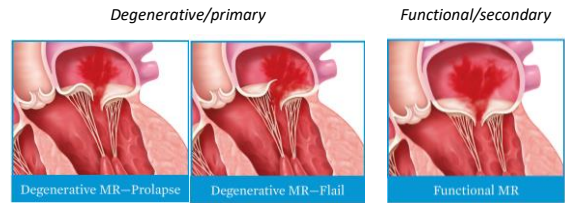


MitraClip results – is New Zealand missing out?

Lars Sondergaard, MD, DMSc
 Professor of Cardiology
 Rigshospitalet, University of Copenhagen
 Denmark

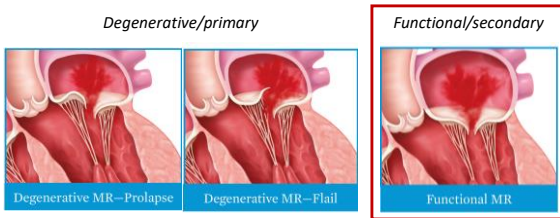
1

Mechanisms of mitral regurgitation



2

Mechanisms of mitral regurgitation



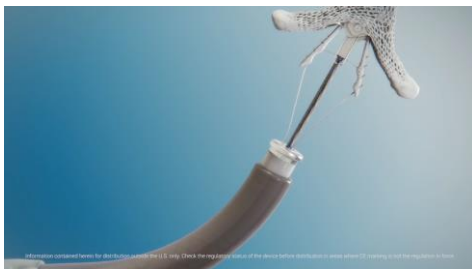
3

Background

- Patients with heart failure (HF) in whom mitral regurgitation (MR) develops secondary to left ventricular dysfunction have a poor prognosis, reduced quality-of-life, frequent hospitalizations for HF and decreased survival
- There are no proven therapies for secondary MR in HF
- Guideline-directed medical therapy and cardiac resynchronization therapy (CRT) may provide symptomatic relief in some pts
- Whether correcting secondary MR improves the prognosis of patients with HF is unknown
- Surgery with a downsized annuloplasty ring has not been demonstrated to be beneficial for secondary MR, and has a high recurrence rate

4

Leaflet repair with MitraClip



5

The slide features the Mitraclip logo (a heart with 'itra.fr' next to it) and the title 'Percutaneous Repair with the MitraClip Device for Severe Secondary Mitral Regurgitation'. Below the title are two images: one showing the MitraClip device in situ on a mitral valve, and another showing a spilled pill bottle with various colored pills. The presenter is identified as 'Jean François OBADIA, on behalf of the MITRA-FR Investigators'. At the bottom left, it says 'ESC Congress Munich 2018'.

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Study Design

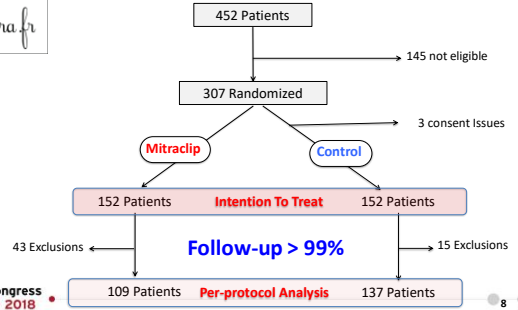
Objective → to evaluate the clinical efficacy of percutaneous mitral valve repair in addition to medical treatment in patients with heart failure and severe functional/secondary mitral regurgitation versus medical treatment alone.

