

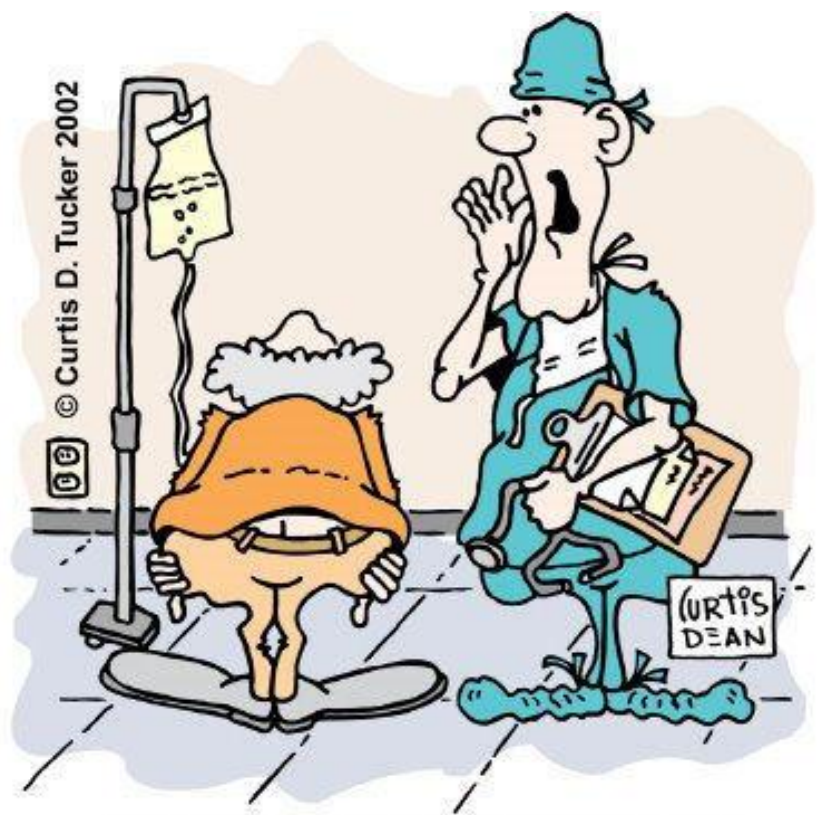
Mitral Valve – What are we up to???

Karl Limmer, MD

Sharp Cardiovascular Center

Disclosures

- Atricure – Consultant and Proctor
- Abbott Structural Heart – Speaker
- Cryolife – Investigator



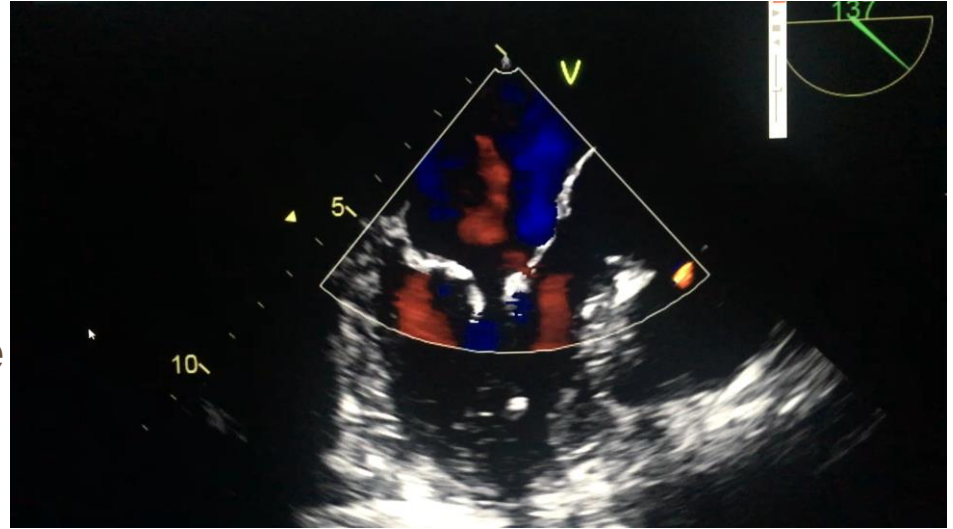
**"Yes! That was very loud Sir, but
I said I wanted to hear your *HEART!*"**

Patient History

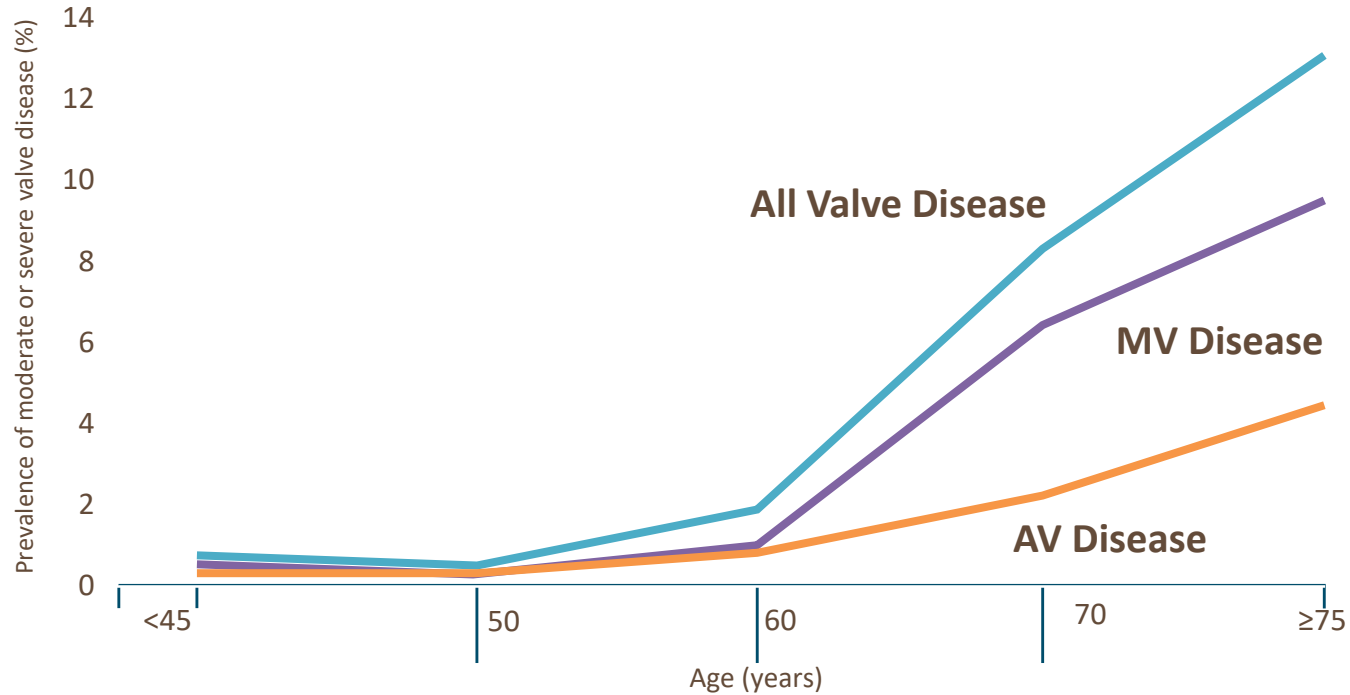
49 yo male with two years of progressive exercise intolerance, **NYHA CLASS I**

Came to care because **twin brother required a mitral valve replacement** one year prior

Echo **Severe mitral regurgitation** with EF 71%



Prevalence of Mitral Valve Disease



Prevalence of Mitral Valve Disease

- Over 4 million people have significant **MR**
- Annual incidence of 250,000 new cases
- Approximately 50,000 Mitral Valve Surgeries annually in the United States



13Hz
12cm

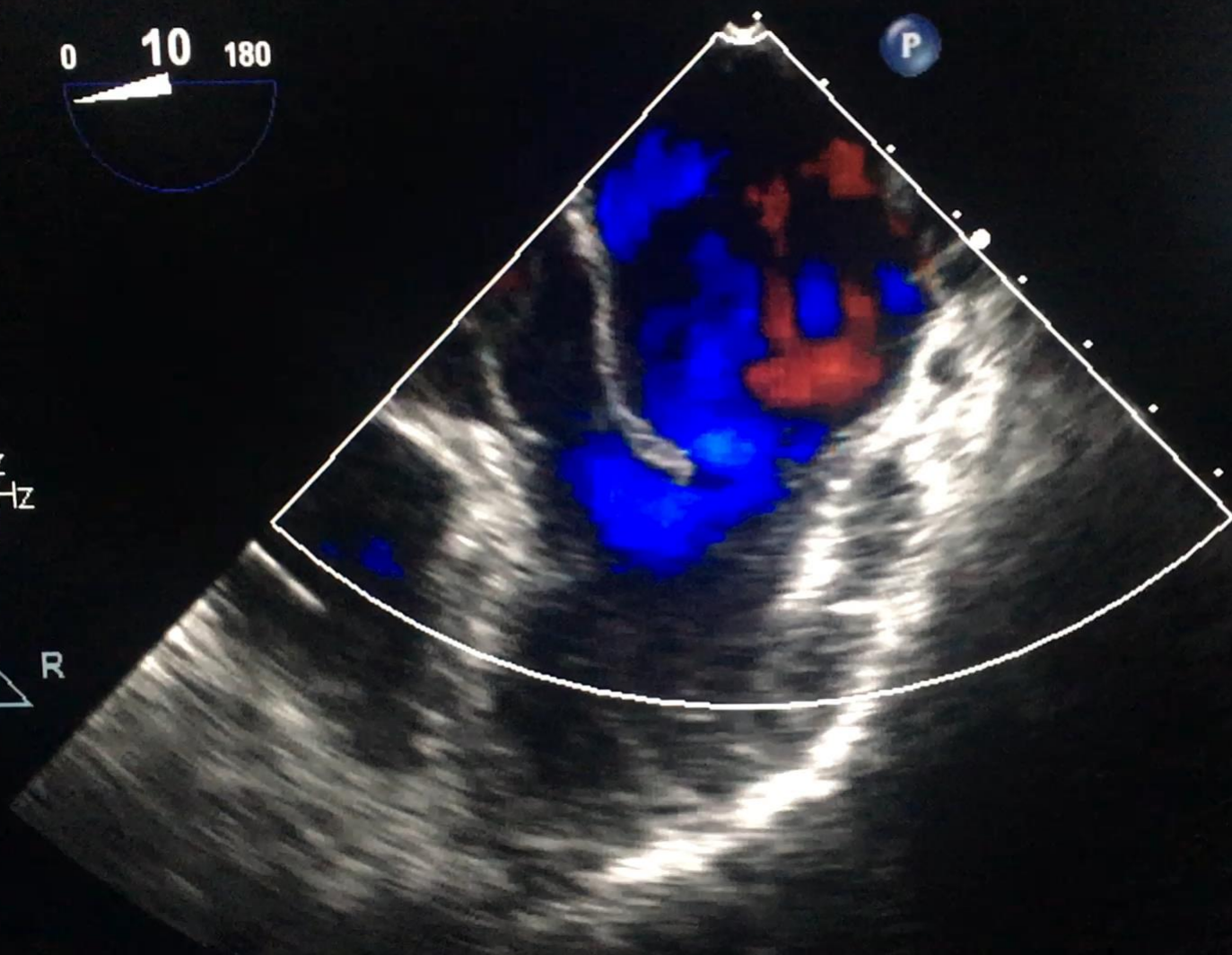


2D

59%
C 50
P Off
Gen

CF

48%
6838Hz
WF 615Hz
4.4MHz



Stages of Valvular Heart Disease

Stage	Definition
A	Risk of valve disease
B	Mild - moderate asymptomatic disease
C	Severe valve disease but asymptomatic C1: Normal LV function C2: Depressed LV function
D	Severe, symptomatic valve disease

Mitral Regurgitation is Classified into 2 Types

MR occurs when the mitral valve fails to close completely, causing blood flow to move backward into the left atrium



PRIMARY VALVE ABNORMALITY

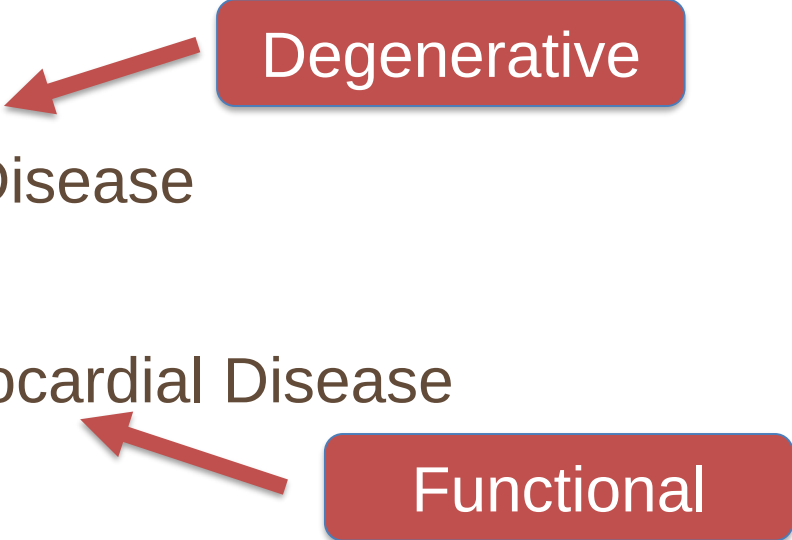
- Leaflets
- Subvalvular apparatus
- Chordae and papillary muscles



SECONDARY LEFT VENTRICLE DILATION

- Leaflet tethering
- Mitral annular dilation
- Incomplete coaptation of the mitral valve

Mitral Regurgitation



Degenerative

Primary MR: Primary Valve Disease

Secondary MR: Primary Myocardial Disease

Functional

Mitral Regurgitation

Primary MR: Primary Valve Disease

Secondary MR: Primary Myocardial Disease

Diagnosis of Severe Mitral Regurgitation by Echo

Quantitative Measures	Specific Criteria*
EROA ≥ 0.4 cm ² Regurgitant volume ≥ 60 ml Regurgitant fraction $\geq 50\%$	Flail leaflet Vena Contracta width ≥ 0.7 cm PISA radius ≥ 1.0 cm Central large jet $> 50\%$ of left atrial area Pulmonary vein systolic flow reversal Enlarged LV with normal function
*Definitely severe if ≥ 4 specific criteria	

Indications for mitral valve surgery for degenerative MR

Symptoms/60/50/40

Indications for mitral valve surgery for degenerative MR

Symptoms

EF <60%

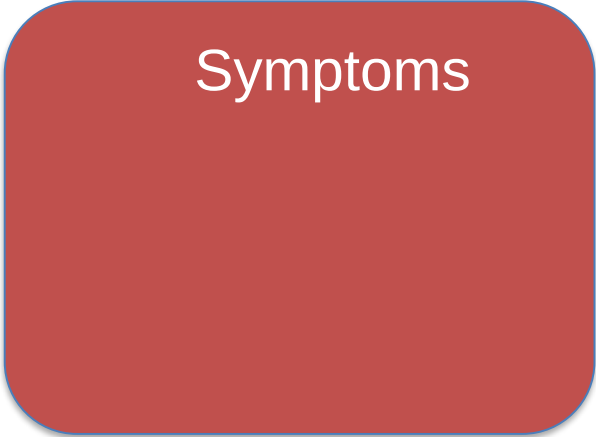
PASP >50

LVEDD >40mm

Atrial Fibrillation

Indications for mitral valve surgery for degenerative MR

Symptomatic patients

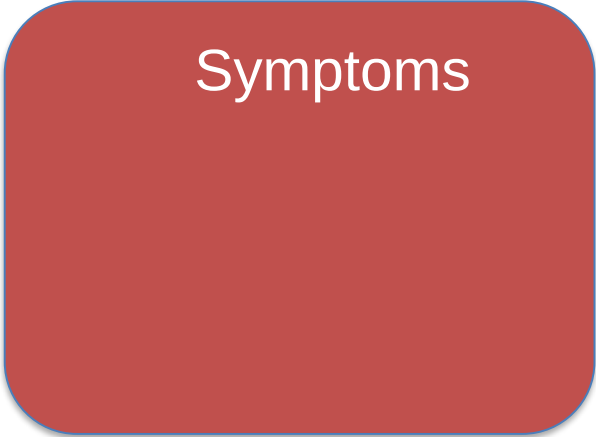


Symptoms

Indications for mitral valve surgery for degenerative MR

Symptomatic patients

Asymptomatic patients

A red rounded rectangle with a thin blue border and a subtle drop shadow, containing the word "Symptoms" in white text.

