

Disclosures

Samin K. Sharma, MD

*Speaker's Bureau for Boston Scientific Corp.,
Abbott Vascular Inc., ABIOMED, CSI*

Annapoorna S. Kini, MD

Nothing to disclose

Gilbert Tang, MD

Consultant for Abbott

Stam Lerakis, MD

Interventional echocardiographer

September 6th 2019- Structural Heart Live Case: AA, 97 yo M



Presentation: Worsening dyspnea on exertion NYHA Class III 6M

PMH: Severe MR, hypertension, hyperlipidemia, chronic AFib not on AC due to risk of falls, syncope s/p dual chamber pacemaker, non-ischemic cardiomyopathy LVEF 35%, frailty

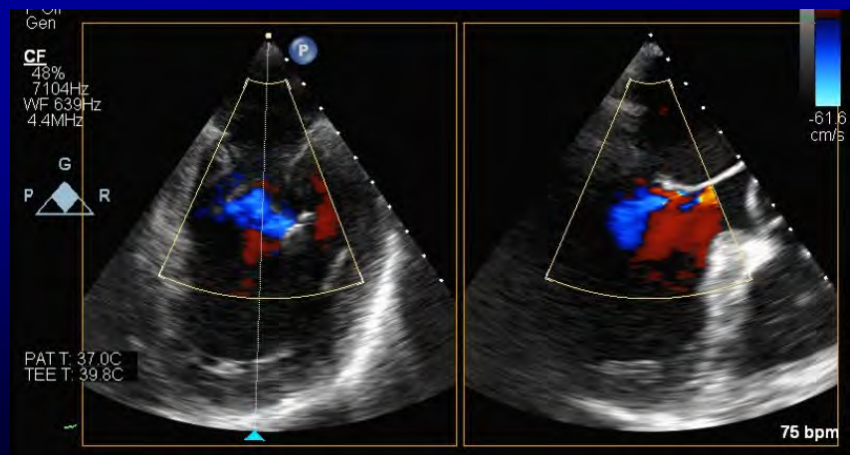
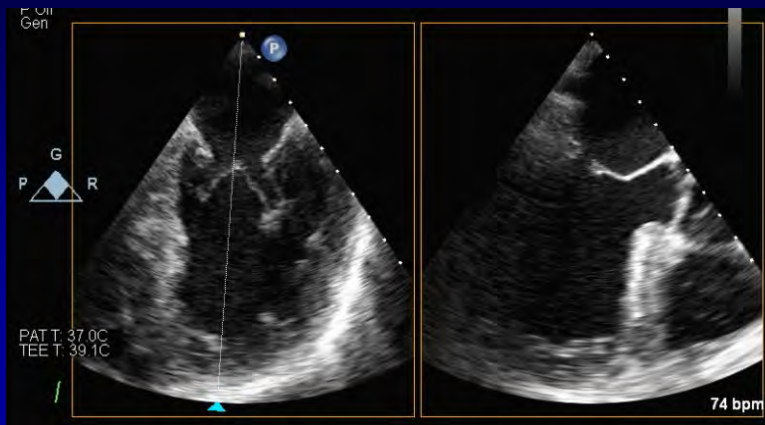
Medications: Aspirin, Enalapril, Furosemide, Metoprolol, Rosuvastatin

EKG (7/8/19): A sense V paced 70 bpm

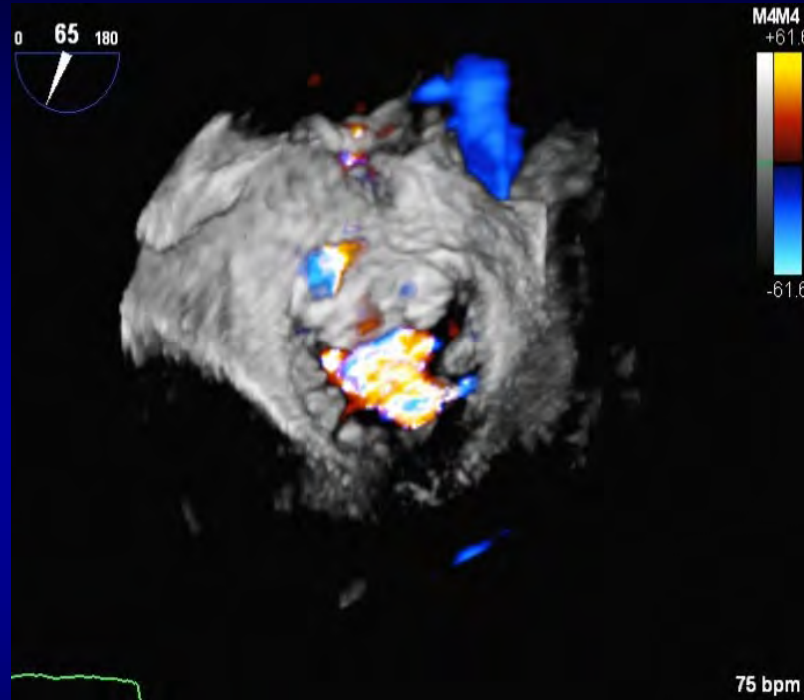
TTE (9/4/19): LVEF 35%, normal LV size (LVIDs 4.0 cm, LVIDd 5.5 cm) with moderate global hypokinesis, mildly dilated LA, severe mitral regurgitation, no MS, mild AI, mild to moderate RV dysfunction, severe TR, PASP 28 mmHg

TEE (9/4/19): Restricted posterior leaflet with severe central to medially directed MR, mitral valve area 5.39cm², Transmitral gradient 2mmHg, PML length=1.53cm, EROA=25mm², Regurgitant volume=39cc

Transesophageal Echocardiogram



3D Transesophageal Echocardiogram



- Severe central to medially directed mitral regurgitation involving the A2/P2 segment
- No mitral stenosis

Continued...

