

« Le traitement percutané de l'insuffisance Mitrale »

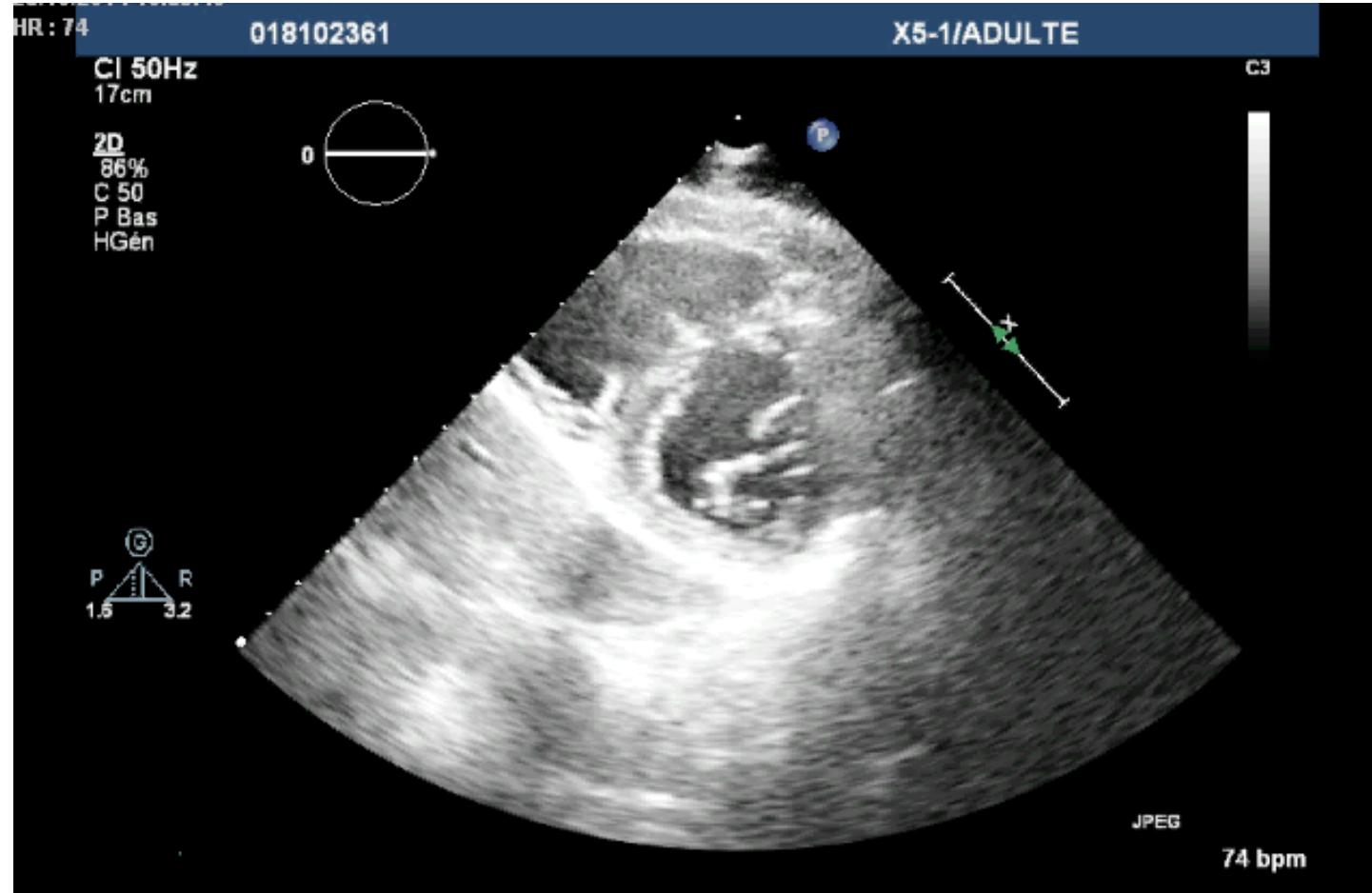
Pr Patrice Guérin
Centre Cardio-thoracique de Monaco (CCM)

04.02.2020

Conflits d'intérêts

- Abbott :
 - honoraria's < 12 000 E
 - Research > 5000 E
- Edwards lifesciences
 - Research < 20 000
- Boston scientific
 - Research < 5000 E
- Medtronic
 - Research < 5000 E
- General Electric Medical System
 - Honoraria's < 5000 E
- Actelion
 - Honoraria's < 5000 E
- Saint Jude medical
 - Honoraria's < 5000 E
- Terumo
 - Research < 5000 E

Edge to edge repair in PMR : the concept



Le traitement percutané de l'insuffisance Mitrale

- Episode 1 : L'idée de la réparation bord à bord de l'IM :

- Ottavio Alfieri : suture de la zone fuyante
 - « Tellement simple que l'on pourrait le faire sans sternotomie »

