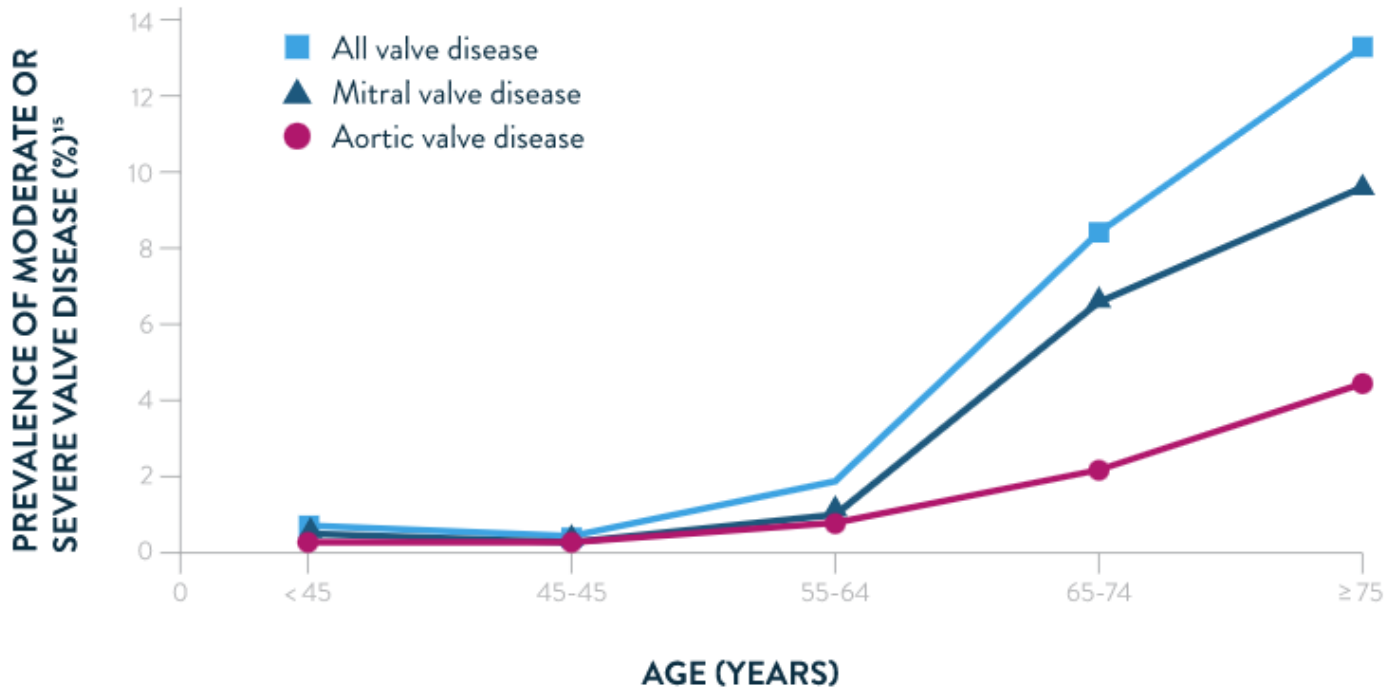
MITRAL REGURGITATION IS SEVERELY UNDER-REFERRED AND UNDER-TREATED

PREVALENCE OF MR

- 2% of the U.S. population has primary MR[5]
- 1 out of 5 heart failure (HF) patients has moderate to severe or severe secondary MR[6-11]



MITRAL REGURGITATION KILLS

If left untreated, MR can initiate a cascade of events leading to heart failure and death, with a 1-year mortality up to 57%.[12]

74% of eligible patients with primary MR were not referred for surgery for valve replacement.[13] Furthermore, nearly 50% of all MR patients will be denied valve replacement surgery due to risks.[14]

When patients symptoms persist despite maximally tolerated medical therapy and surgery is not a viable option, there are minimally invasive options available to treat these patients.


MITRAL REGURGITATION (MR) IS PREVALENT AND GROWING
THE NUMBER OF PEOPLE IN THE UNITED STATES WITH MODERATE TO SEVERE MR IS EXPECTED TO DOUBLE BY 2030[1]
2014
UP TO
2.5
MILLION[1]
2030
UP TO
5
MILLION[1]

There is a new treatment for high-risk patients with MR.

A MINIMALLY INVASIVE PROCEDURE: MITRACLIP THERAPY

For your Mitral Regurgitation patients who are ineligible for surgery or select heart failure patients who remain symptomatic despite guideline-directed medical therapy (GDMT), MitraClip is an important treatment option that can offer improved quality of life.

MEDIAN HOSPITAL STAY
2 DAYS[1]

89%
had MR severity reduction to ≤ 1 + at 1 year[2]

78%
had New York Heart Association (NYHA) Functional Class I or II at 1 year[2]

7.9
number needed to treat secondary MR to prevent 1 death[4]

OVER 100K
PATIENTS TREATED WORLDWIDE*

About the size of a dime

Minimally Invasive Procedure

MINIMALLY INVASIVE

- Percutaneous venous access
- Beating heart procedure (No cardiopulmonary bypass)

REAL-TIME POSITIONING & ASSESSMENT

- Real time MR assessment -Normal Loading conditions
- Repositionable to achieve optimal MR reduction

STABLE PROCEDURE

- Standard Cath lab or hybrid room
- Stable hemodynamics through out procedure

RESULT

- Establishes 7mm Vertical coaptation to reduce MR
- Draws Leaflets together maintaining stable annulus
- Patients are out of the hospital within 2-3 days on average*

MitraClip Clip™ G4 Clip Delivery System Instructions for Use

Test(s) performed by and data on file at Abbott

*Lim_ACC 2020_Contemporary outcomes with MitraClip™ (NTR/XTR) System in Primary Mitral Regurgitation

17

SAVES LIFES

FEWER HOSPITALIZATIONS

PATIENTS FEEL BETTER

MITRACLIP MET ALL PRIMARY ENDPOINTS IN THE COAPT TRIAL[1]

EFFECTIVENESS[1]

Primary endpoint: all heart failure–related hospitalizations within 24 months of follow-up

The annualized rate of all hospitalizations for heart failure was 35.8% per patient-year in the device group as compared with 67.9% per patient-year in the control group (hazard ratio, 0.53; 95% confidence interval [CI], 0.40 to 0.70; $P<0.001$). The number needed to treat to prevent 1 hospitalization for heart failure within 24 months was 3.1 (95% CI, 1.9 to 7.9).