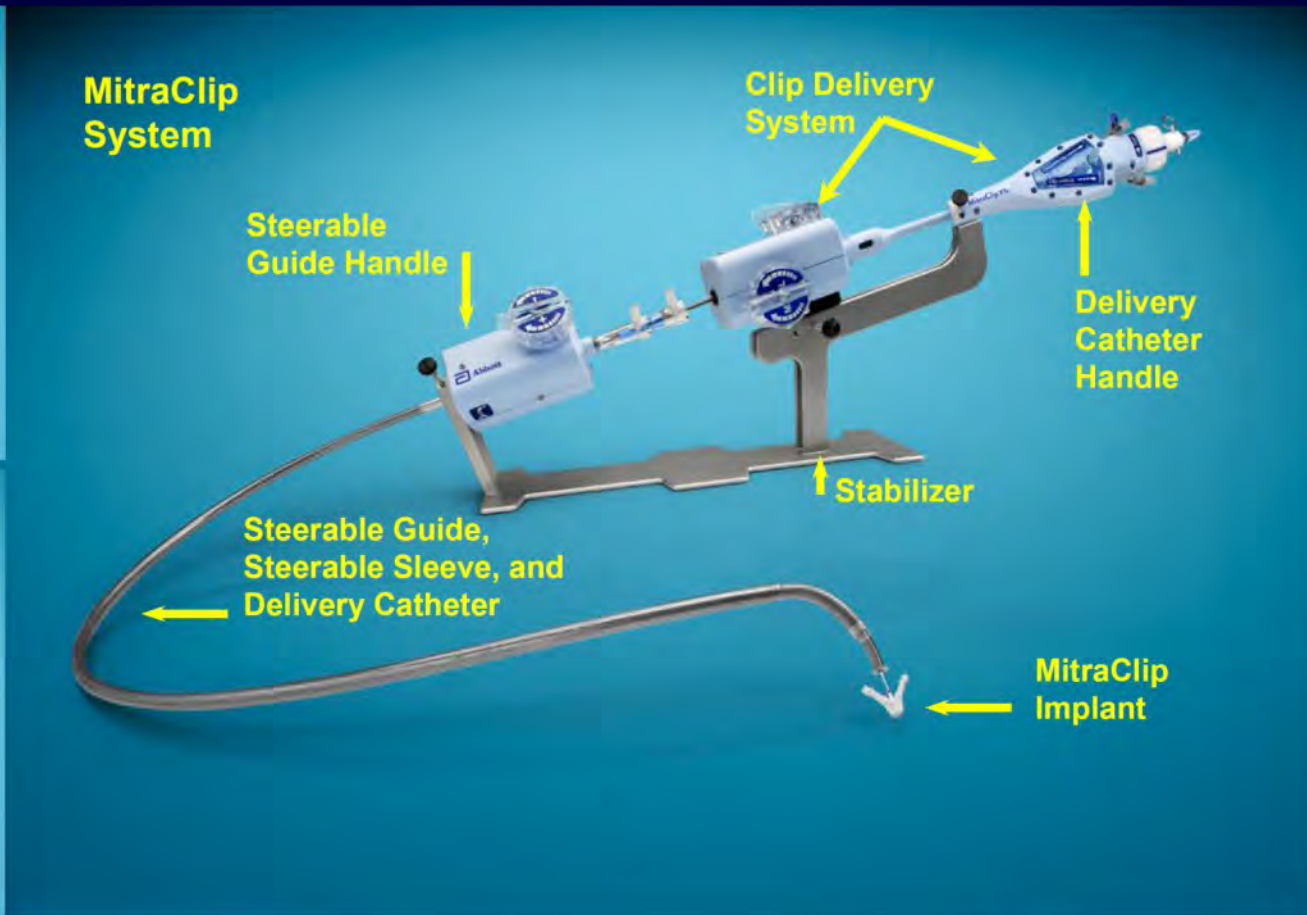
STS risk mortality: 12.8%

Logistic Euroscore mortality: 22.6%

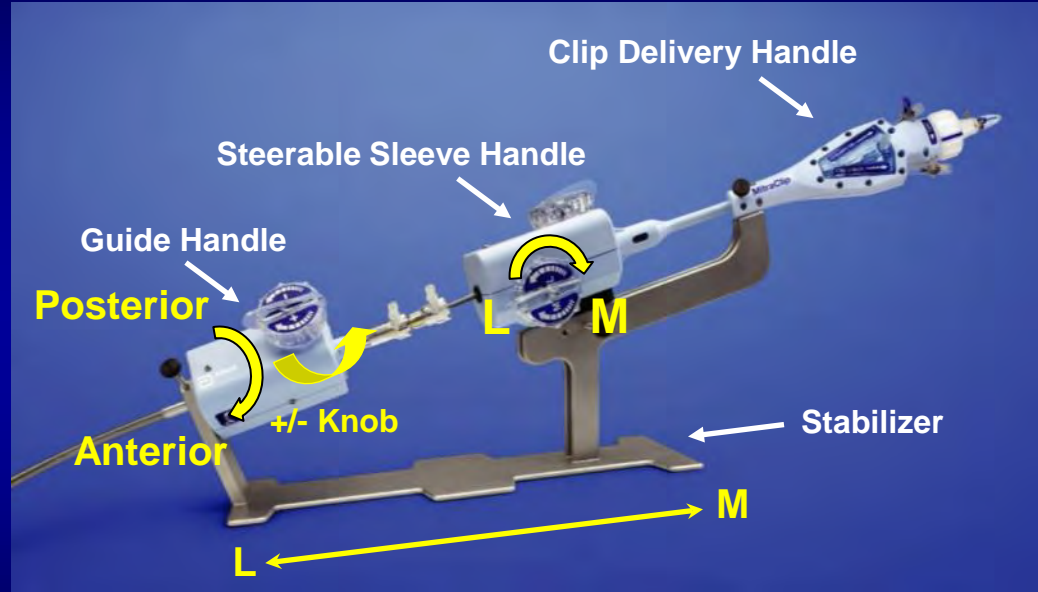
Course: Patient was evaluated by Heart Team and determined to be **prohibitive risk** for surgical MVR due to age, co-morbidities and frailty

Plan: Referred for edge-to-edge mitral valve repair with MitraClip via transfemoral venous access and transseptal puncture under TEE guidance

