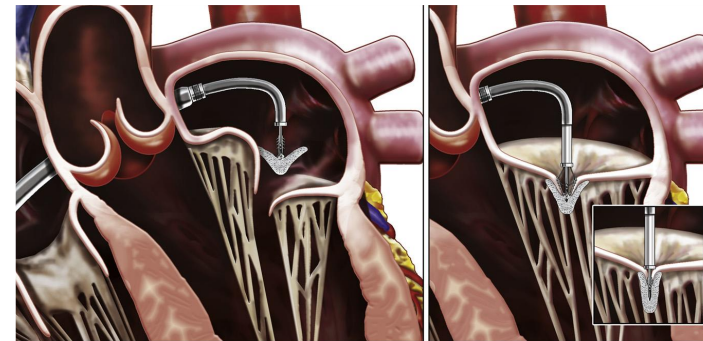
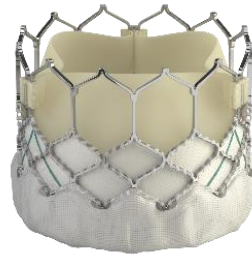


# Implante Valvar Aórtico Transcateter (TAVI) e Mitraclip em 2019



**Cleverson N. Zukowski**

*Doutor em ciências médicas pela FMUSP*

*Cardiologista Intervencionista*

*Supervisor da Linha de Cuidados em Cardologia do Hospital Copa D'Or*

*Supervisor da Hemodinâmica Copa D'Or*

## Potenciais conflitos de interesse com esta apresentação:

Atividades como proctor :

- Edwards Lifesciences
- Medtronic

# TAVI em 2019

**Para quem?**

**Como realizar?**

**Novas fronteiras**

# TAVI em 2019

**Para quem?**

**Como realizar?**

**Novas Fronteiras?**



# EVOLUÇÃO TAVI 2002-2019

Primeiro implante-2002    Registros europeus-2005    Brasil-2009    Partner Trial-2010



## QUAL O ESTADO ATUAL DA TAVI?

- Novas próteses
- Introdutores de menor calibre
- Experiência mundial de > 500.000 casos
- Seleção de pacientes
- Estratégia minimalista