SAFETY[1]

Primary endpoint: freedom from device-related complications through 12 months

The rate of freedom from device-related complications at 12 months was 96.6% (lower 95% confidence limit, 94.8%), a rate that exceeded the objective performance goal of 88.0% for primary safety endpoint ($P<0.001$).

All secondary effectiveness endpoints are powered for superiority of the device group compared with the control group; the secondary safety endpoint of all-cause mortality at 12 months is powered for noninferiority of the device group compared with the control group; the secondary composite safety endpoint all-cause death, stroke, MI, or non-elective (urgent or emergent) cardiovascular surgery for device-related complications at 30 days is powered for noninferiority of the device group compared to a prespecified objective performance goal.

MITRACLIP SAVE LIVES AT YEAR 3[2]

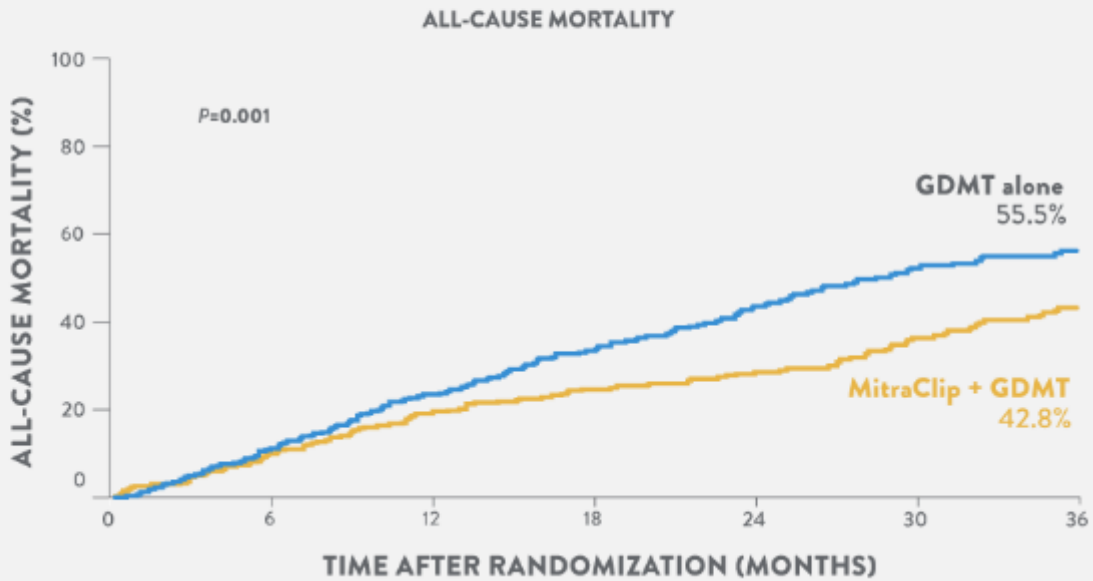
33%

RELATIVE RISK REDUCTION IN MORTALITY[2]

7.9

NEEDED TO TREAT TO PREVENT 1 DEATH[2]

MITRAL REGURGITATION (MR) IS A CAUSE OF DEATH: THE COAPT TRIAL SHOWS THAT MR IS NOT JUST A MARKER[2]



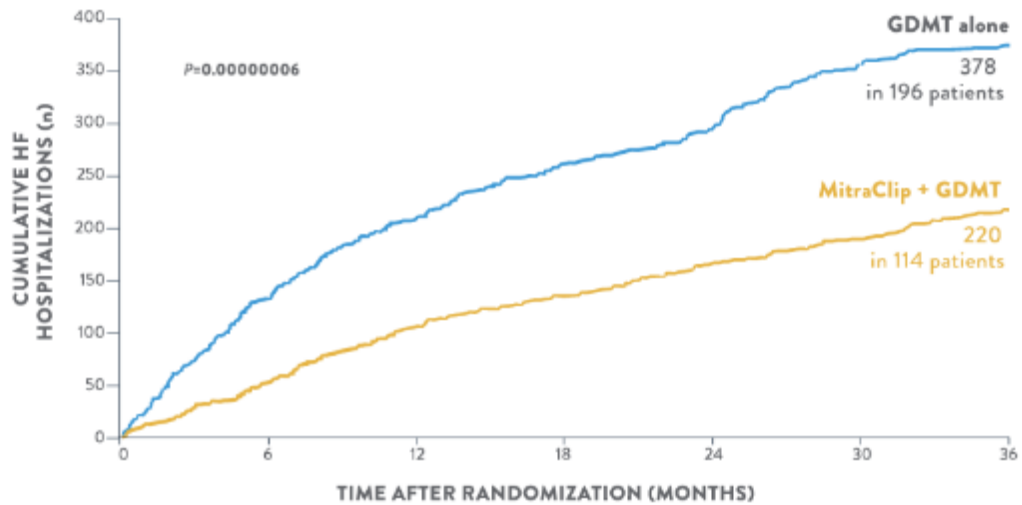
MITRACLIP REDUCES HOSPITALIZATIONS AT YEAR 3[2]

51%

RELATIVE RISK REDUCTION IN HF HOSPITALIZATIONS[2]