THE MITRACLIP® NTR / MITRACLIP XTR SYSTEM



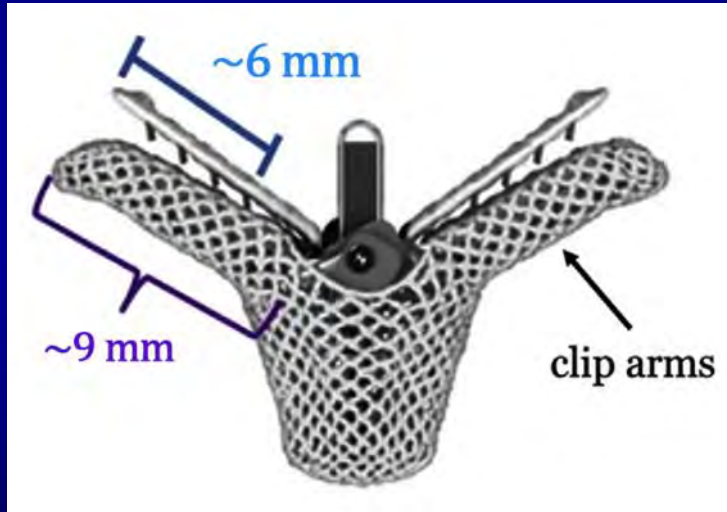
MitraClip XT System Steering



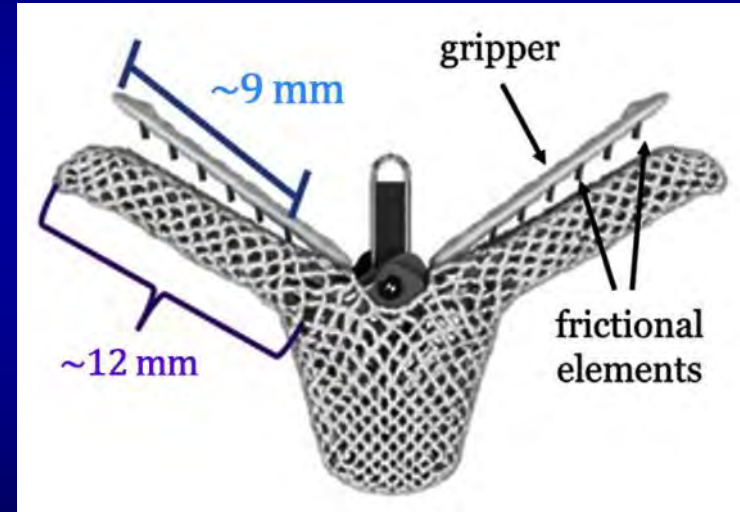
- **Guide Handle – Anterior/Posterior, +/- Knob**
- **Sleeve Handle – Medial/Lateral, Anterior/Posterior Knobs**
- **Clip Delivery Handle – Clip Positioning, Grasping and Deployment**
- **Stabilizer – Medial/Lateral**

Comparison of the Dimension of the NTR and the XTR MitraClip Implants

MitraClip NT/NTR Implant



Latest MitraClip System: XTR



About 3 mm longer arms and grippers as well as 2 additional frictional elements on each grippers

Key Patient Considerations

- Patient will be intubated, under general anesthesia
- Patient may have femoral or radial artery access
- Patient will have 24 French Steerable Guide in femoral vein
- Patient may have bladder (Foley) catheter in place
- Patient will be heparinized during procedure to ACT's greater than 250
- Patient will have TEE probe in place for extended period of time

Anatomic Considerations

For optimal results, the following anatomic patient characteristics should be considered:

- The primary regurgitant jet is non-commissural. If a secondary jet exists, it must be considered clinically insignificant.
- Mitral valve area $\geq 4.0 \text{ cm}^2$
- Minimal calcification in the grasping area
- No leaflet cleft in the grasping area
- Flail width $< 15 \text{ mm}$ and flail gap $< 10 \text{ mm}$

Procedural Outline

- Imaging
- Transseptal
- Steering and positioning the MitraClip® Device
- **Straddling**- Radiopaque markers on the CDS must “straddle” the radiopaque marker at the tip of the guide catheter fluoroscopically. Withdraw the guide to within 1cm of IAS
- Grasping and leaflet insertion assessment
- Clip deployment
- System removal
- Additional clip placement

Cath Lab Apps

Pushing the boundaries of educational mobile applications, benefiting interventional cardiologists around the world.

Our Latest Mobile Apps

CardFlow

CardFlow is a free, comprehensive, and easy-to-use app for interventional cardiologists. It provides a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures. It also includes a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures.



Learn More

IVUSLab

The IVUSLab is a free, comprehensive, and easy-to-use app for interventional cardiologists. It provides a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures. It also includes a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures.



Learn More

OCAD

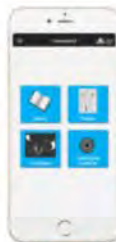
The OCAD is a free, comprehensive, and easy-to-use app for interventional cardiologists. It provides a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures. It also includes a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures.



Learn More

Transcat

The Transcat is a free, comprehensive, and easy-to-use app for interventional cardiologists. It provides a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures. It also includes a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures.



Learn More

IFUSLab

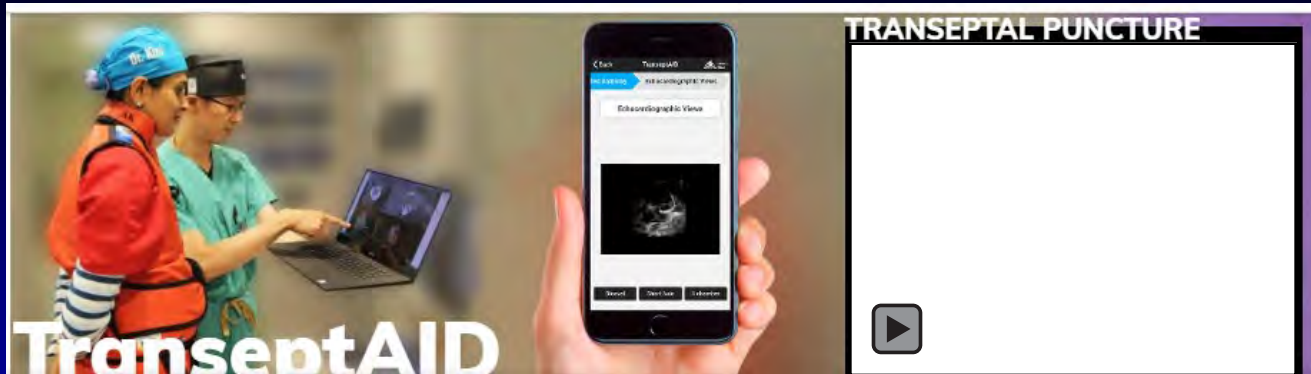
The IFUSLab is a free, comprehensive, and easy-to-use app for interventional cardiologists. It provides a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures. It also includes a comprehensive overview of the latest in interventional cardiology, including the latest in catheterization, stenting, and other procedures.



