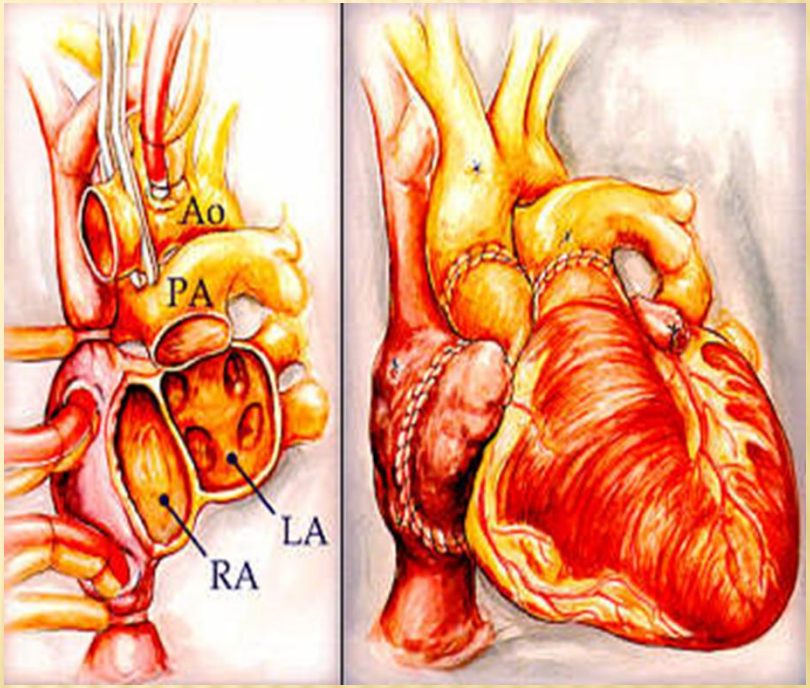
4TH ADMISSION

- Patient got admitted with orthopnea, PND.
- Echo showed severe MR and severe PAH with severe LV dysfunction. Inotropic support given failure stabilized. 2Decho showed severe LV dysfunction and severe MR, severe PAH.
- Patient stabilised with discharged in a stable condition.

THERAPEUTIC DILEMMA

WHAT NEXT ?

MITRACLIP

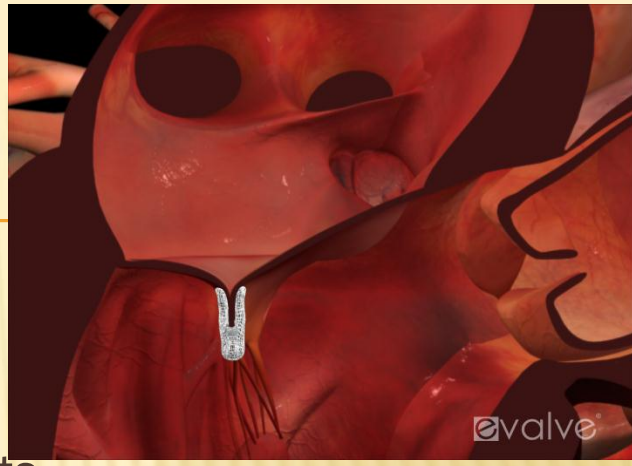


CARDIAC TRANPLANTATION

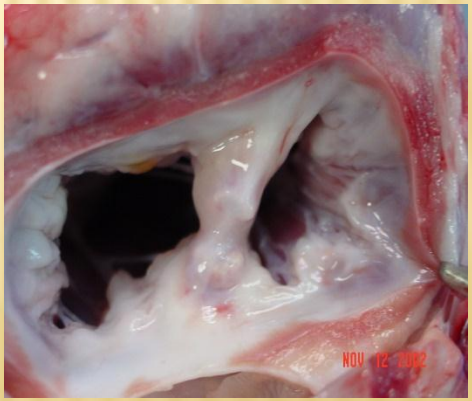
MITRACLIP INDICATIONS

- Intrinsic MV pathology in those with degenerative MR does not respond to medical therapy. These patients with risk for surgery have an alternative treatment of MITRA CLIP because of the favorable safety profile of this device.
- The U.S. FDA approved the MitraClip device in October 2013 for the reduction of “symptomatic MR +++ due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for MV surgery by a heart team”

EDGE TO EDGE & MITRACLIP CONCEPTS



- Facilitates proper leaflet coaptation
  - Degenerative - Anchor flail and prolapsed leaflets
  - Functional - Coapt tethered leaflets to reduce time and force required to close valve
  - Reduces LV volume overload by reducing MR
- Creates tissue bridge
  - May limit dilatation of annulus
    - Septal-lateral (A-P) dimension
  - Supports durability of repair
- Restrains LV wall
  - Limits LV dilatation



