COAPT™ TRIAL

CHANGE THE COURSE OF HEART FAILURE

FOR SELECT HEART FAILURE PATIENTS WITH CLINICALLY SIGNIFICANT SECONDARY MITRAL REGURGITATION

Scan the QR code with your mobile device to learn more about mitral regurgitation

Abbott

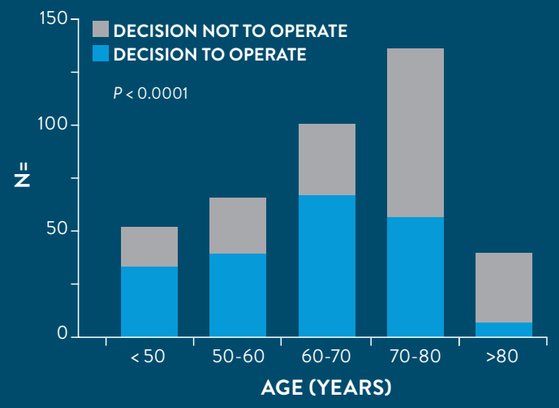
VASTLY UNDERTREATED. IMPACTING SURVIVAL.

HIGHLY PREVALENT[1]

1 in 5 of your heart failure patients have moderate-to-severe and severe secondary MR.[1-6*]

VASTLY UNDERTREATED

SURGICAL INTERVENTION NOT OFFERED OR DENIED**

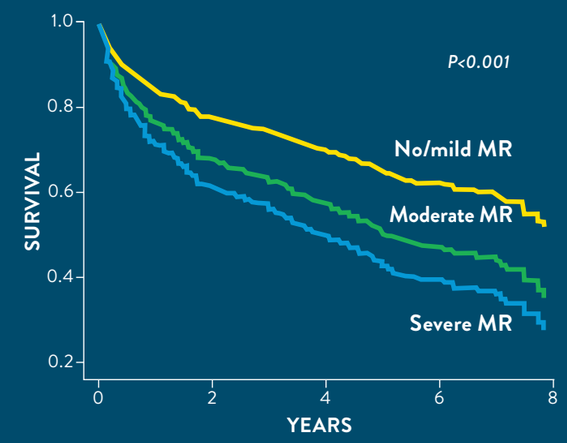


49% of patients with symptomatic severe MR were not operated due to age, co-morbidities, or impaired LV.[7]

SIGNIFICANT IMPACT ON MORTALITY

If left untreated, MR initiates a cascade of events leading to death.

SEVERE SECONDARY MR IS AN INDEPENDENT PREDICTOR OF MORTALITY[11]



Heart failure (HF) patients with severe secondary MR have an even poorer prognosis.[11]

*Heart Failure patients with reduced EF and with moderate to severe and severe secondary MR.
**Based on a survey of severely symptomatic MR patients in NYHA Class III-IV (n = 396); 10% had surgery the following year. The remainder had no surgery; medical management only.

WHAT ARE THE SYMPTOMS OF MR?

In some cases, patients may have MR but not experience any symptoms. In other cases, patients may develop symptoms of heart failure such as:[12-14]

- Fatigue
- Inability to exercise
- Decrease in appetite
- Dry, hacking cough (often worse when lying down)
- Shortness of breath (especially at night)
- Fainting
- Weight gain from retaining fluid
- Accumulation of fluid in feet, ankles, and lungs (edema)

WHAT ARE THE TREATMENT OPTIONS?

MEDICATIONS

A number of medical therapies are available that can treat the symptoms of MR, but they do not address the underlying pathology.[15] Patients with heart failure and clinically significant mitral regurgitation are on guideline-directed medical therapy (GDMT).

SURGERY (PRIMARY MR)

Surgical management, in the form of mitral valve repair or replacement, is the standard of care for patients with severe primary mitral regurgitation. However, up to 50% of patients with MR may not meet the eligibility criteria due to risks associated with age or the presence of comorbidities.[16] For patients with severe secondary mitral regurgitation, guideline-directed medical therapy is the current standard of care.