Learn More

Apps under development

- IVUSLab
- OCAD
- Transcat
- IFUSLab



[Home](#) [Team](#) [Sponsors](#)

TranseptAID is an educational tool with step-by-step illustrations of how to perform transseptal puncture for various procedures.

Image 1
Familiarize yourself with the relevant anatomy of transseptal punctures.

Image 2
Learn about the sheaths, guidewires, needles, and balloons used during the procedure.

Image 3
Study videos highlighting the techniques of transseptal puncture for MitraClip, TMVR, and BMV among other procedures.

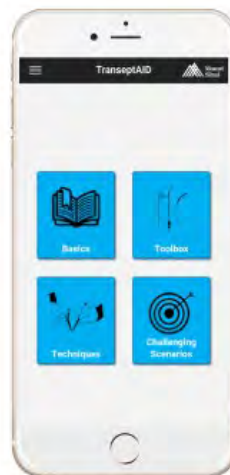
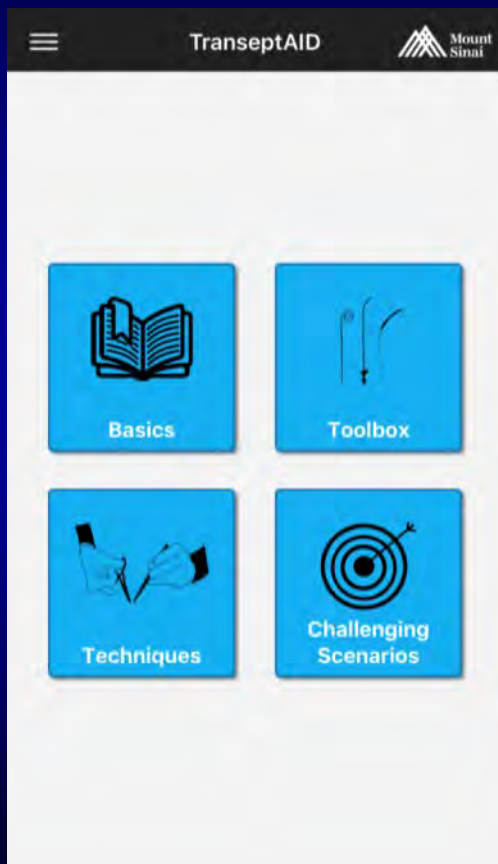
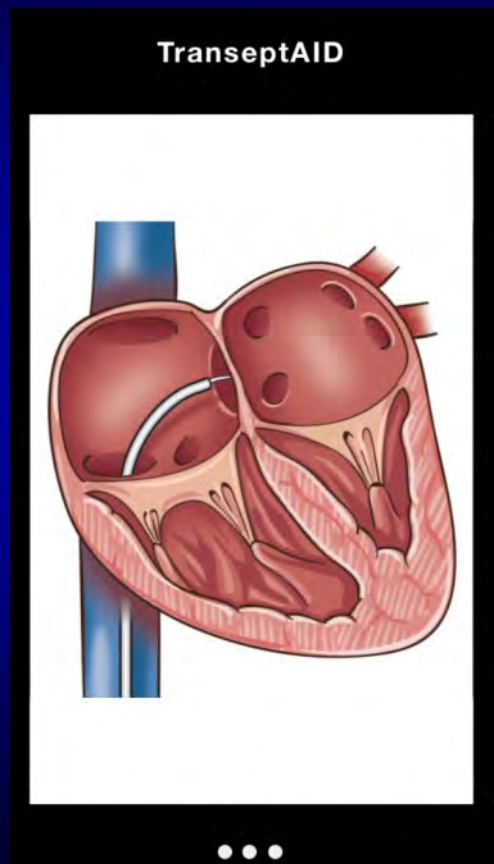


Image 4
Recognize potential challenges of transseptal puncture such as prior septal occluders and hyperelastic septum.

Image 5
Be ready for complications should they arise.

Image 6
Explore the variety of additional information such as echocardiograms, site-specific puncture zones, and closure techniques.