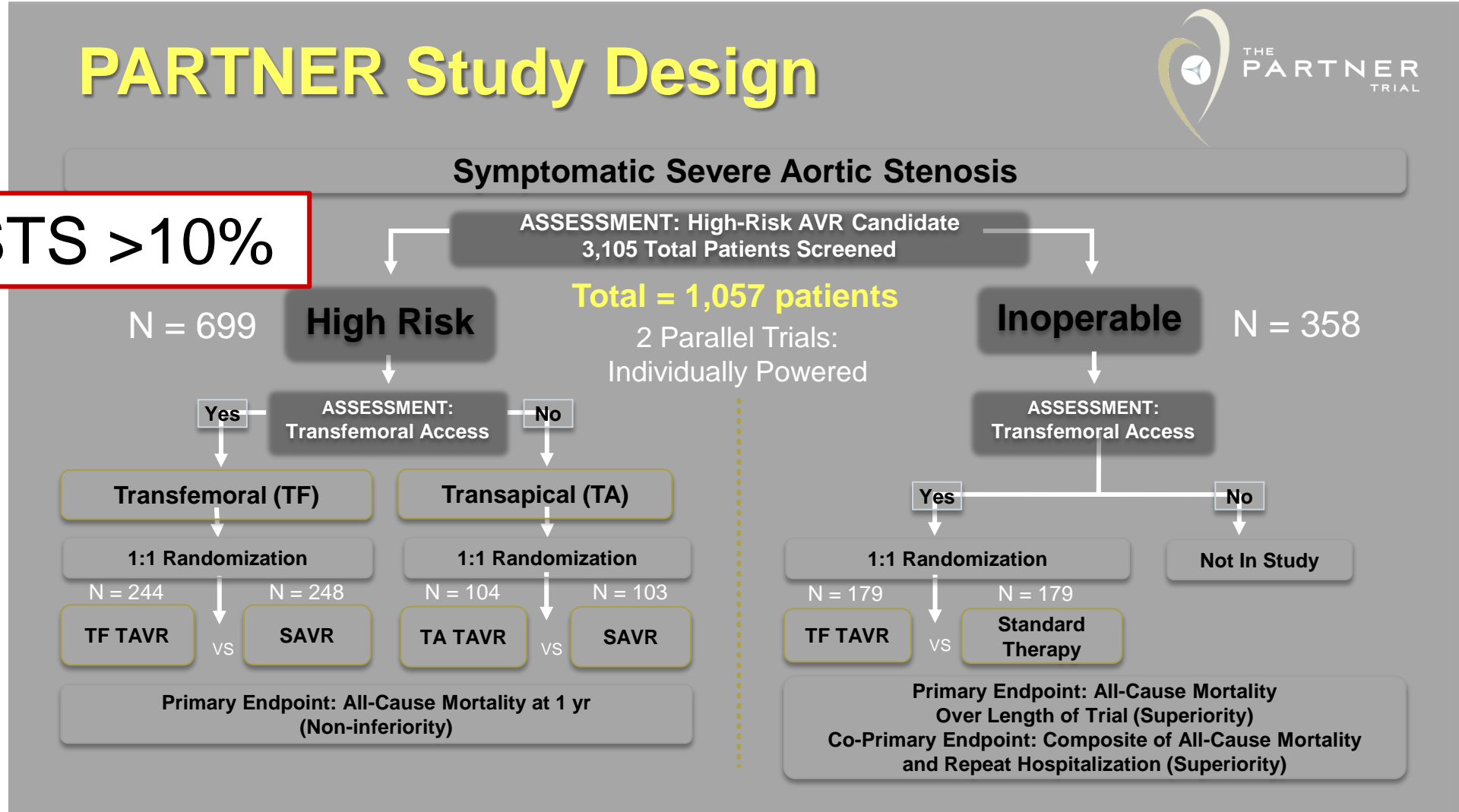


# 2010: primeiro grande ensaio publicado de TAVI

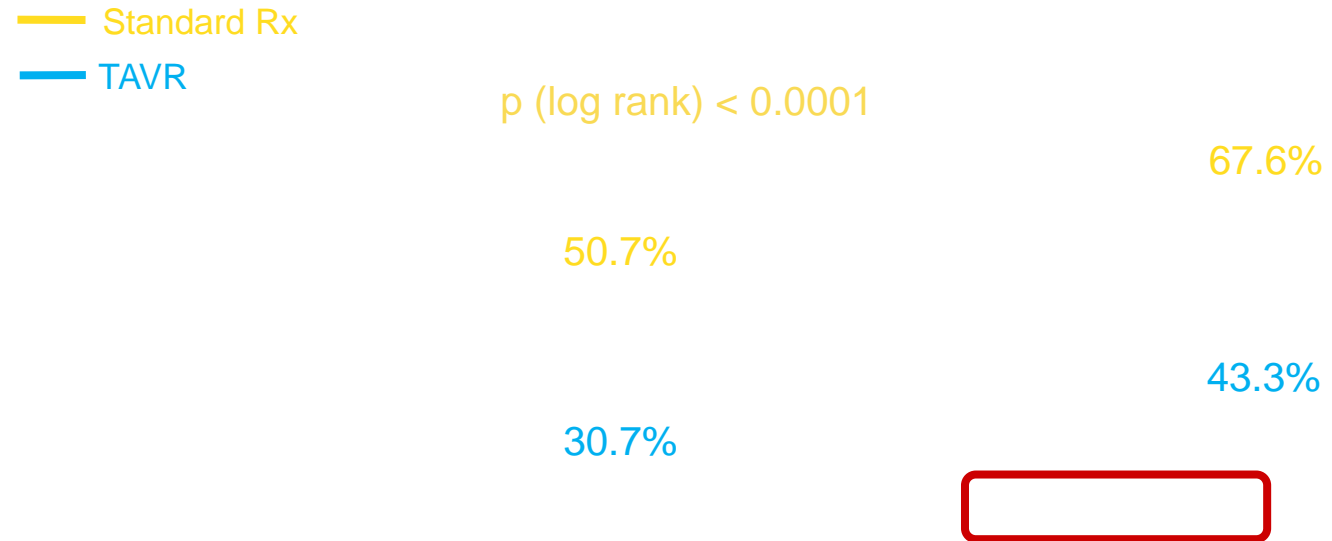
## PARTNER Study Design



**STS >10%**



# Partner Trial: coorte inoperável, mortalidade em 02 anos



Idade média=83 anos

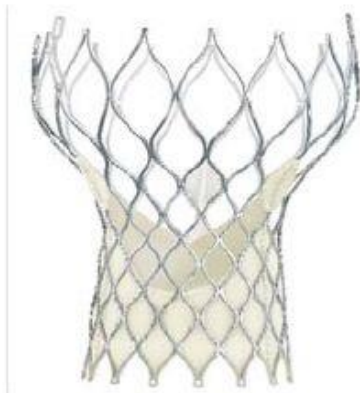
# EVOLUÇÃO TAVI 2008-2019: PRÓTESES

Brasil: 2009

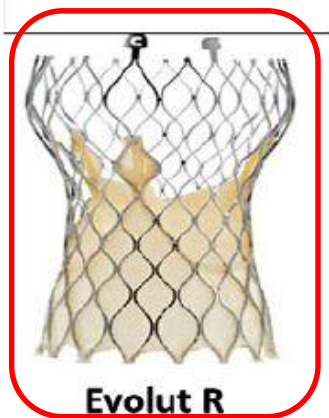
2019



A



