A LANDMARK STUDY TO ESTABLISH A NEW STANDARD OF CARE

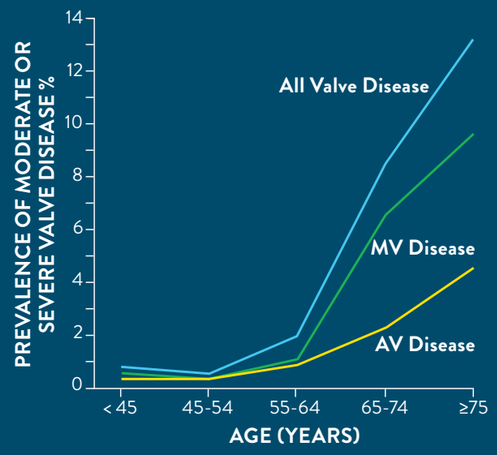
TRANSCATHETER MITRAL VALVE REPAIR WITH MITRACLIP™ THERAPY

Abbott

MITRAL REGURGITATION:

VASTLY UNDERTREATED. IMPACTING SURVIVAL.

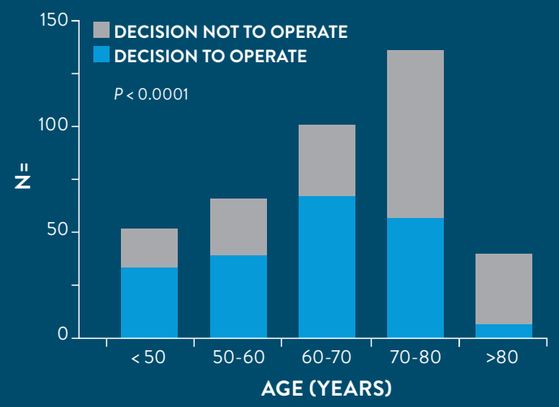
HIGHLY PREVALENT[1]



The prevalence of mitral valve disease is **2-3x** greater than that of aortic valve disease, with over 4 million patients suffering from moderate or severe MR in the U.S. alone.[1-3]

VASTLY UNDERTREATED

SURGICAL INTERVENTION NOT OFFERED OR DENIED*

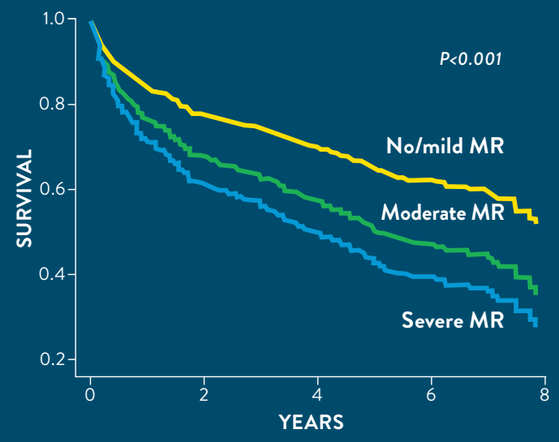


49% of patients with symptomatic severe MR were not operated due to age, co-morbidities, or impaired LV.[4]

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[8]



Heart failure (HF) patients with severe secondary MR have an even poorer prognosis.[8]

*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.

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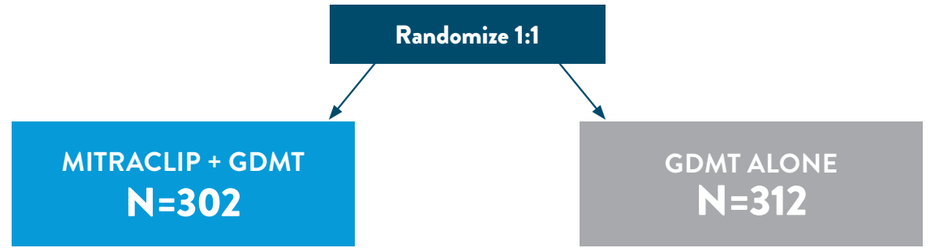
COAPT™ TRIAL

A LANDMARK STUDY IN THE MANAGEMENT OF HEART FAILURE



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.[9]