TranseptAID App



**Free
Download**



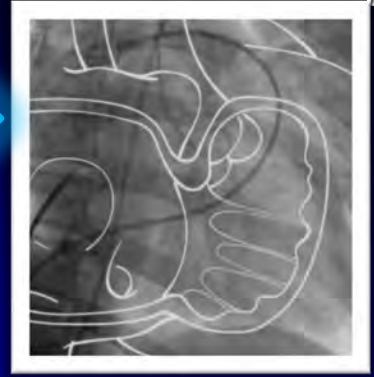
Download on the
App Store



GET IT ON
Google Play



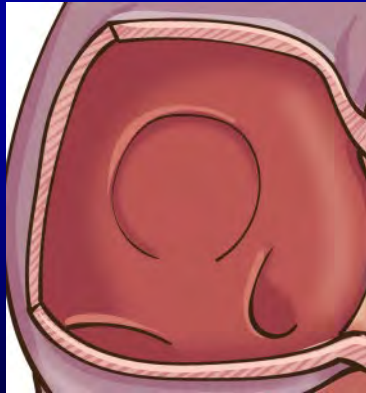
Animations



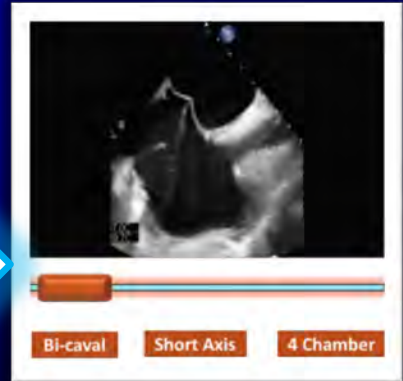
Hybrid images



TranseptAID



Interactive illustrations



Interactive videos



TranseptAID

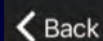


TranseptAID



Home

Techniques



TranseptAID

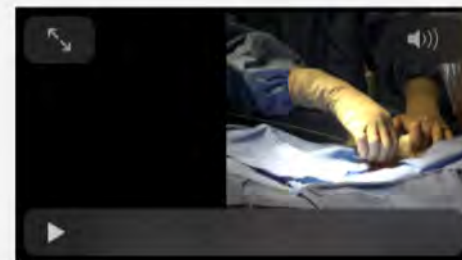


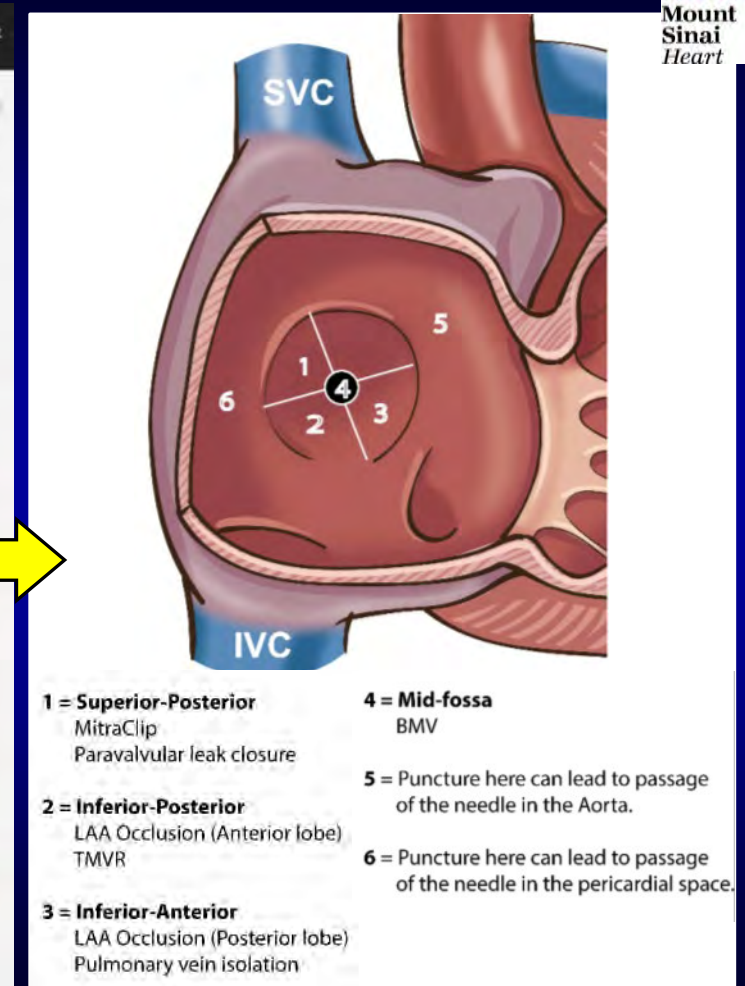
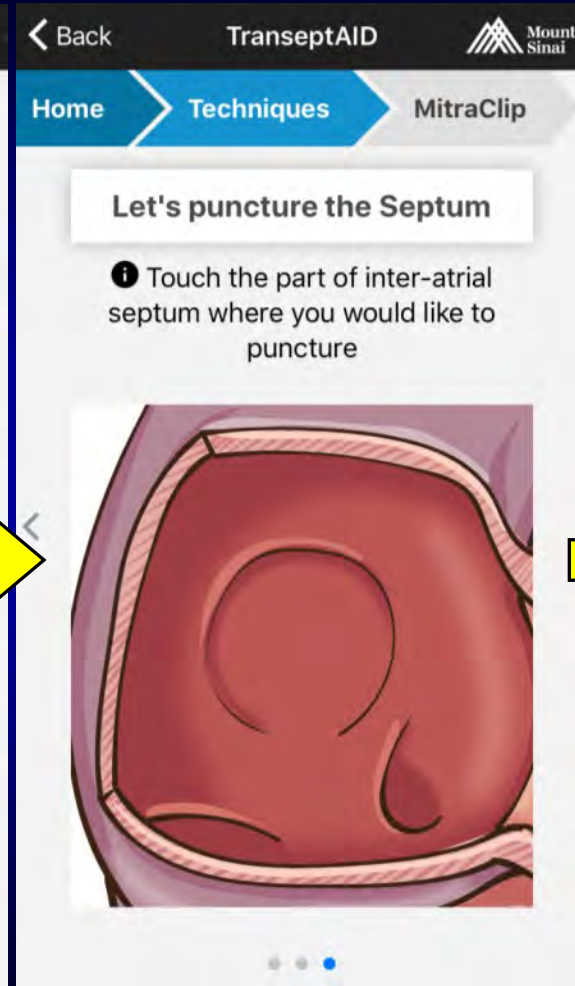
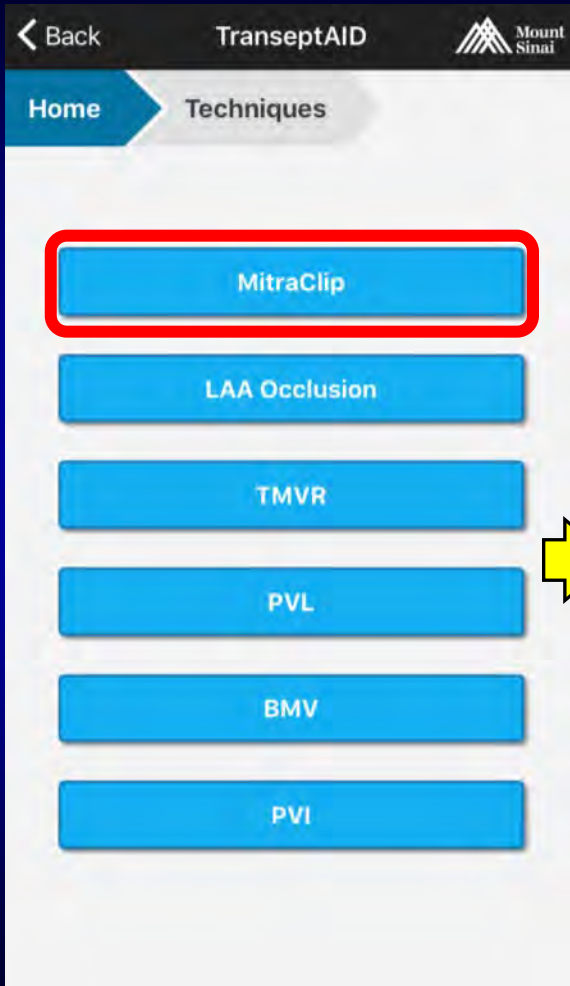
Home