3.0

 # NEEDED TO TREAT TO PREVENT 1 HF HOSPITALIZATION[2]

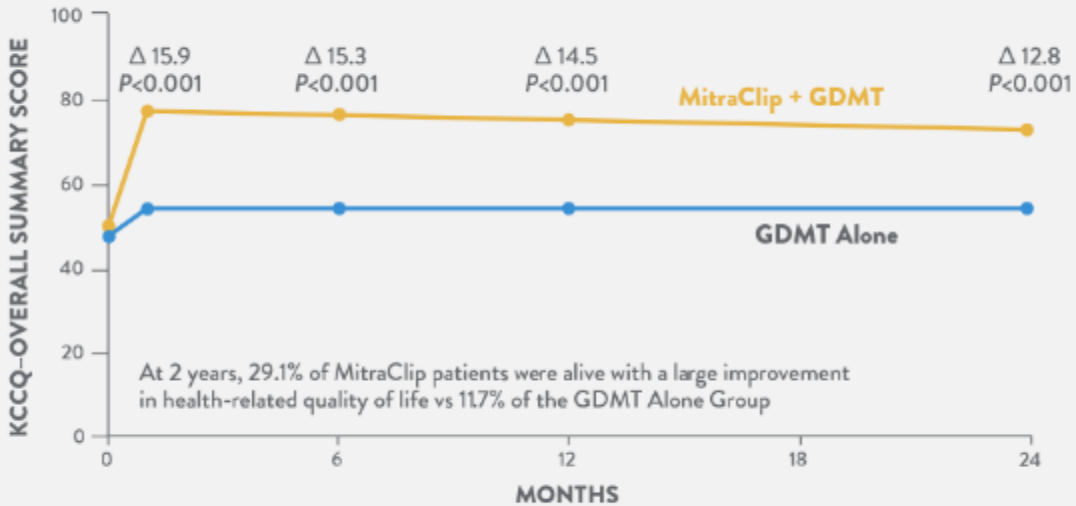


Includes crossover patients (guideline-directed medical therapy [GDMT] only patients that were allowed to cross over to MitraClip after 24 months).

MITRACLIP CHANGES THE COURSE IN PATIENTS' QUALITY OF LIFE[3]

2.5x

MORE LIKELY TO EXPERIENCE A LARGE IMPROVEMENT IN QUALITY OF LIFE WITH MITRACLIP



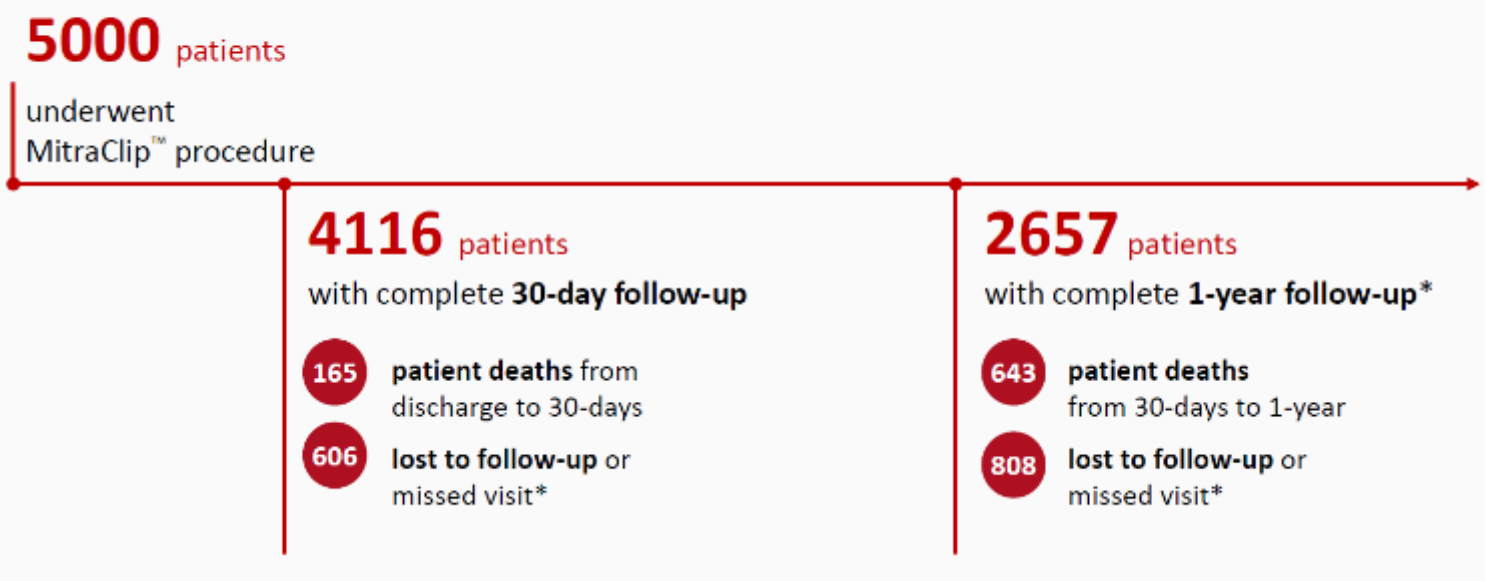
COAPT POST APPROVAL STUDY

OBJECTIVE

To evaluate the **safety and effectiveness** of MitraClip™ in **5000 patients with Secondary MR** in a contemporary real-world setting