Porcine model, 6M

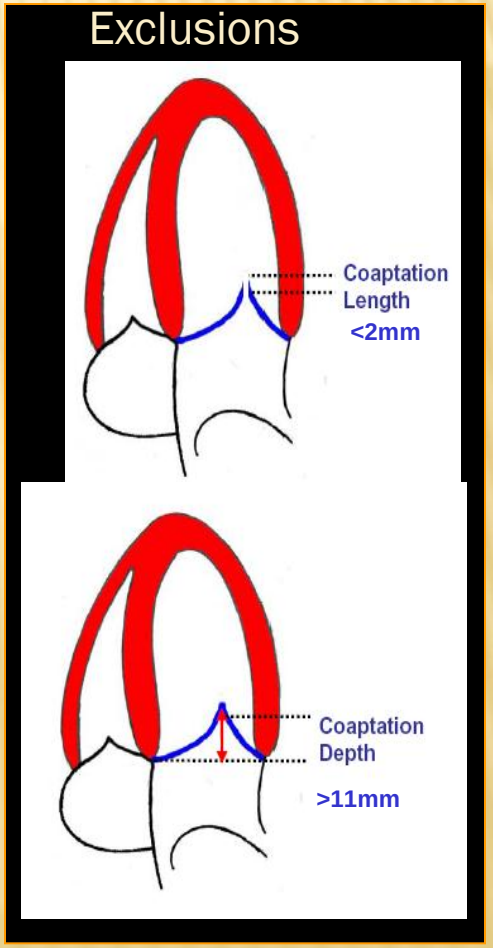
METHODS: KEY ELIGIBILITY CRITERIA

- Age 18 years or older
- Moderate to severe (3+) or severe (4+) MR
  - *Symptomatic*
  - *Asymptomatic with LVEF < 60% or LVESD > 40mm*

    ACC/AHA Guidelines, Circ. 114;450,2006
- MR originates from A2-P2 mal-coaptation
- Candidate for mitral valve surgery
- Transseptal deemed feasible
- Key Exclusions
  - *EF < 25% or LVESD > 55 mm*
  - *Renal insufficiency*
  - *Endocarditis, rheumatic heart disease*

METHODS: ANATOMIC ELIGIBILITY

- TEE evidence of FMR:
  - Absence of Degenerative valve disease
  - Presence of leaflet “tethering”
    - Not exceeding 10mm
- Sufficient leaflet tissue available for mechanical coaptation
  - > 2mm “vertical” leaflet tissue available
  - Protocol anatomic exclusions
    - Coaptation depth >11mm
    - Coaptation length < 2mm
- Absence of severe LV dysfunction
  - Excluding LVID-s > 55mm or EF <25%
  - Ischemic or non-ischemic etiology



- The safety and effectiveness of MitraClip therapy have not been established in patients who have specific mitral valve anatomy that may interfere with proper placement and positioning of the MitraClip device:
  - A mitral valve opening that is too small
  - Calcified mitral valve leaflets
  - A cleft of the mitral valve leaflet
  - A leaflet flail width or leaflet flail gap that is too large
- MitraClip therapy has not been tested in pregnant women or children or infants, and the device may not work for these patients.

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Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II

Ted Feldman, MD,* Saibal Kar, MD,† Sammy Elmariah, MD, MPH,‡§ Steven C. Smart, MD,* Alfredo Trento, MD,‖ Robert J. Siegel, MD,† Patricia Apruzzese, MS,§ Peter Fail, MD,¶ Michael J. Rinaldi, MD,# Richard W. Smalling, MD, PhD,** James B. Hermiller, MD,†† David Heimansohn, MD,‡‡ William A. Gray, MD,§§ Paul A. Grayburn, MD,‖‖ Michael J. Mack, MD,¶¶ D. Scott Lim, MD,## Gorav Ailawadi, MD,*** Howard C. Herrmann, MD,††† Michael A. Acker, MD,‡‡‡ Frank E. Silvestry, MD,††† Elyse Foster, MD,§§§ Andrew Wang, MD,‖‖‖ Donald D. Glower, MD,¶¶¶ Laura Mauri, MD,§### for the EVEREST II Investigators