Primary Composite Endpoint → All-Cause Deaths or Unplanned re-hospitalization for Heart failure at 12 months

Obadia et al. Eurointervention 2015;10:1354-1360

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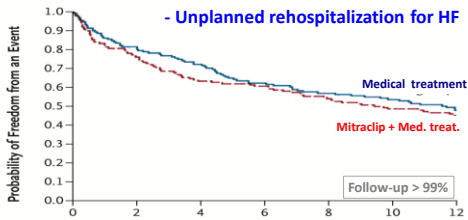
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Primary composite endpoint at 12 months

- All-Cause Death
- Unplanned rehospitalization for HF



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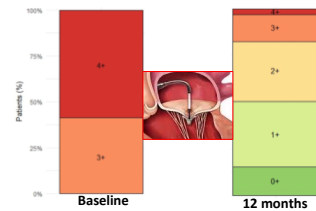
152	123	109	94	86	80	73
151	114	95	91	81	73	67

9



Pre-specified Secondary Endpoints

MR grade evolution (97 paired data)



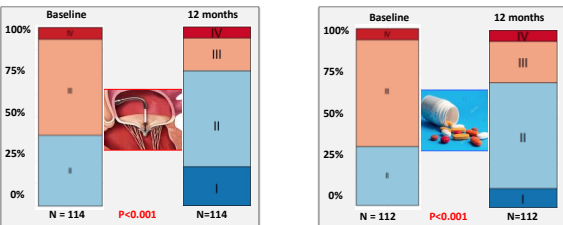
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Pre-specified Secondary Endpoints

NYHA evolution (123 paired data)



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P = NS

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Conclusion

MITRA-FR is the first RCT assessing any MV treatment for secondary MR

Percutaneous procedure was safe and effective
No difference with a control group → Ventricle >>> Valve

More randomized studies are necessary to confirm our results and to define possible sub-group of patients who could benefit from MV repair

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COAPT TRIAL

COAPT

A Randomized Trial of Transcatheter Mitral Valve Leaflet Approximation in Patients with Heart Failure and Secondary Mitral Regurgitation

Gregg W. Stone, MD

On behalf of Michael Mack, William Abraham, JoAnn Lindenfeld and the COAPT Investigators

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The COAPT Trial

Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation

A parallel-controlled, open-label, multicenter trial in ~610 patients with heart failure and moderate-to-severe (3+) or severe (4+) secondary MR who remained symptomatic despite maximally-tolerated GDMT