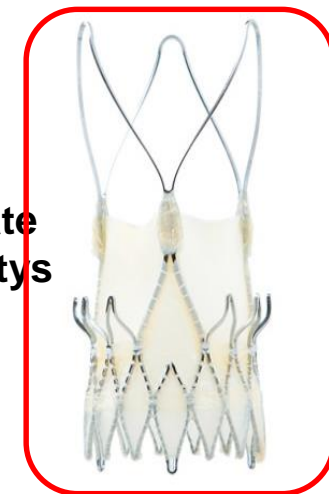
CoreValve



Evolut R



LOTUS



Acurate  
Symetys

B



SAPIEN



SAPIEN XT



SAPIEN 3

# Partner 2: Risco intermediário

*The* NEW ENGLAND  
JOURNAL *of* MEDICINE

STS entre 4 e 8%

17

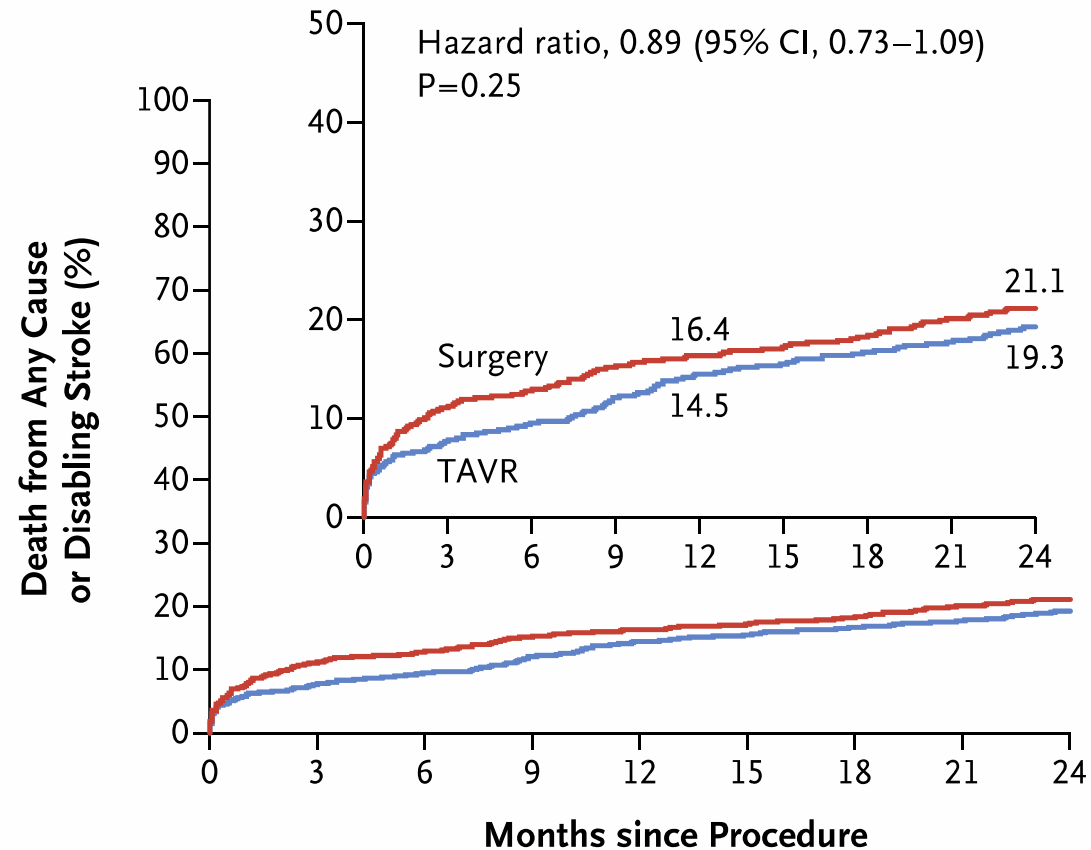
## Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D.,  
Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D.,  
D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D.,  
Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D.,  
Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D.,  
Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D.,  
Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D.,  
Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M.,  
and John G. Webb, M.D., for the PARTNER 2 Investigators\*