Symptoms

Indications for mitral valve surgery for degenerative MR

Symptomatic patients

Asymptomatic patients

LV Systolic Dysfunction

Symptoms

EF <60%

Indications for mitral valve surgery for degenerative MR

Symptomatic patients

Asymptomatic patients

LV Systolic Dysfunction

Pulmonary Hypertension

Symptoms

EF <60%

PASP >50

Indications for mitral valve surgery for degenerative MR

Symptomatic patients

Asymptomatic patients

LV Systolic Dysfunction

Pulmonary Hypertension

LV end systolic dimension

Symptoms

EF <60%

PASP >50

LVESD >40mm

Indications for mitral valve surgery for degenerative MR

Symptomatic patients

Asymptomatic patients

LV Systolic Dysfunction

Pulmonary Hypertension

LV end systolic dimension

Atrial Fibrillation

Symptoms

EF <60%

PASP >50

LVESD >40mm

Atrial Fibrillation

Late Outcomes of Mitral Valve Repair for Mitral Regurgitation Due to Degenerative Disease

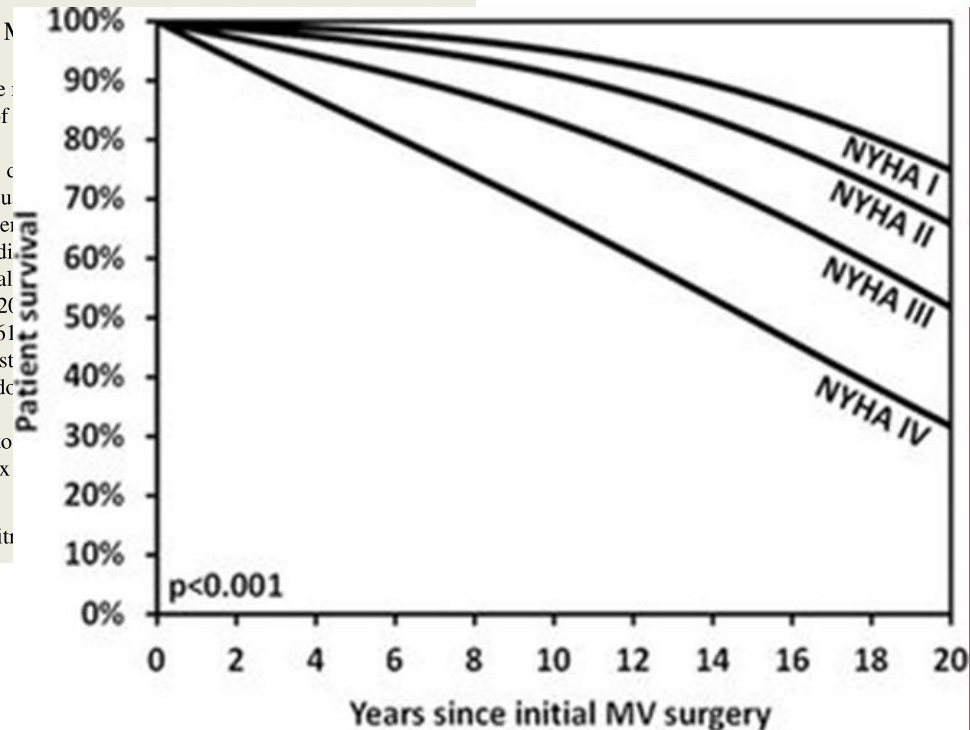
Tirone E. David, MD; Susan Armstrong, MSc; Brian W. M

Background—The pathological spectrum of degenerative diseases of the mitral valve (MR) is broad, and there is limited information on late outcomes of mitral valve repair for different pathologies. This study examines this issue.

Methods and Results—All 840 patients who had MV repair for MR were prospectively followed with clinical and echocardiographic evaluation for a median of 10.4 years. Clinical, hemodynamic, and pathological variables were analyzed in a multivariable analysis. MV repair failed to restore life span to normal. At 20 years, 20% of patients had repeat MV surgery, and the probability of reoperation at 20 years was 20%. Severe MR developed in 37 patients, and moderate MR developed in 61 patients. At 20 years, the freedom from moderate or severe MR was 69.2%.

Conclusions—MV repair for degenerative MR restored life span to normal. Advanced age and complex mitral anatomy were associated with increased risk of recurrent MR. At 20 years, the freedom from moderate or severe MR was 69.2%.

Key Words: degenerative disease of the mitral valve ■ mitral valve repair



Late Outcomes of Mitral Valve Repair for Mitral Regurgitation Due to Degenerative Disease

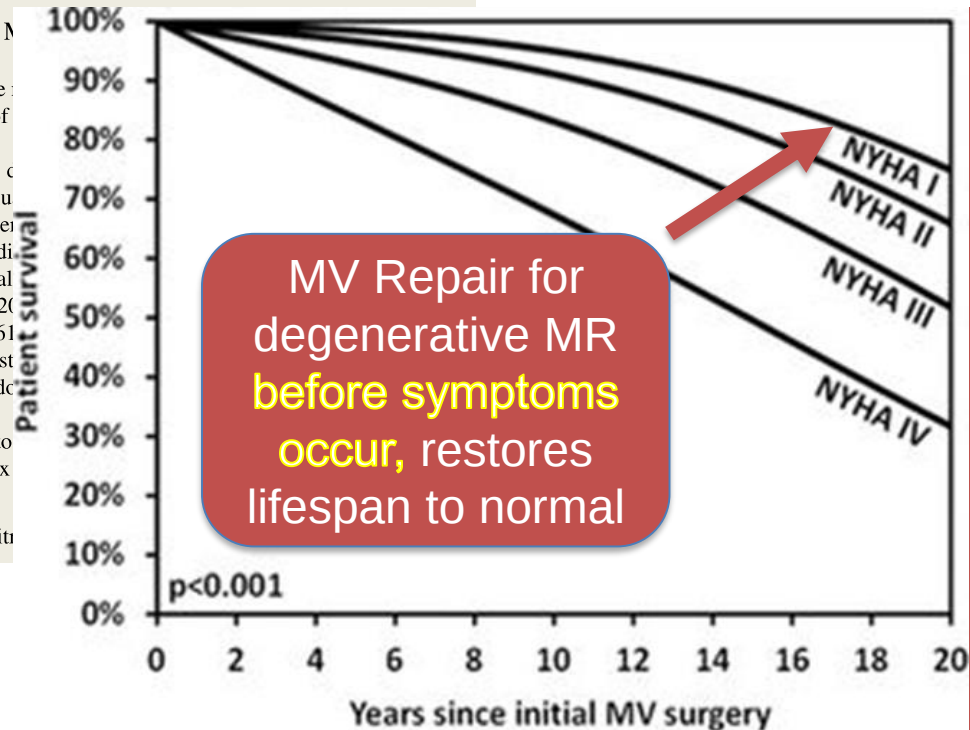
Tirone E. David, MD; Susan Armstrong, MSc; Brian W. M

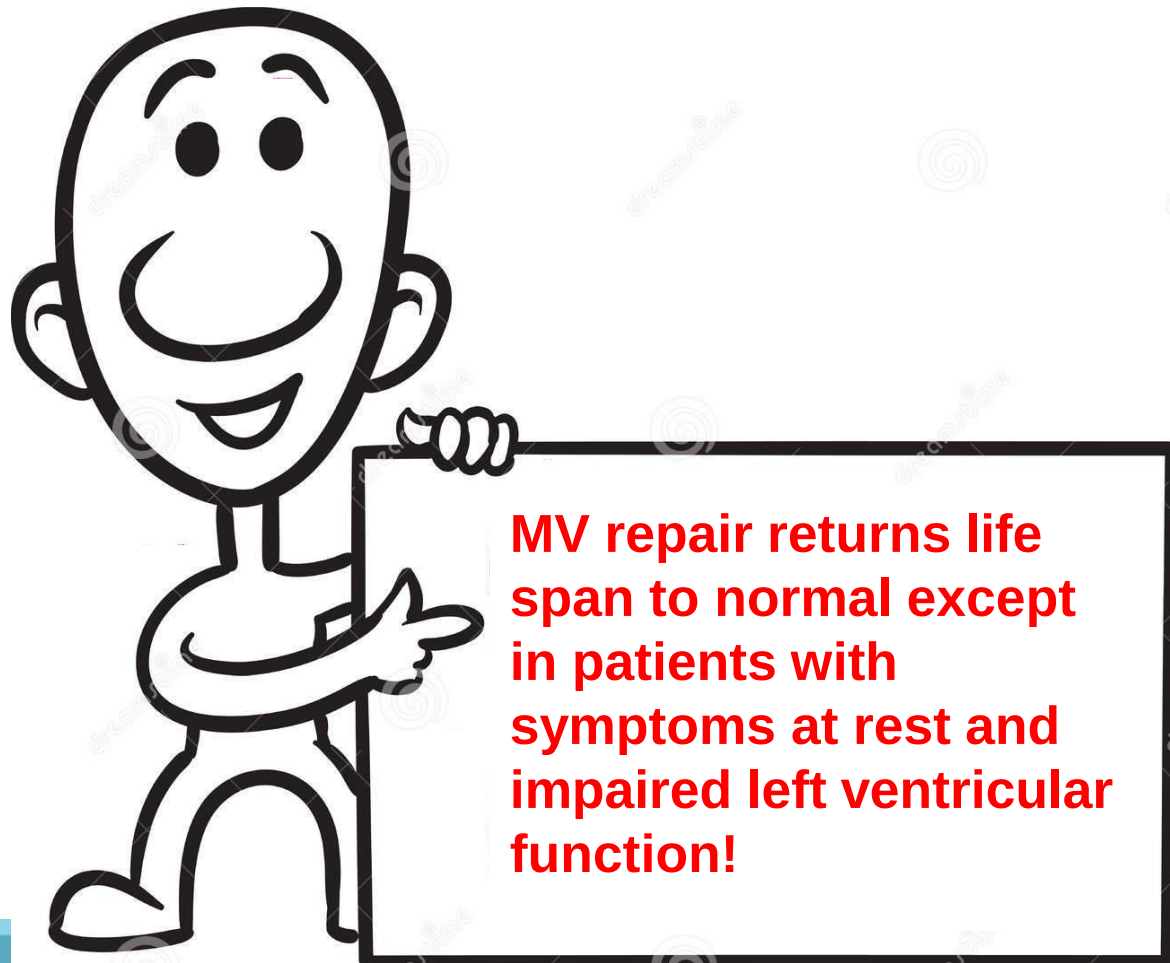
Background—The pathological spectrum of degenerative diseases of the mitral valve (MR) is broad, and there is limited information on late outcomes of mitral valve repair for these pathologies. This study examines this issue.

Methods and Results—All 840 patients who had MV repair for MR were prospectively followed with clinical and echocardiographic evaluation for a median of 10.4 years. Clinical, hemodynamic, and pathological variables were analyzed in a multivariable analysis. MV repair failed to restore life span to normal in patients who had repeat MV surgery, and the probability of reoperation at 20 years was 37% in patients with severe MR developed in 37 patients, and moderate MR developed in 61 patients. In patients with a degree of myxomatous changes in the MV, lack of mitral annuloplasty was associated with increased risk of recurrent MR. At 20 years, the freedom from moderate or severe MR was 69.2%.

Conclusions—MV repair for degenerative MR restored life span to normal and impaired left ventricular function. Advanced age and complex mitral regurgitation were associated with increased risk of recurrent MR. (*Circulation*. 2013;127:1485-1492.)

Key Words: degenerative disease of the mitral valve ■ mitral valve repair





MV repair returns life span to normal except in patients with symptoms at rest and impaired left ventricular function!

Indications for mitral valve surgery for degenerative MR

Symptomatic patients

Asymptomatic patients

LV Systolic Dysfunction

Pulmonary Hypertension

LV end systolic dimension

Atrial Fibrillation

Symptoms

EF <60%

PASP >50

LVESD >40mm

Atrial Fibrillation

Normal LV Function, repair possible?

Indications for Mitral Valve Repair

Asymptomatic Primary MR



Chronic severe MR
Preserved LV Function
Experienced surgical center
Likelihood of repair >95%

Class II

Indications for Mitral Valve Repair

Asymptomatic Primary MR



Chronic severe MR
Preserved LV Function
Experienced surgical center
Likelihood of repair >95%

Class II



Repair is better than
replacement
Patients should be referred to
a *center experienced in repair*

Class I

ORIGINAL RESEARCH ARTICLE



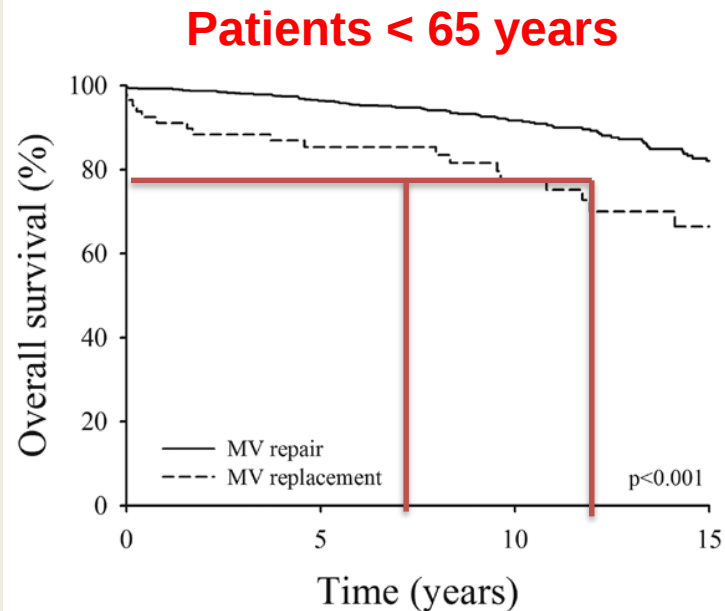
Twenty-Year Outcome After Mitral Repair Versus Replacement for Severe Degenerative Mitral Regurgitation

Analysis of a Large, Prospective, Multicenter, International Registry

Editorial, see p 423

BACKGROUND: Mitral valve (MV) repair is preferred over replacement in clinical guidelines and is an important determinant of the indication for surgery in degenerative mitral regurgitation. However, the level of evidence supporting current recommendations is low, and recent data cast doubts on its validity in the current era. Accordingly, the aim of the present study was to analyze very long-term outcome after MV repair and replacement for degenerative mitral regurgitation with a flail leaflet.