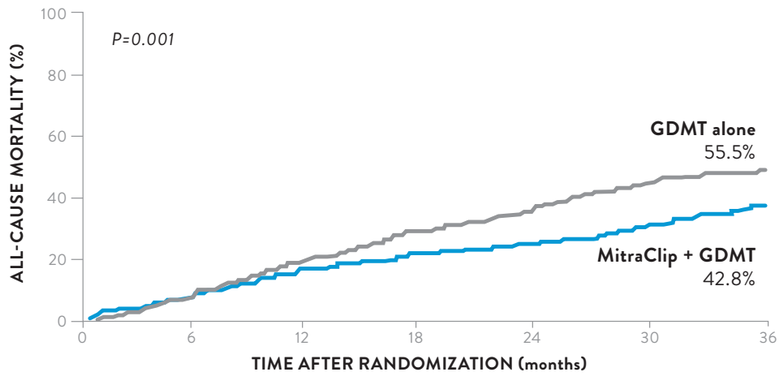
PRIMARY ENDPOINTS

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[10]



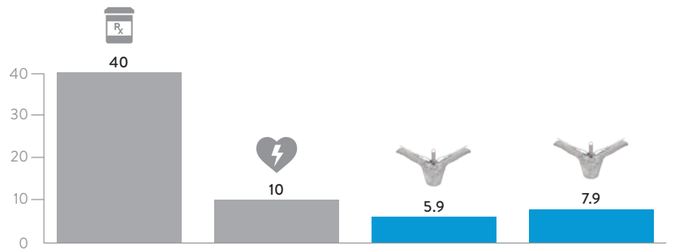
No. at Risk							
MitraClip + GDMT	302	269	238	219	189	128	93
GDMT alone	312	272	223	186	145	91	70

33%
RELATIVE RISK REDUCTION IN MORTALITY

7.9
NUMBER NEEDED TO TREAT TO PREVENT ONE DEATH

MITRACLIP IS THE ONLY MITRAL VALVE DEVICE SHOWN TO IMPROVE SURVIVAL OF HEART FAILURE PATIENTS WITH SECONDARY MR[9]

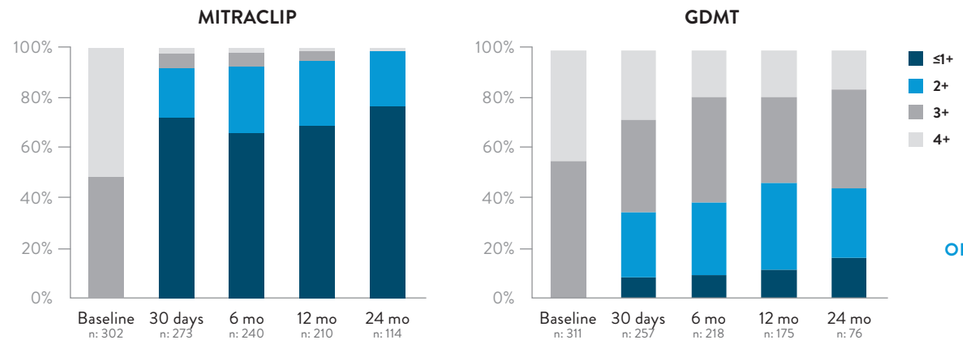
NUMBER NEEDED TO TREAT (NNT) TO PREVENT ONE DEATH FROM ANY CAUSE*



Trial Name:	PARADIGM-HF[11]	CARE-HF[12]	COAPT[9]	COAPT[10]
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

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

PROVIDES DURABLE MR REDUCTION[9]



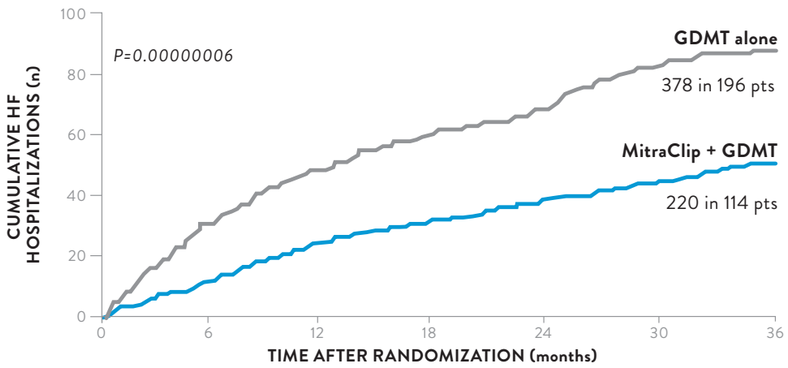
99.1%

OF MITRACLIP PATIENTS HAD MR ≤ 2+ AT 24 MONTHS

Note: Unpaired data

REDUCES HOSPITALIZATIONS FOR HF[10]

HEART FAILURE HOSPITALIZATIONS ARE THE LEADING COST BURDEN TO THE HOSPITAL AND HEALTH CARE SYSTEM.