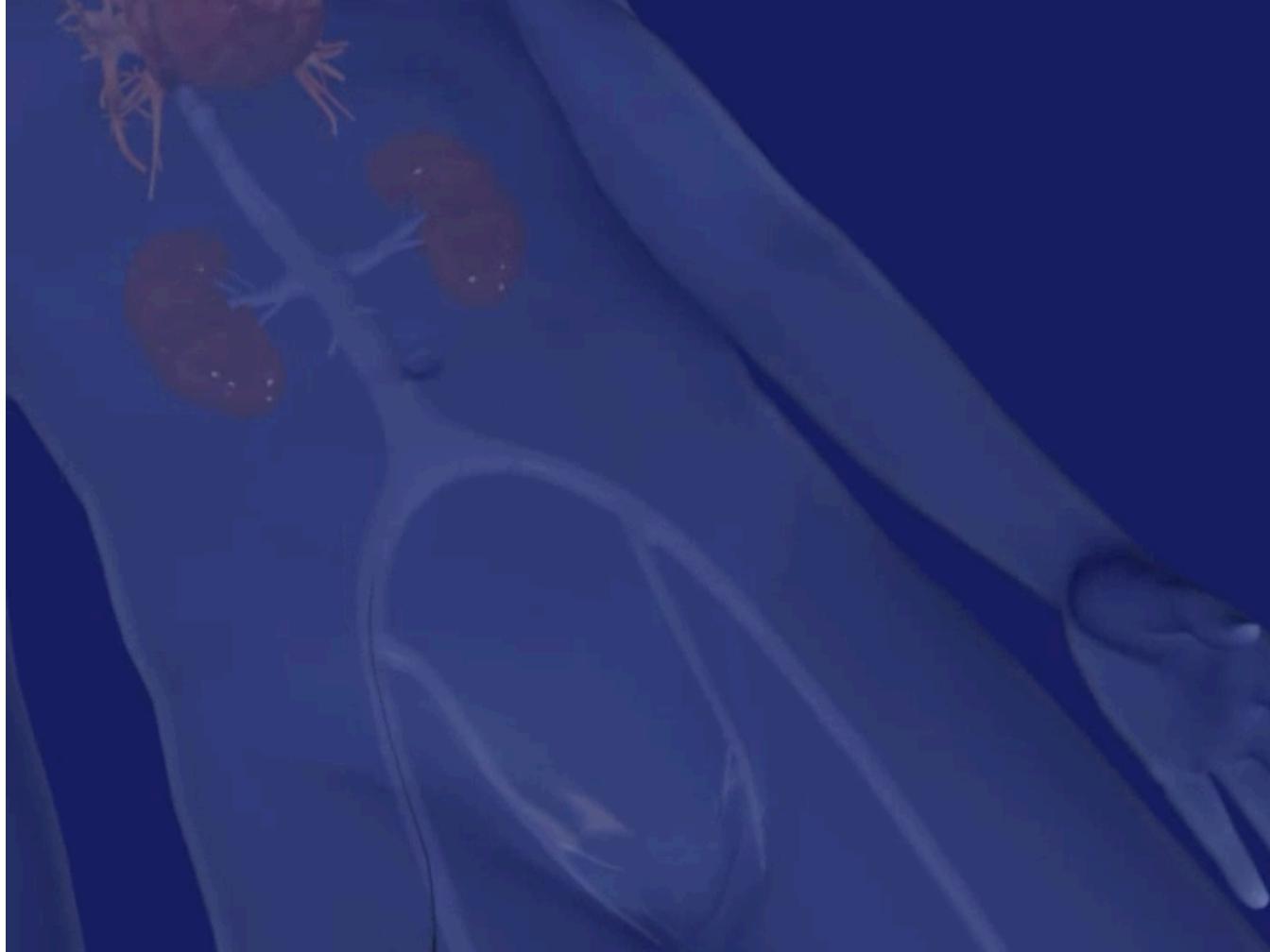
« Eventually, the concept introduced by this type of repair can open the perspective of percutaneous correction of MR. Longer follow-up period is needed to confirm long term expectations with this promising alternative technique of valve repair »

F. Maisano and O. Alfieri 1998

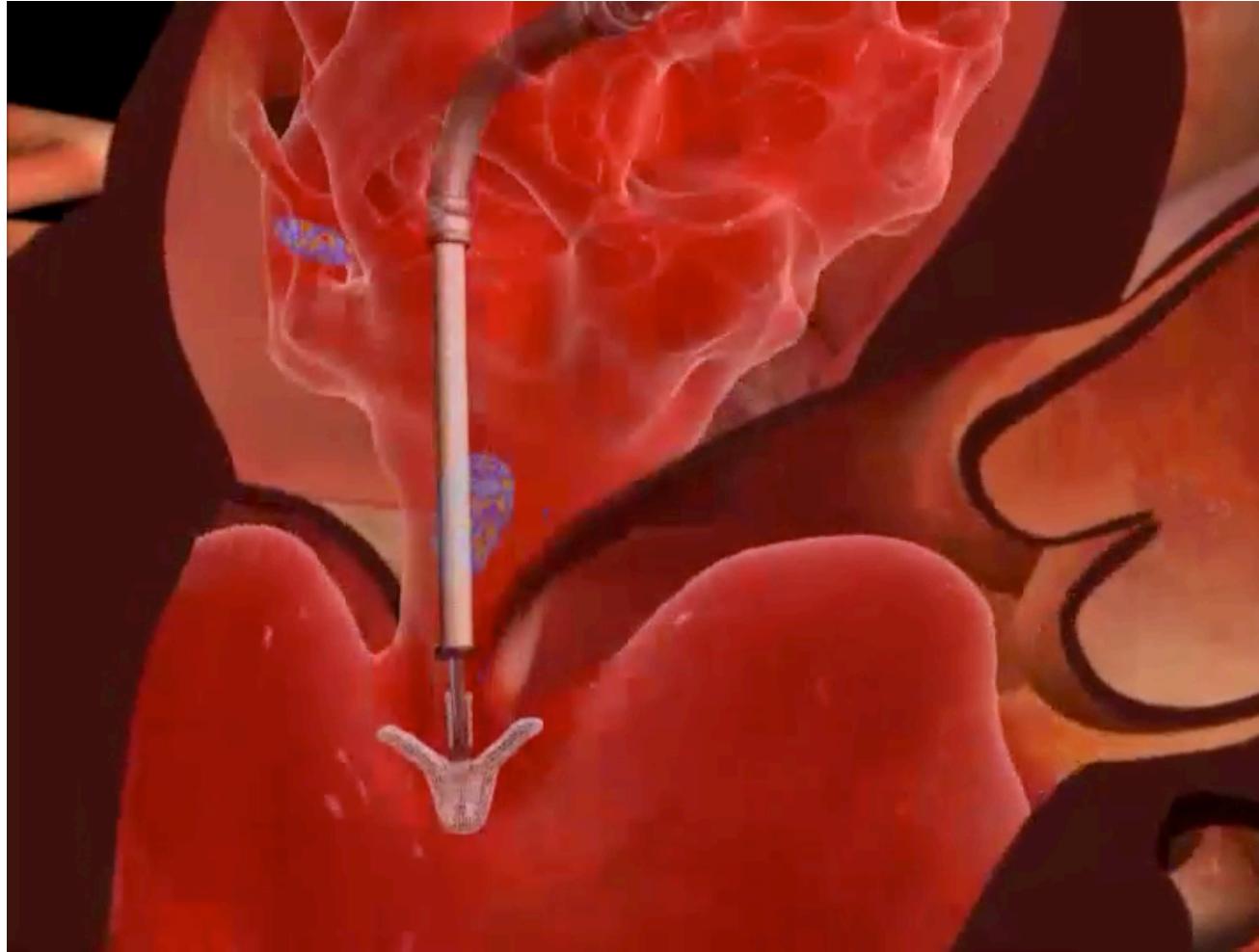
F. Maisano et al. / European Journal of Cardio-thoracic Surgery 13 (1998) 240–246



