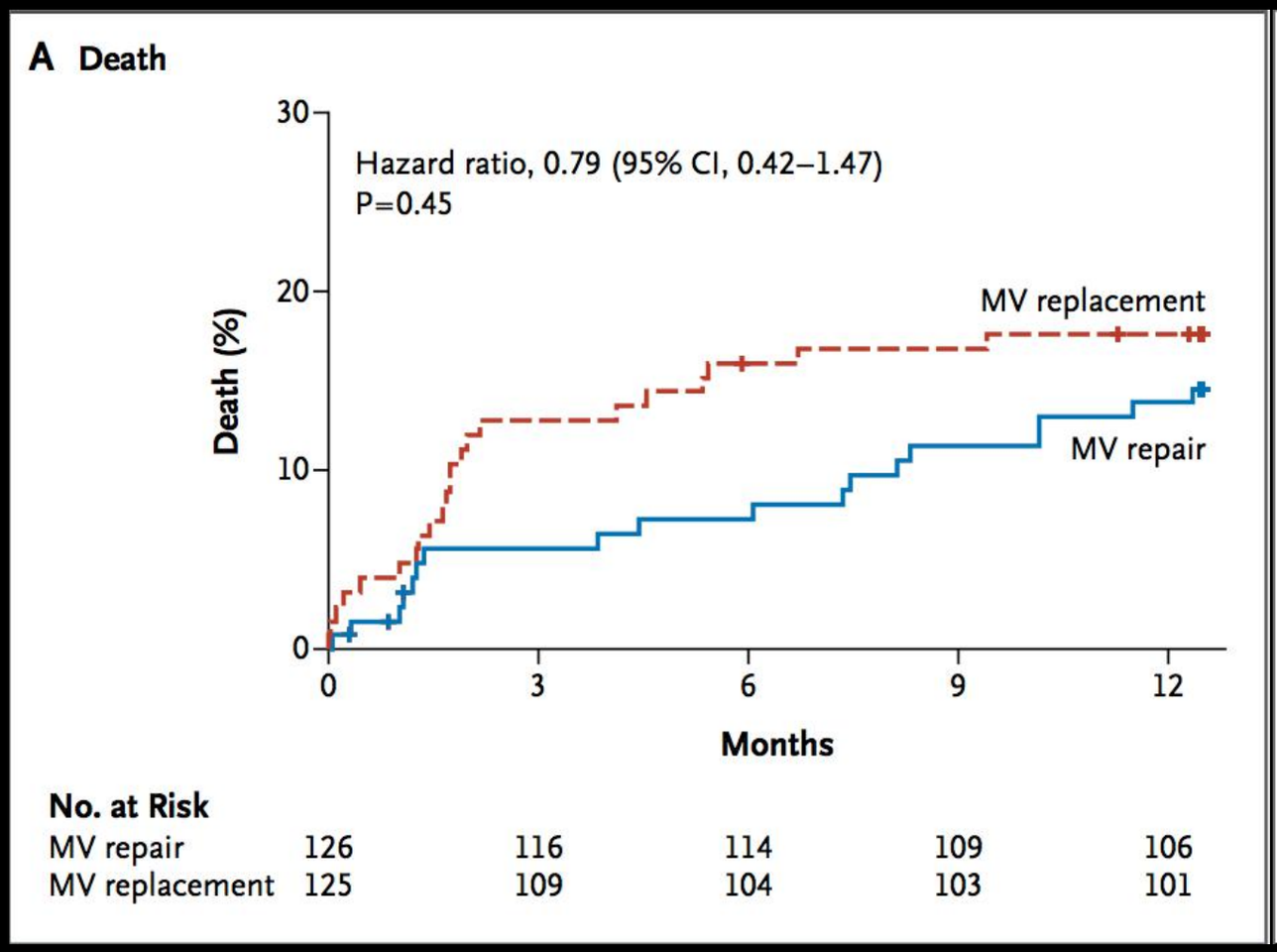
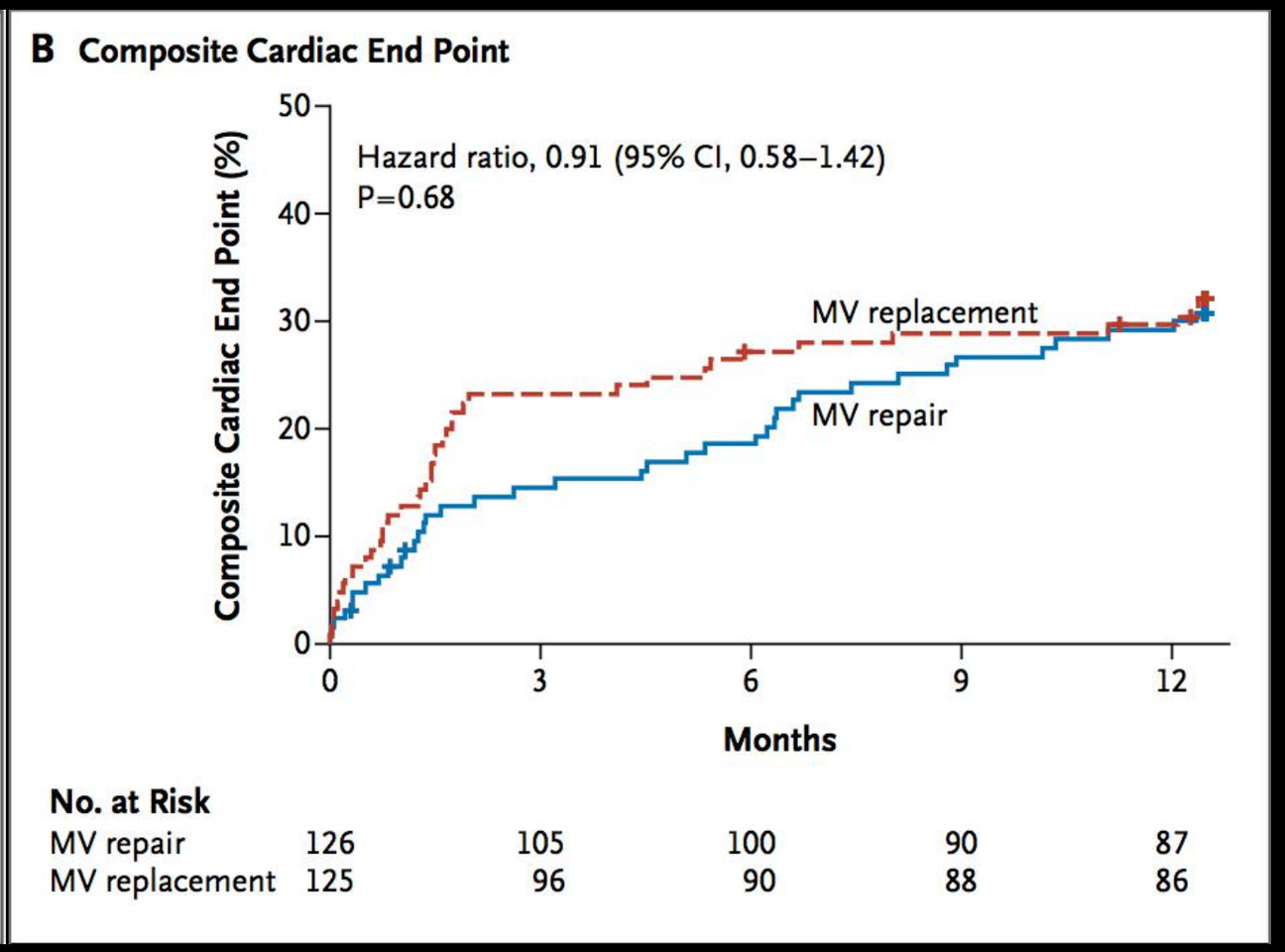
繼發性二尖瓣返流