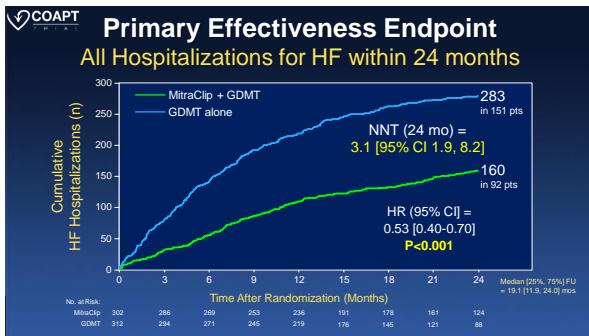
Randomize 1:1*

MitraClip + GDMT
N=305

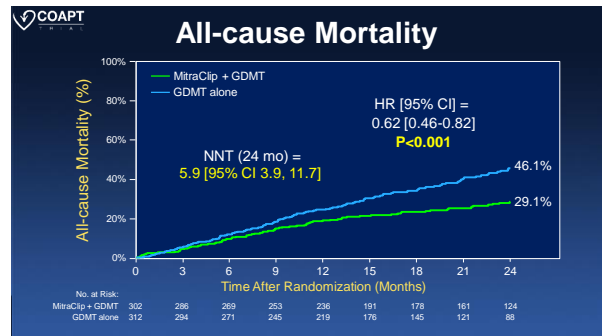
GDMT alone
N=305

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

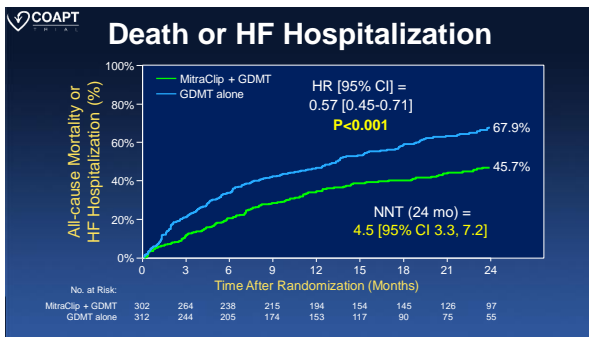
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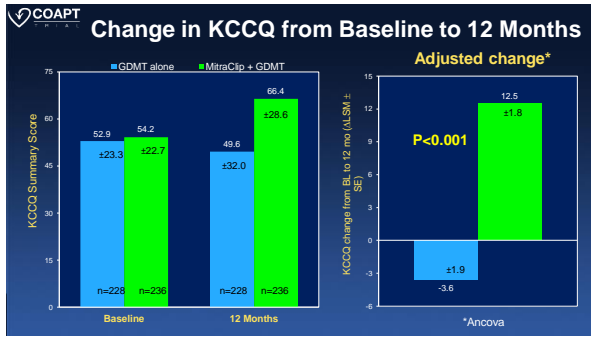
17

24-Month Event Rates (ii)

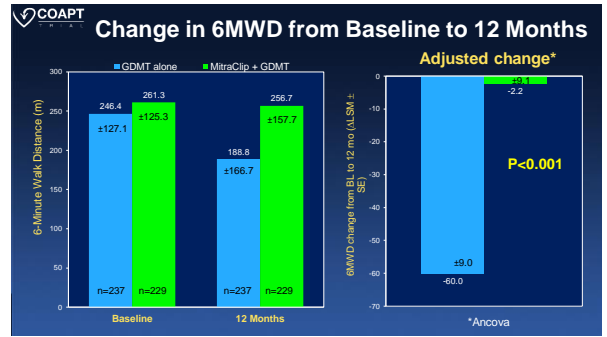
	MitraClip + GDMT (n=302)	GDMT alone (n=312)	HR [95% CI]	P-value
MV intervention or surgery*	4.0%	9.0%	0.61 [0.27, 1.36]	0.23
- MitraClip	3.7%	6.6%	0.99 [0.38, 2.58]	0.99
- Mitral valve surgery	0.4%	2.5%	0.14 [0.02, 1.17]	0.07
PCI or CABG	2.8%	4.3%	0.62 [0.24, 1.60]	0.32
Stroke	4.4%	5.1%	0.96 [0.42, 2.22]	0.93
Myocardial infarction	4.7%	6.5%	0.82 [0.38, 1.78]	0.62
New CRT implant	2.9%	3.3%	0.85 [0.31, 2.34]	0.75
LVAD or heart transplant	4.4%	9.5%	0.37 [0.17, 0.81]	0.01
- LVAD	3.0%	7.1%	0.34 [0.13, 0.87]	0.02
- Heart transplant	1.4%	3.6%	0.35 [0.09, 1.32]	0.12

*Unplanned; Kaplan-Meier time-to-first event rates

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Why are the COAPT Results so Different from MITRA-FR? Possible Reasons

	MITRA-FR (n=304)	COAPT (n=614)
Severe MR entry criteria	Severe FMR by EU guidelines: EROA >20 mm ² or RV >30 mL/beat	Severe FMR by US guidelines: EROA >30 mm ² or RV >45 mL/beat
EROA (mean ± SD)	31 ± 10 mm ²	41 ± 15 mm ²
LVEDV (mean ± SD)	135 ± 35 mL/m ²	101 ± 34 mL/m ²
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%

*MITRA-FR defn: device implant failure, transf or vasc compl req surg, ASD, card shock, cardiac embolism/stroke, tamponade, urg card surg

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Conclusions

- In pts with HF and moderate-to-severe or severe secondary MR who remained symptomatic despite maximally-tolerated GDMT, transcatheter mitral leaflet approximation with the MitraClip was safe, provided durable reduction in MR, reduced the rate of HF hospitalizations, and improved survival, quality-of-life and functional capacity during 24-month follow-up
- As such, the MitraClip is the first therapy shown to improve the prognosis of patients with HF by reducing secondary MR due to LV dysfunction

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