Compare the results of **COAPT PAS** with **COAPT-RCT**

Methods: COAPT PAS—Study Population Through 1 Year

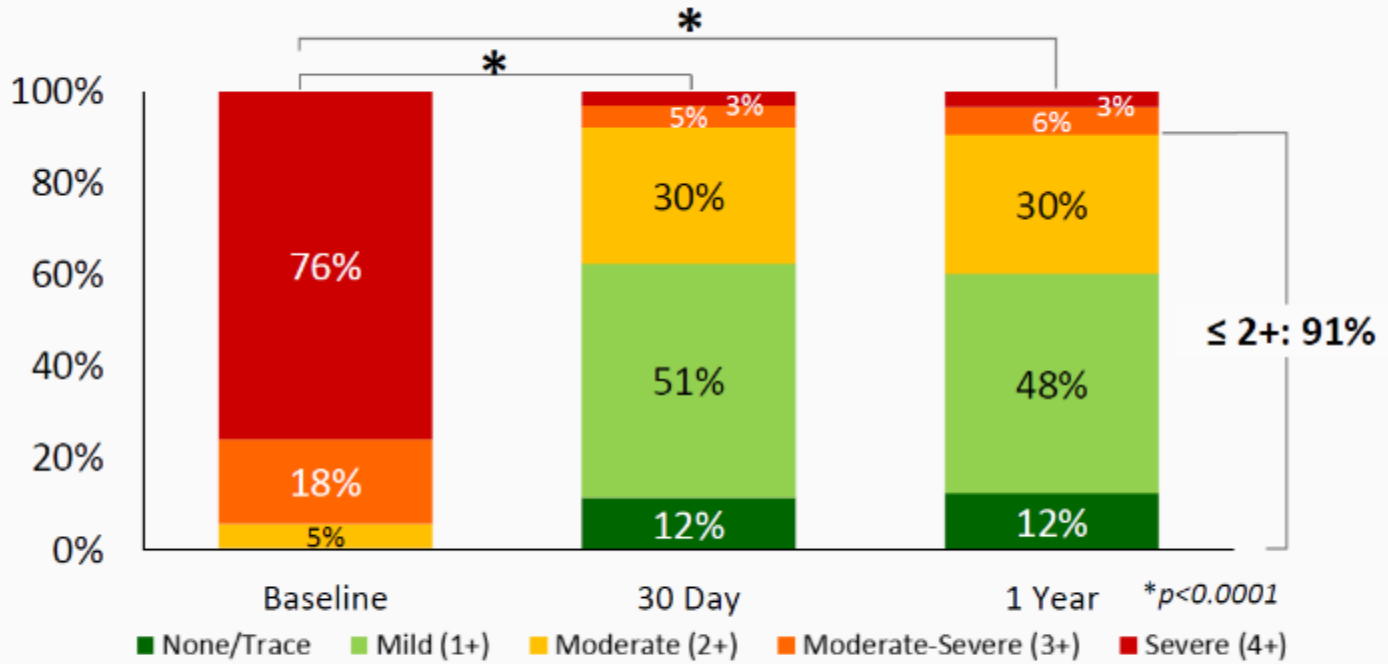


Baseline Characteristics

Demographics, Comorbidities, Echo Measures, Heart Failure (HF) Medications	COAPT RCT MitraClip Arm (N=302)	COAPT PAS (N=5000)
Age (years)	71.7 ± 11.8 (302)	73.1 ± 11.3 (5000)
Female	33.3% (101/302)	42.4% (2120/5000)
Prior MI	51.7% (156/302)	37.6% (1875/4991)
ACE Inhibitors or ARB	67.2% (203/302)	48.2% (2385/4950)
ARN Inhibitors	4.3% (13/302)	9.7% (393/4055)
Beta Blockers	91.1% (275/302)	80.2% (3972/4952)
Diuretics	93.0% (281/302)	83.2% (4123/4953)
Aldosterone Antagonists	50.7% (153/302)	23.6% (1168/4951)

COAPT PAS represents a real-world population of SMR that is older, more often female, has worse functional capacity, frailty, quality of life, MR severity, and less GDMT at baseline

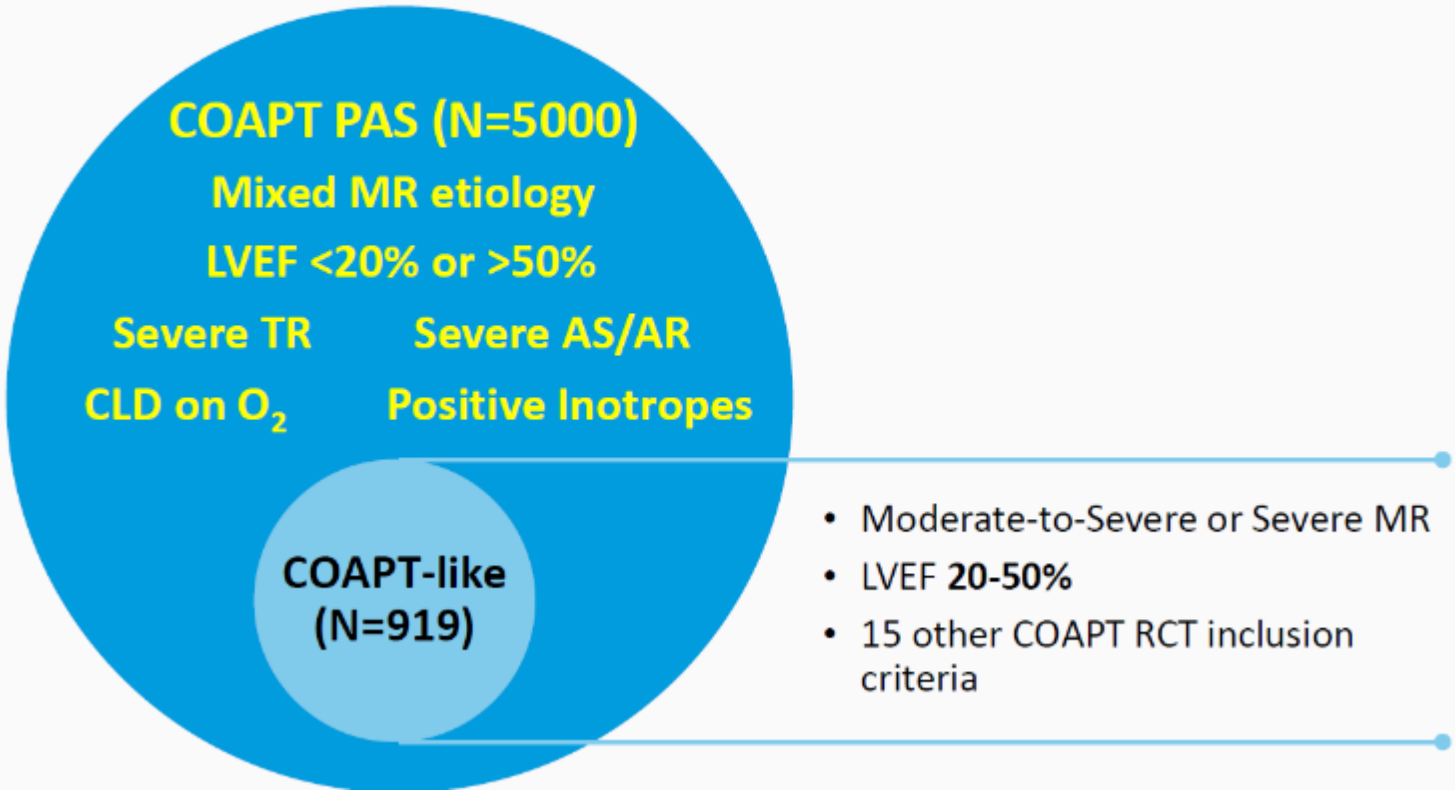
Effective MR Reduction in a Real-World Setting