Functional MR (FMR)

手術二尖瓣修補 vs 手術二尖瓣置換

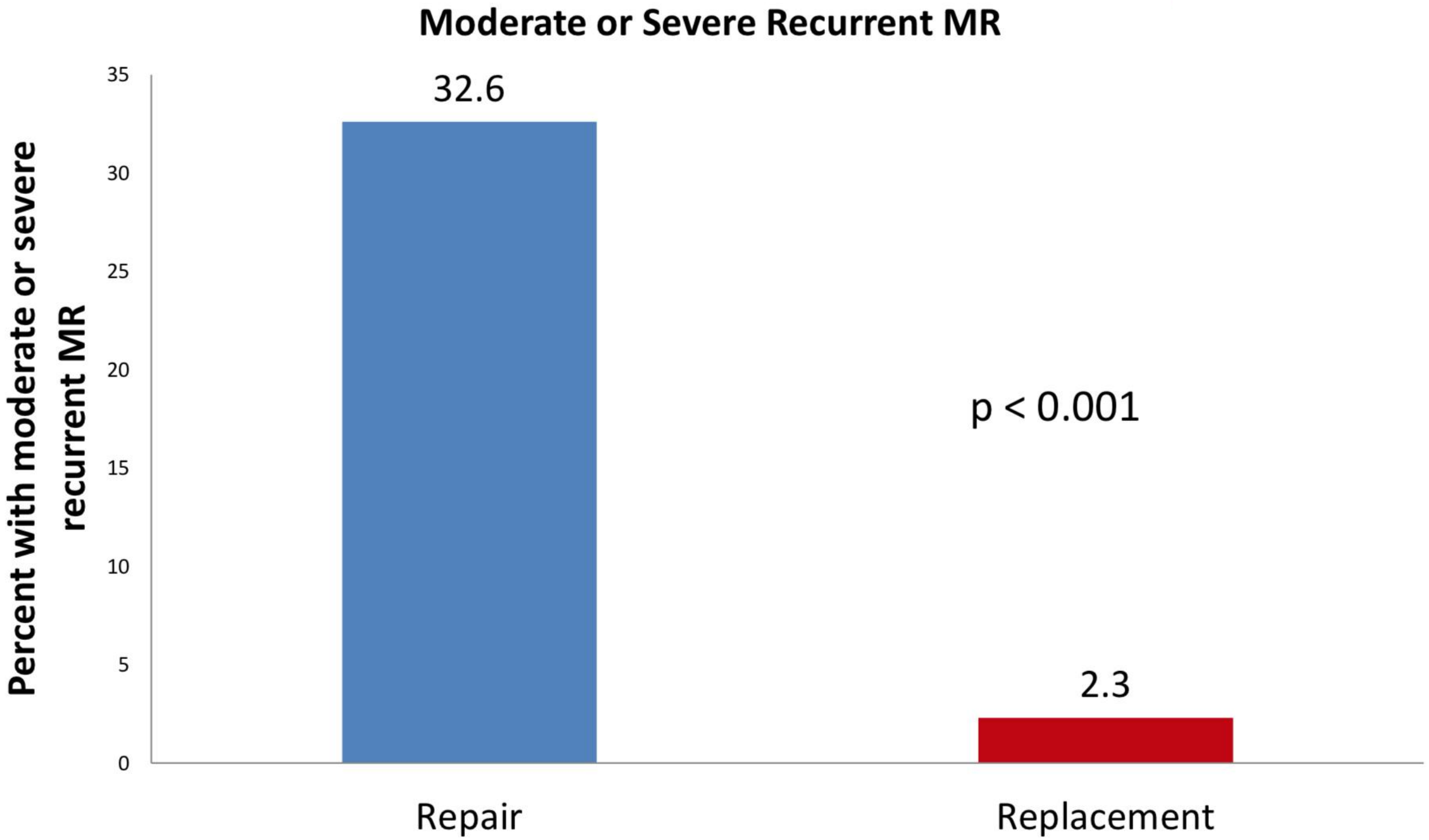




就左心室的重塑及存活率來說, 修瓣與換瓣並無不同

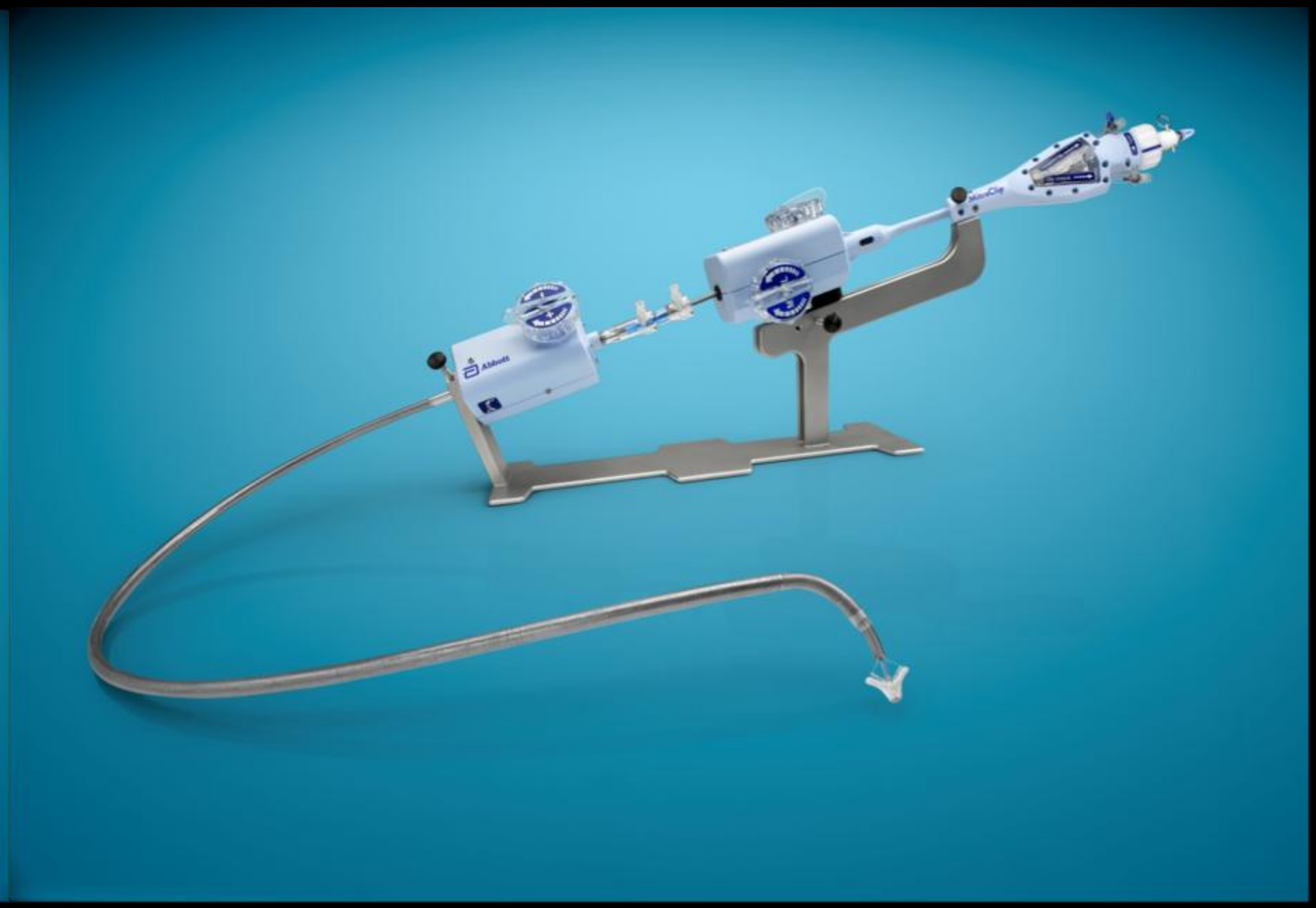
Acker et al. NEJM 2014;370:23-32

Recurrent MR at 1 year



對於修瓣來講, 有較多的二尖瓣返流的復發率(33%)