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Evidence based medicine: Studies are required

IM PRIMITIVES

The NEW ENGLAND
JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

APRIL 14, 2011

VOL. 364 NO. 15

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald G. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

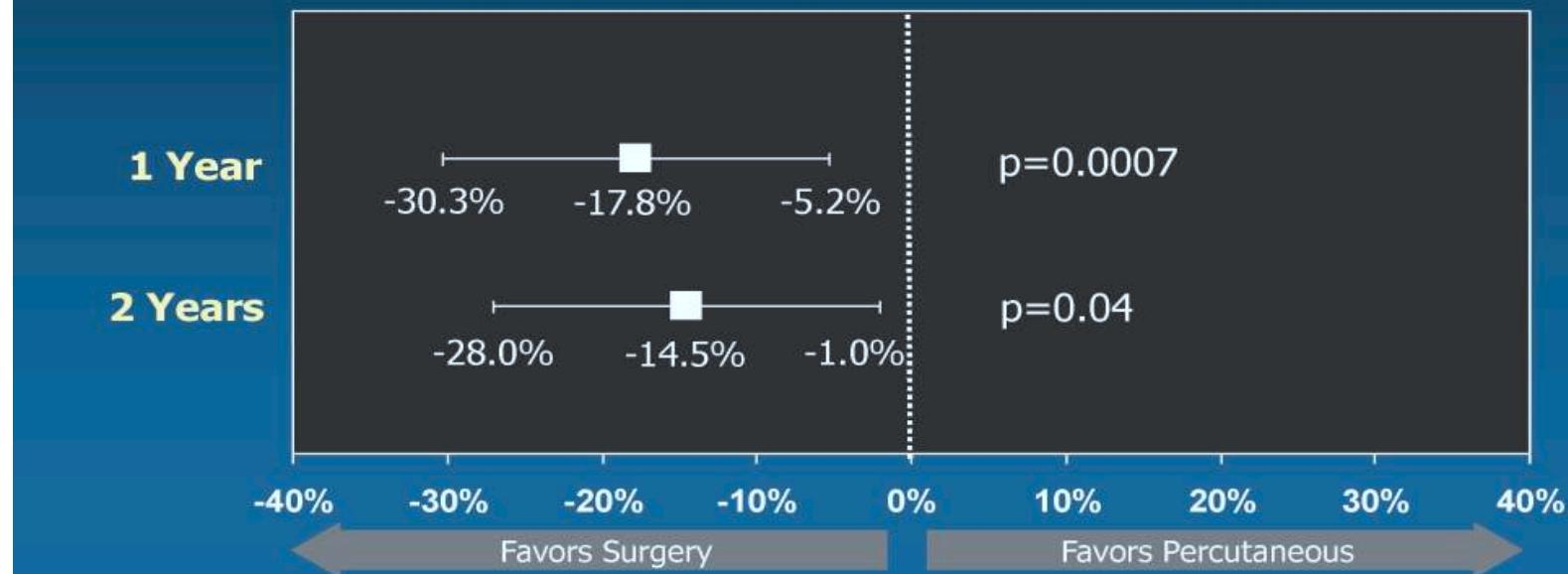
Surgery is better

Primary Effectiveness Analyses at 1 and 2 Years Difference Between Percutaneous & Surgery Intention to Treat Analysis

Primary Effectiveness:

Freedom from death, MV surgery/re-operation or 3+ or 4+ MR

Difference: Percutaneous – Surgery (%, 95% CI)