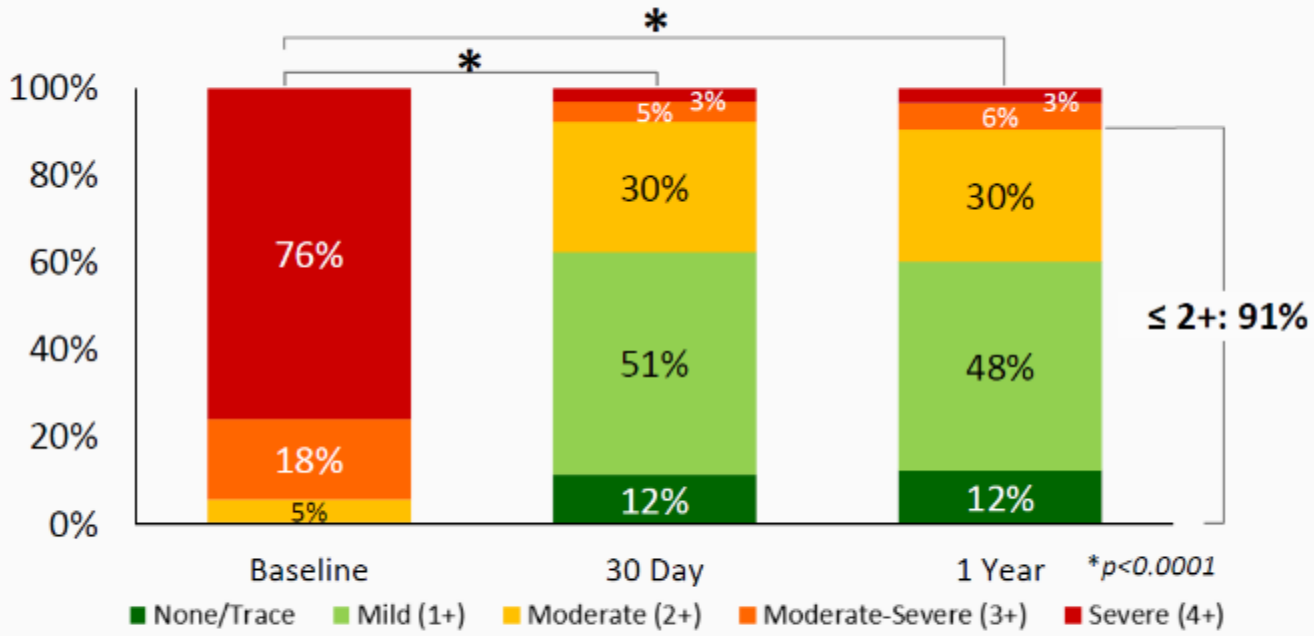
COAPT RCT
MitraClip™ Arm MR
≤2+: 95% at
1 Year from **0%**
at baseline (assessed
by Core Lab)

Patients in COAPT PAS had high proportion of severe MR and achieved significant MR reduction to ≤ 2+ at 1 year following treatment with MitraClip

COAPT PAS Represents a Broad Range of Patients



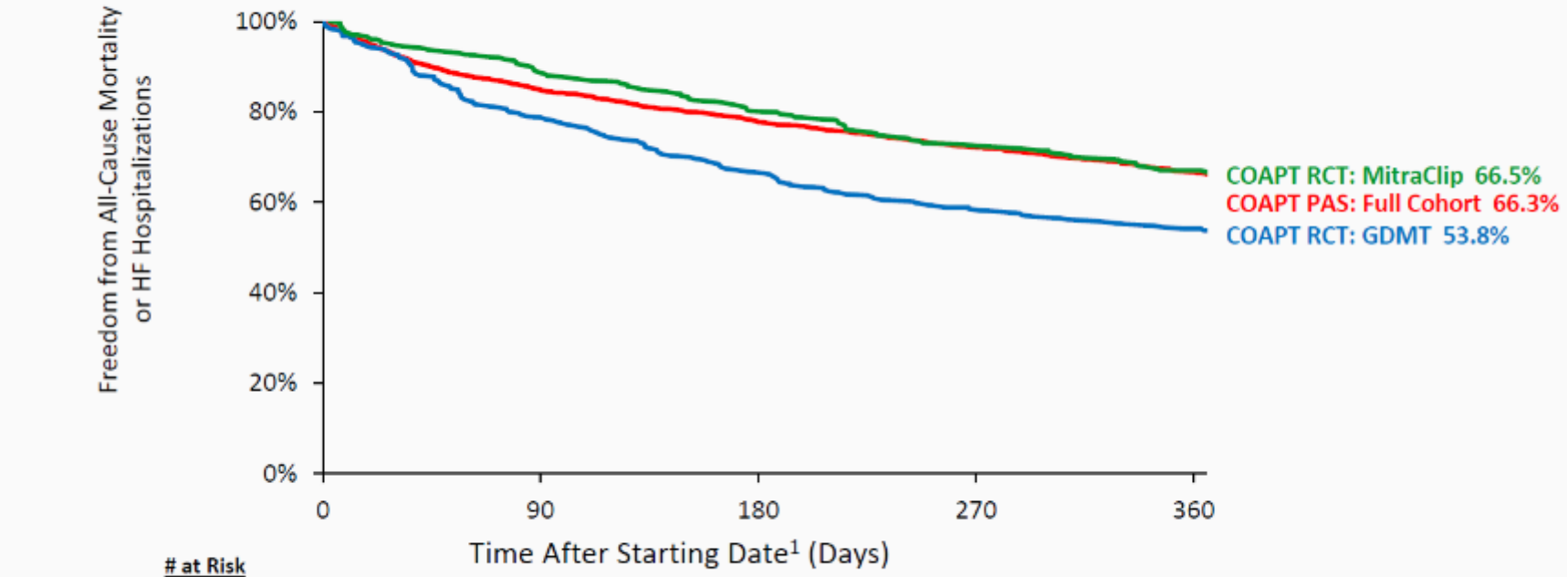
Effective MR Reduction in a Real-World Setting



