



IX Congresso
Novas Fronteiras
em Medicina
Cardiovascular

22 a 24 de Fevereiro 2019

The Village Praia
D'El Rey - Óbidos

ADVANCED HF – CURRENT ROLE OF INTERVENTIONAL CARDIOLOGY

E. Infante de Oliveira

Interventional Heart Failure

A new clinical subspecialty emerges.

BY NAVIN K. KAPUR, MD, FSCAI, FACC

Center for

Advanced Cardiopulmonary Therapies and Transplantation

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Interventional Heart Failure Fellowship- TMB Approved



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Robert Kung Interventional Heart Failure Clinical and Research Fellowship Program

How Can We Help You Today?

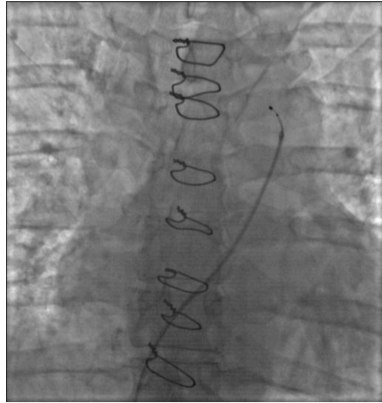


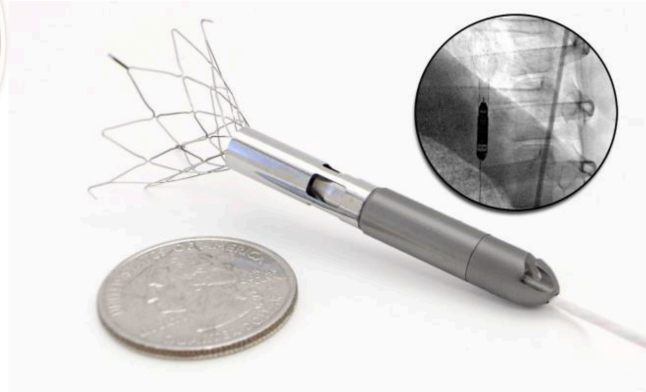
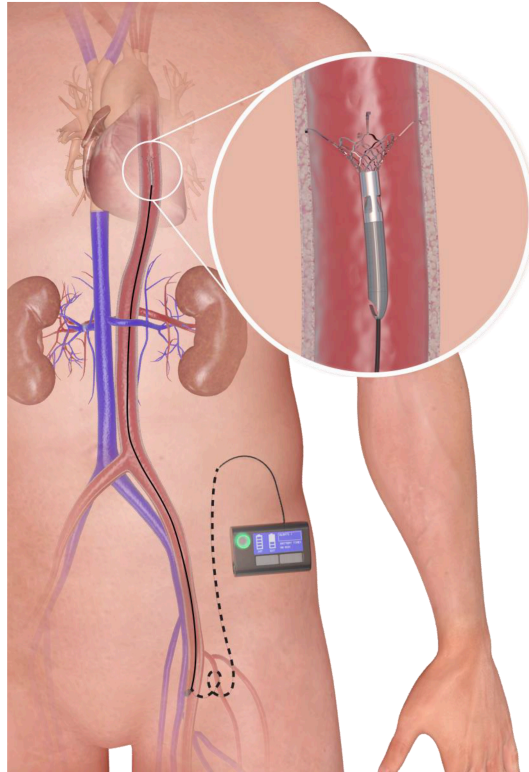






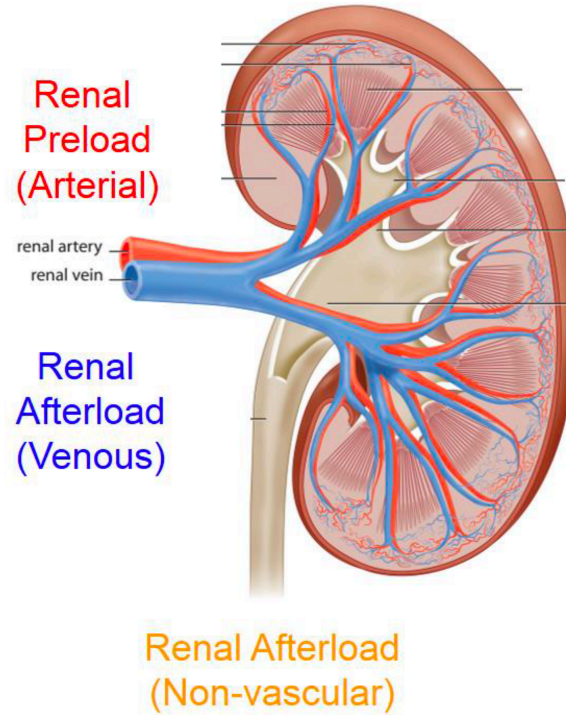
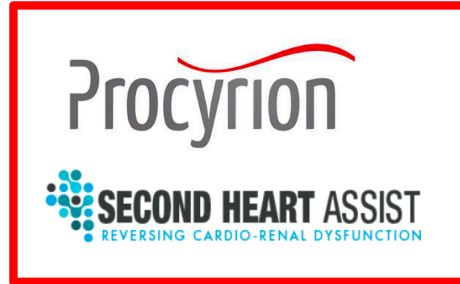
The following ablation parameters were applied at each spot: temperature $>50^{\circ}\text{C}$, energy = 10 W, and time = 120 s.