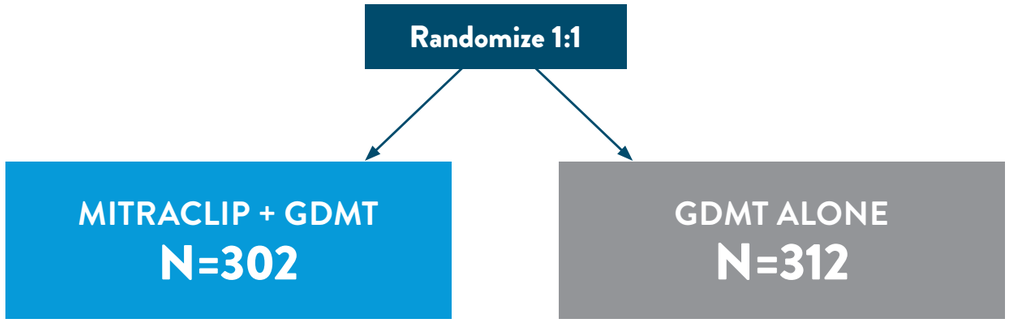
CARDIAC RESYNCHRONISATION THERAPY (SECONDARY MR)

Cardiac resynchronisation therapy is an option recommended for select HF patients.[7]

TRANSCATHETER MITRAL VALVE REPAIR (TMVr) WITH MITRACLIP

TMVr is a minimally invasive mitral valve repair option for patients with MR who are not considered to be suitable candidates for surgery.[12] MitraClip is the only minimally invasive repair option that is included in the ESC heart valve guidelines.[12-14]

A LANDMARK STUDY. TO ESTABLISH A NEW STANDARD OF CARE.[17]



Published in the New England Journal of Medicine, the COAPT Trial was a parallel-controlled, open-label, multicenter trial in 614 patients with heart failure and moderate-to-severe (3+) or severe (4+) secondary MR who remained symptomatic despite maximally-tolerated GDMT.[17]

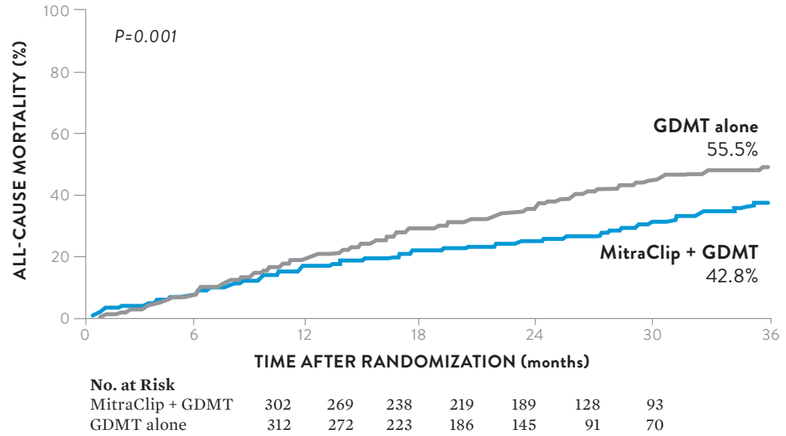
PRIMARY ENDPOINTS:

Effectiveness: All HF hospitalizations through 24 months, analyzed when last patient completes 12-month follow-up

Reduces Complications: 96.6% reported freedom from device-related complications through 12 months

MR KILLS—THE COAPT TRIAL SHOWS THAT IT IS NOT JUST A MARKER

MITRACLIP THERAPY SAVES LIVES[18]