Siham Lazam, MS*
Jean-Louis Vanoverschelde, MD, PhD*
Christophe Tribouilloy, MD, PhD
Francesco Grigioni, MD, PhD
Rakesh M. Suri, MD, PhD
Jean-Francois Avierinos, MD
Christophe de Meester, PhD



20% mortality 9 vs 16 years!

ORIGINAL RESEARCH ARTICLE



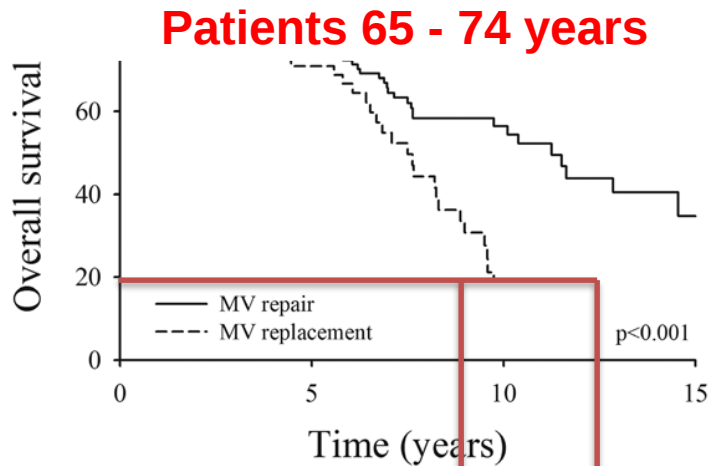
Twenty-Year Outcome After Mitral Repair Versus Replacement for Severe Degenerative Mitral Regurgitation

Analysis of a Large, Prospective, Multicenter, International Registry

Editorial, see p 423

BACKGROUND: Mitral valve (MV) repair is preferred over replacement in clinical guidelines and is an important determinant of the indication for surgery in degenerative mitral regurgitation. However, the level of evidence supporting current recommendations is low, and recent data cast doubts on its validity in the current era. Accordingly, the aim of the present study was to analyze very long-term outcome after MV repair and replacement for degenerative mitral regurgitation with a flail leaflet.

Siham Lazam, MS*
Jean-Louis Vanoverschelde,
MD, PhD*
Christophe Tribouilloy,
MD, PhD
Francesco Grigioni, MD,
PhD
Rakesh M. Suri, MD, PhD
Jean-Francois Avierinos, MD
Christophe de Meester, PhD



repair	103	75	29	10
replacement	55	37	6	

patients > 75 years

50% mortality 12 vs 17 years!

ORIGINAL RESEARCH ARTICLE



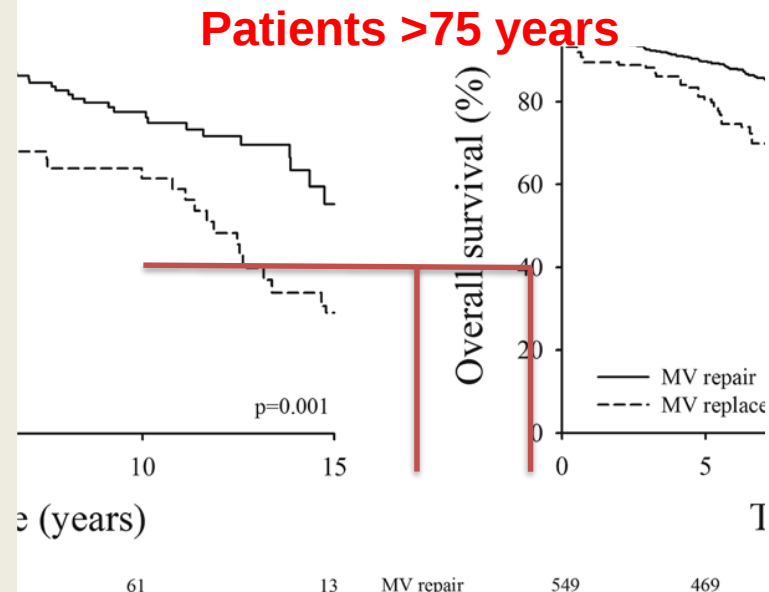
Twenty-Year Outcome After Mitral Repair Versus Replacement for Severe Degenerative Mitral Regurgitation

Analysis of a Large, Prospective, Multicenter, International Registry

Editorial, see p 423

BACKGROUND: Mitral valve (MV) repair is preferred over replacement in clinical guidelines and is an important determinant of the indication for surgery in degenerative mitral regurgitation. However, the level of evidence supporting current recommendations is low, and recent data cast doubts on its validity in the current era. Accordingly, the aim of the present study was to analyze very long-term outcome after MV repair and replacement for degenerative mitral regurgitation with a flail leaflet.

Siham Lazam, MS*
Jean-Louis Vanoverschelde, MD, PhD*
Christophe Tribouilloy, MD, PhD
Francesco Grigioni, MD, PhD
Rakesh M. Suri, MD, PhD
Jean-Francois Avierinos, MD
Christophe de Meester, PhD



50% mortality 7.5 vs 10 years!



Mitral valve repair is superior to mitral valve replacement

Patients live longer when the mitral valve is repaired

Patient History

49 yo male with two years of progressive exercise intolerance,
NYHA CLASS I

MV repair is reasonable in asymptomatic patients with chronic severe primary MR (stage C1) with preserved LV function (LVEF >60% and LVESD <40 mm) in whom the likelihood of a successful and durable repair without residual MR is >95% with an expected mortality rate of <1% when performed at a Heart Valve Center of Excellence

IIa	B
-----	---

Table 17. Summary of Recommendations for Chronic Primary MR

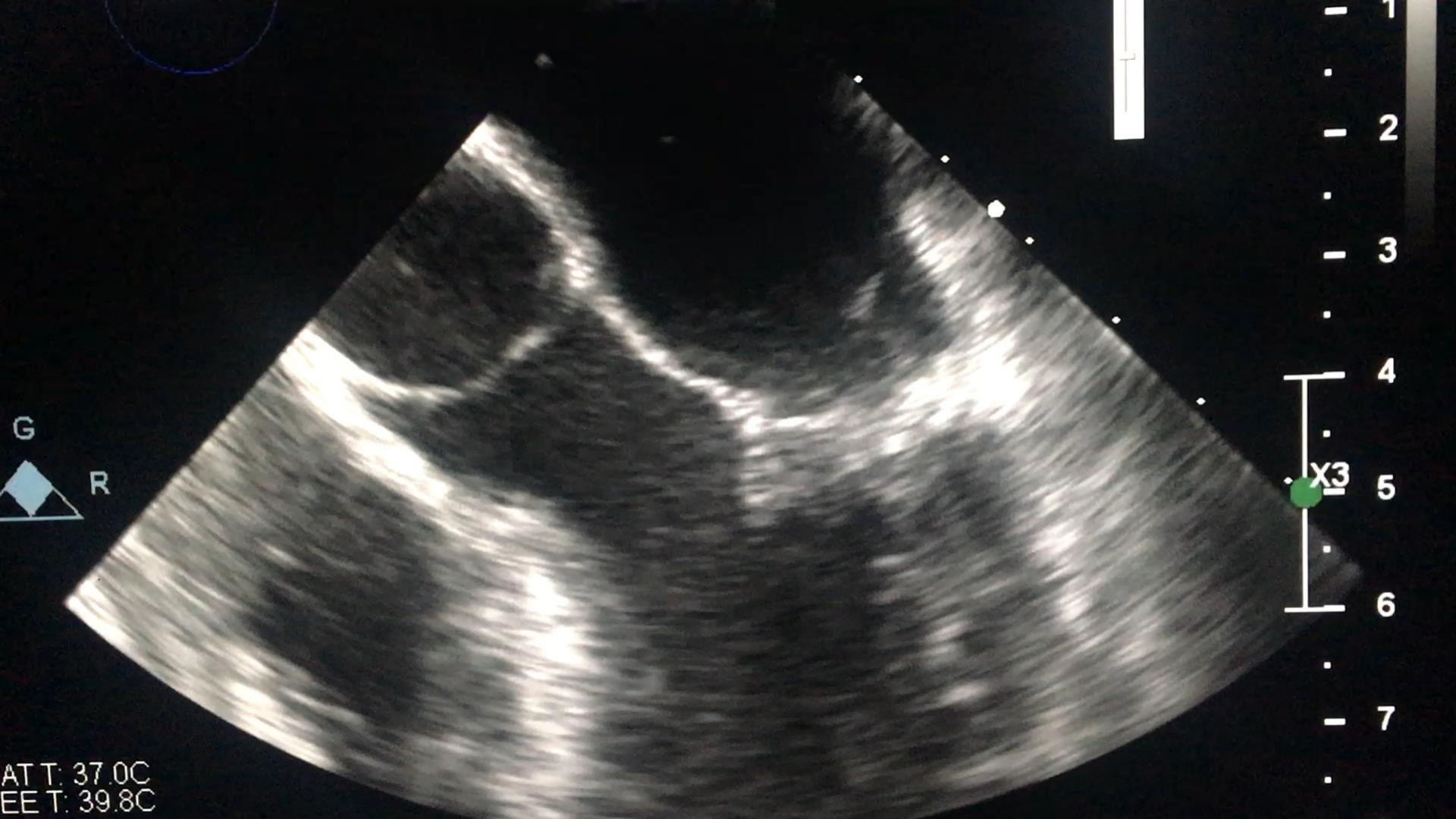
Recommendations	COR	LOE	References
MV surgery is recommended for symptomatic patients with chronic severe primary MR (stage D) and LVEF >30%	I	B	(365,376)
MV surgery is recommended for asymptomatic patients with chronic severe primary MR and LV dysfunction (LVEF 30%–60% and/or LVESD ≥40 mm, stage C2)	I	B	(359–362, 392–394)
MV repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR limited to the posterior leaflet	I	B	(87,364, 395–409)
MV repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR involving the anterior leaflet or both leaflets when a successful and durable repair can be accomplished	I	B	(86,407–413)
Concomitant MV repair or replacement is indicated in patients with chronic severe primary MR	I	B	(414)
LVEF ≤30% (stage D)			
MV repair may be considered in patients with rheumatic mitral valve disease when surgical treatment is indicated if a durable and successful repair is likely or if the reliability of long-term anticoagulation management is questionable	IIb	B	(86,406,413)
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities	IIb	B	(426)
MVR should not be performed for treatment of isolated severe primary MR limited to less than one half of the posterior leaflet unless MV repair has been attempted and was unsuccessful	III: Harm	B	(87,407–409)

R



L





2D
56%
C 50
P Off
Gen



CF
48%
6482Hz
WF 583Hz
4.4MHz



PAT T: 37.0C

Mitral Valve Repair for Degenerative MR

Symptoms

EF <60%

PASP >50

LVESD >40mm

Atrial Fibrillation

Long term results are improved when referred for repair before symptoms

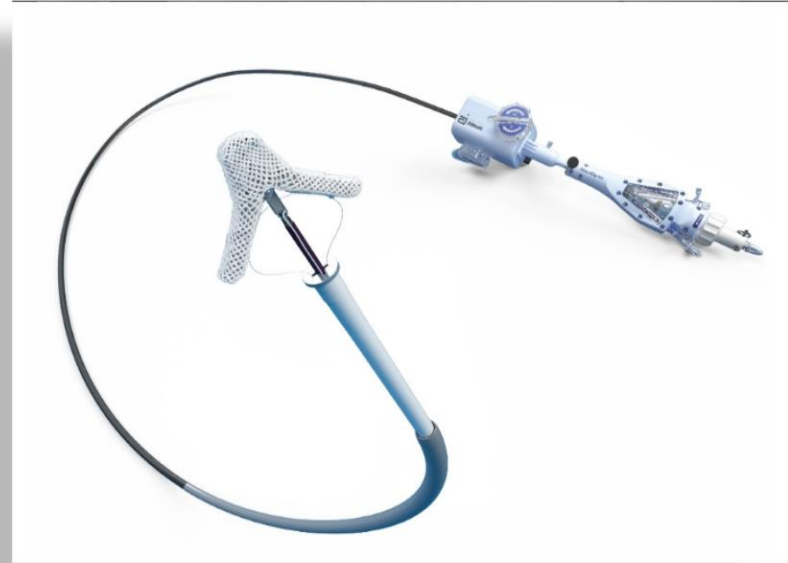
Mitral repair offers significant improvement in survival vs replacement

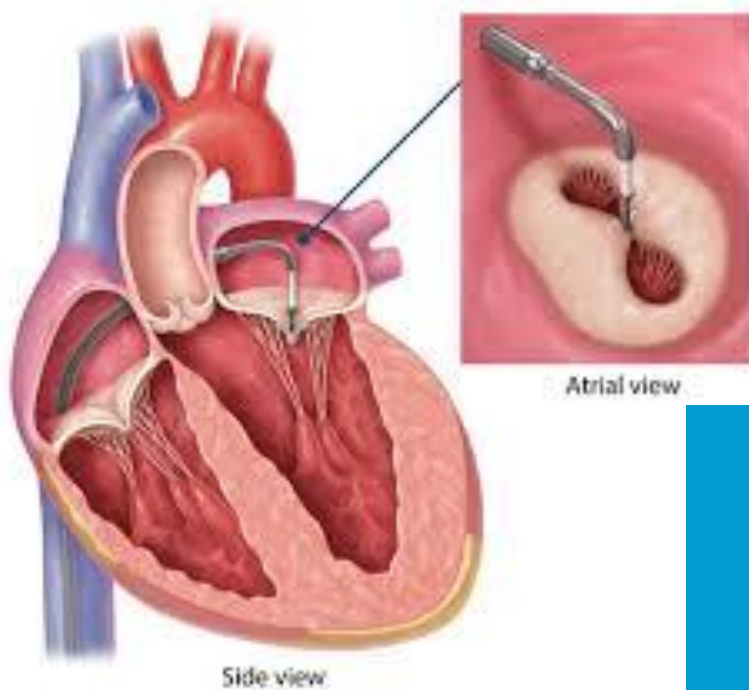
**What about
non-surgical
options???**



Transcatheter MV repair MitraClip

- Based on a surgical approach wherein the anterior leaflet and posterior leaflet are mechanically coapted
- Transseptal access via right transfemoral venous approach

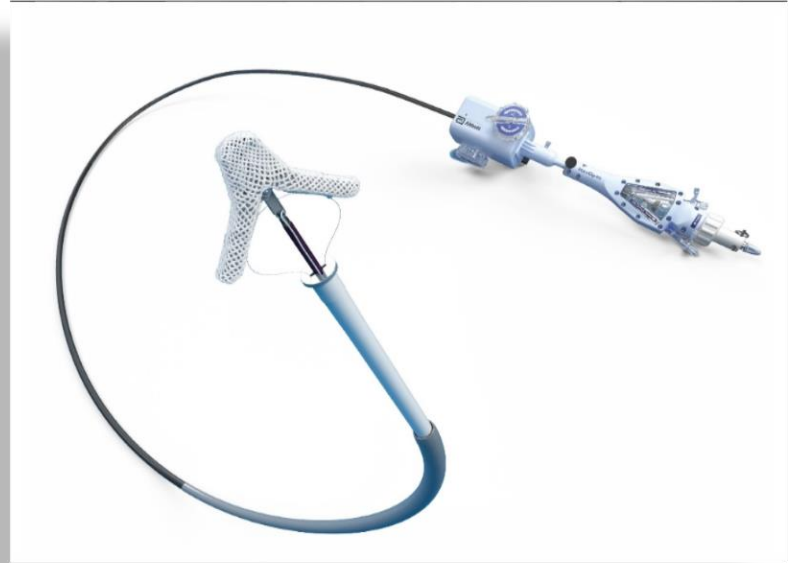




Indications for transcatheter MV repair

Primary MR: Primary Valve Disease

Chronic severe MR
Severely symptomatic
Prohibited surgical risk
Reasonable life expectancy



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

ABSTRACT

BACKGROUND In the second Endovascular Valve Edge-to-Edge Repair Study trial, treatment of mitral regurgitation (MR) with a novel percutaneous device showed superior safety compared with surgery, but less effective reduction in MR at 1 year.