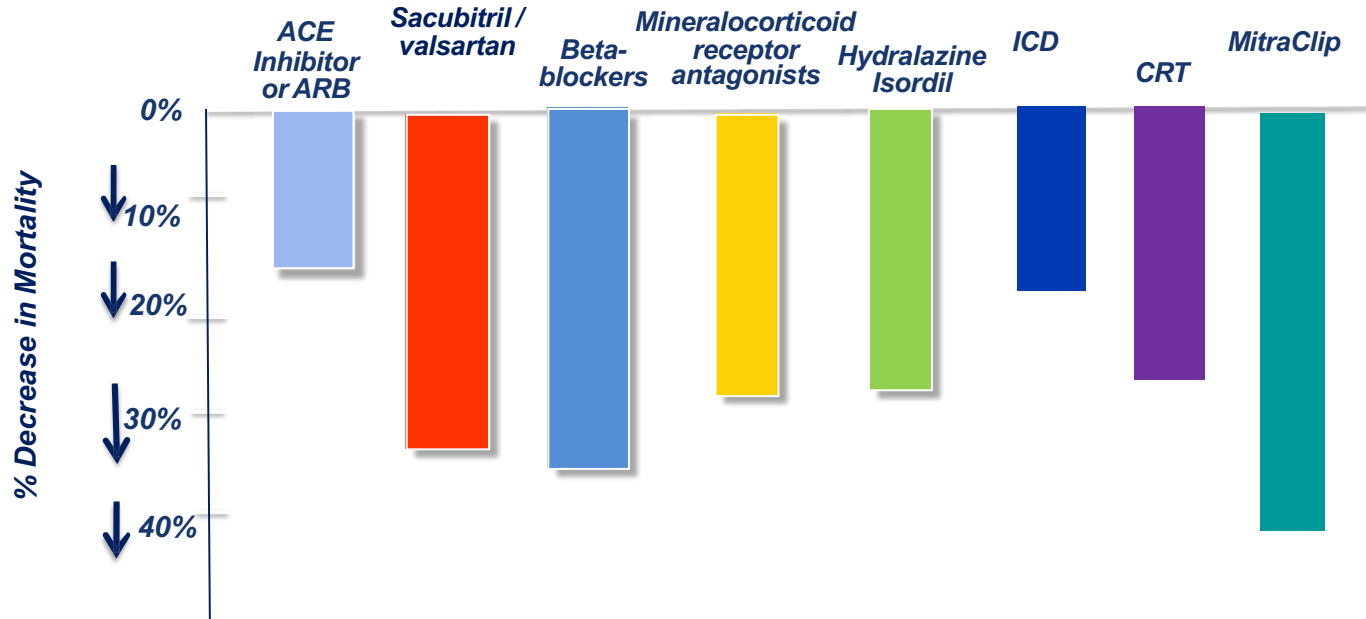
Micro-Axial Pump
Stentless Anchoring Tines
18Fr Catheter Delivery System







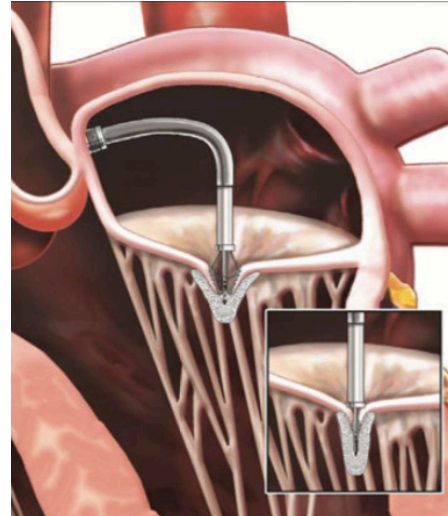
Impacto na mortalidade de diferentes modalidades terapêuticas



JoAnn Lindenfeld, TCT 2018



MitraClip tem impacto prognóstico na regurgitação funcional?





RECOMMENDED BY WHO DECEMBER 15, 2018 VOL. 379 NO. 50

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

J. E. Olshansky, D. M. Olshansky, C. Laurent, D. Jiang, G. Bonnet, N. Ples, T. Lefebvre, C. Plet, F. Boudou, D. Corbi, M. Najjar, P. Ollivier, C. Lefebvre, C. Saint-Etienne, E. Torgue, L. Lemaire, N. Karam, N. Michel, M. Gilard, E. Donat, J. N. Trochu, B. Cormier, X. Armony, F. Boute, D. Maucort-Boulch, C. Barthe, C. Samson, J. Guerin, A. Vahanian, and M. Monin, for the MITRA-FR Investigators*

- **Symptomatic** despite Optimal Treatment (NYHA $\geq$ II).
- At least **one hospitalization** for HF within 12 months preceding randomization
- Severe Secondary MR $\rightarrow$ **ERO $> 20 \text{ mm}^2$** or **R.vol $> 30 \text{ mL/beat}$**
- **15% $< \text{EF} < 40\%$**
- Not eligible for surgery “Heart Team”
- **Centralized echocardiographic Corelab**

MITRA-FR

Percutaneous Repair with the MitraClip Device for Severe Functional/Secondary Mitral Regurgitation

Multicenter, randomized, open-label, controlled phase 3 trial in patients with chronic heart failure, reduced LVEF and severe secondary MR conducted in France (37 centers)

Randomize 1:1

MitraClip + GDMT
N=152

GDMT alone
N=152

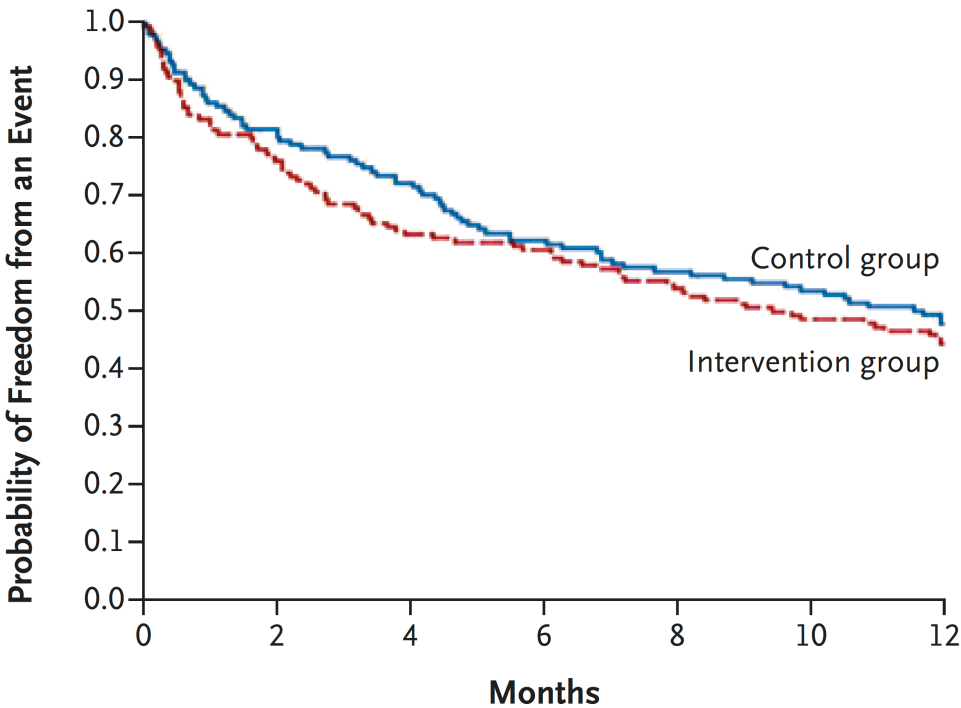
Primary endpoint: all-cause death + unplanned hospit. for HF at 12m



Centros participantes: experiência ≥ 5 casos



Death from any cause or hospitalization for heart failure



No. at Risk

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



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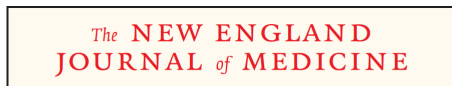
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High risk of bias!