Techniques

MitraClip

Initial Steps

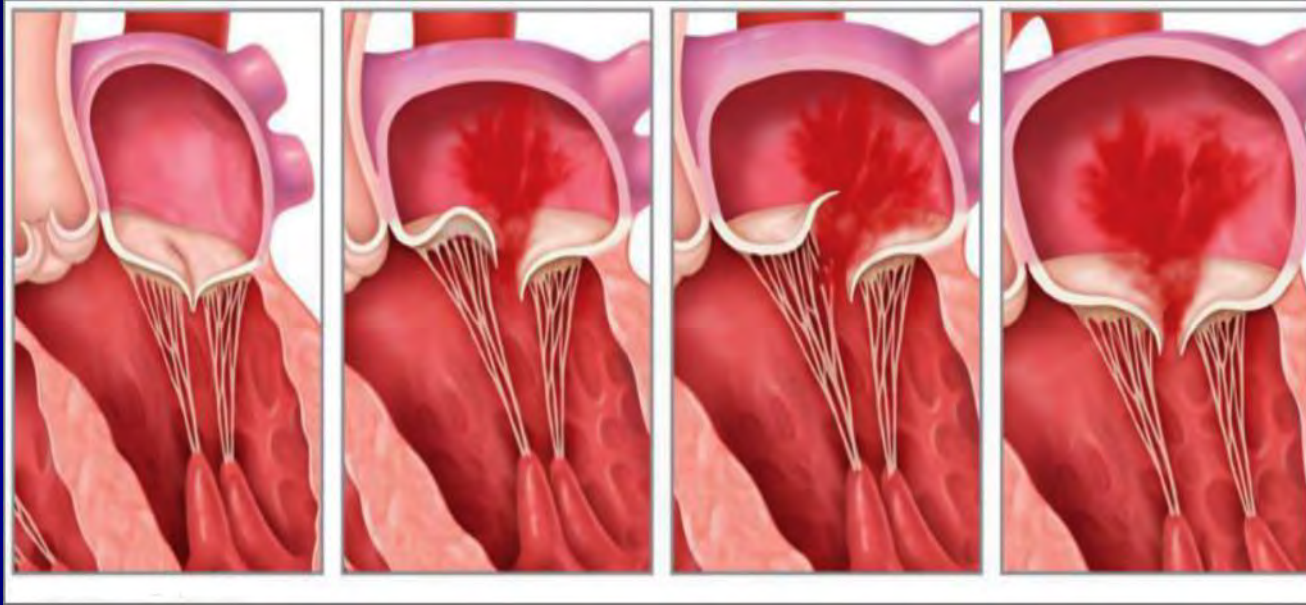








Etiology of Mitral Regurgitation (MR)



Normal

Degenerative MR
- Prolapse

Degenerative MR
- Flail

Functional MR
Ischemic vs.
non-ischemic

- Due to dilated LV, mitral annulus or regional disruption of LV, MV apparatus

General Principles of Therapy for MR Etiology



Primary MR

No Medical Therapy
(Diuretics palliative)

**Surgery for symptoms
or LV dysfunction**
(Repair > Replacement)

**Consider prophylactic
repair for low risk with
long term survival**

Secondary MR

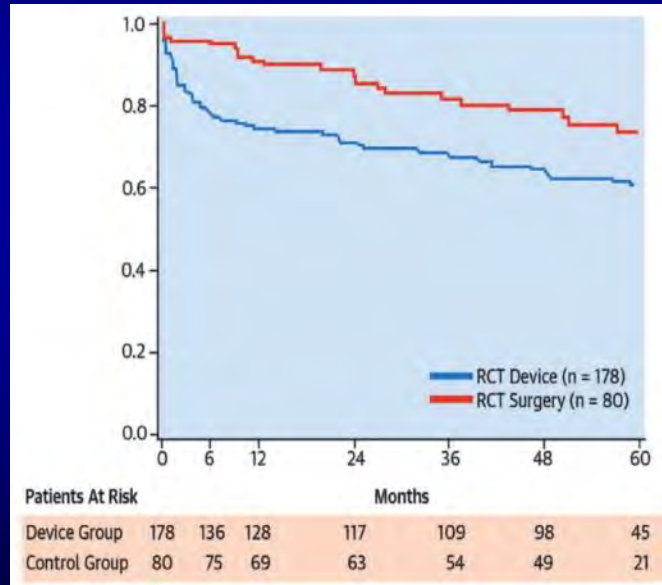
**Medical
Therapy first**
(BB, ACE/ARB, Aldactone, Diuretics)

CRT

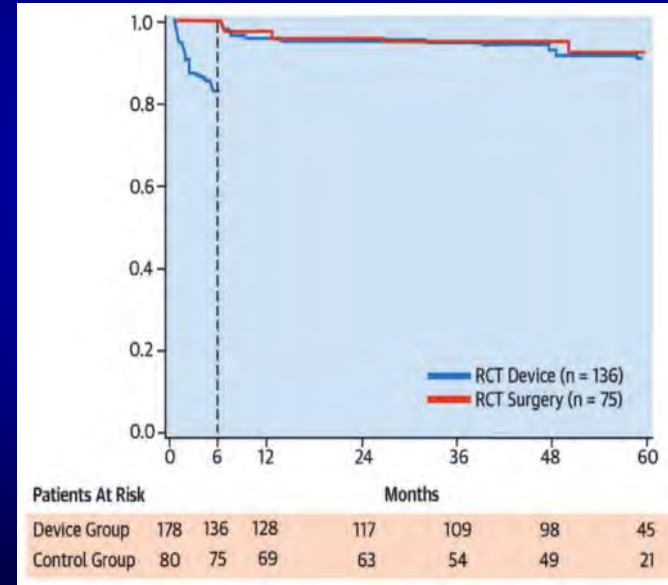
**Surgery only in highly
selected pts with CHF**
(Class 3/4 symptomatic and
acceptable surgical risk)

EVEREST II Trial: 5-Year Clinical Outcomes – Percutaneous Repair and Surgery for MR