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

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

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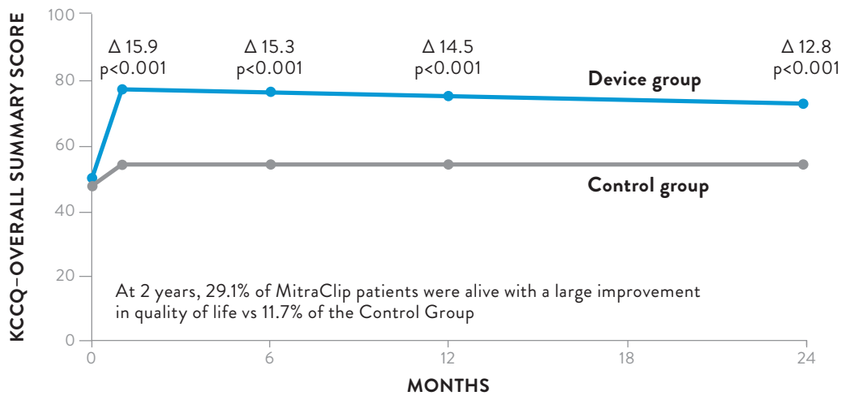
IMPROVES QUALITY OF LIFE[13]



2.5X

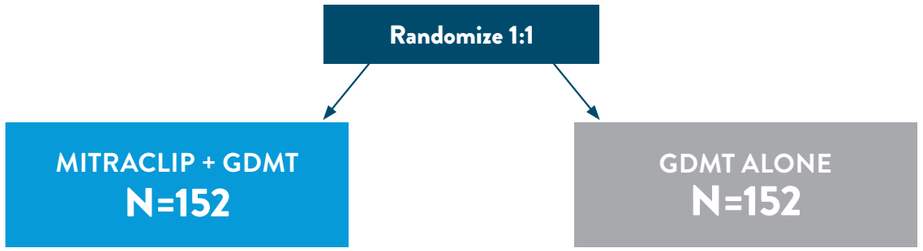
MORE LIKELY TO EXPERIENCE A LARGE IMPROVEMENT IN QUALITY OF LIFE WITH MITRACLIP

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

96.6% FREEDOM FROM DEVICE RELATED COMPLICATIONS AT 12 MONTHS

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

THE MITRA-FR TRIAL[14]



- 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

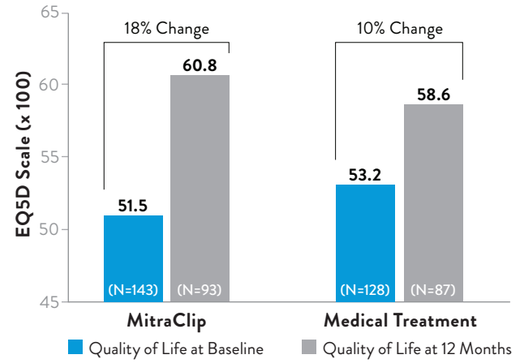
PRIMARY ENDPOINT:

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

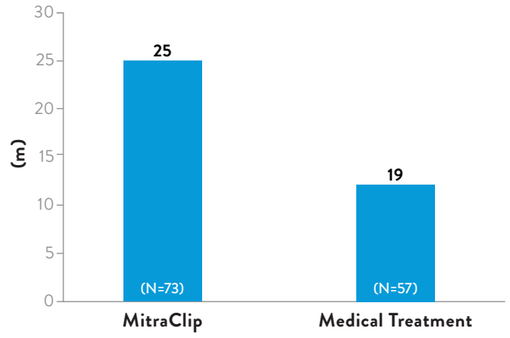
HOWEVER, QUALITY OF LIFE IMPROVED IN THE MITRACLIP GROUP[14]

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[15]

	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[14]