OBJECTIVES This study sought to evaluate the final 5-year clinical outcomes and durability of percutaneous mitral valve (MV) repair with the MitraClip device compared with conventional MV surgery.

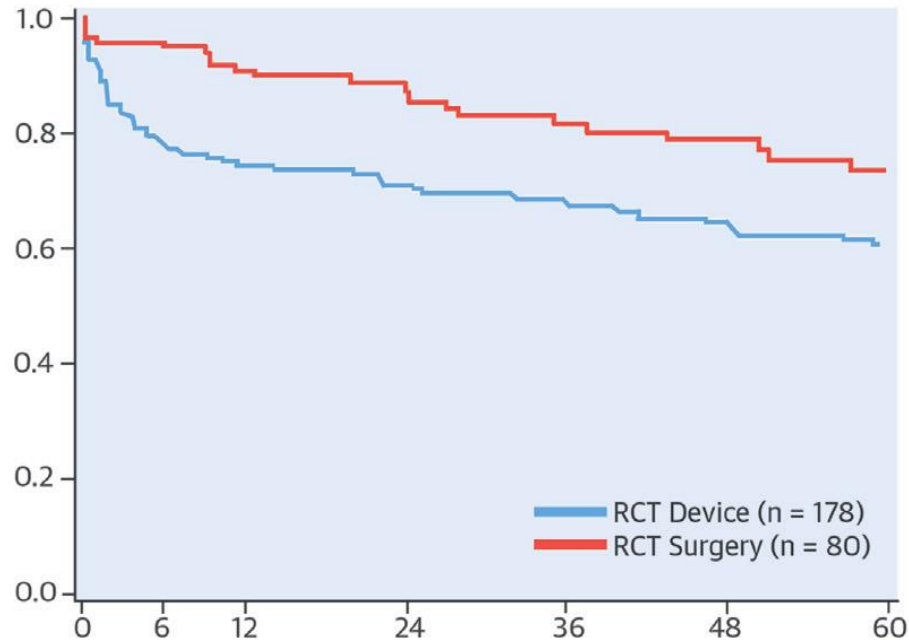
METHODS Patients with grade 3+ or 4+ MR were randomly assigned to percutaneous repair with the device or conventional MV surgery in a 2:1 ratio (178:80). Patients prospectively consented to 5 years of follow-up.

RESULTS At 5 years, the rate of the composite endpoint of freedom from death, surgery, or 3+ or 4+ MR in the as-treated population was 44.2% versus 64.3% in the percutaneous repair and surgical groups, respectively ($p = 0.01$). The difference was driven by increased rates of 3+ to 4+ MR (12.3% vs. 1.8%; $p = 0.02$) and surgery (27.9% vs. 8.9%; $p = 0.003$) with percutaneous repair. After percutaneous repair, 78% of surgeries occurred within the first 6 months. Beyond 6 months, rates of surgery and moderate-to-severe MR were comparable between groups. Five-year mortality rates were 20.8% and 26.8% ($p = 0.4$) for percutaneous repair and surgery, respectively. In multivariable analysis, treatment strategy was not associated with survival.

CONCLUSIONS Patients treated with percutaneous repair more commonly required surgery for residual MR during the first year after treatment, but between 1- and 5-year follow-up, comparably low rates of surgery for MV dysfunction with either percutaneous or surgical therapy endorse the durability of MR reduction with both repair techniques. (EVEREST II Pivotal Study High Risk Registry; [NCT00209274](#)). (J Am Coll Cardiol 2015;66:2844-54) © 2015 by the American College of Cardiology Foundation.

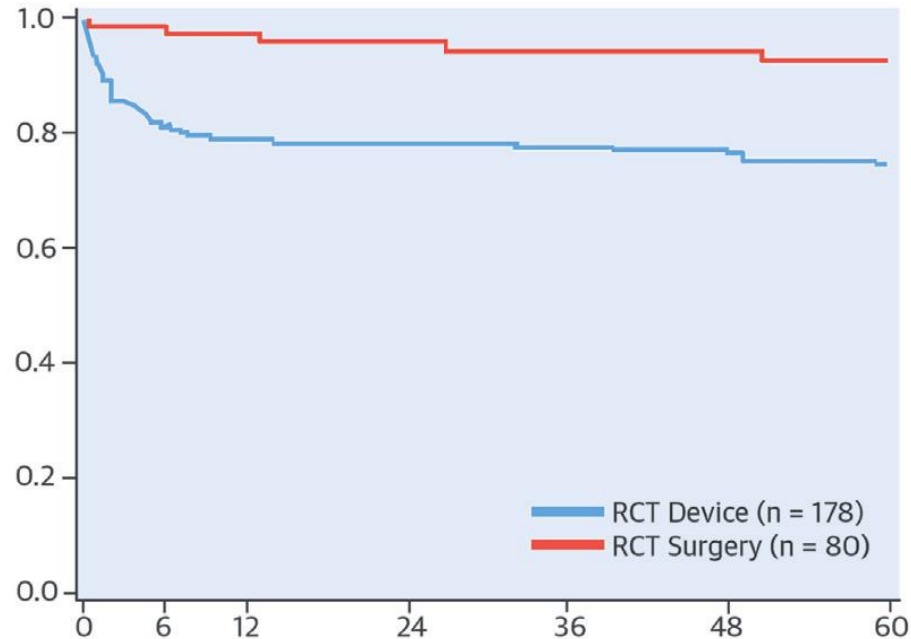
EVEREST II – 5 Year Results

Freedom from Death, reoperation or MV surgery



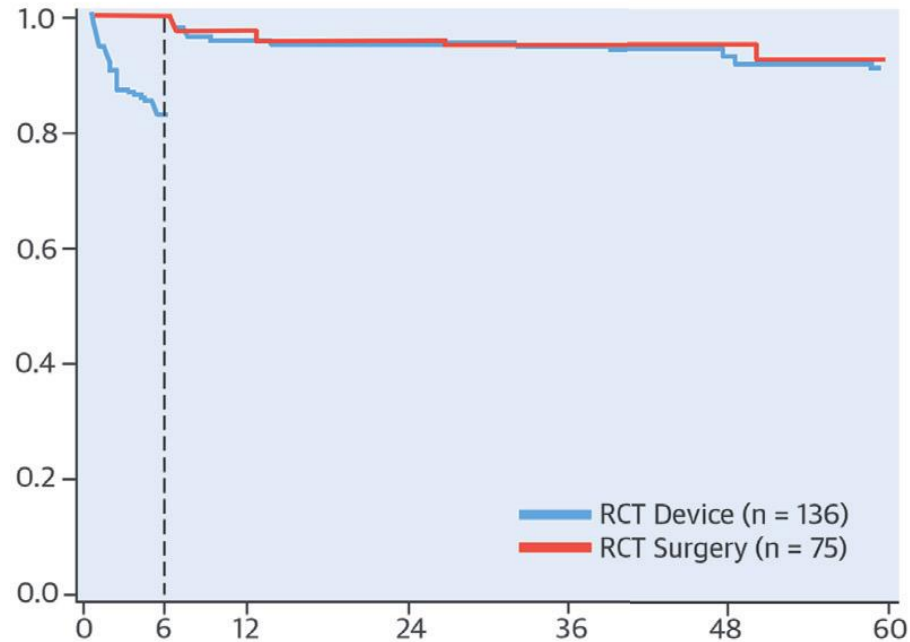
EVEREST II – 5 Year Results

Freedom from MV Surgery or Reoperation



EVEREST II – 5 Year Results

Freedom from MV surgery or reoperation after 6 months



Improved Functional Status and Quality of Life in Prohibitive Surgical Risk Patients With Degenerative Mitral Regurgitation After Transcatheter Mitral Valve Repair



D. Scott Lim, MD,* Matthew R. Reynolds, MD, MSc,†‡ Ted Feldman, MD,§ Saibal Kar, MD,||

Howard C. Herrmann, MD,||

Paul Grayburn, MD,†‡ M

METHODS A prohibitive-risk DMR cohort was identified by a multidisciplinary heart team that retrospectively evaluated high-risk DMR patients enrolled in the EVEREST (Endovascular Valve Edge-to-Edge Repair Study) II studies.

RESULTS A total of 141 high-risk DMR patients were consecutively enrolled; 127 of these patients were retrospectively identified as meeting the definition of *prohibitive risk* and had 1-year follow-up (median: 1.47 years) available. Patients were elderly (mean age: 82.4 years), severely symptomatic (87% New York Heart Association class III/IV), and at prohibitive surgical risk (STS score: $13.2 \pm 7.3\%$). TMVR (MitraClip) was successfully performed in 95.3%; hospital stay was 2.9 ± 3.1 days. Major adverse events at 30 days included death in 6.3%, myocardial infarction in 0.8%, and stroke in 2.4%. Through 1 year, there were a total of 30 deaths (23.6%), with no survival difference between patients discharged with MR $\leq 1+$ or MR $2+$. At 1 year, the majority of surviving patients (82.9%) remained MR $\leq 2+$ at 1 year, and 86.9% were in New York Heart Association functional class I or II. Left ventricular

TMVR in prohibitive surgical risk patients is associated with safety and good clinical outcomes, including decreases in rehospitalization, functional improvements, and favorable ventricular remodeling, at 1 year.

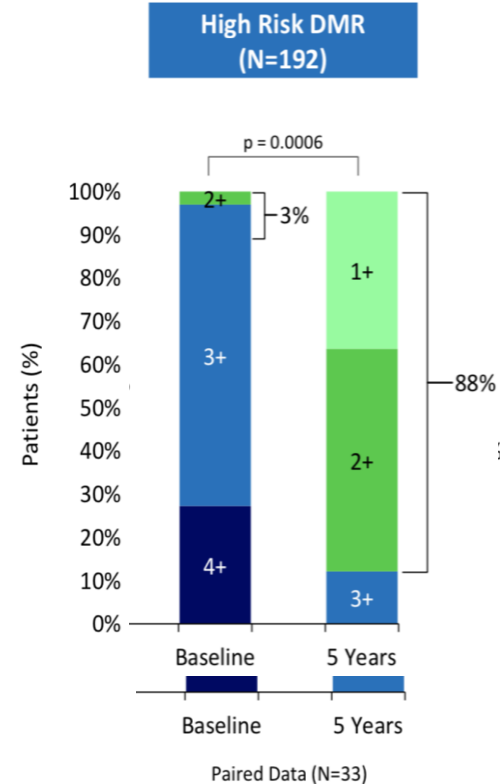
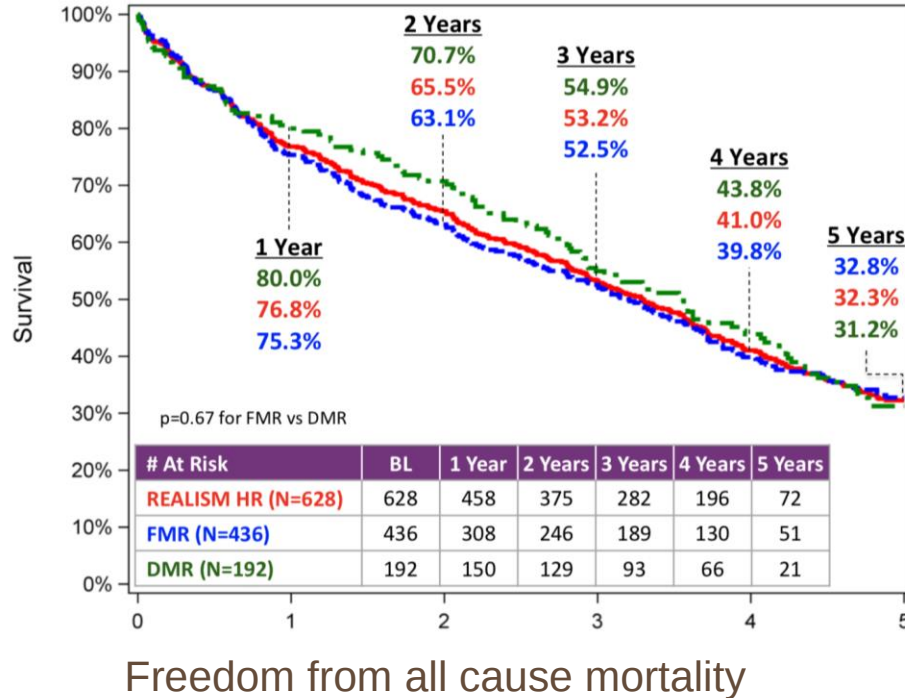
EVEREST Realism High Risk

Characteristic	Prohibitive Risk DMR N = 127
Age (mean $\pm$ SD)	82 $\pm$ 9 years
Patients over 75 years of age	84%
Male Gender	55%
Coronary Artery Disease	73%
Prior Myocardial Infarction	24%
Previous Cardiovascular Surgery	48%
Atrial Fibrillation History	71%
Prior Stroke	10%
Diabetes	30%
Moderate to Severe Renal Disease	28%
Chronic Obstructive Pulmonary Disease	32%
STS Mortality Risk (mean $\pm$ SD) [v2.73, replacement]	13.2 $\pm$ 7.3%
SF-36 QoL Physical Component Score (mean $\pm$ SD)	32.0 $\pm$ 8.7
SF-36 QoL Mental Component Score (mean $\pm$ SD)	46.1 $\pm$ 12.5

EVEREST Realism High Risk

Post-Procedural and Discharge Results	Prohibitive Risk DMR N = 127
Post-Procedural (mean $\pm$ SD)	
ICU/CCU duration	1.4 $\pm$ 1.8 days
Length of hospital stay	2.9 $\pm$ 3.1 days
Discharge MR, (%)	
MR $\leq$ 2+ at Discharge	82%
MR $\leq$ 1+ at Discharge	54%
Discharged home, (%)	
	87%