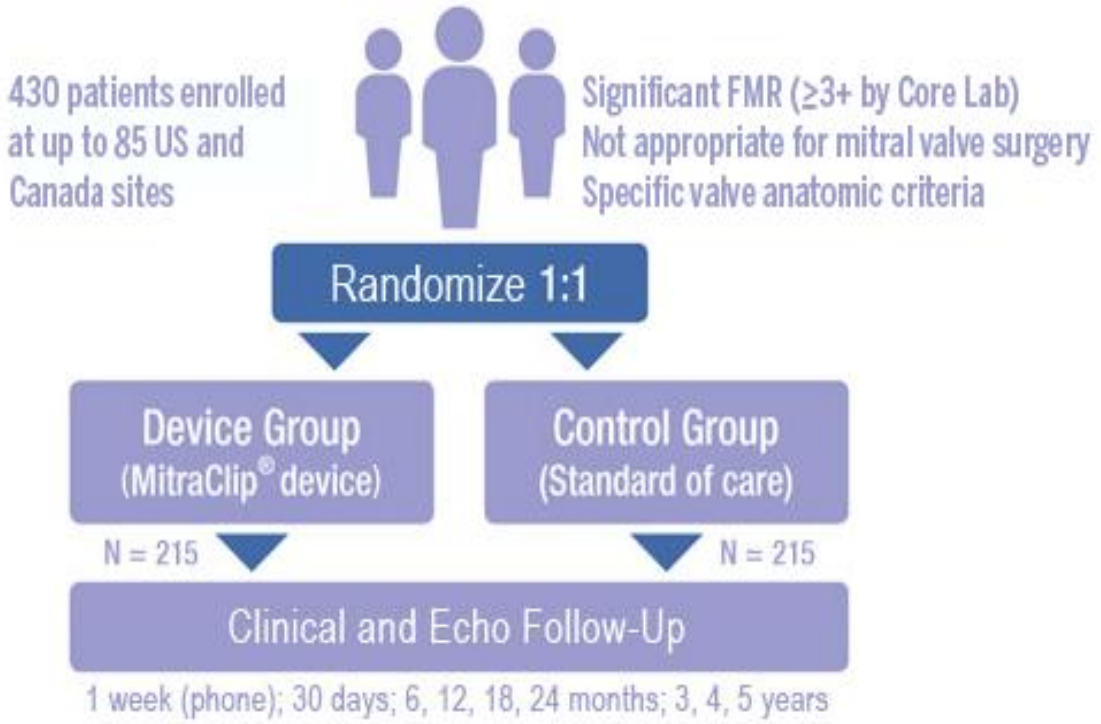
RESULTS

- The final 5-year results of the EVEREST II trial supported the superiority of surgery in reducing MR but clearly supported the long-term safety of the MitraClip and the durability of MR reduction after percutaneous repair.
- Beyond 1 year, worsening MR and surgery for MV dysfunction occurred rarely after either surgery or percutaneous repair.
- Similarly, improvements in heart failure symptoms and in LV dimensions remained stable through 5-year follow-up, mitigating concerns that residual MR after device placement and the absence of an annuloplasty ring with the device would result in progressive worsening of MR and LV dilation.

CLINICAL OUTCOMES ASSESSMENT OF THE MITRACLIP PERCUTANEOUS THERAPY FOR HIGH SURGICAL RISK PATIENTS (COAPT)

Trial Design

The diagram below illustrates the COAPT Trial design:



MitraClip vs. Optimal Therapy RCTs

	COAPT	RESHAPE-HF
N patients, sites	420 @ up to 75 in US	800 @ up to 75 in EU
FMR grade (core lab)	3+ - 4+	3+ - 4+
NYHA class	II, III, or ambulatory IV	III or ambulatory IV
LVEF	≥20%	≥15% - ≤40%
STS criteria	≥8 or other major risk factors	No
LV volumes	LVESD ≤60 mm	LVEDD ≥55 mm
Primary efficacy endpoint (superiority)	Recurrent HF hospitalization (ITT)	Death or Recurrent HF hospitalization (ITT)
Primary safety endpoint (noninferiority)	Death, stroke, AKI, LVAD or cardiac transplant @1 year (ITT)	-
Health Economics	Assessed	Assessed

ACS Annals of Cardiothoracic Surgery

Systematic Review

A meta-analysis of MitraClip system versus surgery for treatment of severe mitral regurgitation

Benjamin Wan[1], Mohammad Rahnavardi[1], David H. Tian[1], Kevin Phan[1,2], Stine Munkholm-Larsen[1,3], Paul G. Bannon[1,2], Tristan D. Yan[1,2]

[1]The Systematic Review Unit, The Collaborative Research (CORE) Group, Macquarie University, Sydney, Australia; [2]Department of Cardiothoracic Surgery, Royal Prince Alfred Hospital, University of Sydney, Sydney, Australia; [3]Department of Cardiology, Hvidovre University Hospital, Copenhagen, Denmark

CONCLUSION

- Despite a higher risk profile in the MitraClip patients compared to surgical intervention, the clinical outcomes were similar although surgery was more effective in reducing MR in the early post procedure period. We conclude the non-inferiority of the MitraClip as a treatment option for severe, symptomatic MR in comparison to conventional valvular surgery

Table 1. Indications for HT

Cardiogenic shock requiring either continuous intravenous inotropic support or MCS with an intraaortic balloon pump counterpulsation device or MCS
Persistent NYHA class IV congestive HF symptoms refractory to maximal medical therapy (LVEF <20%; peak $\dot{V}O_2$ <12 mL · kg^{-1} · min^{-1})
Intractable or severe anginal symptoms in patients with coronary artery disease not amenable to percutaneous or surgical revascularization
Intractable life-threatening arrhythmias unresponsive to medical therapy, catheter ablation, and/or implantation of intracardiac defibrillator
NYHA indicates New York Heart Association.

CONTRAINDICATIONS TO HT

- A severely increased risk of right heart failure and mortality after heart transplantation is thought to be present:[31]
- When the PVR is >5 Wood units (>400 dynes.sec.cm^{-5}), or the PVRI is >6 Wood units.m^2 in children), or the TPG exceeds 16 to 20 mmHg.
- If the systolic pulmonary artery pressure exceeds 60 mmHg in conjunction with any one of the preceding three variables.
- If the PVR can be reduced to <2.5 with a vasodilator only at the cost of a fall in arterial systolic blood pressure <85 mmHg

THANK YOU