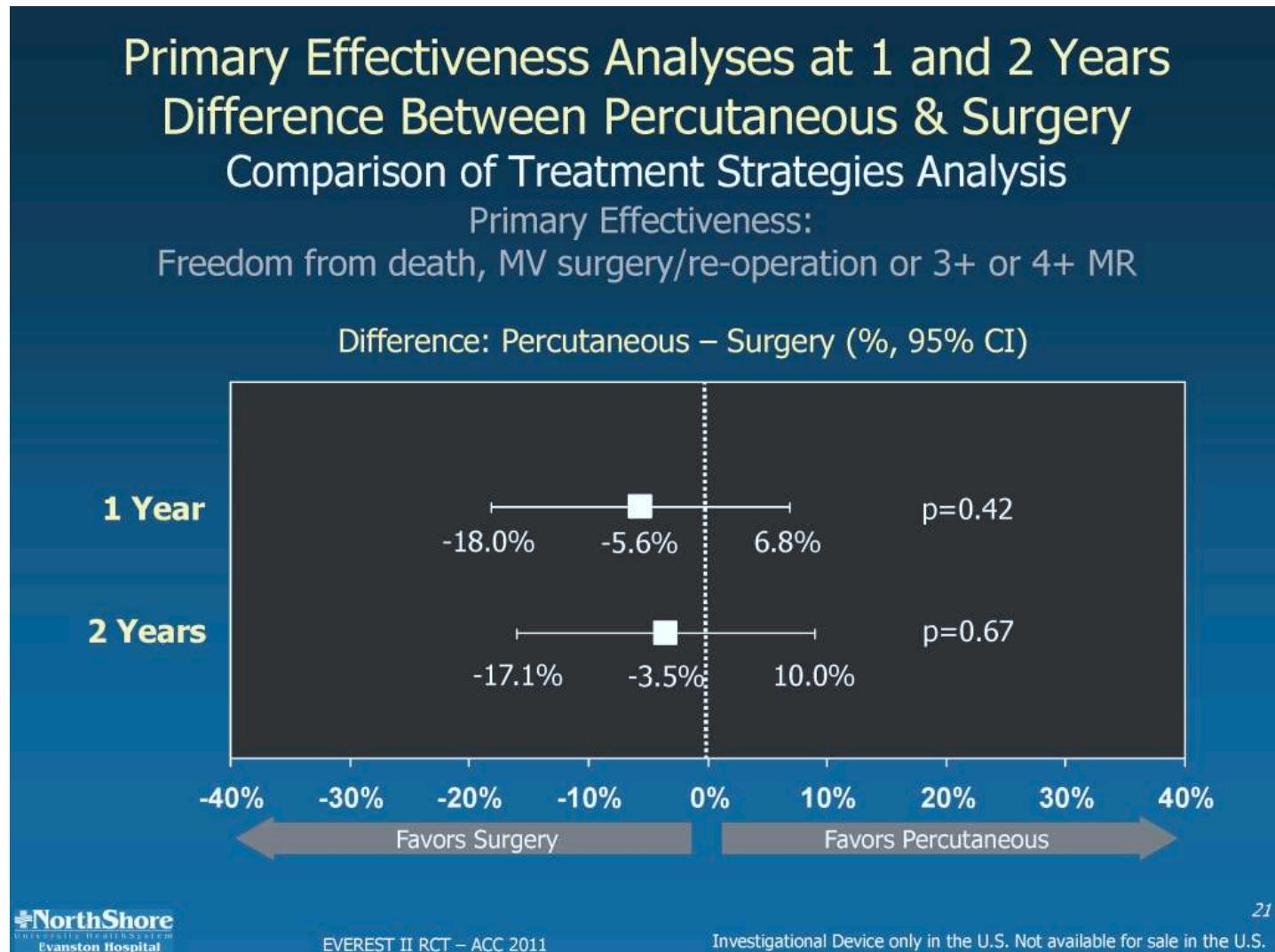


Surgery is better...but MC is safer

Safety Endpoint: 30 Day MAE Intention to Treat

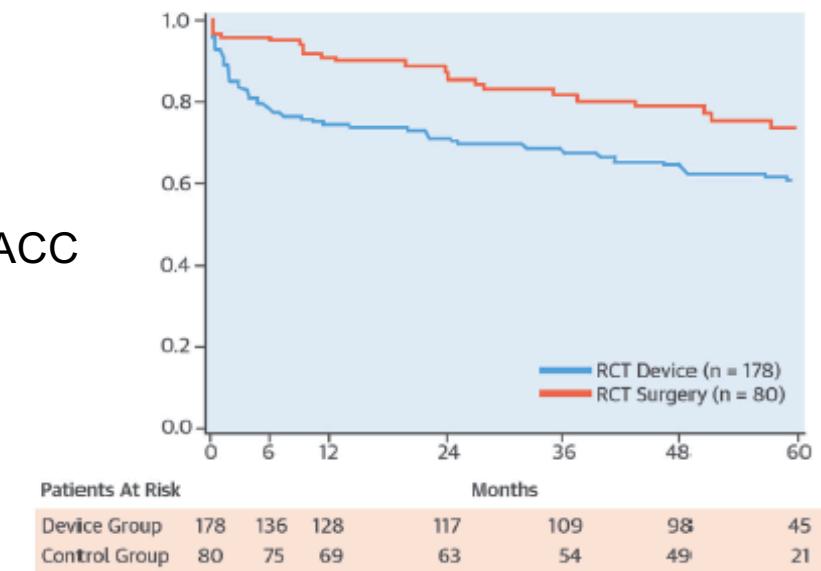
30 Day MAE	# (%) Patients experiencing event	
	Percutaneous (N=180)	Surgery (N=94)
Death	2 (1.1%)	2 (2.1%)
Major Stroke	2 (1.1%)	2 (2.1%)
Re-operation of Mitral Valve	0	1 (1.1%)
Urgent / Emergent CV Surgery	4 (2.2%)	4 (4.3%)
Myocardial Infarction	0	0
Renal Failure	1 (0.6%)	0
Deep Wound Infection	0	0
Ventilation > 48 hrs	0	4 (4.3%)
New Onset Permanent Atrial Fib	2 (1.1%)	0
Septicemia	0	0
GI Complication Requiring Surgery	2 (1.1%)	0
Transfusions \geq 2 units	24 (13.3%)	42 (44.7%)
TOTAL % of Patients with MAE	15.0%	47.9%
Difference (Percutaneous – Surgery) = -32.9% p<0.001; (95% CI: -20.7%, -45.0%)		