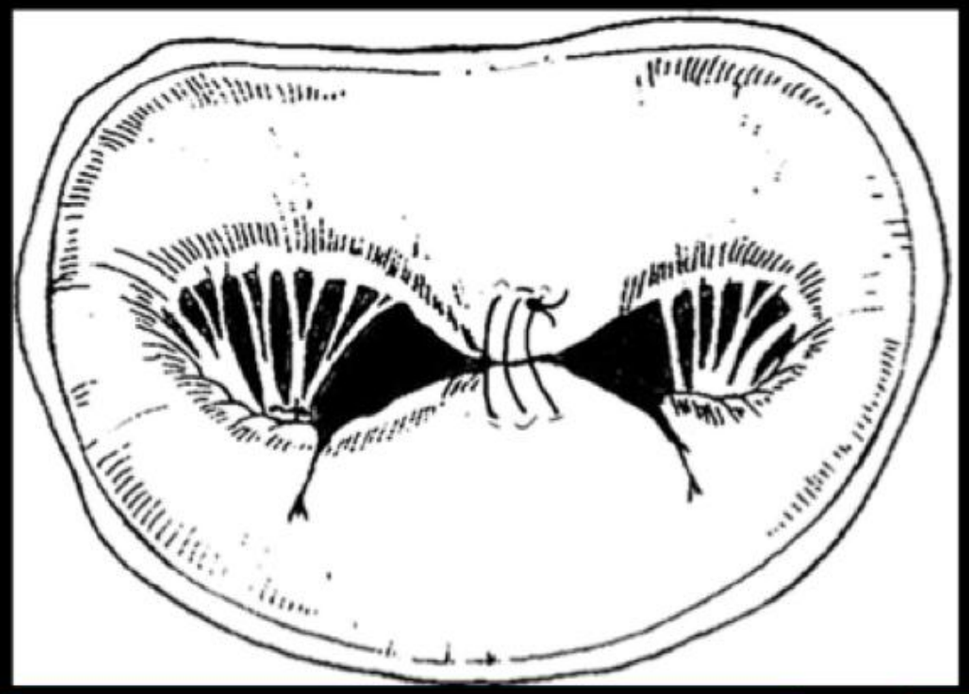
MitraClip system
經導管"緣對緣"二尖瓣修複術

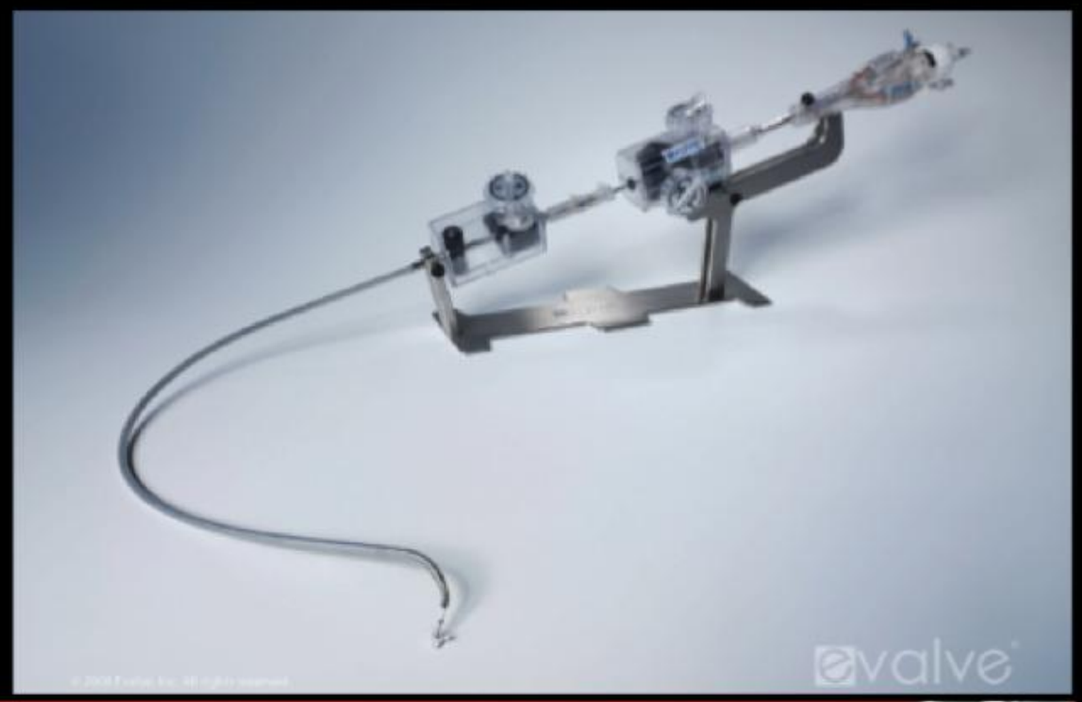


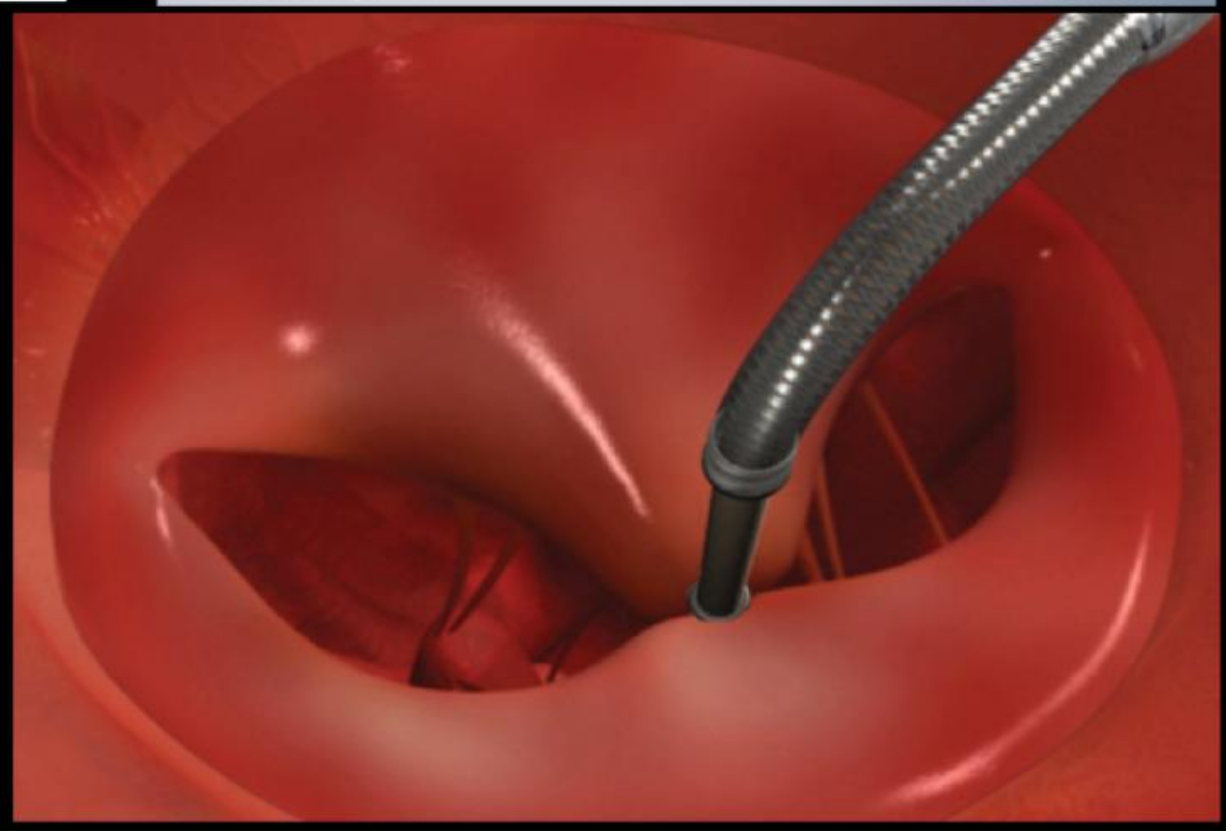
2018 ESC, TCT 最熱門的主題

MitraClip system

經導管"緣對緣"二尖瓣修複術







ESC 2018, München

TCT 2018, San Diego

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

J.-F. Obadia, D. Messika-Zeitoun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, D. Carrié, M. Nejjari, P. Ohlmann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, M. Gilard, E. Donal, J.-N. Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, G. Samson, P. Guerin, A. Vahanian, and N. Mewton, for the MITRA-FR Investigators*

ABSTRACT

BACKGROUND

In patients who have chronic heart failure with reduced left ventricular ejection fraction, severe secondary mitral-valve regurgitation is associated with a poor prognosis. Whether percutaneous mitral-valve repair improves clinical outcomes in this patient population is unknown.

METHODS

We randomly assigned patients who had severe secondary mitral regurgitation (defined as an effective regurgitant orifice area of >20 mm² or a regurgitant volume of >30 ml per beat), a left ventricular ejection fraction between 15 and 40%, and symptomatic heart failure, in a 1:1 ratio, to undergo percutaneous mitral-valve repair in addition to receiving medical therapy (intervention group; 152 patients) or to receive medical therapy alone (control group; 152 patients). The primary efficacy outcome was a composite of death from any cause or unplanned hospitalization for heart failure at 12 months.

RESULTS

At 12 months, the rate of the primary outcome was 54.6% (83 of 152 patients) in the intervention group and 51.3% (78 of 152 patients) in the control group (odds ratio, 1.16; 95% confidence interval [CI], 0.73 to 1.84; P=0.53). The rate of death from any cause was 24.3% (37 of 152 patients) in the intervention group and 22.4% (34 of 152 patients) in the control group (hazard ratio, 1.11; 95% CI, 0.69 to 1.77). The rate of unplanned hospitalization for heart failure was 48.7% (74 of 152 patients) in the intervention group and 47.4% (72 of 152 patients) in the control group (hazard ratio, 1.13; 95% CI, 0.81 to 1.56).

CONCLUSIONS

Among patients with severe secondary mitral regurgitation, the rate of death or unplanned hospitalization for heart failure at 1 year did not differ significantly between patients who underwent percutaneous mitral-valve repair in addition to receiving medical therapy and those who received medical therapy alone. (Funded by the French Ministry of Health and Research National Program and Abbott Vascular; MITRA-FR ClinicalTrials.gov number, NCT01920698.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Obadia at Hôpital Cardiovasculaire Louis Pradel, Chirurgie Cardio-Vasculaire et Transplantation Cardiaque, 28, Ave. Doyen Lépine, 69677 Bron CEDEX, France, or at jean-francois.obadia@chu-lyon.fr.