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Elevada taxa de complicações (15%)

Elevada taxa de insucesso (18%)

Table 2. Perioperative Complications and Prespecified Serious Adverse Events (Intention-to-Treat Population).*

Variable	Intervention Group (N=152)	Control Group (N=152)
Perioperative complications during device implantation — no./total no. (%)†	21/144 (14.6)	NA
Device-implantation failure	6/144 (4.2)‡	NA
Hemorrhage resulting in transfusion or vascular complication resulting in surgical intervention	5/144 (3.5)	NA
Atrial septum lesion or atrial septal defect	4/144 (2.8)	NA
Cardiogenic shock resulting in intravenous inotropic support	4/144 (2.8)	NA
Cardiac embolism, including gas embolism and stroke	2/144 (1.4)	NA
Tamponade	2/144 (1.4)	NA
Urgent conversion to heart surgery	0	NA



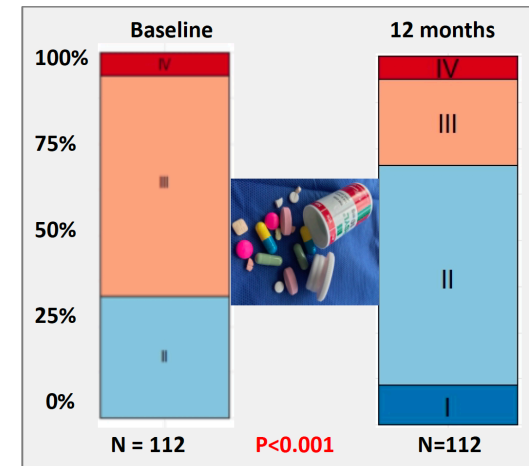
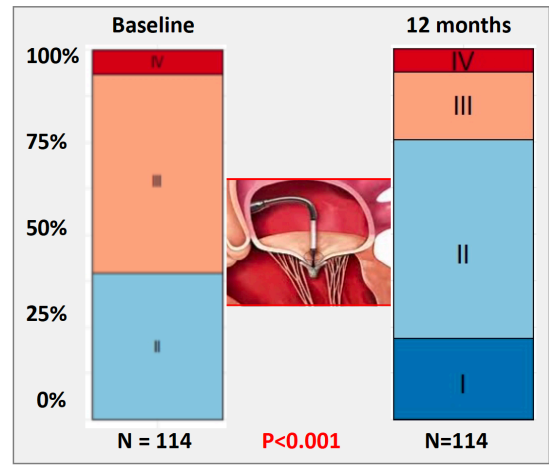


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A terapia médica estaria otimizada antes da aleatorização?



Prespecified Secondary Endpoints NYHA evolution (paired data)





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End-points ecocardiográficos aos 12 meses

	Percutaneous Repair Group (n=152)			Optimal Medical Treatment Group (n=152)			P value for comparison between study groups
Change from baseline in echocardiographic measures	N	Value	P value between Baseline and 12 Mo	N	Value	P value between Baseline and 12 Mo	
Effective regurgitant orifice area - mm ²	60	-15 [-23.5 ; -8]	<0.0001	71	-4 [-11 ; 5]	0.03	<0.0001
End-systolic diameter - mm	89	2 [-2 ; 7]	0.002	81	0 [-3 ; 4]	0.92	0.06
Ejection fraction - %	86	-3 [-8 ; 4]	0.14	76	2 [-4 ; 8]	0.02	0.004
Pulmonary artery systolic pressure - mmHg	64	-6.5 [-18 ; 4.5]	0.001	59	-3 [-17 ; 3]	0.007	0.81
6-minute walk variation - m	73	25 [-40 ; 71]	0.08	57	19 [-27 ; 75]	0.06	0.82

Dados incompletos



MITRA-FR:

- Dados incompletos / omissos:
 - Ecocardiografia (< 50%)
 - BNP, QoL, NYHA
 - Evolução da terapia médica (tipo, dose, frequência)
 - Regurgitação tricúspide e função VD
 - Resultados dos *respondedores*
- Elevada taxa de complicações
- Elevada taxa de desvio ao protocolo / risco de viés
- Terapeutica médica otimizada?
- Provavelmente subdimensionado (população / seguimento)





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,
J.J. Sarembock, A. Breke, S.O. Marx, D.J. Cohen, N.J. Weissman,
and M.J. Mack, for the COAPT Investigators*



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 614 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=302

GDMT alone
N=312

Primary endpoints:

Effectiveness: All HF hospitalizations through 24 mos, analyzed when last pt completes 12-mo FU

Safety: Freedom from device-related complications through 12 months





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Key Inclusion Criteria

1. Ischemic or non-ischemic cardiomyopathy with LVEF 20%-50% and LVESD ≤ 70 mm
2. Moderate-to-severe (3+) or severe (4+) secondary MR confirmed by an independent echo core laboratory prior to enrollment (US ASE criteria)
3. NYHA functional class II-IVa (ambulatory) despite a stable maximally-tolerated GDMT regimen and CRT (if appropriate) per societal guidelines
4. Pt has had at least one HF hospitalization within 12 months and/or a BNP ≥ 300 pg/ml* or a NT-proBNP ≥ 1500 pg/ml*
5. Not appropriate for mitral valve surgery by local heart team assessment
6. IC believes secondary MR can be successfully treated by the MitraClip

Adjusted by a 4% reduction in the BNP or NT-proBNP cutoff for every increase of 1 kg/m² in BMI >20 kg/m²





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Key Inclusion Criteria

1. Ischemic or non-ischemic cardiomyopathy with LVEF 20%-50% and LVESD ≤ 70 mm
2. Moderate-to-severe (3+) or severe (4+) secondary MR confirmed by an independent echo core laboratory prior to enrollment (US ASE criteria)
3. NYHA functional class II-IVa (ambulatory) despite a stable maximally-tolerated GDMT regimen and CRT (if appropriate) per societal guidelines
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Adjusted by a 4% reduction in the BNP or NT-proBNP cutoff for every increase of 1 kg/m² in BMI >20 kg/m²





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Central Echo Core Lab and Eligibility Committee Review