EVEREST Realism High Risk



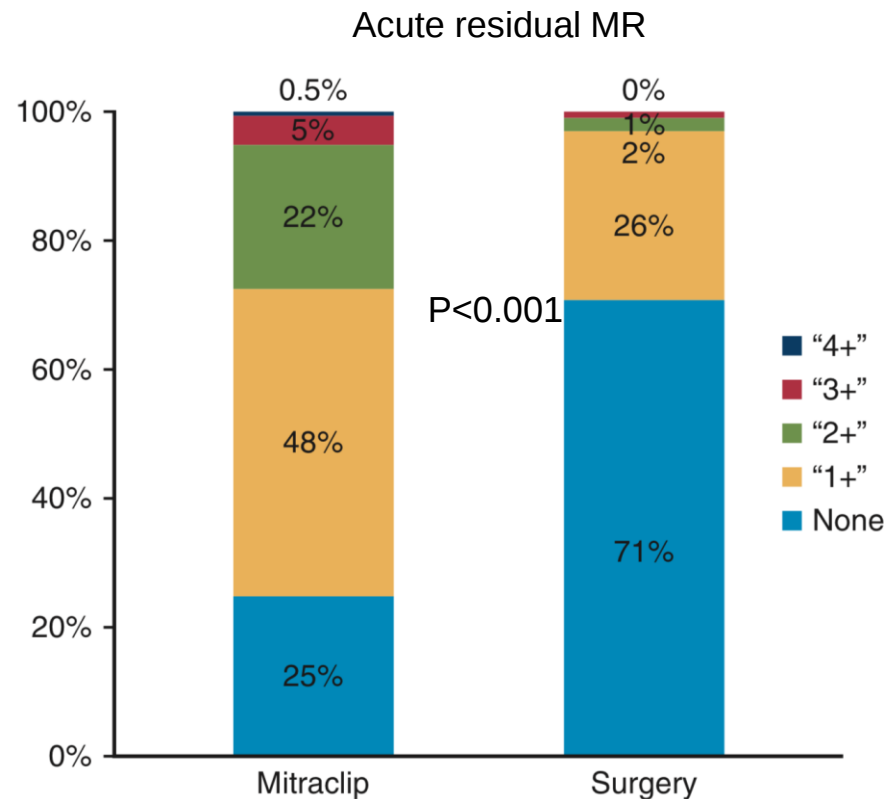
Transcatheter or surgical repair for degenerative mitral regurgitation in elderly patients: A propensity-weighted analysis

Nicola Buzzatti, MD,^a Mathias Van Hemelrijck, MD,^b Paolo Denti, MD,^a Stefania Ruggeri, MS,^a Davide Schiavi, BS,^a Iside Stella Scarfò, MD,^a Diana Reser, MD,^b Maurizio Taramasso, MD,^b Alberto Weber, MD,^b Giovanni La Canna, MD,^a Michele De Bonis, MD,^a Francesco Maisano, MD,^b and Ottavio Alfieri, MD^a

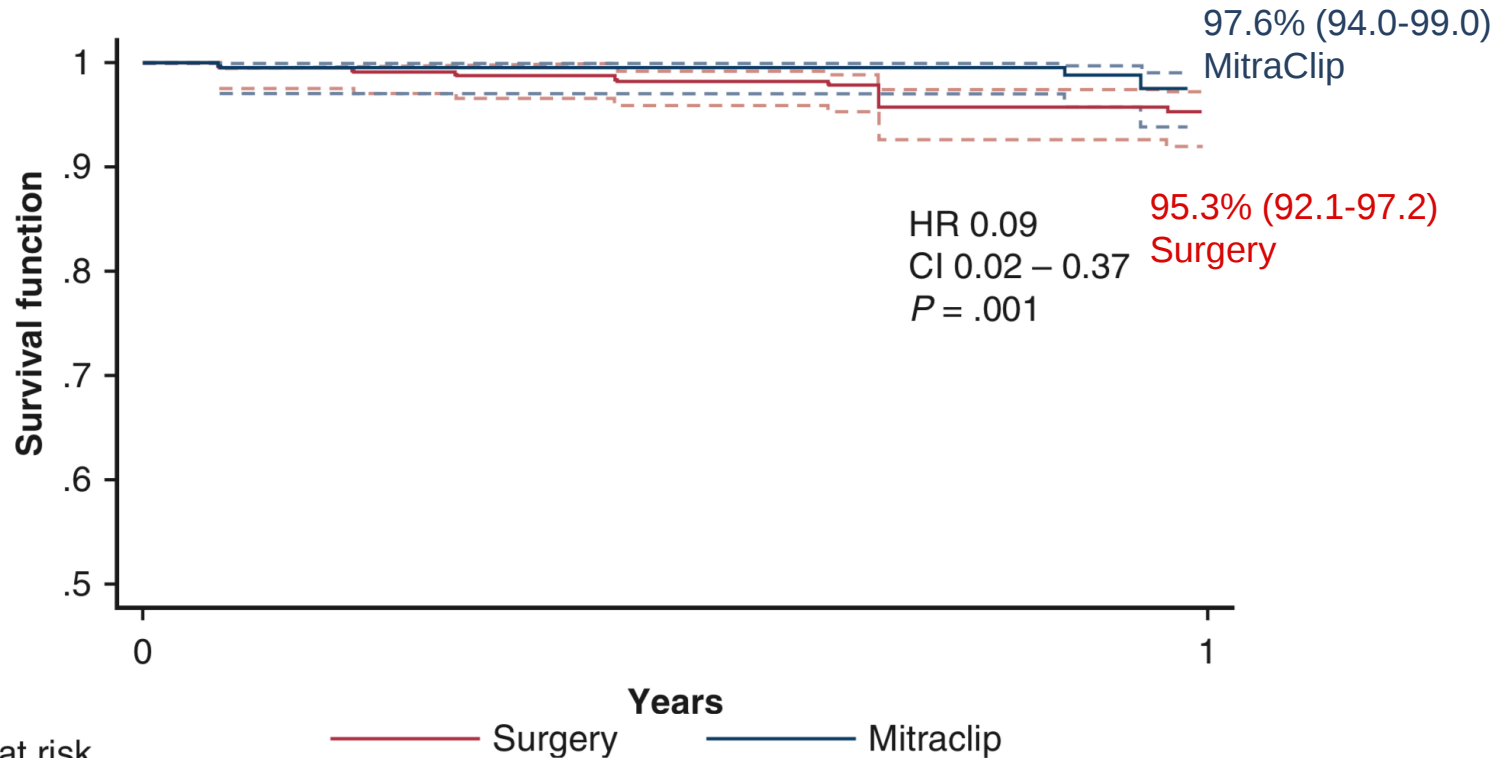
(J Thorac Cardiovasc Surg 2019; ■:1-9)

Post-operative data

	Surgery SoW = 305.08	MitraClip SoW = 247.49	P value
Residual MR $\geq 2+$	8.5 (2.8)	67.7 (27)	<.001
LCOS	52.8 (17)	8.0 (3.3)	.001
Inotropes > MD	124.7 (41)	18.0 (7.3)	<.001
AKI	134.2 (45)	26.3 (11)	<.001
Ventilation hours	15 [11; 19]	5 [0; 10]	<.001
Ventilation >24 h	37.2 (12)	1.1 (0.5)	<.001
NIMV	61.9 (24)	9.8 (6.2)	.002
Sepsis	11.3 (3.7)	1.2 (0.5)	.118
Serious bleeding	26.1 (15)	6.0 (2.3)	.003
Transfusion need	111.5 (37)	15.1 (6.1)	<.001
Stroke	4.2 (1.4)	2.5 (1.0)	.741
ICU LOS, d	1 [1; 2]	0 [0; 1]	<.001
ICU LOS >1 d	128.4 (42)	19 (7.8)	<.001
Postoperative LOS, d	7 [5; 9]	4 [4; 6]	<.001
In-hospital death	2.8 (0.9)	2.7 (1.1)	.853
Discharge home	2.5 (0.8)	170.6 (69)	<.001



1-year survival



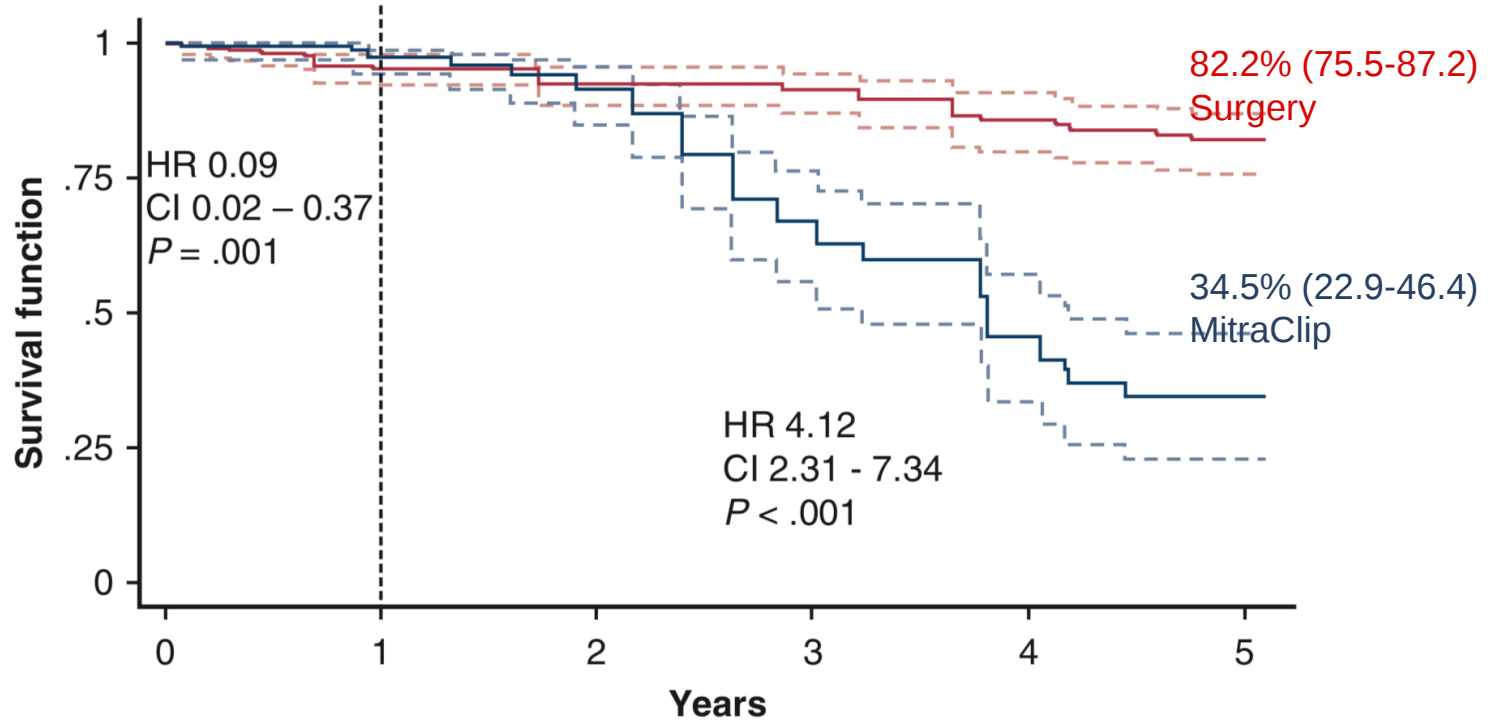
Surgery 294.4

Mitraclip 243.2

242.3

163.3

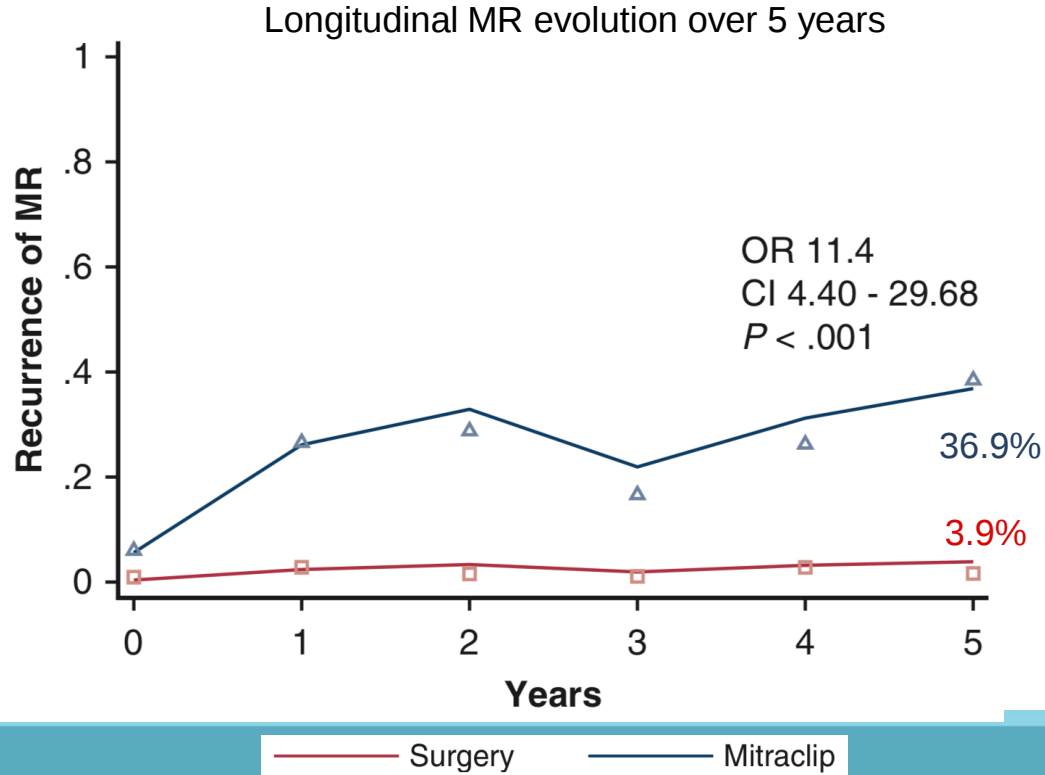
5-year survival



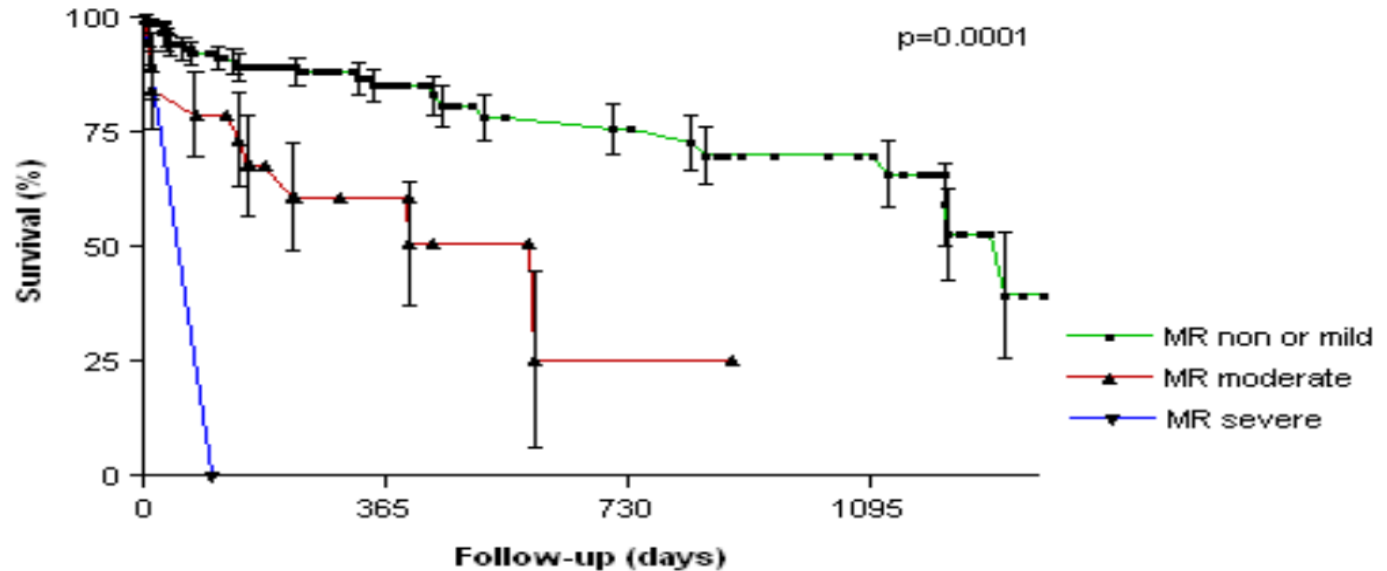
Number at risk

	Surgery	Mitraclip
Surgery 294.4	242.3	177.7
Mitraclip 243.2	163.3	77.1
	147.3	41.5
	121.4	25.0
	100.0	15.8

Follow-up: > 2+ MR



Residual moderate MR is a strong predictor of mortality after MitraClip



Mitraclip vs Surgery for DMR



- In degenerative MR Mitra Clip is the preferred choice in high risk patients

Mitraclip vs Surgery for DMR



- MitraClip is associated with reduced acute morbidity and improved short-term survival compared to surgery in elderly pts with DMR

Mitraclip vs Surgery for DMR



- Surgery is the preferred treatment in low and intermediate risk patients with DMR

Mitraclip vs Surgery for DMR



- In low-intermediate risk elderly pts, the decision is strongly influenced by the ability to achieve optimal correction of MR using the MitraClip.