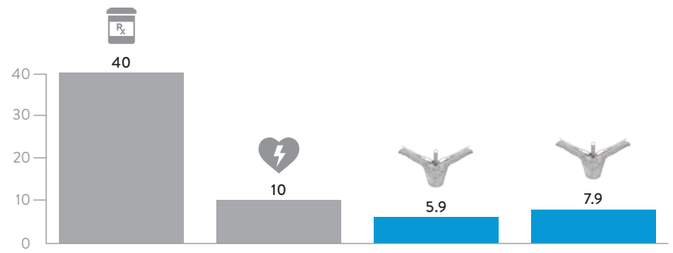


No. at Risk							
MitraClip + GDMT	302	269	238	219	189	128	93
GDMT alone	312	272	223	186	145	91	70

33%

RELATIVE RISK REDUCTION IN MORTALITY

NUMBER NEEDED TO TREAT (NNT) TO PREVENT ONE DEATH FROM ANY CAUSE*



Trial Name:	PARADIGM-HF[19]	CARE-HF[20]	COAPT[17]	COAPT[18]
Mean Follow-up:	27 Months	29.4 Months	19.1 Months**	22.9 Months
Drug/Device Name:	Entresto (GDMT)	CRT + GDMT	MitraClip + GDMT	MitraClip + GDMT

7.9

NUMBER NEEDED TO TREAT TO PREVENT ONE DEATH

*Data from different trials with similar follow up periods; incremental benefits due to test drug/device above background therapy.
**Median follow-up duration.

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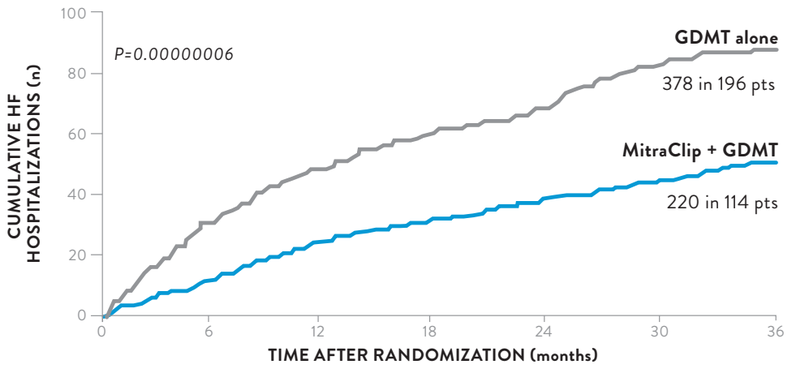
MITRACLIP IS THE ONLY DEVICE THERAPY SHOWN TO IMPROVE SURVIVAL OF HEART FAILURE PATIENTS WITH SECONDARY MR[17]

REDUCES HOSPITALIZATIONS FOR HF[18]