# Partner 2-Risco intermediário

## A Intention-to-Treat Population



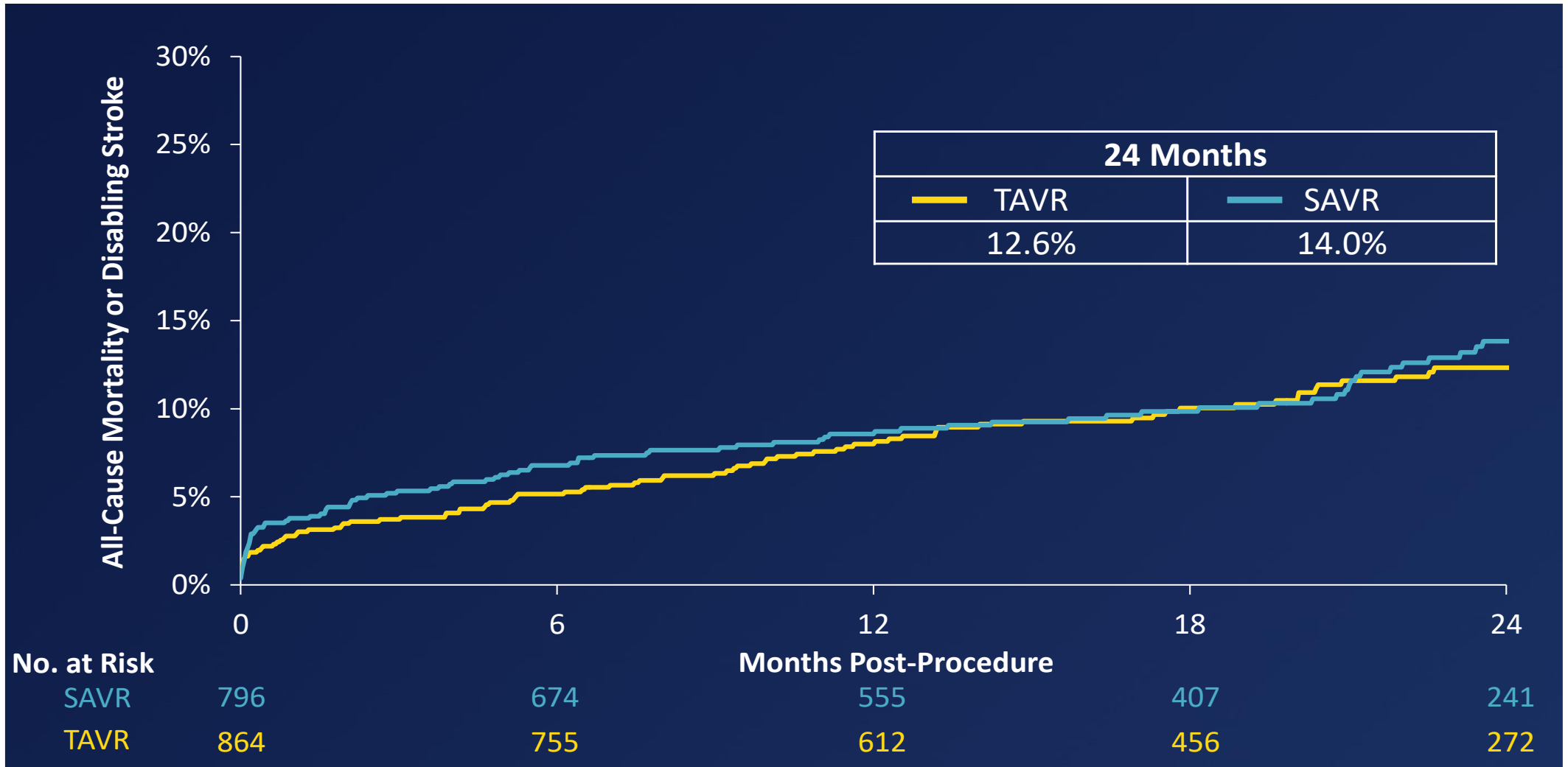
### No. at Risk

TAVR	1011	918	901	870	842	825	811	801	774
Surgery	1021	838	812	783	770	747	735	717	695

Idade média=82 anos

# SURTAVI TRIAL ACC 2017

## DESFECHO PRIMÁRIO: MORTALIDADE E AVC





# SURTAVI TRIAL ACC 2017

## características clínicas

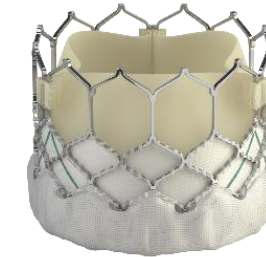
n (%) or mean $\pm$ SD	TAVR (N=864)	SAVR (N=796)
Age, years	79.9 $\pm$ 6.2	79.7 $\pm$ 6.1
Male sex	498 (57.6)	438 (55.0)
Body surface area, m <sup>2</sup>	1.9 $\pm$ 0.2	1.9 $\pm$ 0.2
STS PROM, %	4.4 $\pm$ 1.5	4.5 $\pm$ 1.6
Logistic EuroSCORE, %	11.9 $\pm$ 7.6	11.6 $\pm$ 8.0
Diabetes mellitus	295 (34.1)	277 (34.8)
Serum creatinine >2 mg/dl	14 (1.6)	17 (2.1)
Prior stroke	57 (6.6)	57 (7.2)
Prior TIA	58 (6.7)	46 (5.8)
Peripheral vascular disease	266 (30.8)	238 (29.9)
Permanent pacemaker	84 (9.7)	72 (9.0)