COAPT RCT
MitraClip™ Arm MR
≤2+: 95% at
1 Year from **0%**
at baseline (assessed
by Core Lab)

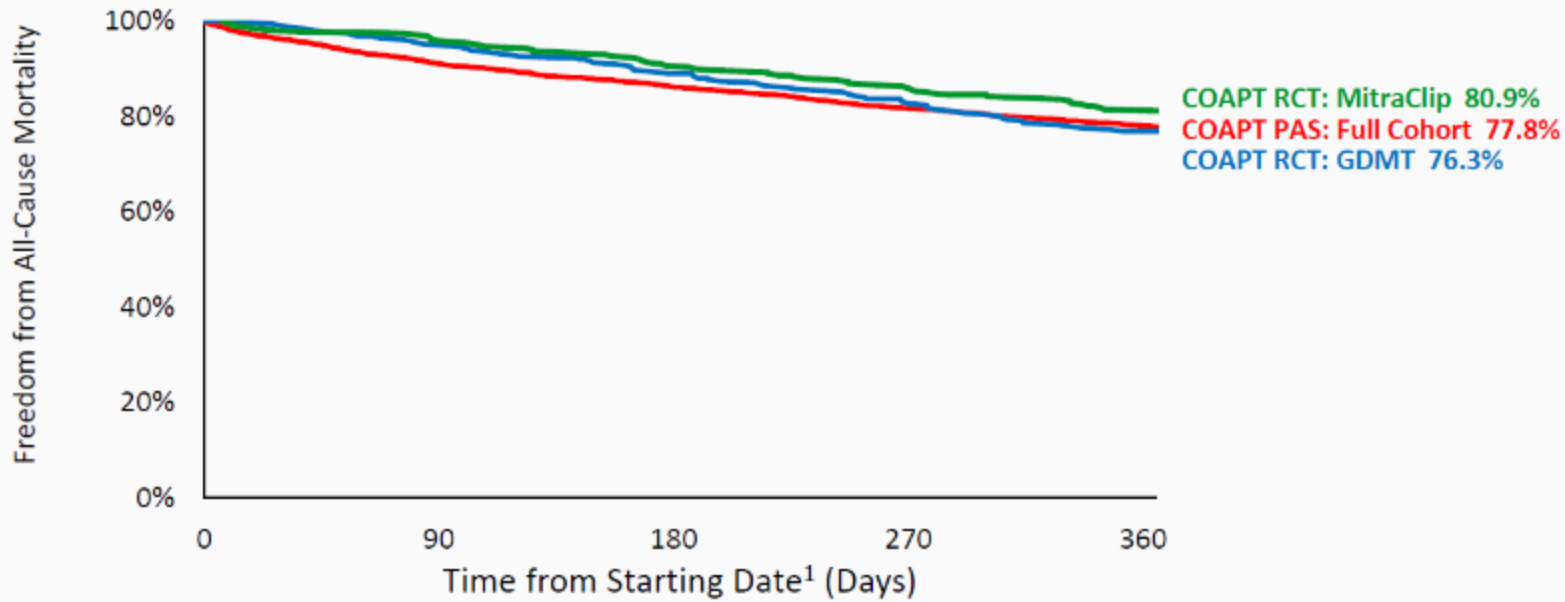
Patients in COAPT PAS had high proportion of severe MR and achieved significant MR reduction to ≤ 2+ at 1 year following treatment with MitraClip

Freedom from All-Cause Mortality or HF Hospitalizations



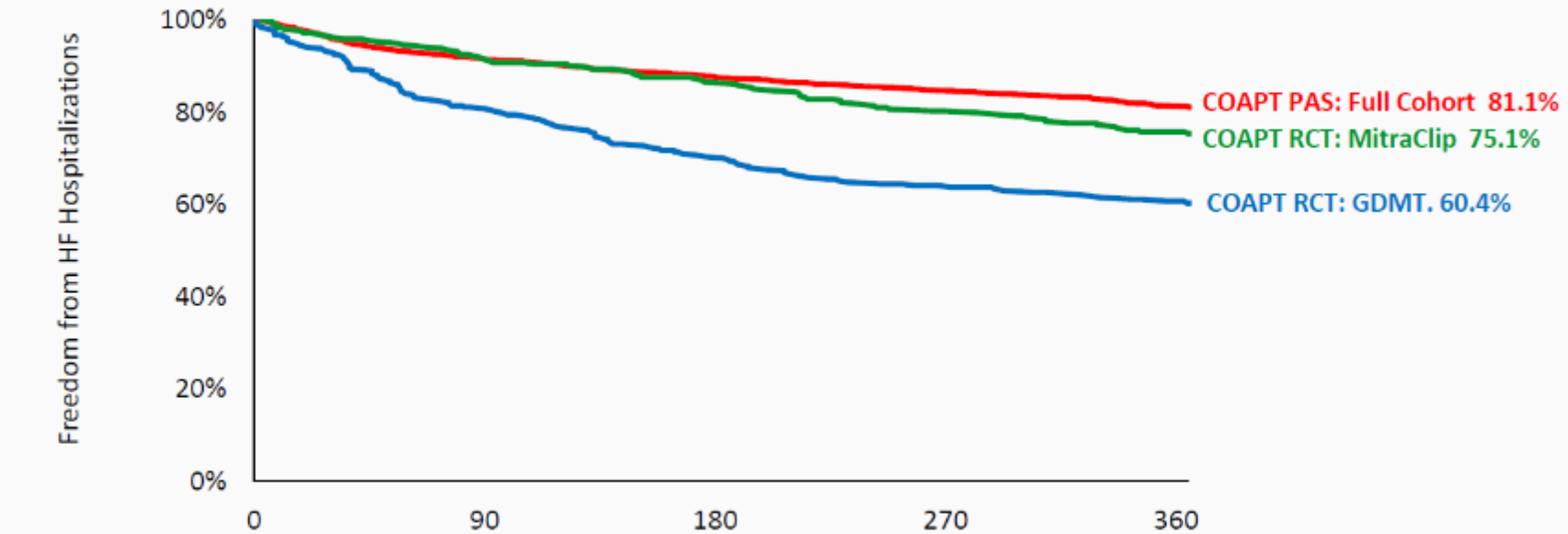
# at Risk					
COAPT RCT: MitraClip	302	265	238	216	196
COAPT PAS	5000	3217	2923	2700	1834
COAPT RCT: GDMT	312	245	206	176	156