*A list of investigators in the MITRA-FR trial is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on August 27, 2018, at NEJM.org.

DOI: 10.1056/NEJMoa1805374

MITRA-FR, 2018/08/27

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*

ABSTRACT

BACKGROUND

Among patients with heart failure who have mitral regurgitation due to left ventricular dysfunction, the prognosis is poor. Transcatheter mitral-valve repair may improve their clinical outcomes.

METHODS

At 78 sites in the United States and Canada, we enrolled patients with heart failure and moderate-to-severe or severe secondary mitral regurgitation who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy. Patients were randomly assigned to transcatheter mitral-valve repair plus medical therapy (device group) or medical therapy alone (control group). The primary effectiveness end point was all hospitalizations for heart failure within 24 months of follow-up. The primary safety end point was freedom from device-related complications at 12 months; the rate for this end point was compared with a prespecified objective performance goal of 88.0%.

RESULTS

Of the 614 patients who were enrolled in the trial, 302 were assigned to the device group and 312 to the control group. The annualized rate of all hospitalizations for heart failure within 24 months 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 rate of freedom from device-related complications at 12 months was 96.6% (lower 95% confidence limit, 94.8%; P<0.001 for comparison with the performance goal). Death from any cause within 24 months occurred in 29.1% of the patients in the device group as compared with 46.1% in the control group (hazard ratio, 0.62; 95% CI, 0.46 to 0.82; P<0.001).

CONCLUSIONS

Among patients with heart failure and moderate-to-severe or severe secondary mitral regurgitation who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy, transcatheter mitral-valve repair resulted in a lower rate of hospitalization for heart failure and lower all-cause mortality within 24 months of follow-up than medical therapy alone. The rate of freedom from device-related complications exceeded a prespecified safety threshold. (Funded by Abbott; COAPT ClinicalTrials.gov number, NCT01626079.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Stone at Columbia University Medical Center, Cardiovascular Research Foundation, 1700 Broadway, 8th Fl., New York, NY 10019, or at gs2184@columbia.edu.

*A list of investigators, institutions, and research organizations participating in the COAPT trial is provided in the Supplementary Appendix, available at NEJM.org.