Surgery is not better in comparaison of treatment strategy

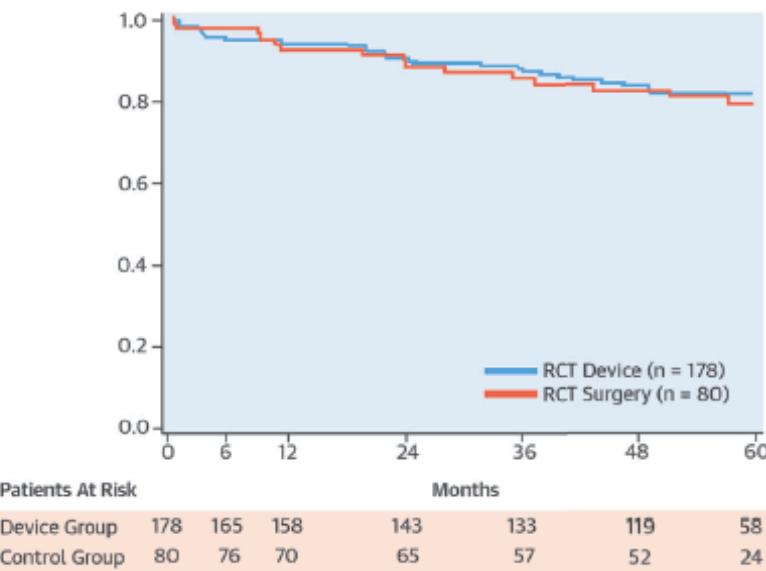


Feldman et al. JACC
66. 25, 2015

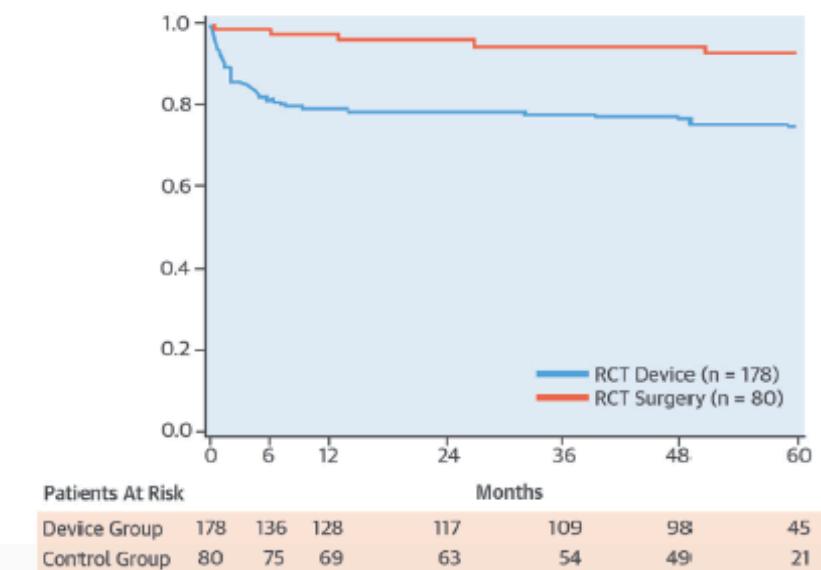
A. Freedom From Death, MV Surgery or Reoperation



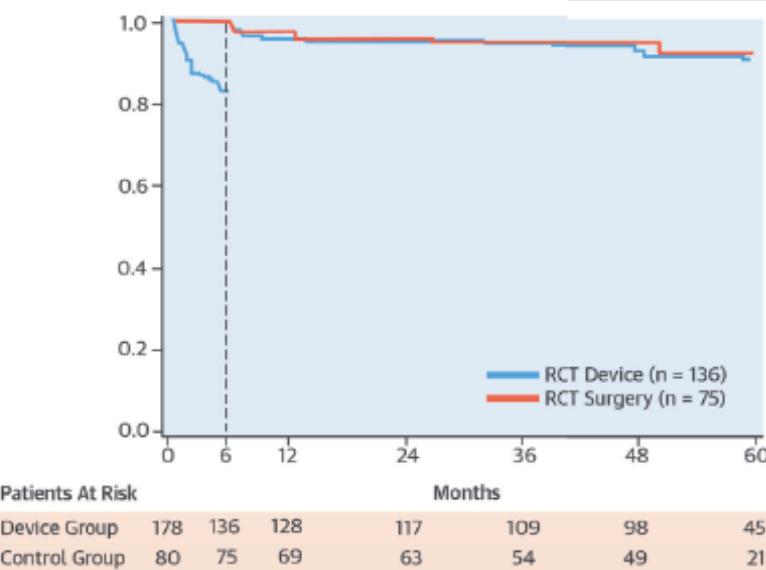
B. Freedom From Death



C. Freedom From MV Surgery or Reoperation



D. Landmark Analysis of Freedom From MV Surgery or Reoperation Beyond 6 Months



Le traitement percutané de l'insuffisance Mitrale

- Episode 5 : Evaluation HAS (CNEDIM)
- Episode 6 : Autorisation (ASA II)
 - Patients avec insuffisance mitrale sévère, d'origine dégénérative, symptomatique malgré une prise en charge médicale optimale, non éligibles à la chirurgie et répondant aux critères échographiques d'éligibilité.
 - Tous ces critères et en particulier la contre-indication chirurgicale doivent être validés par une équipe multidisciplinaire ad hoc.
 - Les patients ayant une espérance de vie inférieure à un an compte tenu de facteurs extracardiaques (comorbidités) ne sont pas éligibles à la technique (non indication).

Le traitement percutané de l'insuffisance Mitrale

- Episode 5 : Evaluation HAS (CNEDIM)
- Episode 6 : Autorisation (ASA II)
- Episode 7 : Registre commun CNEDIM/SFC : MITRAGISTER
 - (Pr JF. Obadia ; Pr B. lung ; Pr P. Guerin)
- Episode 8 : Quid du patient à haut risque non contre indiqué ?
 - PHRC MITRA-HR (2016) : Etude de non infériorité ; 66 patients (cible 330)
 - PHRC : 1,3 millions d'Euros.
 - Abbott