Mitral Regurgitation

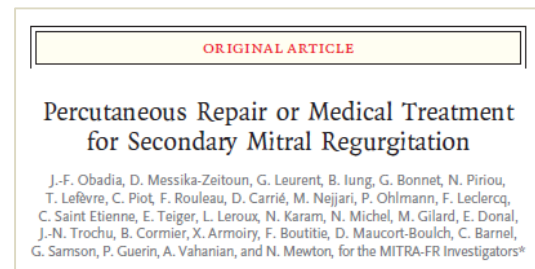
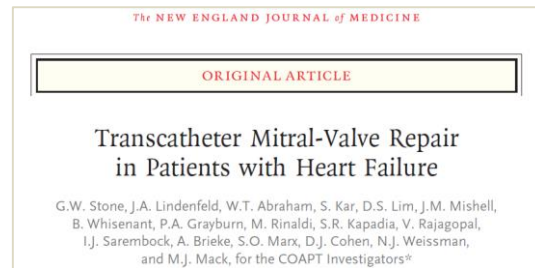
Primary MR: Primary Valve Disease

Secondary MR: Primary Myocardial Disease

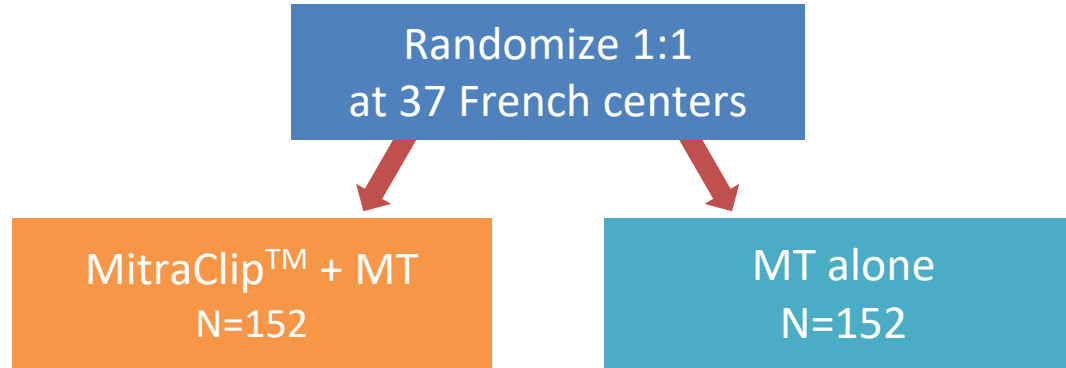
Two RCTS on device treatment of SMR Reported Primary Results in 2018

MITRACLIP™+GDMT AGAINST GDMT FOR HF PATIENTS WITH SECONDARY MR

- COAPT™
 - MR severity defined per ACC/AASE guidelines
 - Sponsored by Abbott, for label expansion for symptomatic secondary MR $\geq 3+$
- Mitra-FR
 - MR severity defined per European guidelines
 - Funded by French government, for MitraClip reimbursement for secondary MR



The MITRA-FR Trial



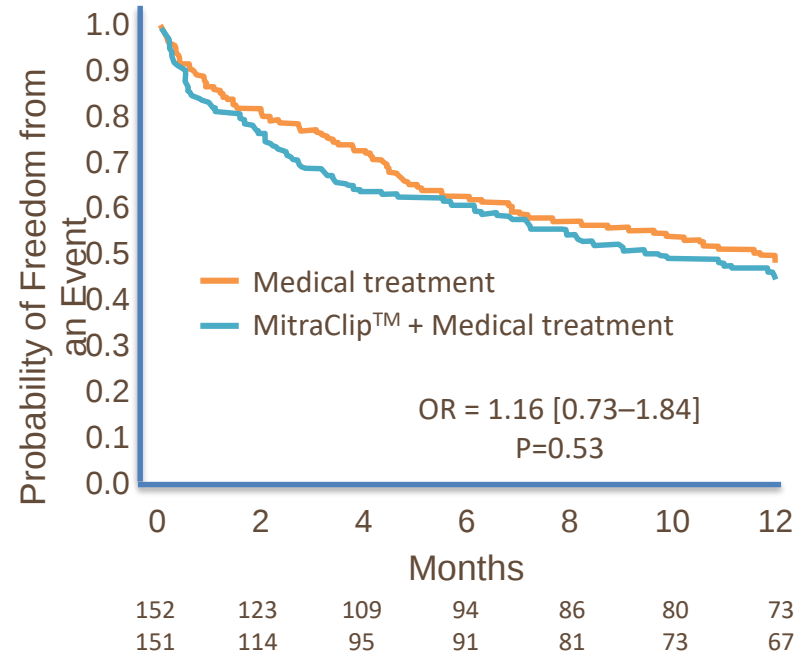
Primary endpoint: Freedom from death or HF hospitalizations through 12 months

The MITRA-FR Trial



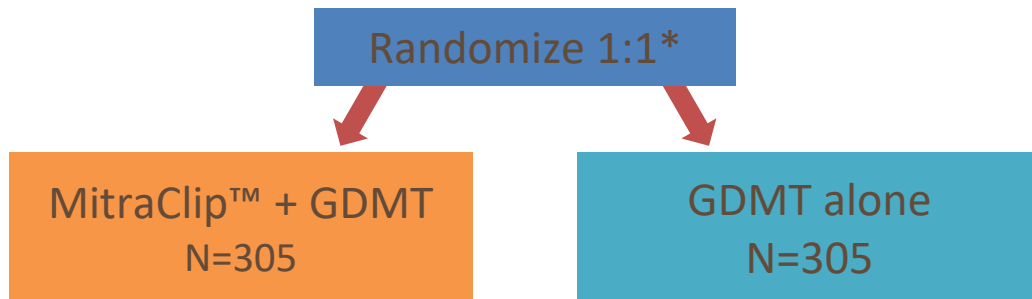
Primary Composite Endpoint

- All-Cause Death
- Unplanned rehospitalization for HF



The COAPT™ Trial

CARDIOVASCULAR OUTCOMES ASSESSMENT OF THE MITRACLIP
PERCUTANEOUS THERAPY FOR HEART FAILURE PATIENTS WITH FUNCTIONAL
MITRAL REGURGITATION



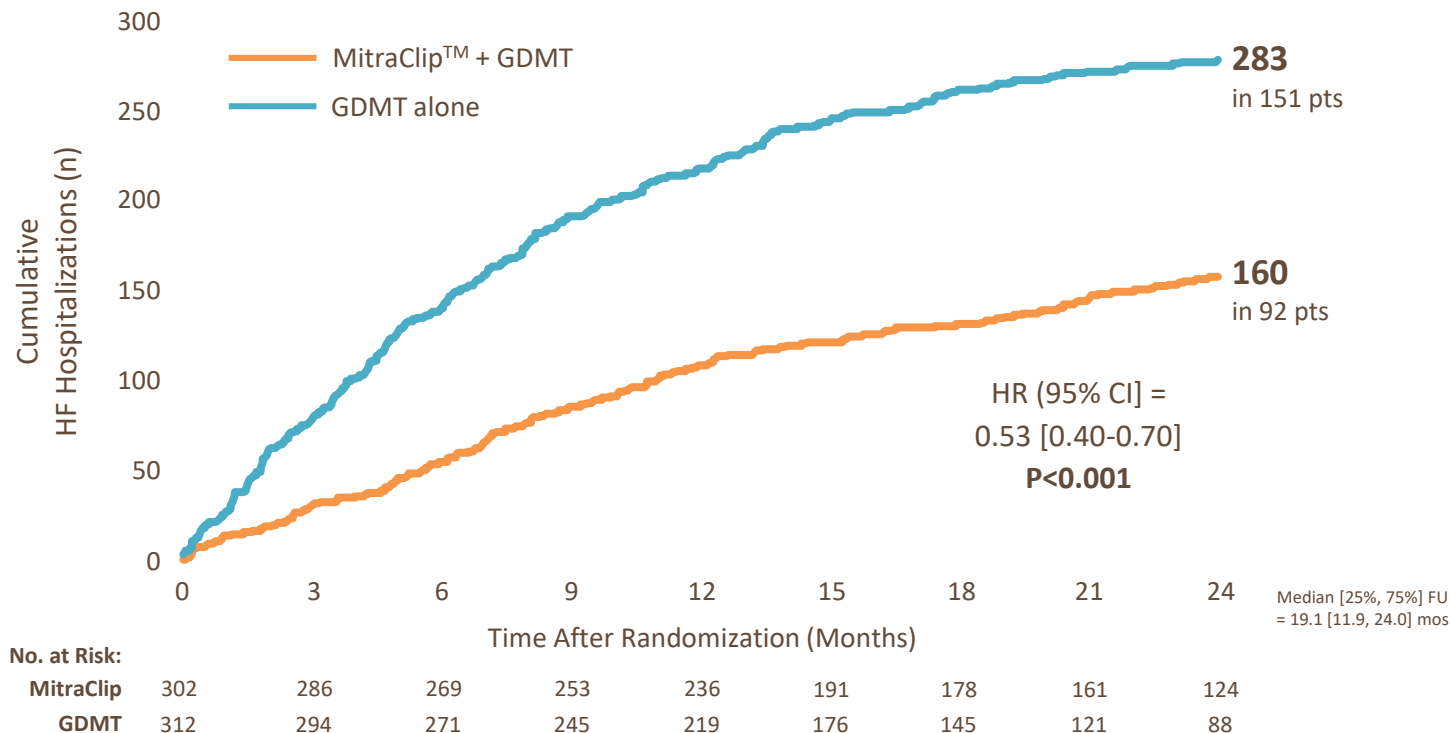
*Stratified by cardiomyopathy etiology
(ischemic vs. non-ischemic) and site

Stone GW et al. NEJM 2018

SHARP

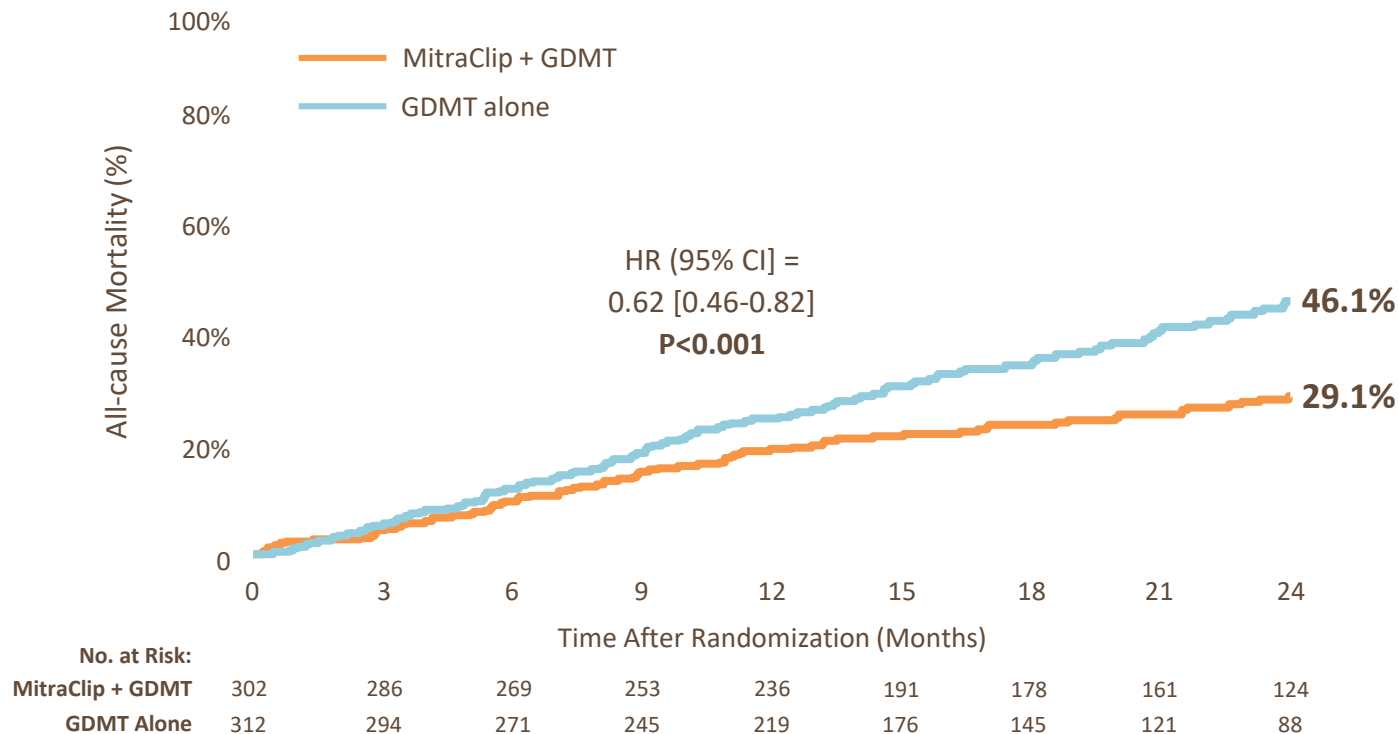
Primary Effectiveness Endpoint

ALL HOSPITALIZATIONS FOR HF WITHIN 24 MONTHS



Primary Effectiveness

SURVIVAL



Indications for transcatheter MV repair

Secondary MR: Functional Valve Disease

Symptomatic moderate to severe secondary MR
LVEF 20 - 50%
left ventricular end systolic dimension (LVESD) ≤ 70 mm
Symptoms persist despite GDMT



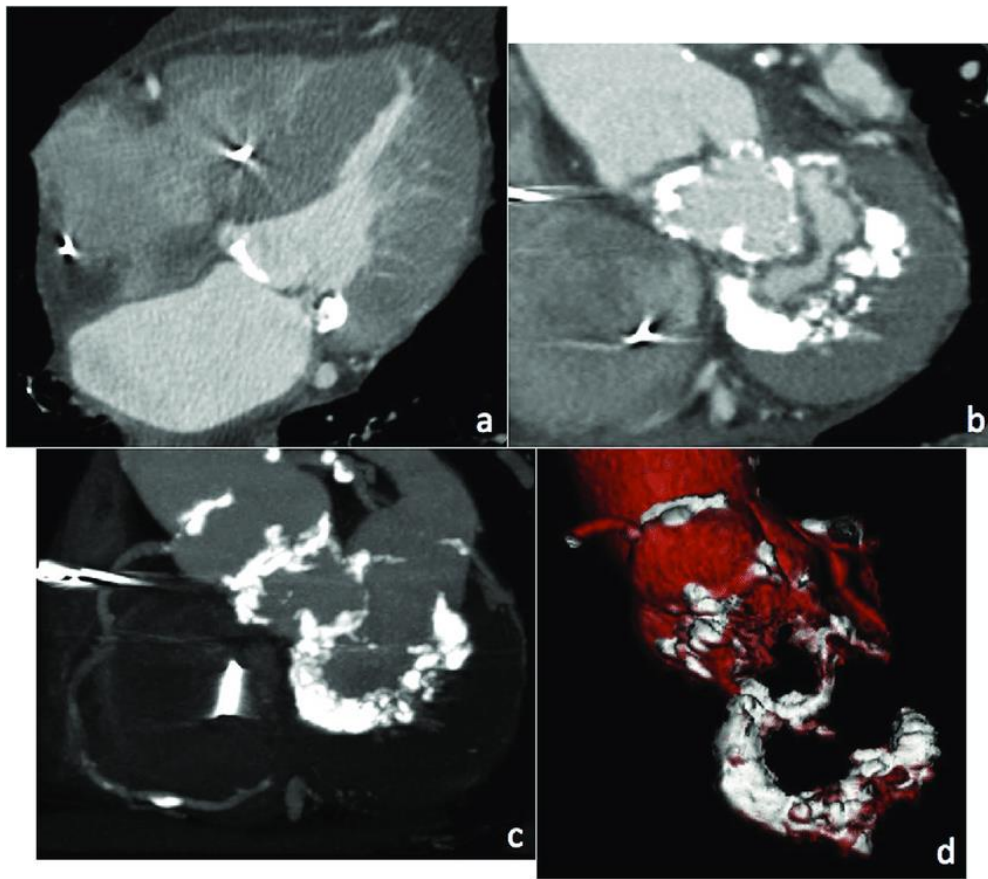
Mitral Valve What's New???