Freedom from All-Cause Mortality Through 1 Year



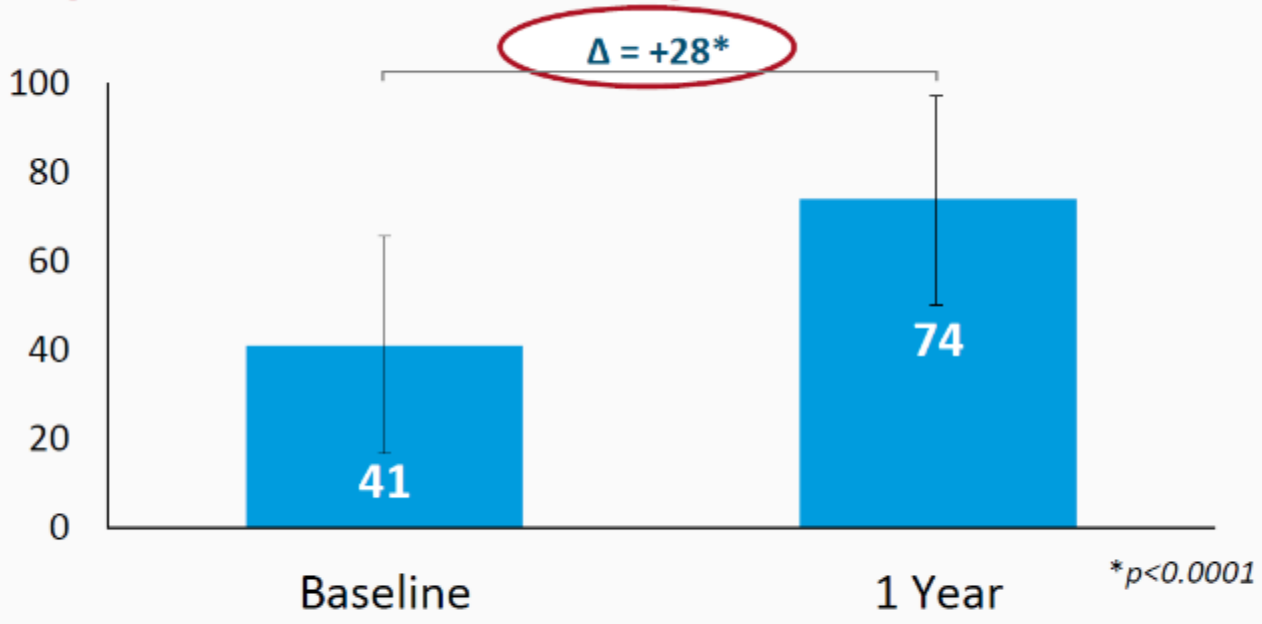
# at Risk					
COAPT RCT: MitraClip	302	286	269	255	238
COAPT PAS	5000	3435	3218	3036	2114
COAPT RCT: GDMT	312	294	272	247	223

Freedom from HF Hospitalizations Through 1 Year



# at Risk					
COAPT RCT: MitraClip	302	265	238	216	196
COAPT PAS	5000	3217	2923	2700	1834
COAPT RCT: GDMT	312	245	206	176	156

Improvement in Quality of Life: KCCQ Score



COAPT RCT

MitraClip KCCQ score

53 → 72

Δ = +17

Patients in COAPT PAS had lower baseline quality of life yet achieved significant improvement in quality of life at 1 year following MitraClip

Conclusions

COAPT PAS—**Largest prospective observational study** to report **1-year clinical outcomes from 5000 patients with SMR** treated with MitraClip™ in a **contemporary, real-world setting** following COAPT RCT and FDA approval

Despite the presence of more comorbidities, worse functional capacity, quality of life, MR severity, and less GDMT at baseline compared with COAPT RCT MitraClip arm, COAPT-PAS patients achieved:

- **Similar reduction in the combined endpoint of all-cause mortality/HFH**
- Significant improvement in quality of life and symptoms at 1 year
- Significant and durable reduction in MR grade to ≤2+ (91%) at 1 year
- Faster procedure times with low adverse event rates

2020 ACC/AHA GUIDELINE FOR VALVULAR HEART DISEASE RECOMMENDS TEER FOR PRIMARY AND NOW, SECONDARY MR PATIENTS

"**A mitral transcatheter edge-to-edge repair is of benefit to patients** with severely symptomatic primary mitral regurgitation who are at high or prohibitive risk for surgery, as well as to a select subset of patients with secondary mitral regurgitation who remain severely symptomatic despite guideline-directed management and therapy for heart failure."[1]

TEER IS AN UPGRADED CLASS 2A RECOMMENDATION FOR SELECT PRIMARY MR PATIENTS

Class 2A, LOE B-NR

In severely symptomatic patients (NYHA class III or IV) with primary severe MR and high or prohibitive surgical risk, transcatheter edge-to-edge repair (TEER) is reasonable if mitral valve anatomy is favorable for the repair procedure and patient life expectancy is at least 1 year.