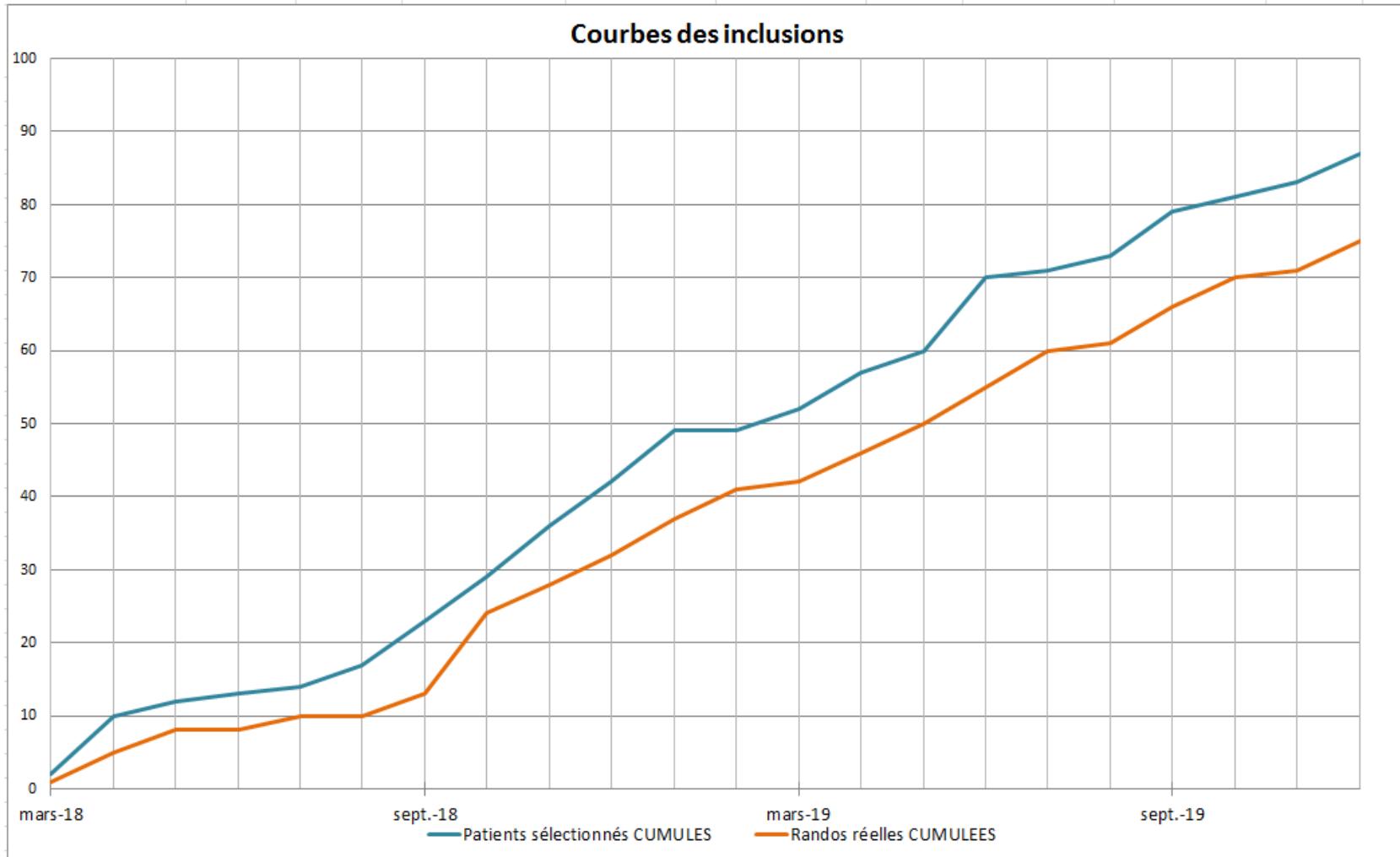
Mitra HR

Multicentre and randomized study of MITRACLIP® transcatheter mitral valve repair in patients with severe PMR eligible for high-risk surgery

- **Aim** : to perform the first randomized trial showing the non-inferiority of MitraClip® versus Surgery at 12 months after the procedure for patient with a severe primary mitral regurgitation with high surgical risk
- Efficacy
- Security



Mitra HR



IM secondaire

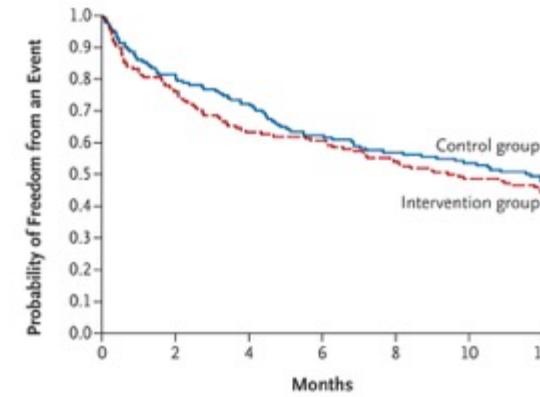
- The story of a long fight...
 - FMR is a consequence of cardiomyopathy
 - FMR is the security discharge of the bad left ventricle
- FMR : DCM Consequence? DMC Cause ? DCM Marker of risk ?
- Until 2018...



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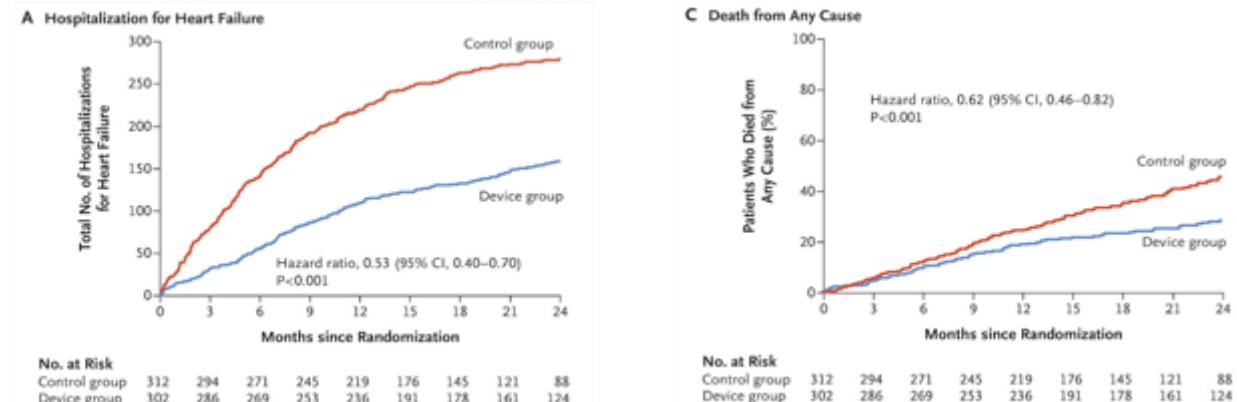
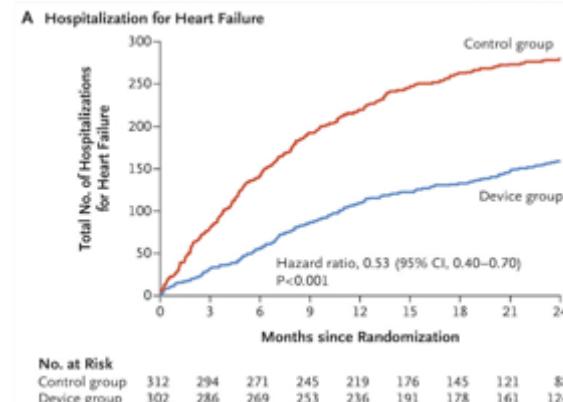
- Episode 9 : concomitamment IM II

- MITRA-FR
- COAPT
- MITRA-FR à 2 ans



No. at Risk	Control group	152	123	109	94	86	80	73
	Intervention group	151	114	95	91	81	73	67