# Risco intermediário: TAVI superior



## Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis

*Vinod H Thourani, Susheel Kodali, Raj R Makkar, Howard C Herrmann, Mathew Williams, Vasilis Babaliaros, Richard Smalling, Scott Lim, S Chris Malaisrie, Samir Kapadia, Wilson Y Szeto, Kevin L Greason, Dean Kereiakes, Gorav Ailawadi, Brian K Whisenant, Chandan Devireddy, Jonathon Leipsic, Rebecca T Hahn, Philippe Pibarot, Neil J Weissman, Wael A Jaber, David J Cohen, Rakesh Suri, E Murat Tuzcu, Lars G Svensson, John G Webb, Jeffrey W Moses, Michael J Mack, D Craig Miller, Craig R Smith, Maria C Alu, Rupa Parvataneni, Ralph B D'Agostino Jr, Martin B Leon*

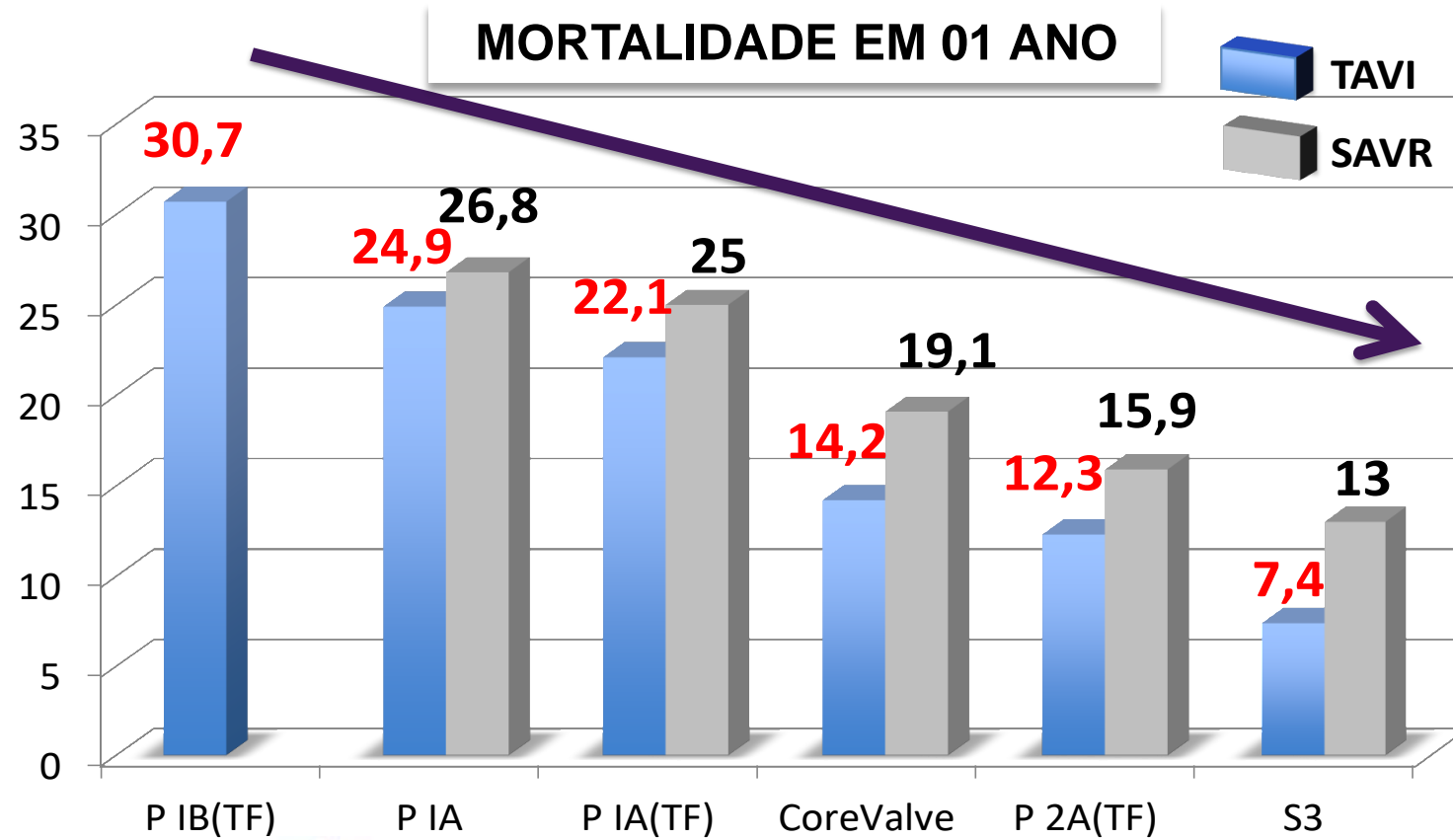


Unadjusted Clinical Events (%)	30 Days		1 Year	
	TAVR	Surgery	TAVR	Surgery
<b>Death</b>				
All-cause	1.1	4.0	7.4	13.0
Cardiovascular	0.9	3.1	4.5	8.1
<b>Neurological Events</b>				
Disabling Stroke	1.0	4.4	2.3	5.9
All Stroke	2.7	6.1	4.6	8.2
All-cause Death and Disabling Stroke	2.0	8.0	8.4	16.6