PATIENT SUBGROUP		Clinical Outcomes
EROA > 0.30 cm^2 or LVEDVi ≤ 96 mL/m^2 [90% of COAPT Pts]	COAPT[9]	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[9] (MITRA-FR like)	Improves quality of life and functional capacity
EROA > 0.20 cm^2 LVEDVi 135 ± 35 mL/m^2	MITRA-FR[14]	Reduces MR, improves quality of life and functional capacity*
Broad range of patients with SMR	EVEREST II[16-17], ACCESS-EU[18-20], REALISM[21-22], TRAMI[23-25]	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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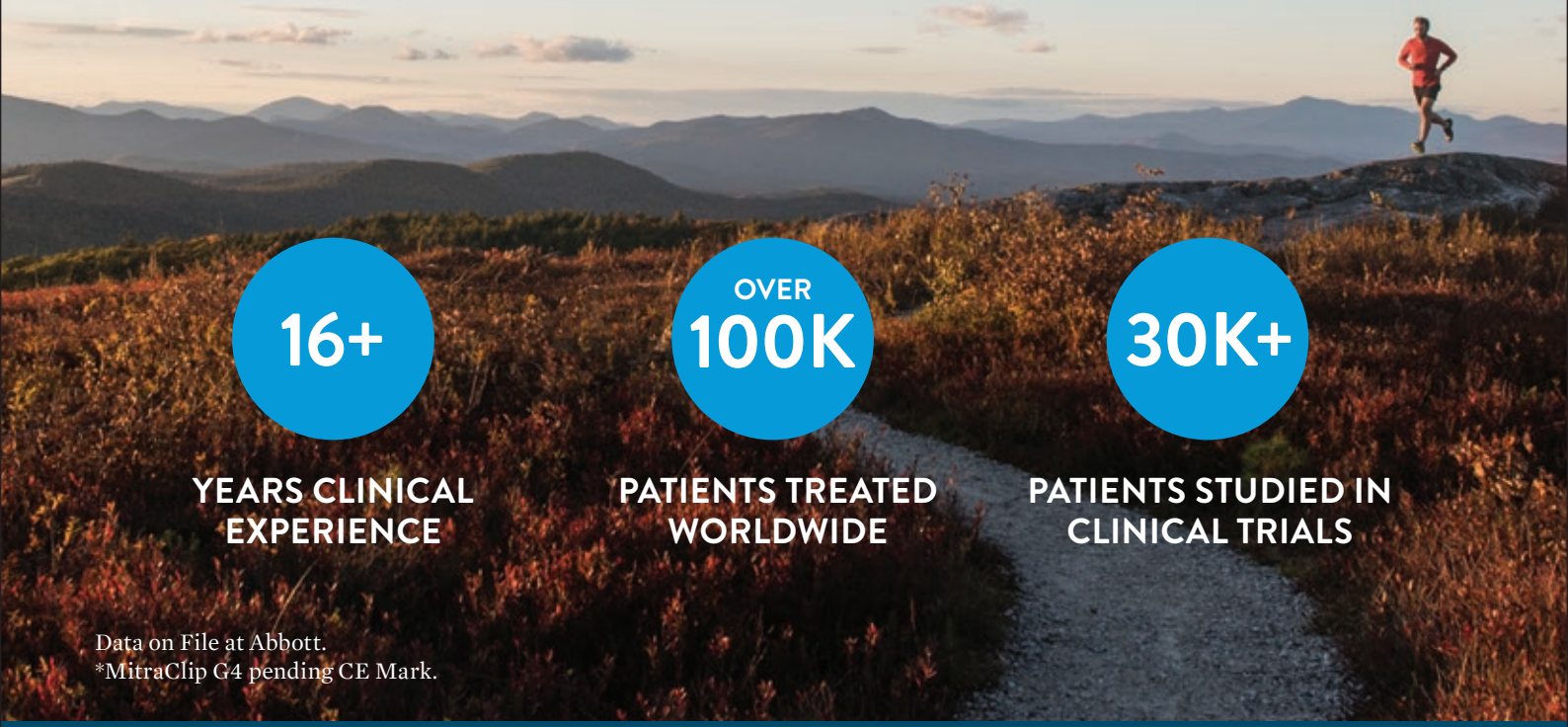
MITRACLIP–FIRST AND FOREMOST

THE FIRST

- The first transcatheter mitral valve device
- Durable outcomes demonstrated to 5 years
- The first mitral valve intervention proven more effective than GDMT alone for select heart failure patients with clinically significant MR

THE FOREMOST

- Over 16 years of dedication to the treatment of MR
- Over 100,000 patients treated worldwide
- Over 30,000 patients studied in clinical trials
- Over 16 years of dedicated support of training and education for transcatheter mitral valve procedures
- Fourth generation technology platform*



16+
YEARS CLINICAL EXPERIENCE

OVER 100K
PATIENTS TREATED WORLDWIDE

30K+
PATIENTS STUDIED IN CLINICAL TRIALS

Data on File at Abbott.
*MitraClip G4 pending CE Mark.

For more information about Transcatheter Mitral Valve Repair with MitraClip Therapy or the COAPT Trial, contact your Abbott sales representative or visit AdvancedHeartTherapies.com.

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