1. A Central Echo Core Lab confirmed the presence of 3+ - 4+ secondary MR
2. Potentially eligible pts were then presented by the local site investigators on weekly calls to a Central Eligibility Committee consisting of at a minimum a heart failure specialist and expert mitral valve surgeon
3. The CEC confirmed that all eligibility criteria were met, especially 1) use of maximally-tolerated GDMT for heart failure, and treatment with CRT, defibrillators and revascularization if appropriate, and that 2) mitral valve surgery was not considered appropriate at the treating center and would not be offered to the patient, even if randomized to control
4. Pts not meeting these criteria were rejected, or in some cases were deferred and could be re-presented after suitable GDMT had been instituted if the pt remained symptomatic and repeat echo still showed 3+-4+ MR



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Elevada taxa de implantação (95%)
Elevada taxa de sucesso (95%)

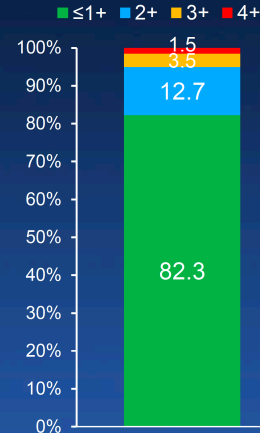


MitraClip Procedure (n=302)

MitraClip procedure attempted	293/302 (97.0%)
Clip implanted (MitraClip procedure attempted)	287/293 (98.0%)
Clip implanted (all patients)	287/302 (95.0%)
Mean # of clips implanted	1.7 ± 0.7 (n=293)
- 0 clips implanted	6 (2.0%)
- 1 clip implanted	106 (36.2%)
- 2 clips implanted	157 (53.6%)
- 3 clips implanted	23 (7.9%)
- 4 clips implanted	1 (0.3%)
Procedure duration (mins)	162.9 ± 118.1
- Device procedure time (mins)	118.9 ± 63.5
- Device time (mins)	82.7 ± 80.8
- Fluoroscopy time (mins)	33.9 ± 23.2

TTE at discharge (n=260)

MR grade





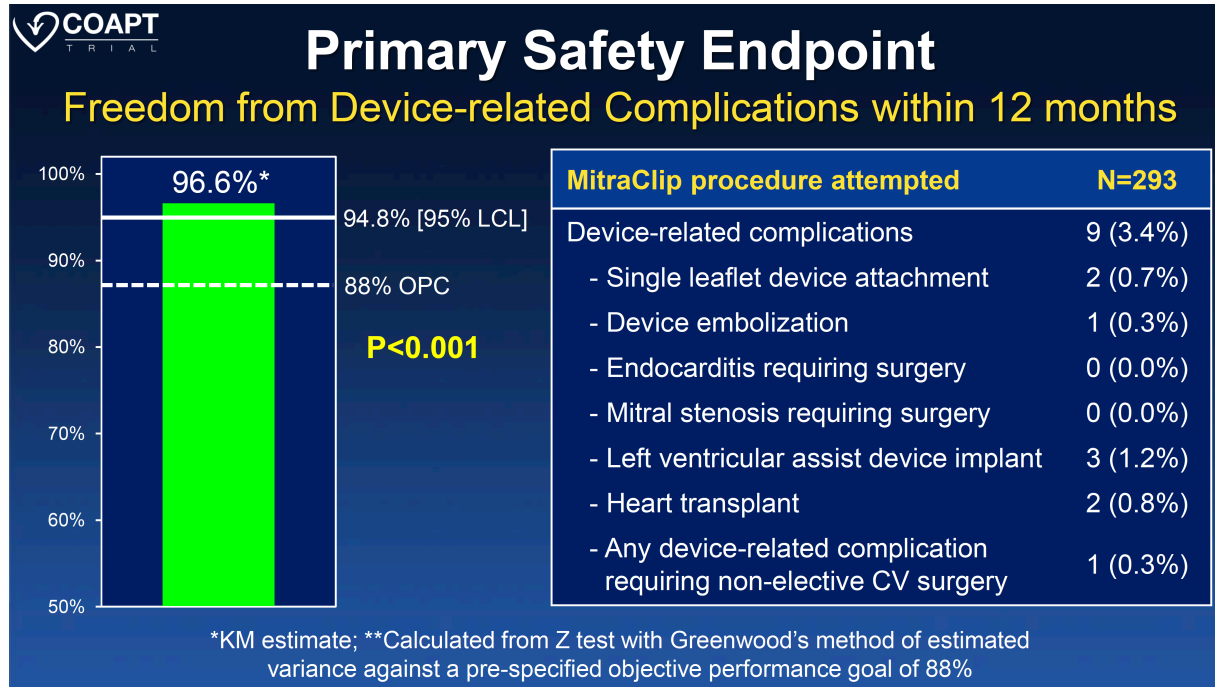
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Reduzida taxa de complicações (3.4%)





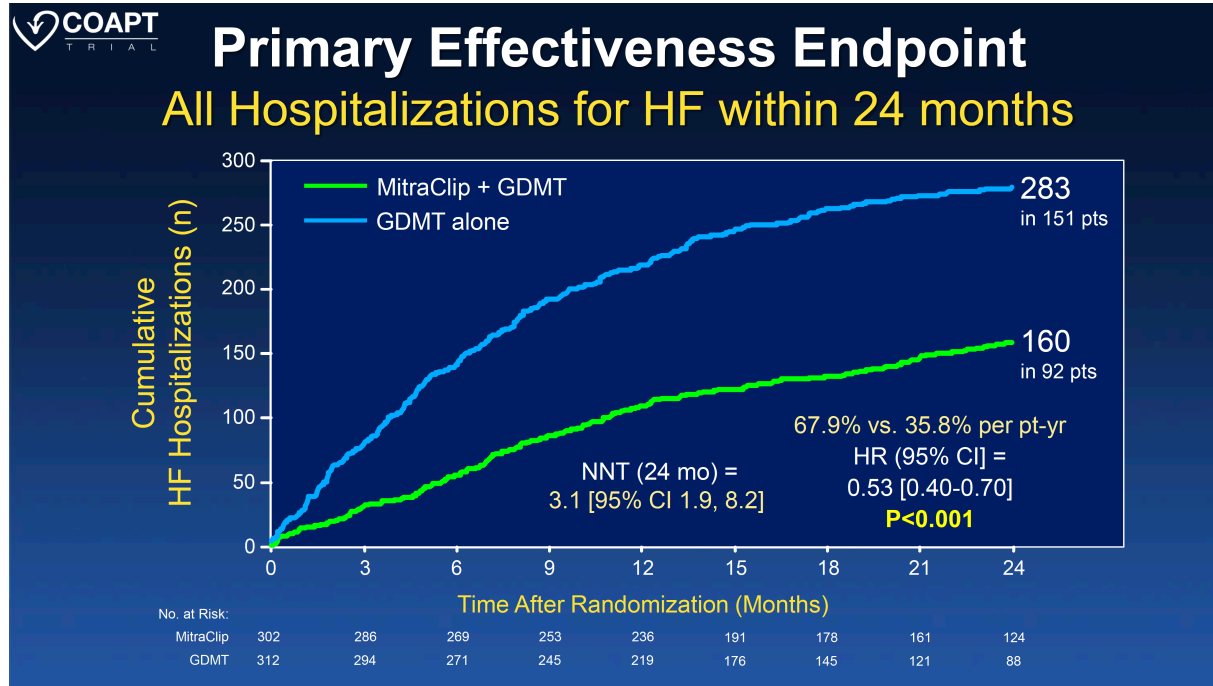
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Redução relativa de 43% e absoluta 32%
NNT 3 (24 meses)