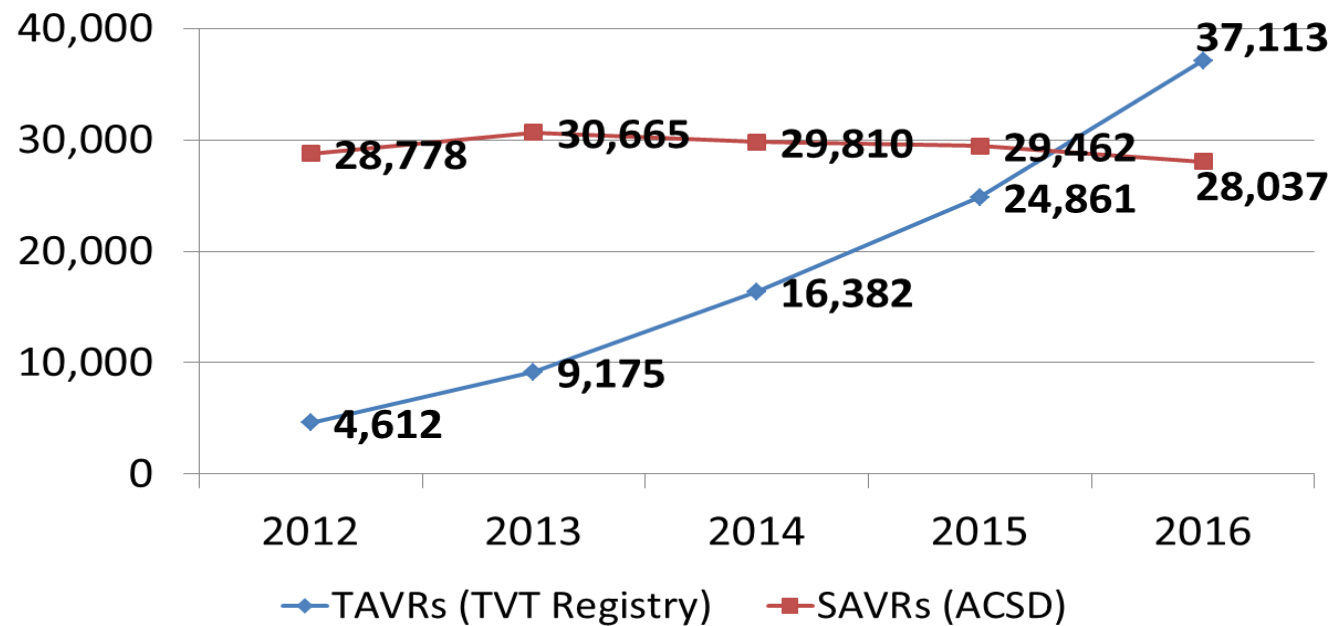
# EVOLUÇÃO TAVI 2008-2019

## Principais causas:

- AVC
- VASCULARES
- IAO PARAVALVAR



# Registro TVT: TAVI VS. cirurgia



**Podemos indicar TAVI para  
pacientes de risco baixo?**