Freedom from Death, MV Surgery or Reoperation

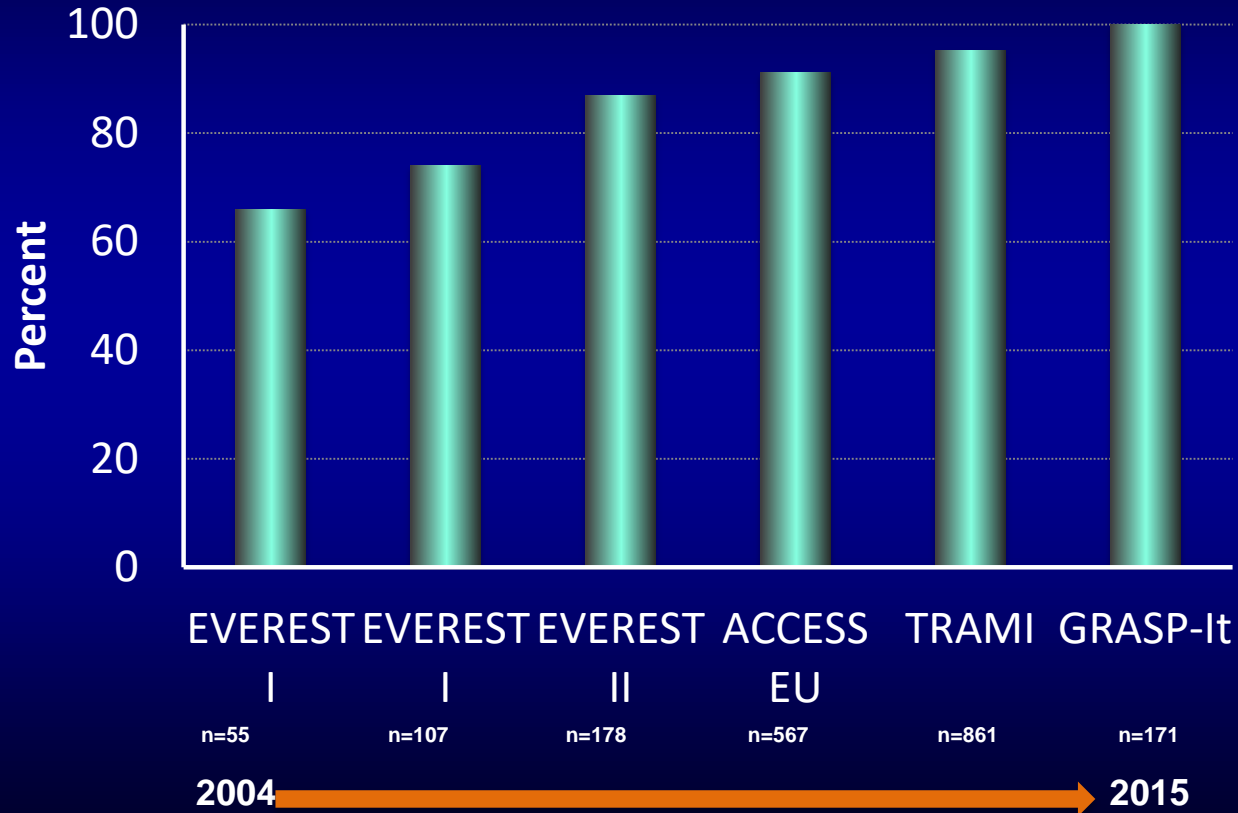


Landmark Analysis of Freedom from Death, MV Surgery or Reoperation Beyond 6 Months



Acute Procedure Success Rate

MitraClip(s) implanted & MR $\leq 2+$



COAPT: Trial design

~420 patients enrolled at up to 75 US sites

Significant FMR ($\geq 3+$ by core lab)

High risk for mitral valve surgery

Specific anatomical criteria

Randomize 1:1

MitraClip

N=210

Control group

Standard of care

N=210

Clinical and TTE follow-up:

1, 6, 12, 18, 24, 36, 48, 60 months

COAPT Trial: Primary Endpoints

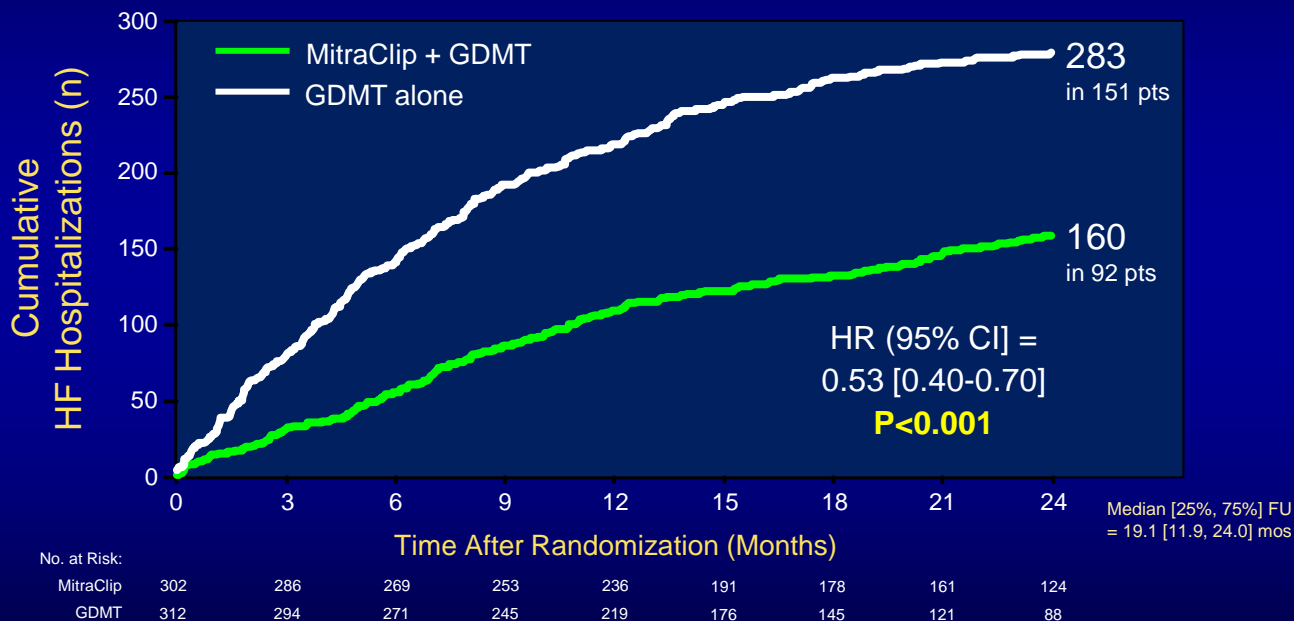


- **Primary Effectiveness (min 1-year follow-up all pts)**
 - **Recurrent heart failure hospitalizations**
 - **Superiority hypothesis (Andersen-Gill)**
- **Primary Safety (1 year)**
 - **Composite of all-cause death, stroke, worsening kidney function, or LVAD or cardiac transplant**
 - **Non-inferiority hypothesis**