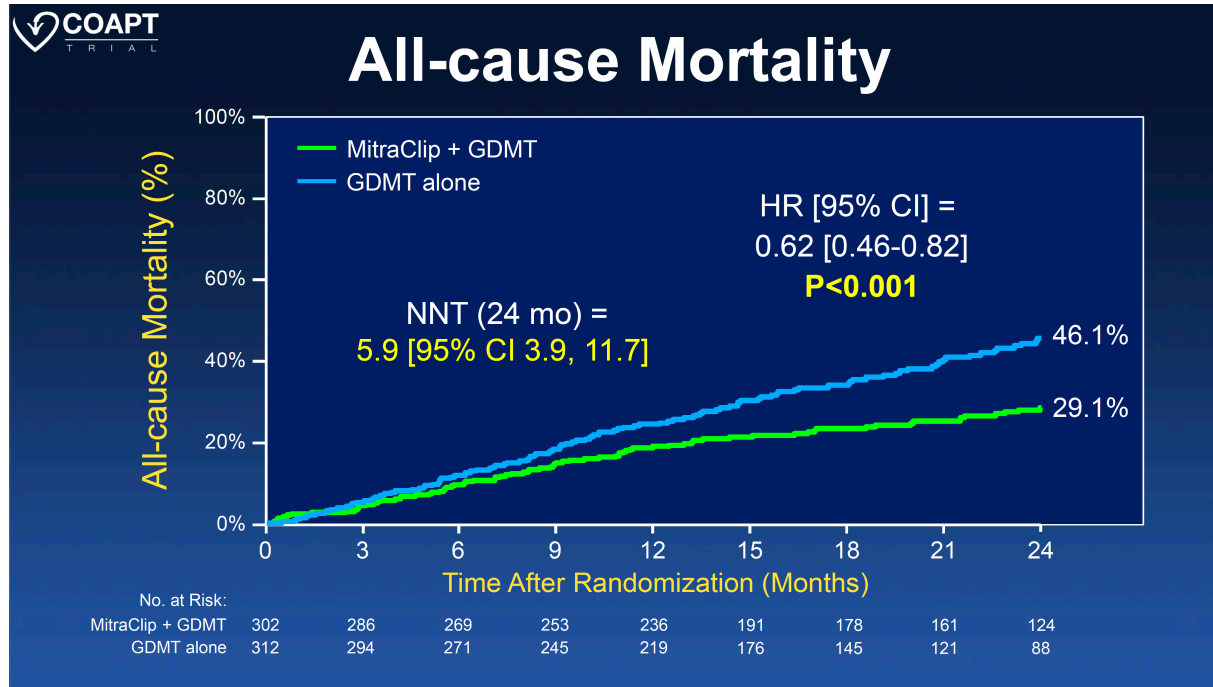
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Redução absoluta 17%
NNT 6 (24 meses)



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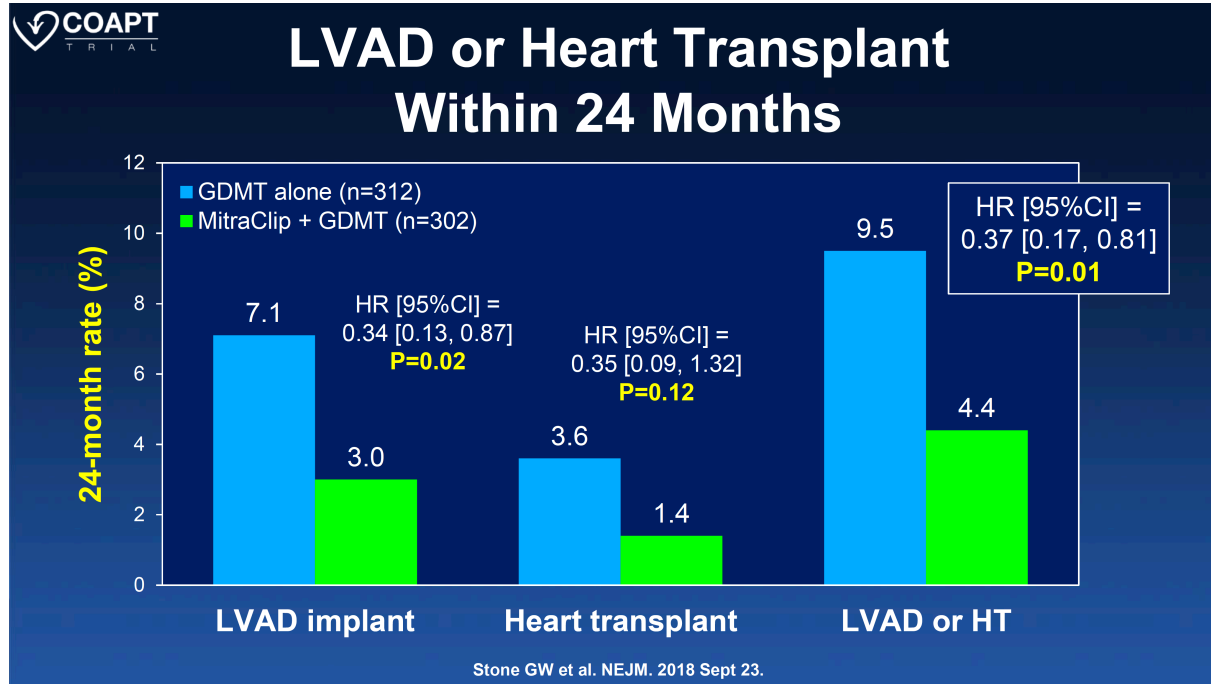
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Suporte ventricular e transplante