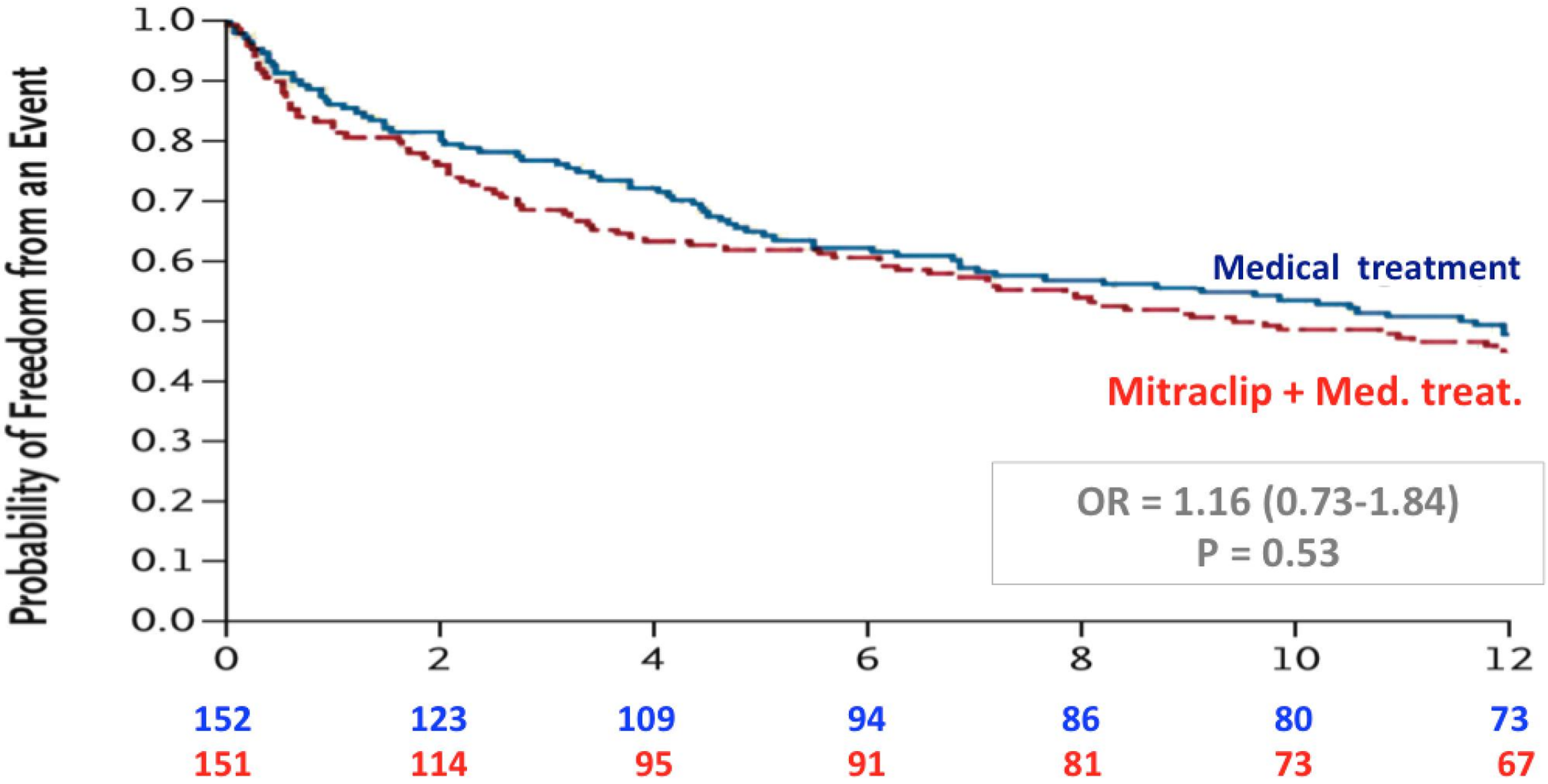
This article was published on September 23, 2018, at NEJM.org.

DOI: 10.1056/NEJMoa1806640

COAPT, 2018/09/23

Primary composite endpoint *(99% follow-up)*

- All-Cause Death