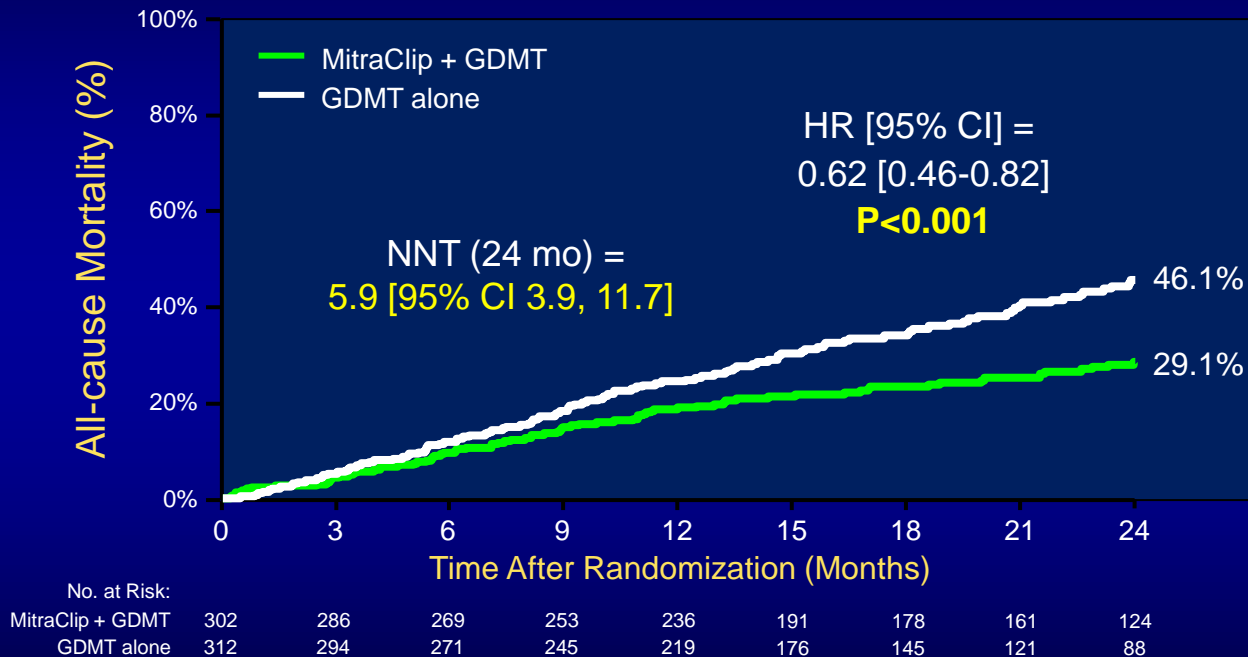


Primary Effectiveness Endpoint

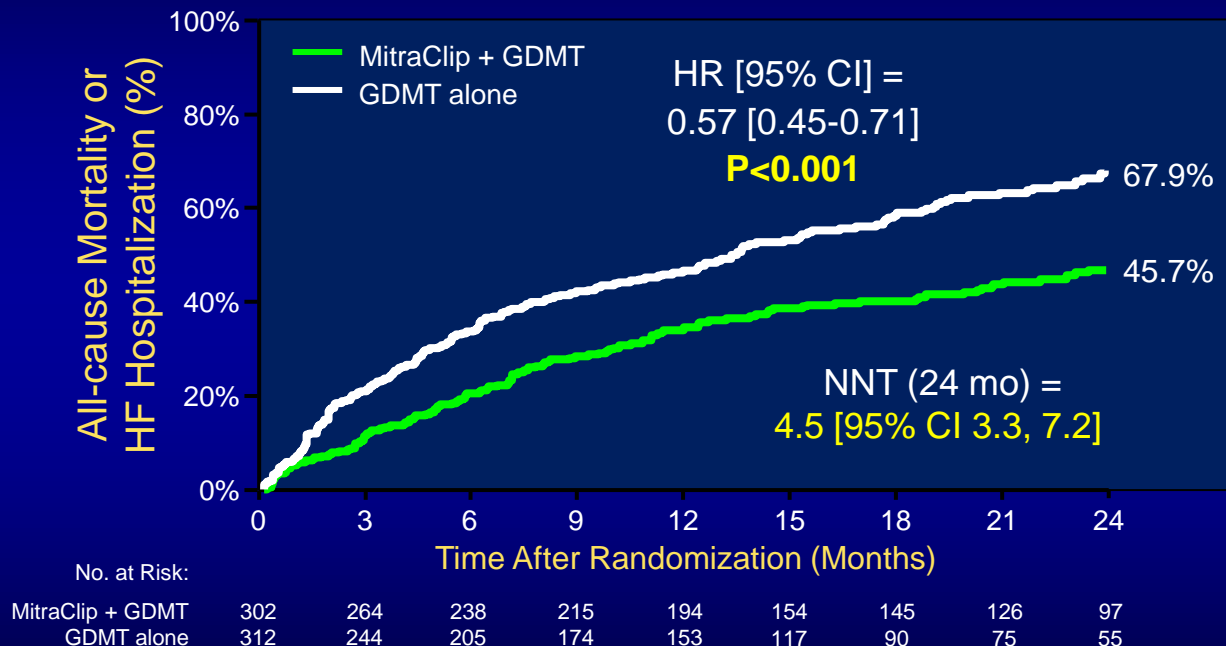
All Hospitalizations for HF within 24 months



All-cause Mortality



Death or HF Hospitalization



Evidence base **Therapy for MR**

	Degenerative	Functional
Low Surgical Risk	✓ Surgical MVR	? Surgical MVR ??
High Surgical Risk	✓ Surgical MVR ✓ Commercial MitraClip-registry	✓ MitraClip COAPT Trial

Intrepid Twelve Valve: APOLLO Trial

Medtronic Inc.

- Circular inner stent to house the valve plus a outer fixation ring to engage the mitral annular anatomy.
- The outer fixation ring is designed to accommodate the dynamic variability of the native mitral annulus while isolating the inner valve assembly throughout the cardiac cycle.
- A flexible brim is attached to the atrial end of the fixation ring which facilitates imaging

Valve Characteristics	
Implant Shape	Circular
Construction	Self-expanding nitinol Frame, outer and inner polyester fabric skirt Inner valve structure of 27 mm (orifice area 2.4 cm ² Outer diameter 43, 46 or 50 mm
Leaflet	Trileaflet Bovine Pericardium
Catheter Size OD	35 Fr
Access Site	T-Apical