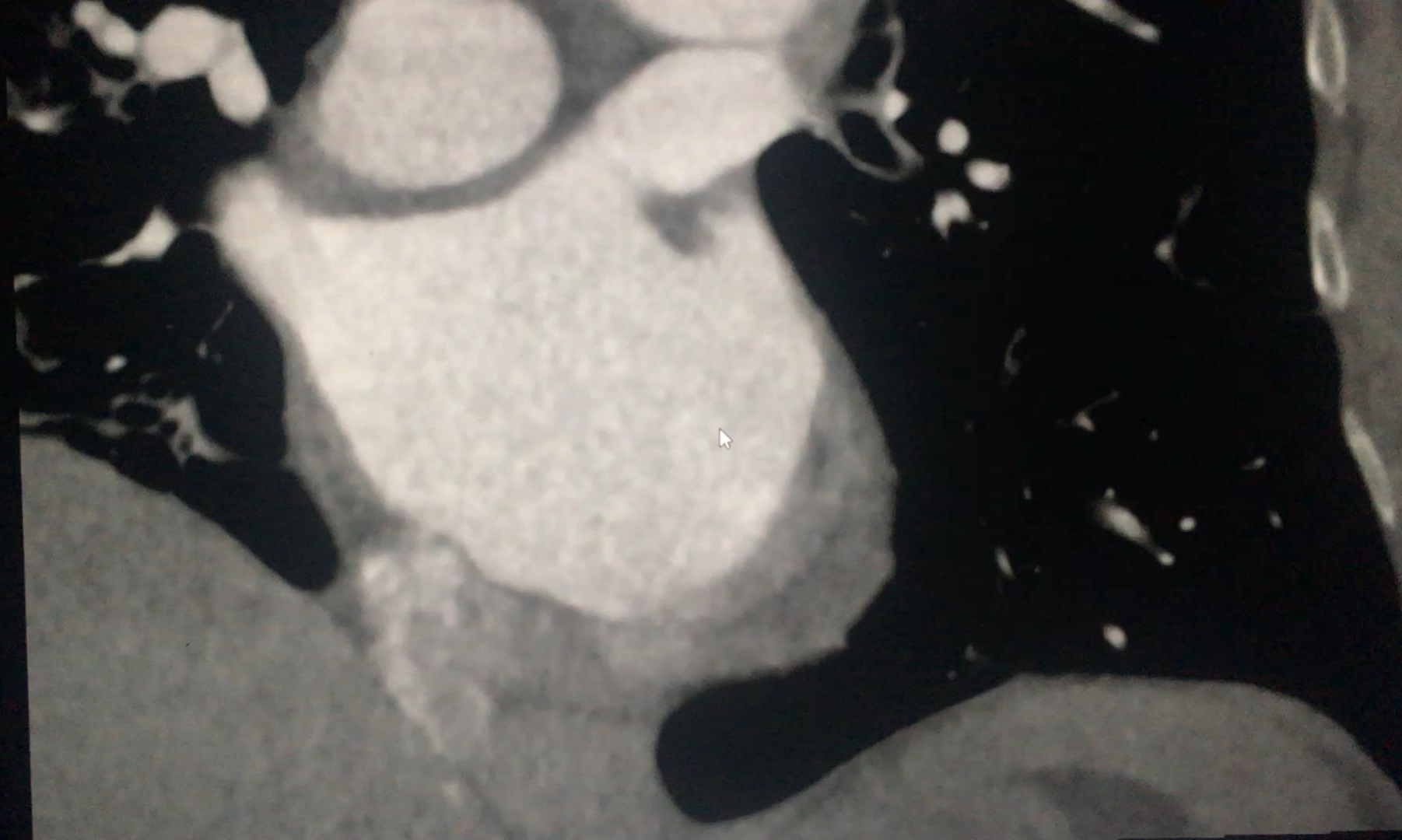


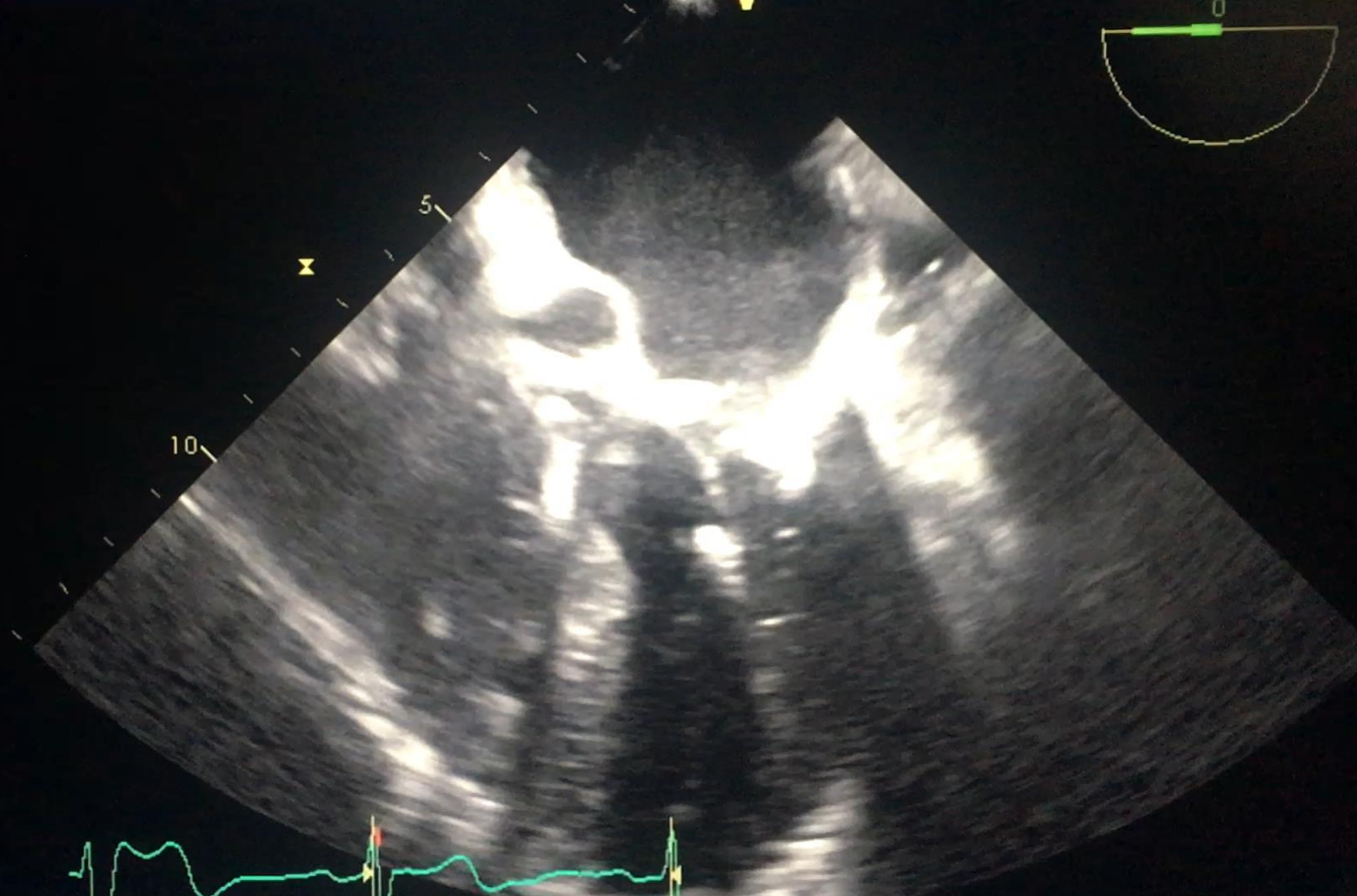
BIG MAC

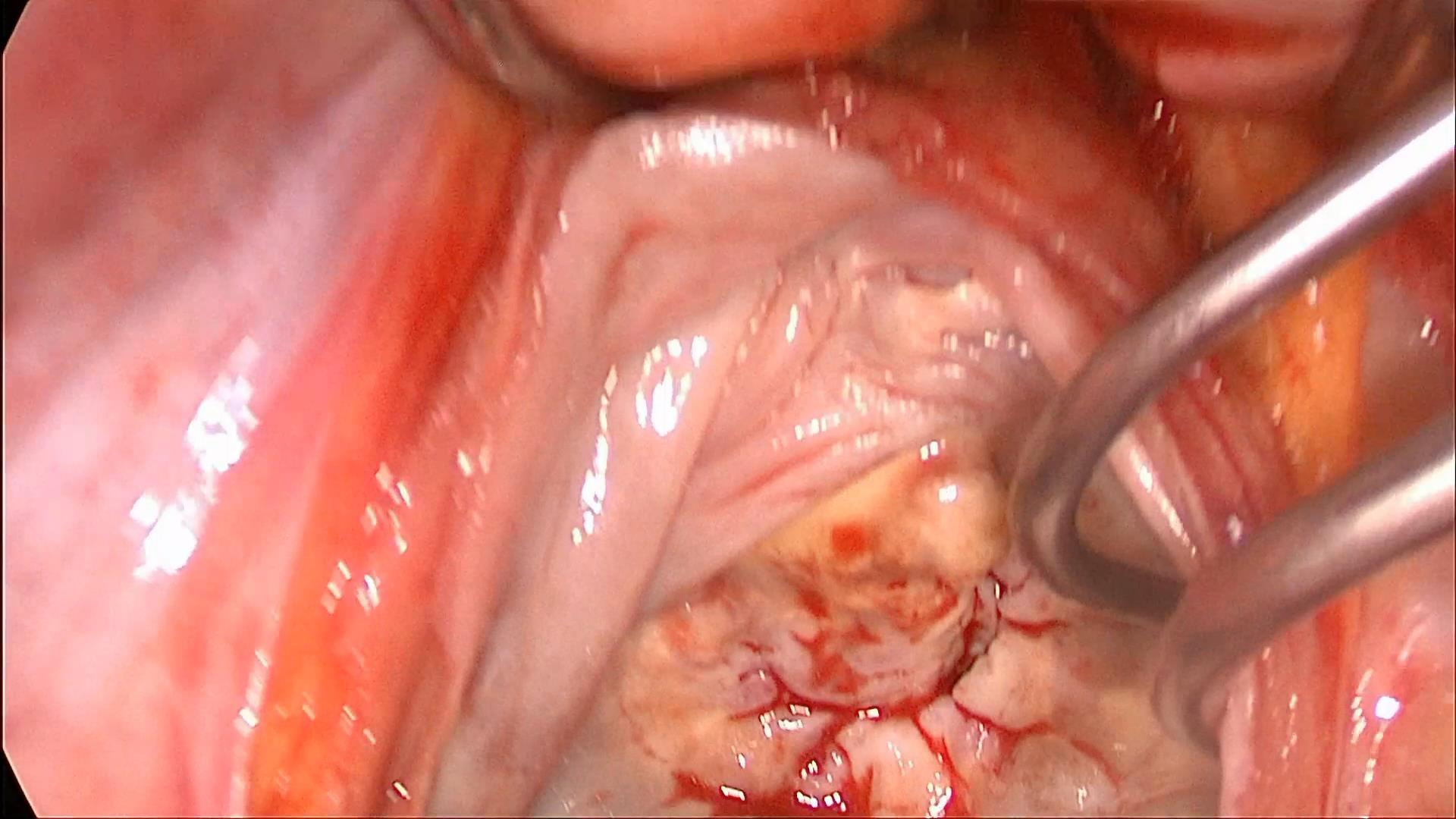


BIG MAC

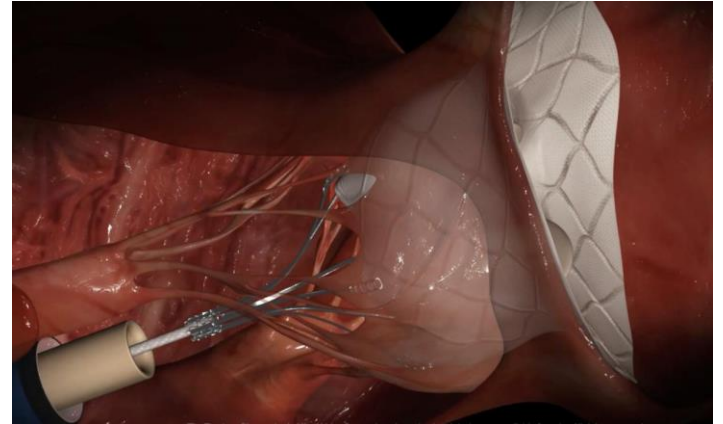








Percutaneous Mitral Valve Replacement Tendyne





TENDYNE

Bioprosthetic Mitral Valve System

The Tendyne Bioprosthetic Mitral Valve System is an investigational device, not available for sale. *All rights reserved.*
CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use.