- Unplanned rehospitalization for HF



Obadia JF et al. N Engl J Med. 2018 Aug 27. doi: 10.1056/NEJMoa1805374

Mitra.fr

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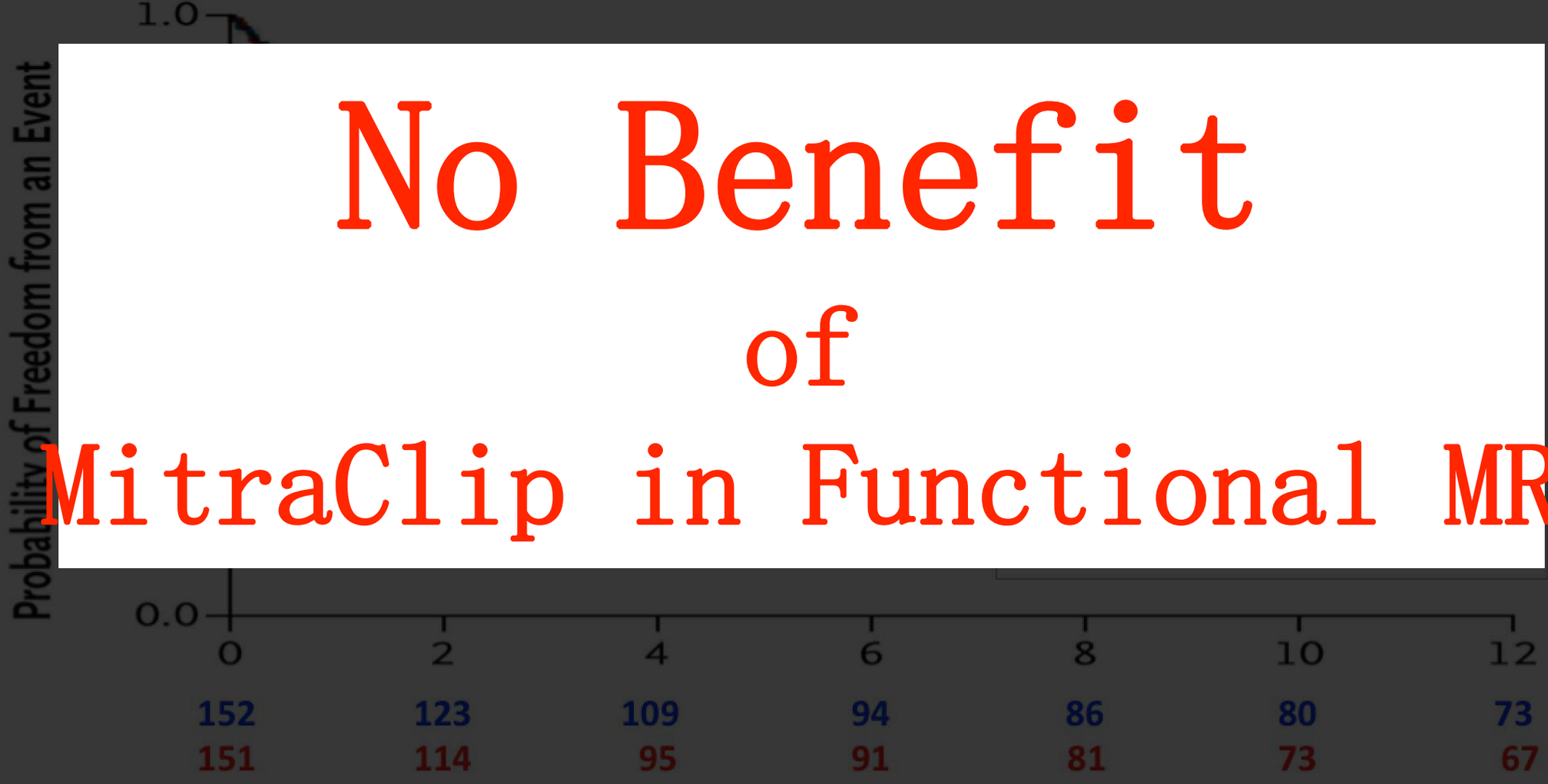