Redução relativa de 60%



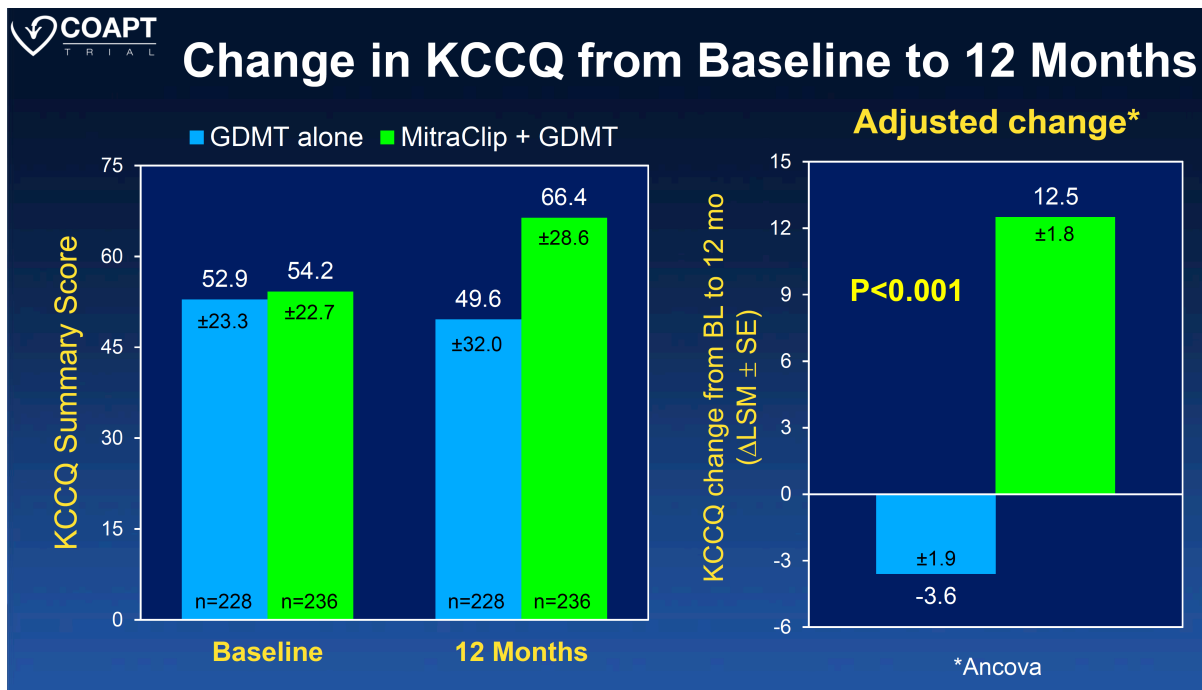


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Melhoria da qualidade de vida



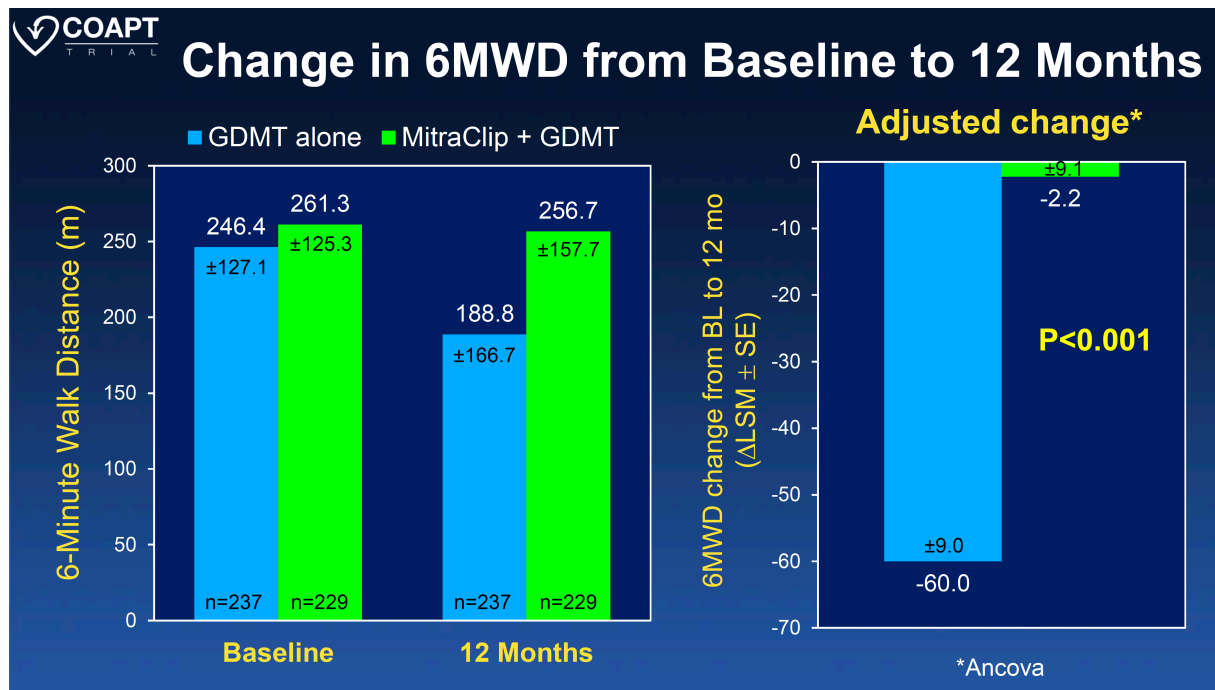


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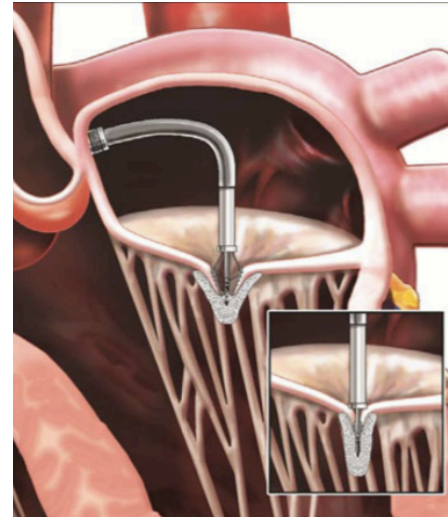
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Superior capacidade funcional





Como interpretar os diferentes resultados?



Quais as diferenças?