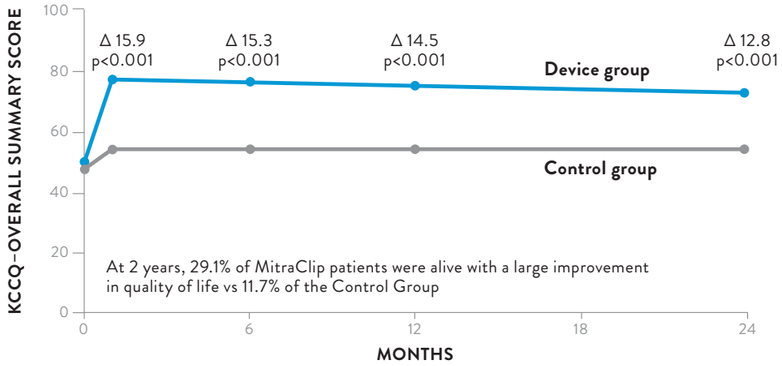
No. at Risk

MitraClip + GDMT	302	269	238	219	189	128	93
GDMT alone	312	272	223	185	144	89	68

51%
RELATIVE RISK REDUCTION IN HEART FAILURE HOSPITALIZATIONS

3.0
NUMBER NEEDED TO TREAT TO PREVENT ONE HEART FAILURE HOSPITALIZATION

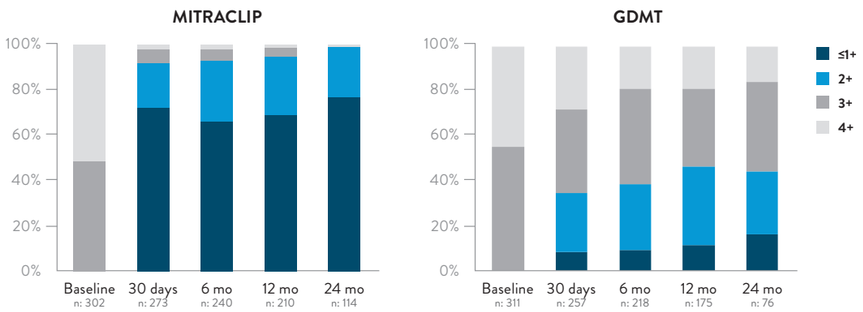
IMPROVES QUALITY OF LIFE[21]



2.5X
MORE LIKELY TO EXPERIENCE A LARGE IMPROVEMENT IN QUALITY OF LIFE WITH MITRACLIP

Note: KCCQ Minimum for Clinically Important Difference (MCID)= 5 points; Large Improvement Defined as ≥20 Points in KCCQ from baseline; quality of life is assessed only in surviving patients

PROVIDES DURABLE MR REDUCTION[17]



Note: Unpaired data

99.1%
OF MITRACLIP PATIENTS HAD MR ≤ 2+ AT 24 MONTHS

96.6%
FREEDOM FROM DEVICE RELATED COMPLICATIONS AT 12 MONTHS

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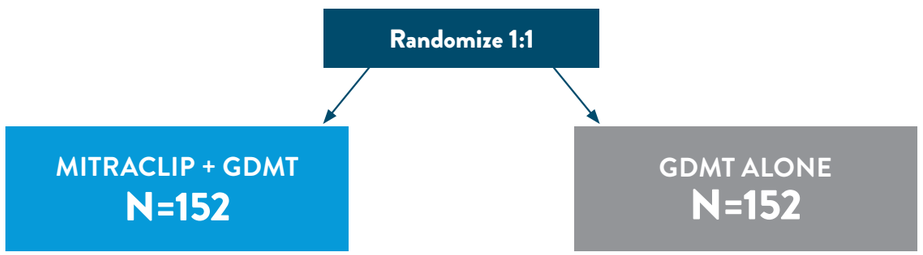
WHAT IS THE MITRA-FR TRIAL AND WHY ARE THE RESULTS DIFFERENT FROM COAPT?

THE MITRA-FR TRIAL[22]



- The MITRA-FR trial was an independent multicenter, randomized, open-label, controlled phase 3 trial that was conducted in France
- Hospices Civils de Lyon, a public academic institution assumed overall responsibility for the trial
- Primary funding was provided by the French Ministry of Health and Research National Program
- Abbott provided the devices

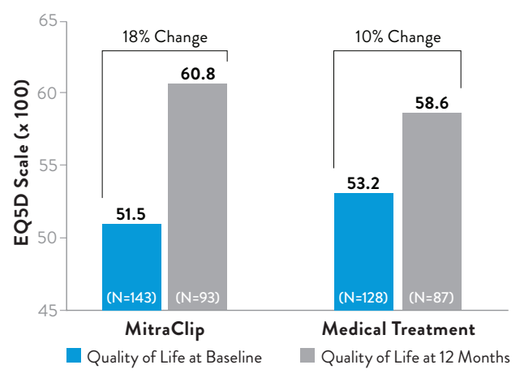
PRIMARY ENDPOINT:

- All cause deaths or unplanned hospitalization for heart failure at 12 month

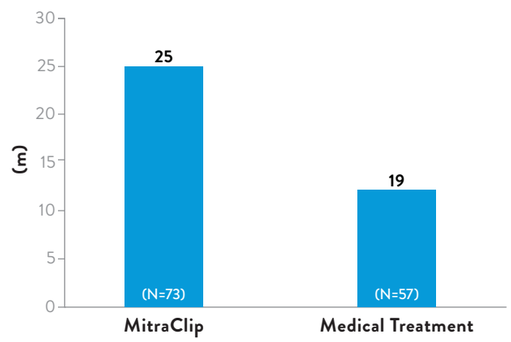
HOWEVER, QUALITY OF LIFE IMPROVED IN THE MITRACLIP GROUP[22]

The Quality of Life score (according to the EQ5D scale developed by the EuroQol group) and the 6 Minute Walk Test Distance were higher at 12 months in the MitraClip group than in the control group at 12 months.

QUALITY OF LIFE SCORE AT BASELINE AND 12 MONTHS



IMPROVEMENT IN 6 MINUTE WALK DISTANCE RELATIVE TO BASELINE AT 12 MONTHS



MITRA-FR AND COAPT ARE 2 DIFFERENT TRIALS THAT STUDIED 2 DIFFERENT PATIENT GROUPS[23]

	MITRA-FR	COAPT
Severe MR entry criteria	Severe SMR by EU guidelines: EROA >20 mm^2 or RV >30 mL/beat	Severe SMR by US guidelines: EROA >30 mm^2 or RV >45 mL/beat
% of patients with an EROA <0.3 cm^2	52%	14%
LVEDV	70% of patients had an LV EDD >65 mm	Exclusion criteria of patients with LVESD >70mm
GDMT at baseline and FU	Receiving HF meds at baseline—allowed variable adjustment in each group during follow-up per "real-world" practice	CEC confirmed pts were failing maximally-tolerated GDMT at baseline—few major changes during follow-up
Acute results: No clip / ≥3+ MR	9% / 9%	5% / 5%
Procedural complications*	14.6%	8.5%
12-mo MitraClip ≥3+ MR	17%	5%
Mortality outcomes	No difference in device vs control group	38% reduction

*MITRA-FR definition: device implant failure, transfusion or vascular complications requiring surgery, ASD, card shock, cardiac embolism/stroke, tamponade, urgent cardiac surgery

CLINICAL BENEFITS FOR BROAD RANGE OF PATIENTS WITH SMR ARE DEMONSTRATED WITH MITRACLIP[22]

PATIENT SUBGROUP		Clinical Outcomes
EROA > 0.30 cm^2 or LVEDVi ≤ 96 mL/m^2 [90% of COAPT Pts]	COAPT[17]	Reduces MR, reduces heart failure hospitalizations, improves survival, quality of life, and functional capacity
EROA ≤ 0.30 cm^2 or LVEDVi > 96 mL/m^2 [10% of COAPT Pts]	COAPT[17] (MITRA-FR like)	Improves quality of life and functional capacity
EROA > 0.20 cm^2 LVEDVi 135 ± 35 mL/m^2	MITRA-FR[22]	Reduces MR, improves quality of life and functional capacity*
Broad range of patients with SMR	EVEREST II[24-25], ACCESS-EU[26-28], REALISM[29-30], TRAMI[31-33]	Reduces MR, reduces heart failure hospitalizations, improves quality of life, and functional capacity

*Table 56, Supplement to Obadia JF et al. Percutaneous repair or medical treatment for secondary regurgitation. *N Engl J Med* 2018; 379:2297-2306.