TEER IS A NEW CLASS 2A RECOMMENDATION FOR SELECT SECONDARY MR PATIENTS

Class 2A, LOE B-R

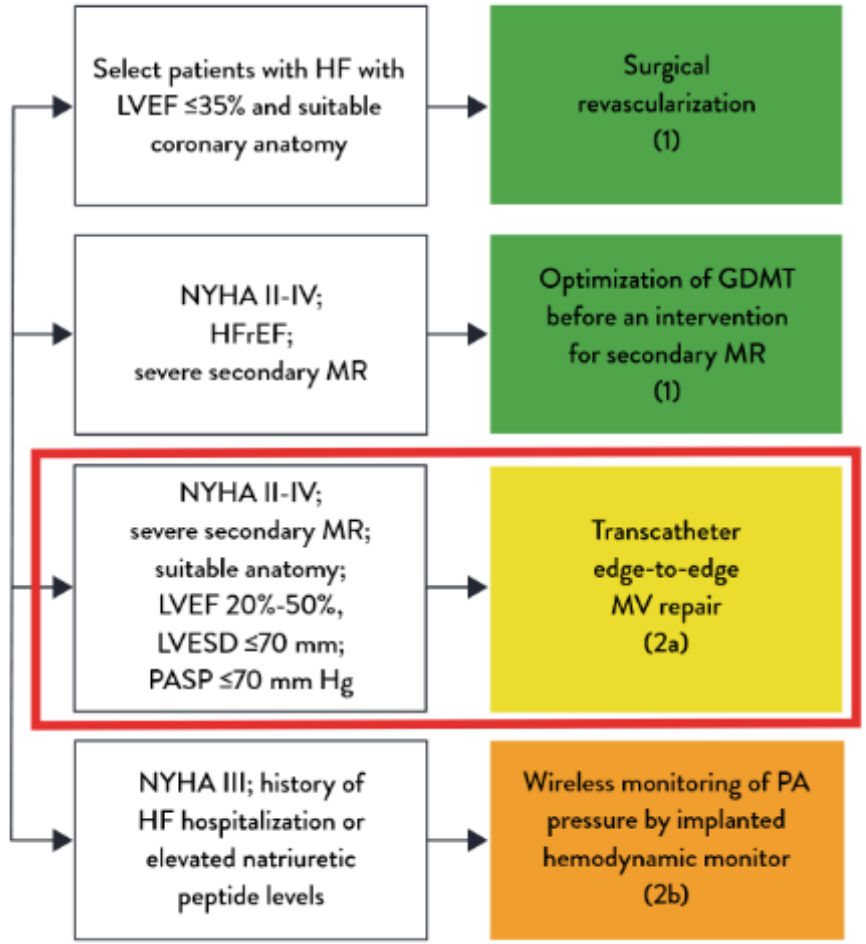
In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF < 50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal GDMT for HF (Stage D), TEER is reasonable in patients with appropriate anatomy as defined on TEE and with LVEF between 20% and 50%, LVESD ≤ 70 mm, and pulmonary artery systolic pressure ≤ 70 mm Hg.

In April 2022, the American Heart Association (AHA), American College of Cardiology (ACC) and Heart Failure Society of America (HFSA) formally updated their clinical practice guideline[1] for the management of patients with heart failure.

Key highlights regarding TEER include:

TEER has been strengthened to a Class 2a recommendation for COAPT-like* Secondary MR Patients, reinforcing the 2020 Valvular Heart Disease Guideline[2].

FIGURE 9. CONSIDER ADDITIONAL THERAPIES ONCE GDMT OPTIMIZED

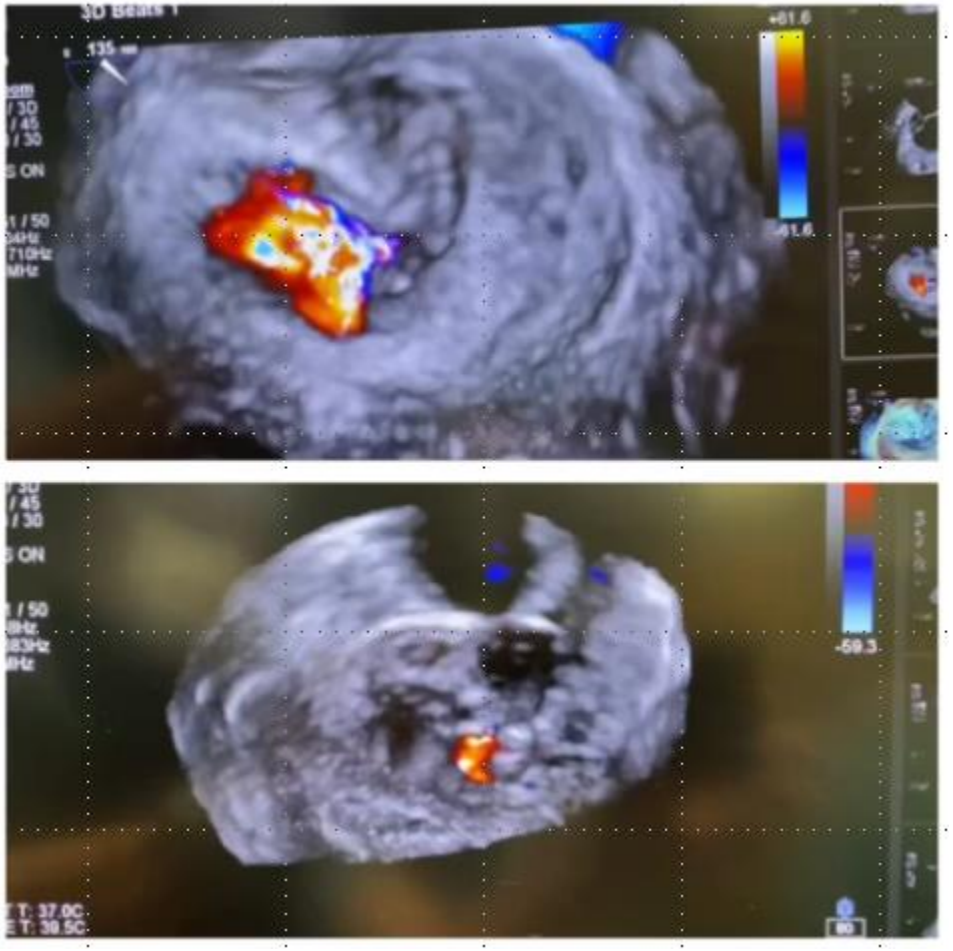


PROCEDURE DETAILS

- **Procedure was performed in the cath lab under general anesthesia – one interventional cardiologist, 2 cardiac anesthesiologists.**
- **Visualization via fluoroscopy and transesophageal echocardiography.**
- **Procedure Time: ~ 40 minutes.**
- **Successful reduction of MR from 4+ to 1+ using MitraClip x 1.**
- **Complications: None.**

TEE COMPARISON:

Pre & Post MitraClip



POST OP COURSE

Uncomplicated.

Immediate improvement in shortness of breath post procedure.

Discharged home the following day in stable condition.

No readmissions, recurrent CHF symptoms post operatively.


ROPER ST. FRANCIS
HEALTHCARE
MitraClip Patient