Dimensões ventriculares / gravidade da RM

	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

	COAPT (n=614)	MITRA-FR (n=304)
EROA, mm ² (mean ± SD)	41 ± 15	31 ± 10
- <30 mm ²	14% (80/591)	52% (157/301)
- 30 – 40 mm ²	46% (270/591)	32% (95/301)
- >40 mm ²	41% (241/591)	16% (49/301)



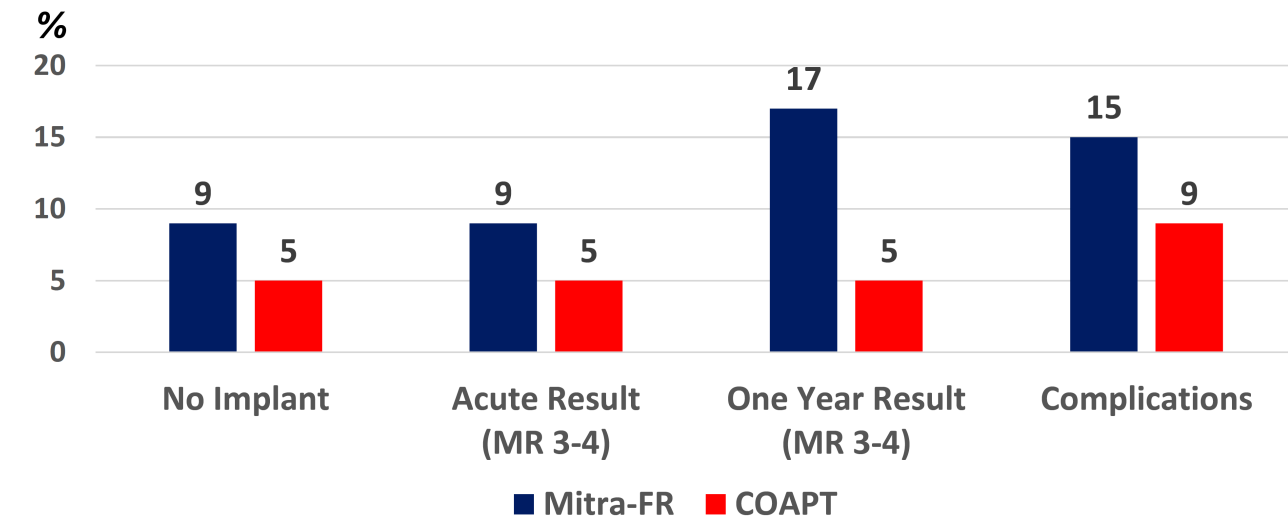
Quais as diferenças?

Terapêutica médica otimizada

	MITRA-FR (n=304)	COAPT (n=614)
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

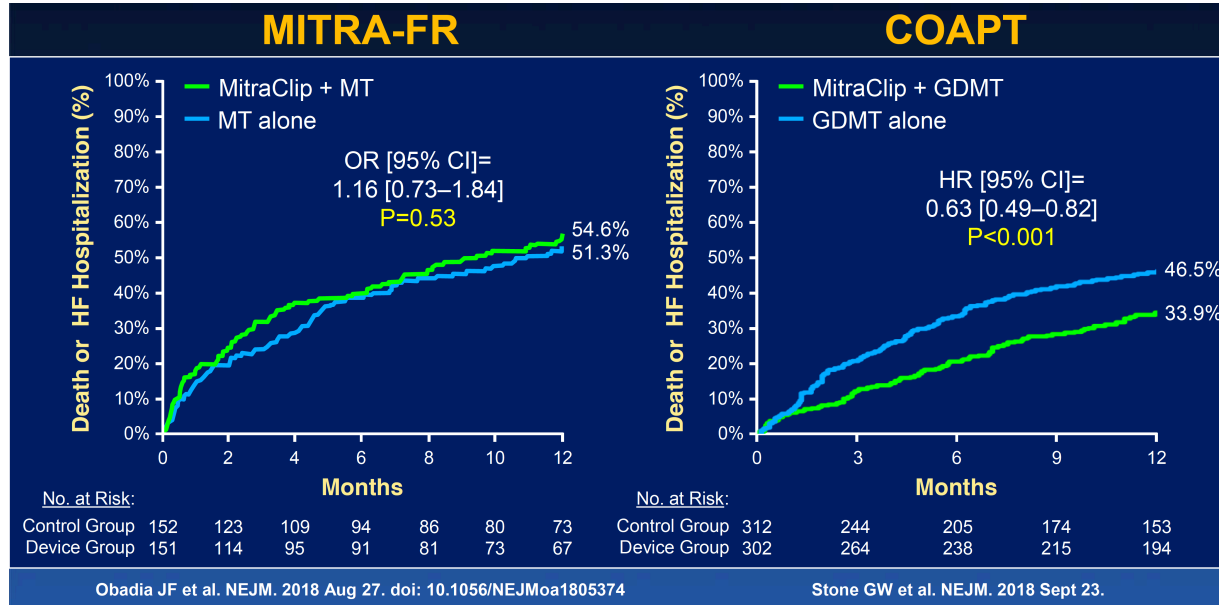


MITRA-FR SAFETY AND EFFICACY IN PERSPECTIVE





Quais as diferenças? Internamento e mortalidade





COAPT vs. MITRA-FR

- Dobro da amostra
- Dobro do seguimento
- Maior gravidade da RM
- Optimização terapêutica confirmada
- Maior taxa de implante
- Maior taxa de sucesso
- Menor taxa de complicações





Implicações do COAPT

MitraClip na RM funcional grave ou moderada a grave (EROA > 30 mm²), refractária a terapia convencional otimizada, melhora o prognóstico:

- Reduz a hospitalização por IC
- Reduz a mortalidade
- Melhora a qualidade de vida
- Melhora a capacidade funcional





Internamento - NNT 3
Mortalidade - NNT 6



[Perspective](#) > [theheart.org on Medscape](#) > [Trials and Fibrillations with Dr John Mandrola](#) > TCT 2018

COMMENTARY

MitraClip for Secondary MR -- The Redux

John M. Mandrola, MD

[DISCLOSURES](#) | September 23, 2018

“COAPT was a clear winner”