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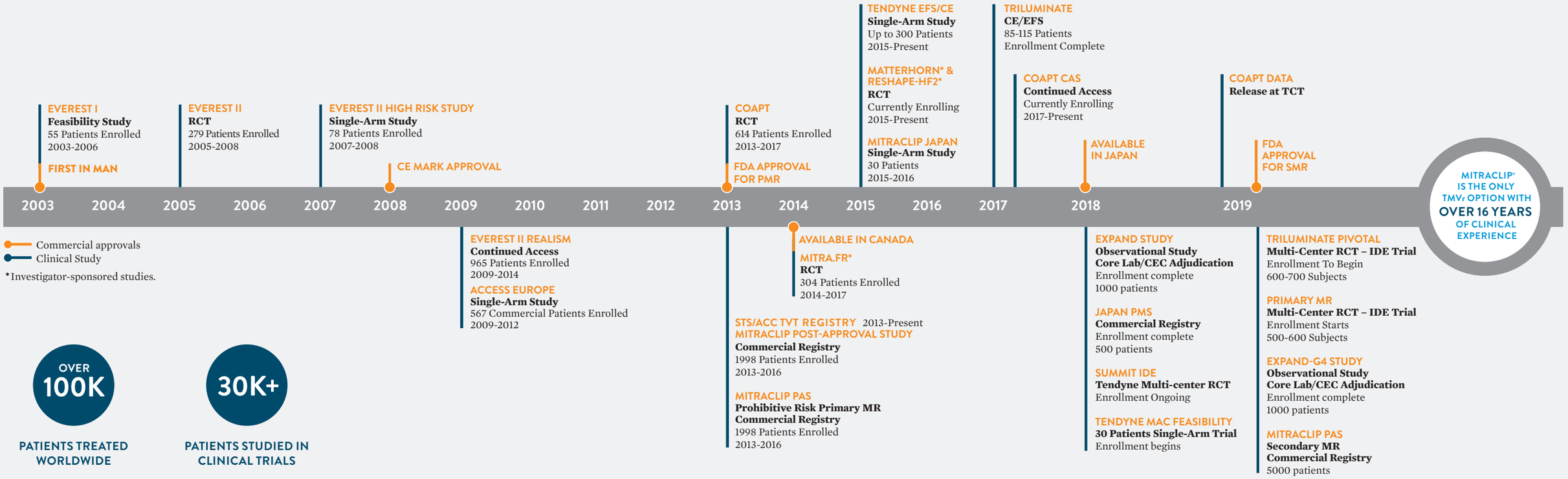
GLOBALLY, MITRACLIP HAS OVER 16 YEARS OF CLINICAL EXPERIENCE[34]



TAKING ACTION FOR MR PATIENTS

PATIENT TREATMENT PATHWAY

1 IDENTIFY MITRACLIP CANDIDATES FOR EVALUATION

Candidates for MitraClip therapy should meet the following criteria:[35]

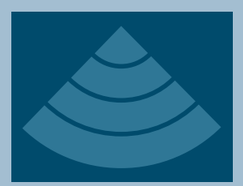
- ✓ Significant MR
- ✓ Severely symptomatic
- ✓ Symptoms and MR severity persist despite maximally-tolerated GDMT
- ✓ Not suitable for surgery because of age or severe comorbidities such as liver disease and pulmonary hypertension

A diagnosis of severe MR is based on multiple parameters, including:[19]

- Valve anatomy
- Regurgitant severity
- Left ventricular size
- Systolic function

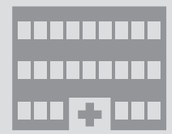
2 SEND TRANSTHORACIC ECHO (TTE) TO ASSIST IN EVALUATIONS

Send patients to a MitraClip Center with TTE views to ensure efficient analysis of the mitral valve and to assess initial anatomic eligibility of MitraClip therapy.



3 CONSULT A TRANSCATHETER MITRAL VALVE REPAIR (TMVr) CENTER

The 2016 ESC/HF and 2017 ESC/EACTS guidelines recommend that complex patients like those with severe, symptomatic MR be evaluated by a Heart Valve Center of Excellence, such as a MitraClip Center.[19]



ASK YOUR MITRACLIP REPRESENTATIVE FOR A LIST OF TMVr CENTERS NEAR YOU.

Structural Heart

Hear the murmur

A MITRAL REGURGITATION
MOBILE EXPERIENCE
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