Summit Clinical Trial Design

- Randomized Cohort
- Non-Randomized Cohort
- Mitral Annular Calcification (MAC) Cohort

Summit Clinical Trial

Inclusion Criteria:

- Symptomatic, moderate-to-severe or severe mitral regurgitation, or severe mitral annular calcification (MAC)
- NYHA Functional Classification $\geq$ II (if Class IV, patient must be ambulatory)
- The local site heart team determines that the subject has been adequately treated per applicable standards

Summit Clinical Trial

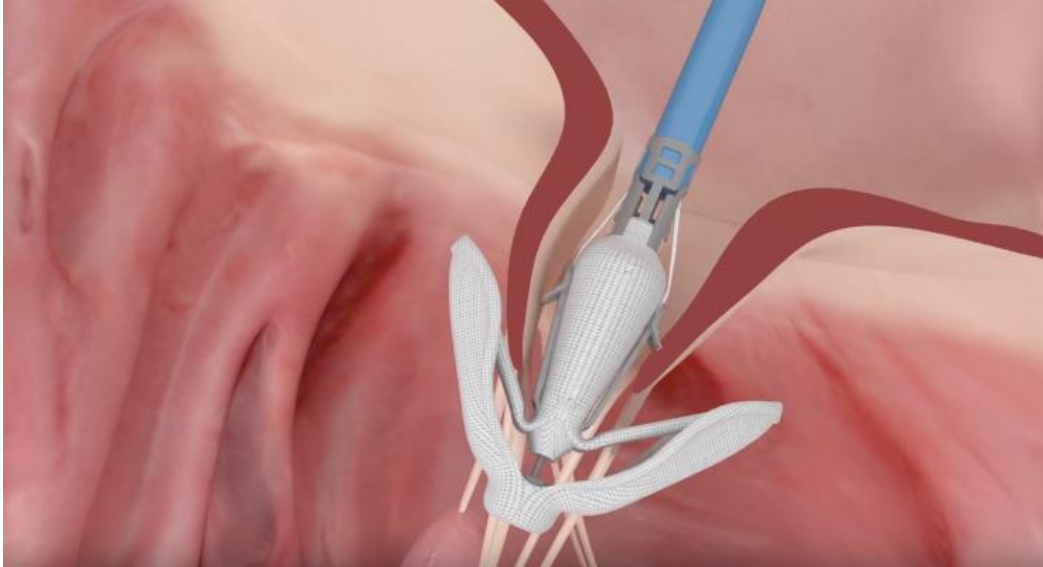
Exclusion Criteria:

- Left ventricular ejection fraction < 25%
- Left ventricular end diastolic diameter > 7.0 cm
- Prior surgical or interventional treatment of mitral valve involving implantation of prosthetic material
- Severe tricuspid regurgitation or any tricuspid valve disease requiring surgery or transcatheter intervention
- Subject undergoing hemodialysis due to chronic renal failure
- life expectancy of less than 12 months

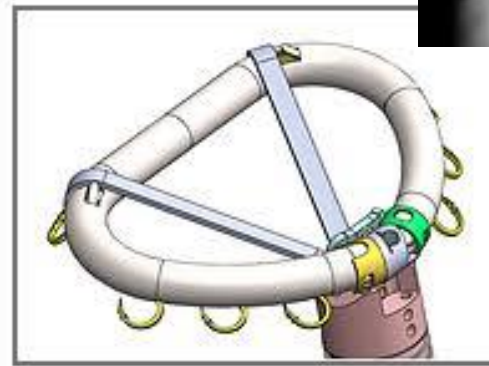
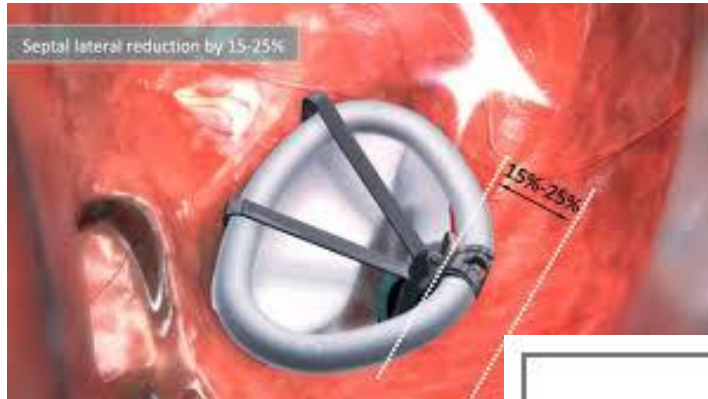
Edwards Cardioband



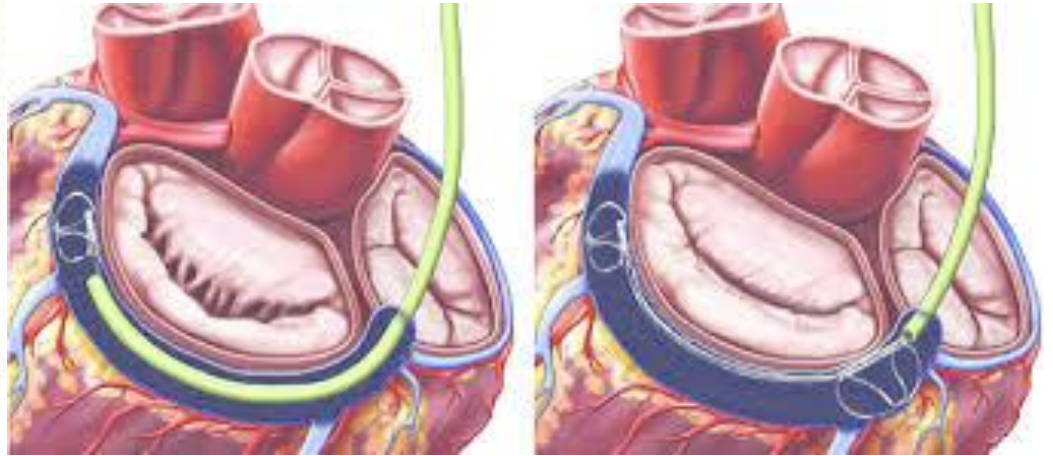
Edwards Pascal



Valcare Amend Ring



Coronary Sinus Annuloplasty



Harpoon Neochords



THANK YOU!



TENDYNE

SHARP®

**Summit Clinical Trial
Open for Enrollment!**

SHARP®

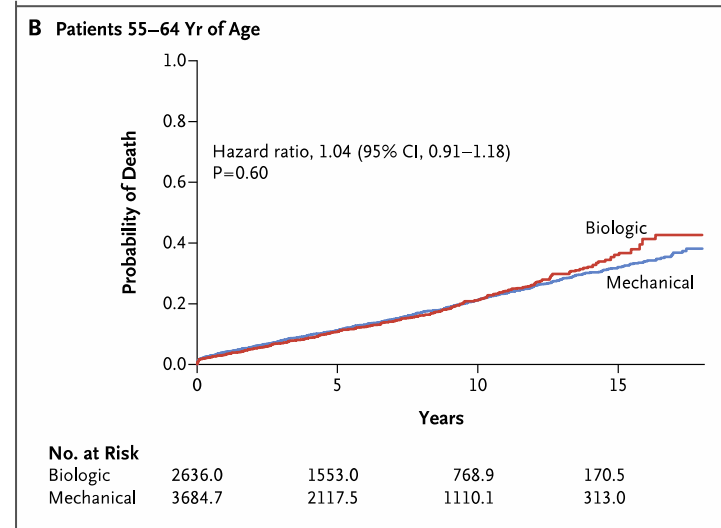
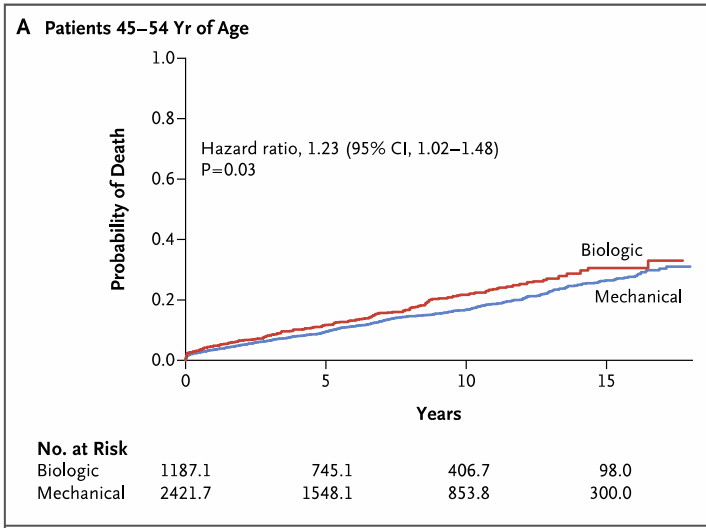
ORIGINAL ARTICLE

Mechanical or Biologic Prostheses for Aortic-Valve and Mitral-Valve Replacement

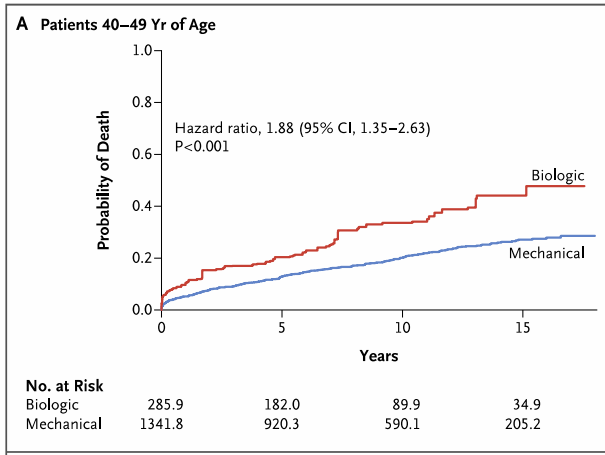
Andrew B. Goldstone, M.D., Ph.D., Peter Chiu, M.D., Michael Baiocchi, Ph.D.,
Bharathi Lingala, Ph.D., William L. Patrick, M.D., Michael P. Fischbein, M.D., Ph.D.,
and Y. Joseph Woo, M.D.

ABSTRACT

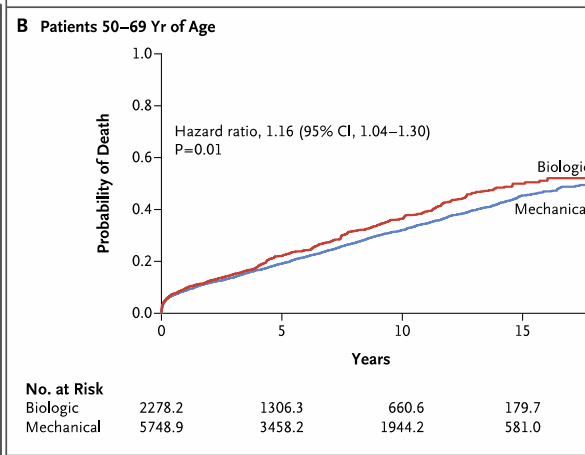
SURVIVAL FOLLOWING AVR



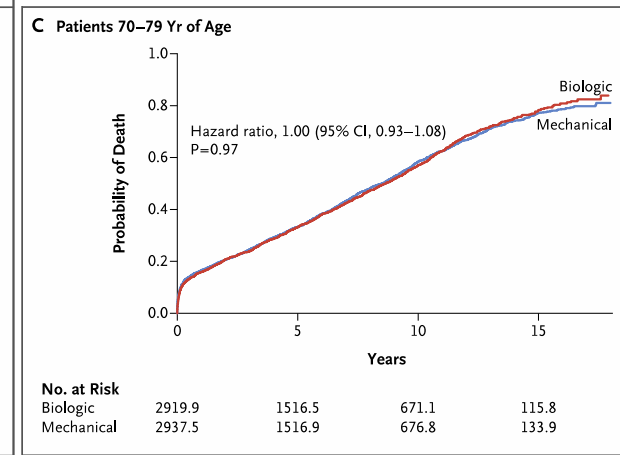
Survival Following Mitral Valve Replacement



40-49 years



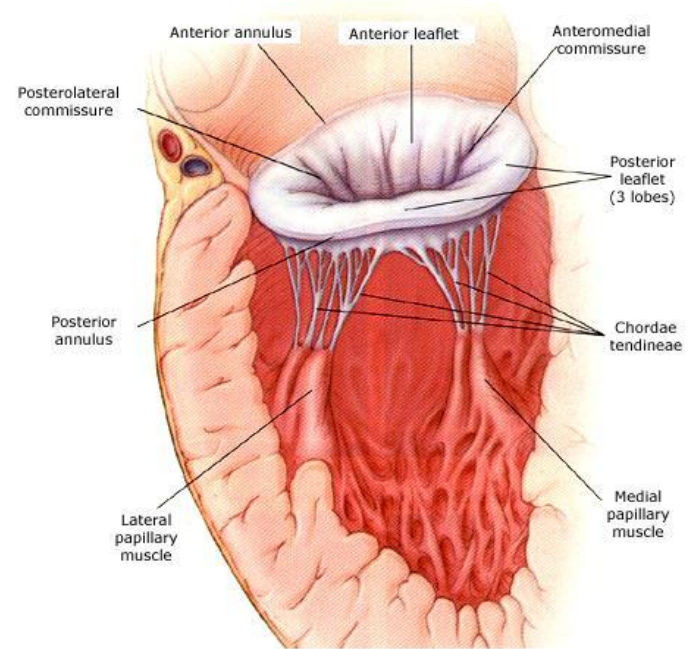
50-69 years



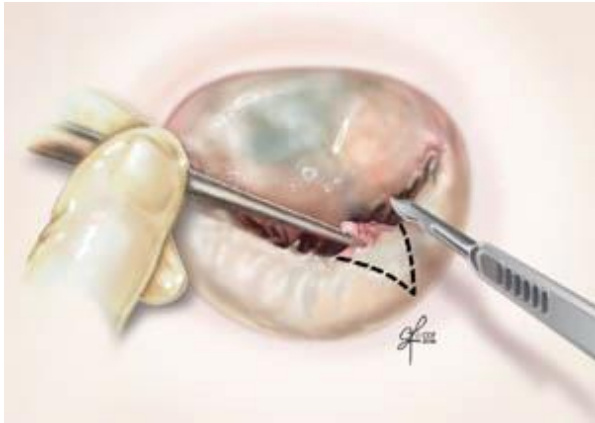
70-79 years

Mitral Valve Repair

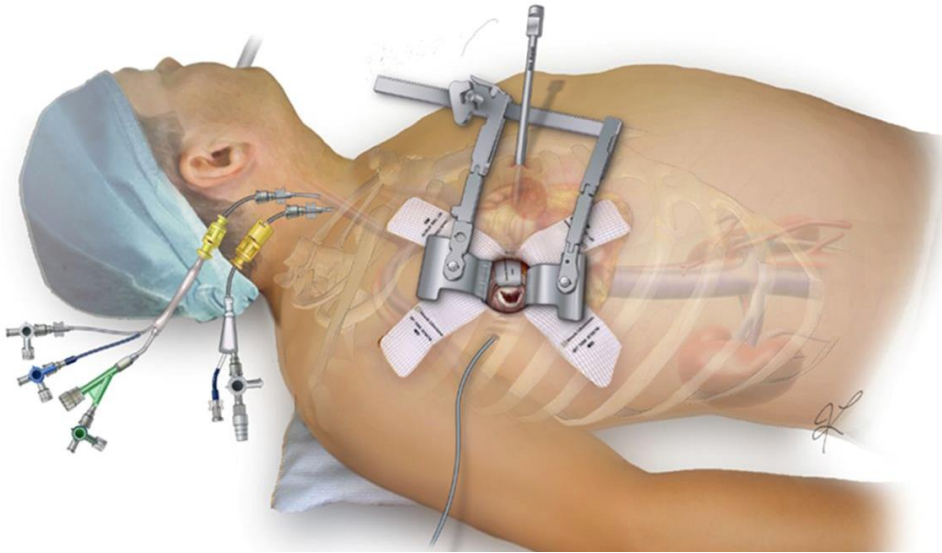
- Lower operative risk than mitral replacement
- Improved left ventricle function – less heart failure
- Freedom from valve complications – infections, embolism
- No need for anticoagulation



Mitral Valve Repair Techniques



Minimally Invasive Mitral Valve repair



Minimally Invasive Mitral Valve Repair



Minimally Invasive Mitral Valve repair

- More rapid recovery
- Less pain
- Less need for blood transfusions
- More cosmetically appealing
- More quick return to work and full activity

Discussion

Questions & Answers

Thank you