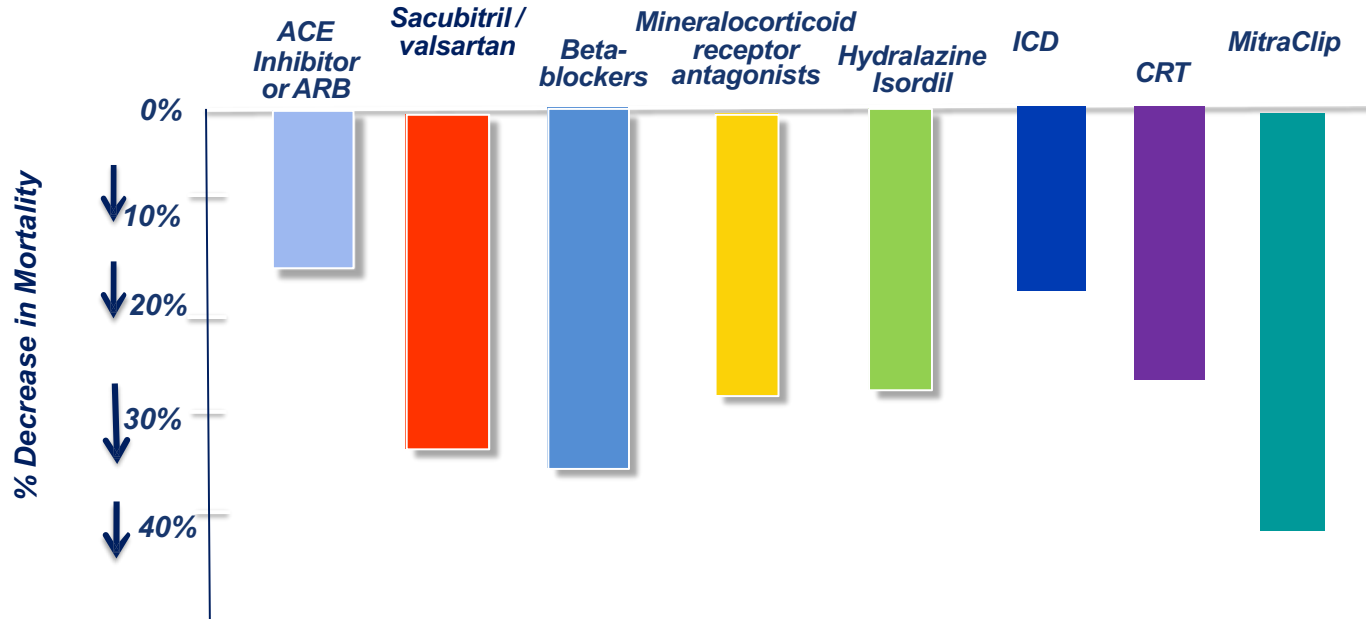


“Maybe the problem
isn't just the failing
ventricle.”





Impacto na mortalidade de diferentes modalidades terapêuticas



JoAnn Lindenfeld, TCT 2018





IX Congresso
Novas Fronteiras
em Medicina
Cardiovascular

22 a 24 de Fevereiro 2019

The Village Praia
D'El Rey - Óbidos

ADVANCED HF – CURRENT ROLE OF INTERVENTIONAL CARDIOLOGY

E. Infante de Oliveira

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Medication Use at Baseline

Maximally-tolerated doses	MitraClip + GDMT (n=302)	GDMT alone (n=312)
Beta-blocker	91.1%	89.7%
ACEI, ARB or ARNI	71.5%	62.8%
Mineralocorticoid receptor antagonist	50.7%	49.7%
Nitrates	6.3%	8.0%
Hydralazine	16.6%	17.6%
Diuretic	89.4%	88.8%
Chronic oral anticoagulant	46.4%	40.1%
Aspirin	57.6%	64.7%
P2Y12 receptor inhibitor	25.2%	22.8%
Statin	62.6%	60.6%

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Major Changes in HF Meds w/i 12 Months

	MitraClip + GDMT (n=302)	GDMT alone (n=312)	P value
ACEI, ARB or ARNI			
- ↓ dose by >50% or discontinue	6.6%	4.8%	0.33
- ↑ dose by >100% or new drug started	7.6%	7.4%	0.91
Beta-blocker			
- ↓ dose by >50% or discontinue	5.3%	5.1%	0.92
- ↑ dose by >100% or new drug started	8.6%	3.8%	0.01
Mineralocorticoid receptor antagonist			
- ↓ dose by >50% or discontinue	0.7%	0.6%	1.00
- ↑ dose by >100% or new drug started	5.3%	2.6%	0.08
Nitrates			
- ↓ dose by >50% or discontinue	0.0%	0.0%	1.00
- ↑ dose by >100% or new drug started	1.0%	1.9%	0.51
Hydralazine			
- ↓ dose by >50% or discontinue	1.0%	0.0%	0.12
- ↑ dose by >100% or new drug started	4.3%	3.8%	0.77



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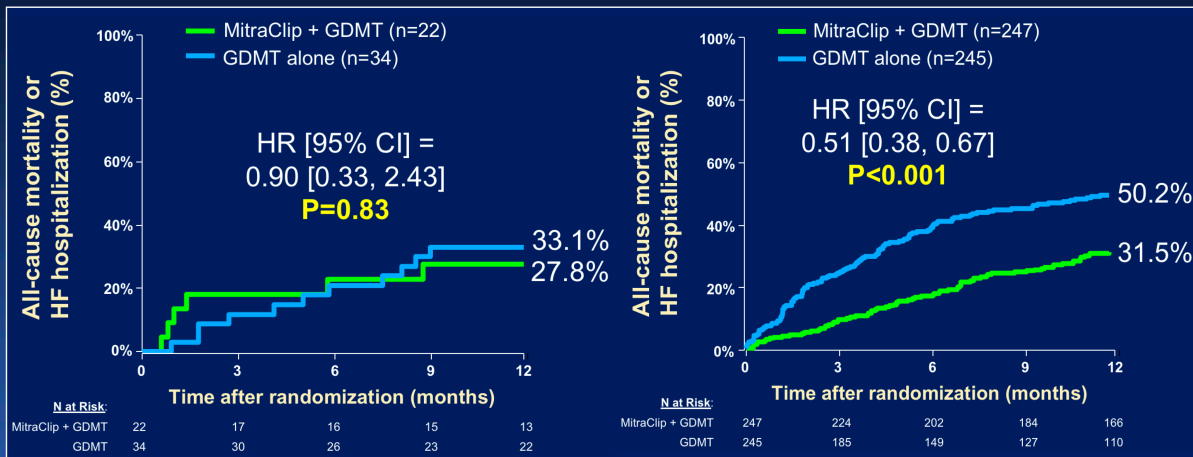


Impact of EROA and LVEDV: **All patients**

All-cause mortality or HF hospitalization through 12 months

EROA ≤ 30 mm² and LVEDVI > 96 ml/m²
(N=56; 10.2%)

EROA > 30 mm² and/or LVEDVI ≤ 96 ml/m²
(N=492; 89.8%)





EDITORIAL VIEWPOINT

Proportionate and Disproportionate Functional Mitral Regurgitation

A New Conceptual Framework That Reconciles the Results of the MITRA-FR and COAPT Trials

Paul A. Grayburn, MD, Anna Sannino, MD, Milton Packer, MD