FDA +





ITT Primary composite endpoint >99% follow-up

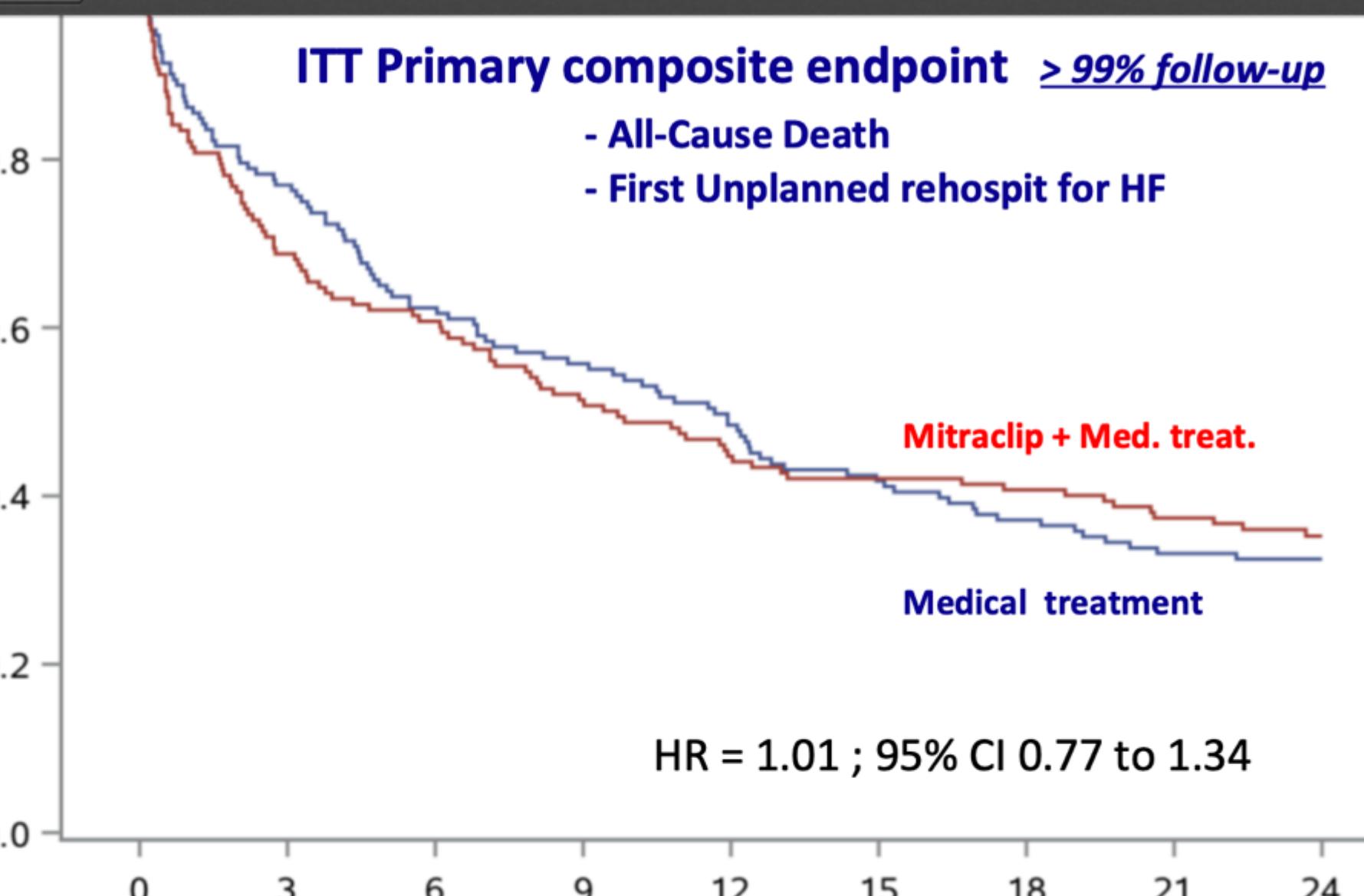
- All-Cause Death
- First Unplanned rehospital for HF

2 ans

Mitraclip + Med. treat.