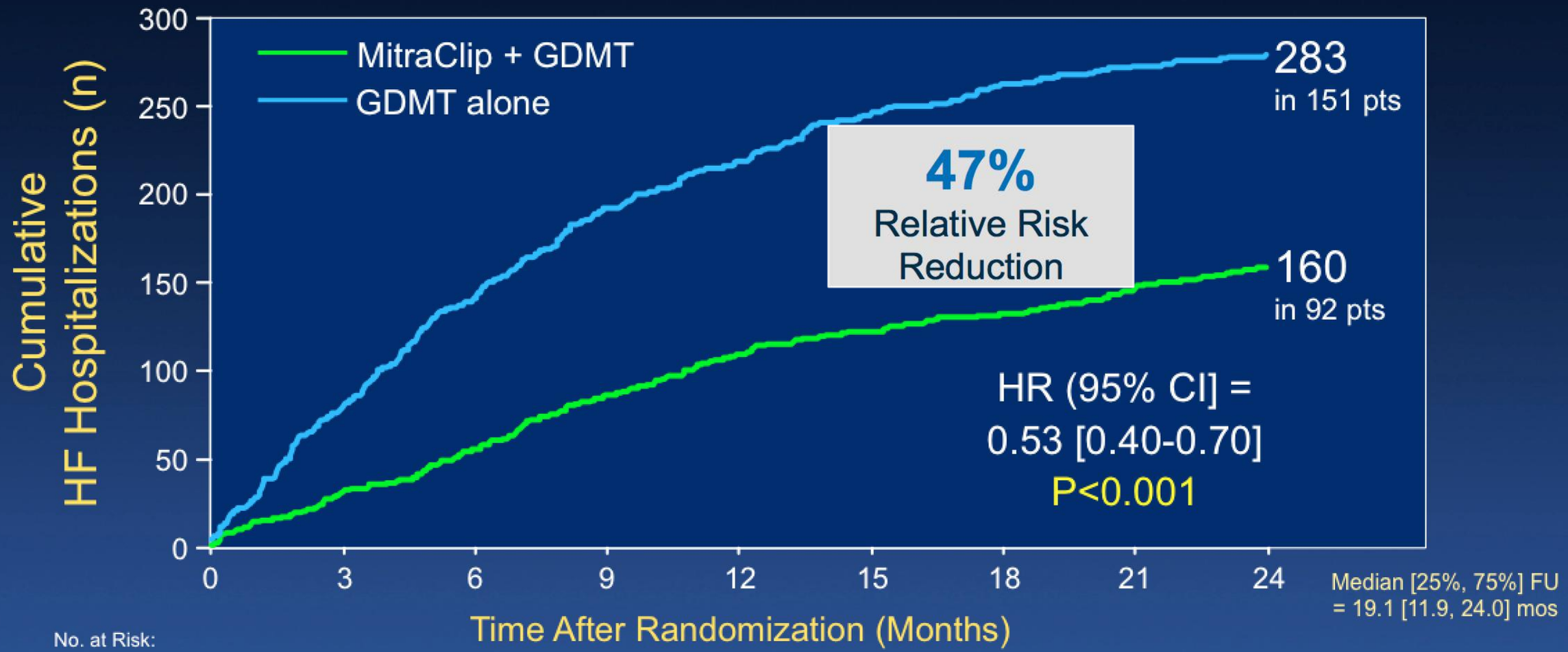
No Benefit of MitraClip in Functional MR

Obadia JF et al. N Engl J Med. 2018 Aug 27. doi: 10.1056/NEJMoa1805374

COAPT TRIAL

Primary Effectiveness Endpoint

All Hospitalizations for HF within 24 months



Median [25%, 75%] FU = 19.1 [11.9, 24.0] mos

No. at Risk:

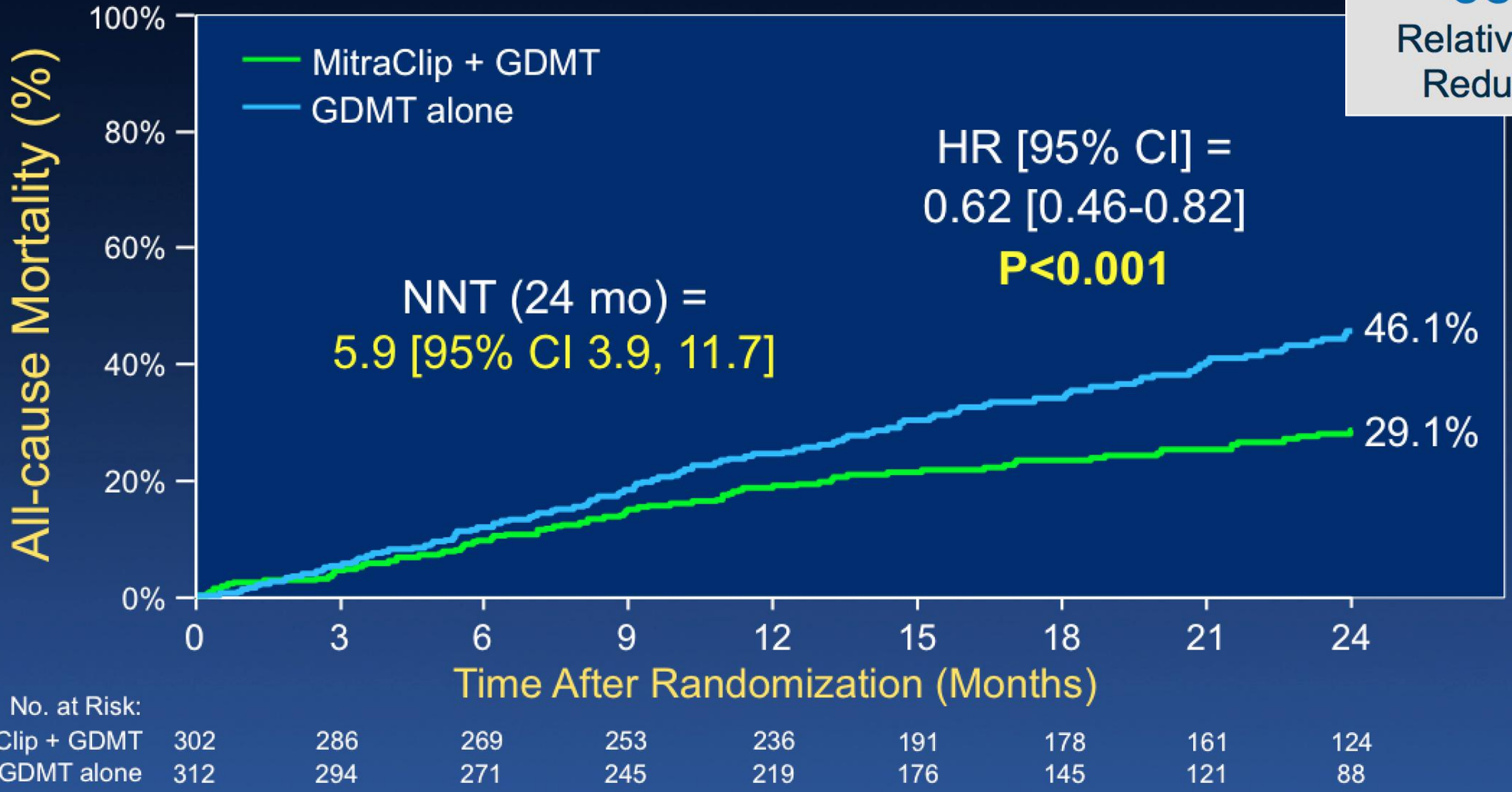
MitraClip	302	286	269	253	236	191	178	161	124
GDMT	312	294	271	245	219	176	145	121	88

Stone GW et al. TCT 2018

COAPT TRIAL

All-cause Mortality

38%
Relative Risk Reduction



No. at Risk:

MitraClip + GDMT	302	286	269	253	236	191	178	161	124
GDMT alone	312	294	271	245	219	176	145	121	88

Stone GW et al. TCT 2018

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

Possible Reasons

		MITRA-FR (n=304)	COAPT (n=614)
Population	**Pre-specified entry criteria**		
	• Severe MR	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
	• LVESD	No limits	≤ 70 mm within prior 90 days
	Observed at baseline		
	• EROA (mean ± SD)	31 ± 10 mm^2	41 ± 15 mm^2
	• <0.30	52% (157/301)	14% (80/591)
	• 0.30-0.40	32% (95/301)	46% (270/591)
	• >0.40	16% (49/301)	41% (241/591)
	• Indexed LVEDV (mean ± SD)	135 ± 35 mL/m^2	101 ± 34 mL/m^2
Médication	**GDMT at baseline and FU**	Receiving HF meds at baseline – allowed variable adjustment in each group during follow-up per "real-world" practice	Central Eligibility Committee confirmed pts were failing maximally-tolerated GDMT at baseline – few major changes during follow-up

Results from clinical trials are not directly comparable. Information provided for educational purposes only

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

Possible Reasons

		MITRA-FR (n=304)	COAPT (n=614)
Population	**Pre-specified entry criteria**		
	• Severe MR	Severe FMR by EU guidelines: EROA	Severe FMR by US guidelines: EROA mL/beat
	• LVESD		90 days
	Observed		
	• EROA (		
	• <0.3		)
	• 0.30		1)
	• >0.4		1)
	• Indexed		m^2
Médication	**GDMT at baseline and FU**	Receiving HF meds at baseline – allowed variable adjustment in each group during follow-up per "real-world" practice	Central Eligibility Committee confirmed pts were failing maximally-tolerated GDMT at baseline – few major changes during follow-up

COAPT selected the SMR patients with **SEVERER MR and LESS FAILING LV**, and strictly confirmed maximal dose of medication has been applied

Results from clinical trials are not directly comparable. Information provided for educational purposes only