Medical treatment

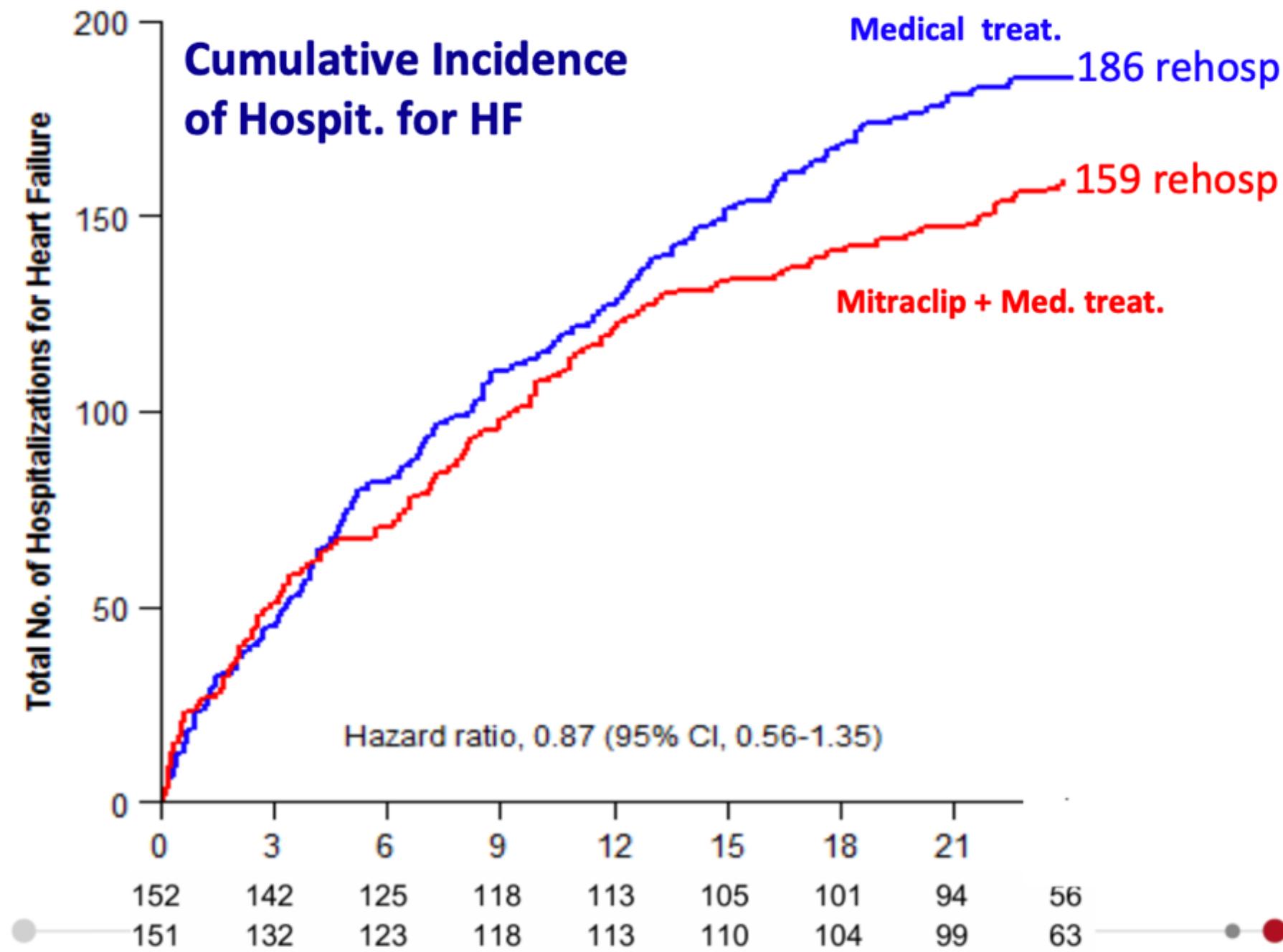
HR = 1.01 ; 95% CI 0.77 to 1.34



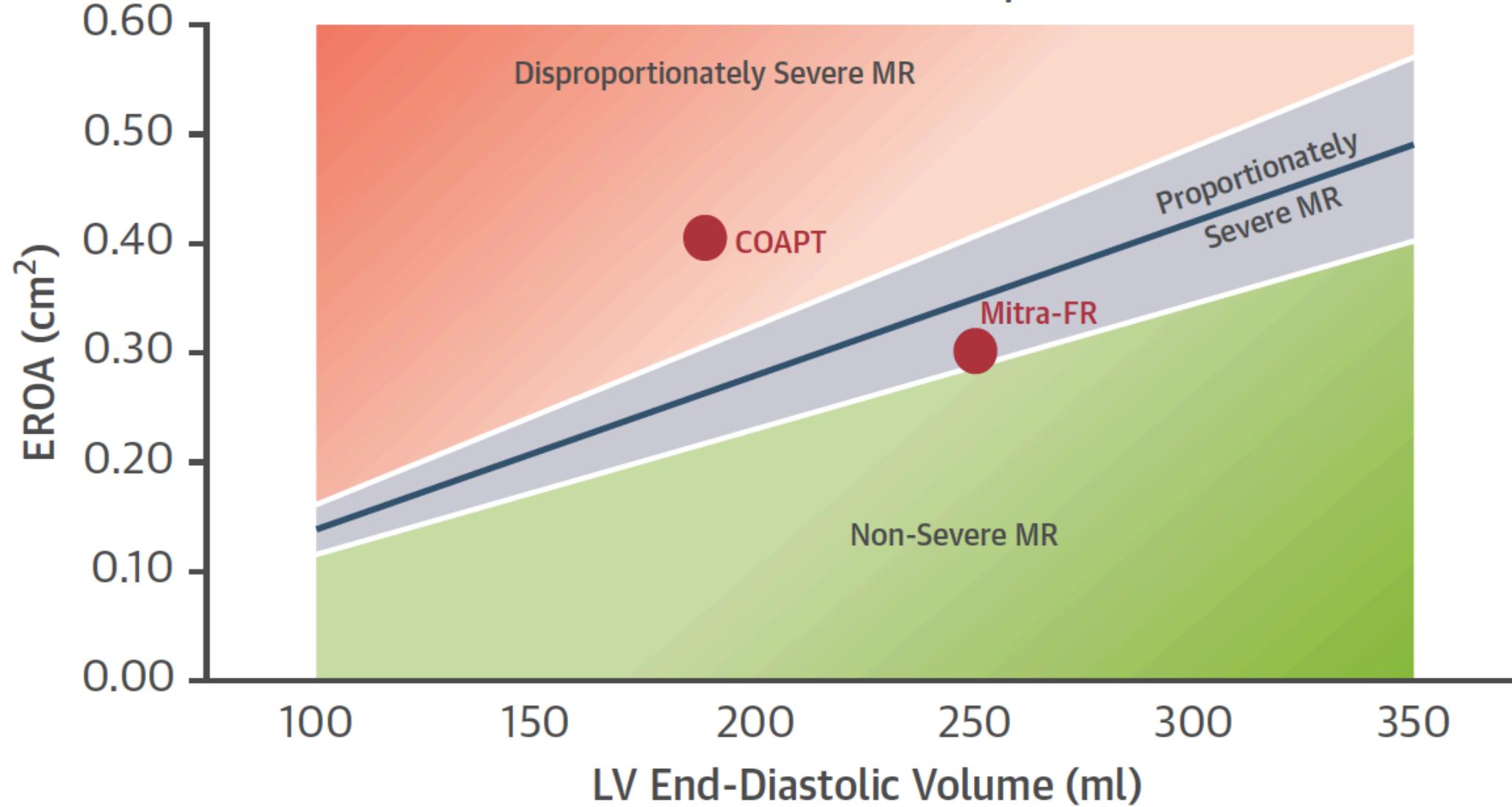
Control group	152	116	94	84	73	63	56	50
Intervention group	151	103	91	77	67	63	61	56



Cumulative Incidence of Hospit. for HF



EROA vs LVEDV at LVEF 30%, RF 50%



The EROA is dependent on both the LVEDV and the LVEF

Amélioration du SA : ASA de niveau III.



Patients avec une insuffisance mitrale secondaire de grade 3+/4+ symptomatique malgré une prise en charge médicale optimale et remplissant les critères suivants :

- non éligibles à la chirurgie de réparation ou de remplacement valvulaire,
- ayant eu une hospitalisation pour insuffisance cardiaque dans les 12 mois précédent l'intervention,
- ayant une fraction d'éjection ventriculaire gauche comprise entre 20 et 50%,
- et une surface de l'orifice régurgitant $> 0,3 \text{ cm}^2$ et un volume télédiastolique indexé du ventricule gauche $\leq 96 \text{ mL/m}^2$.

Merci