# Risco Baixo: TAVI vs. cirurgia

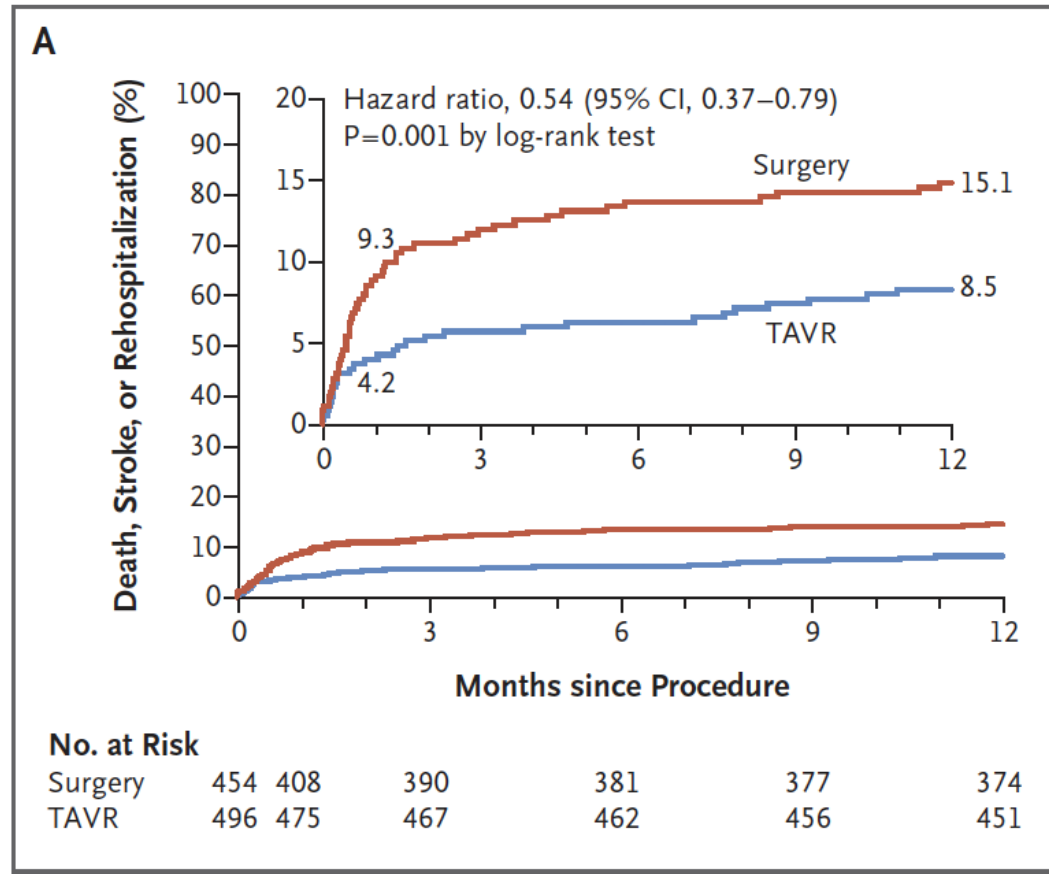
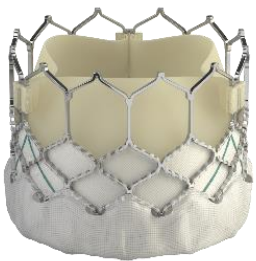
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators\*

Idade média=73 anos



# Risco Baixo: TAVI vs. cirurgia

The NEW ENGLAND JOURNAL of MEDICINE

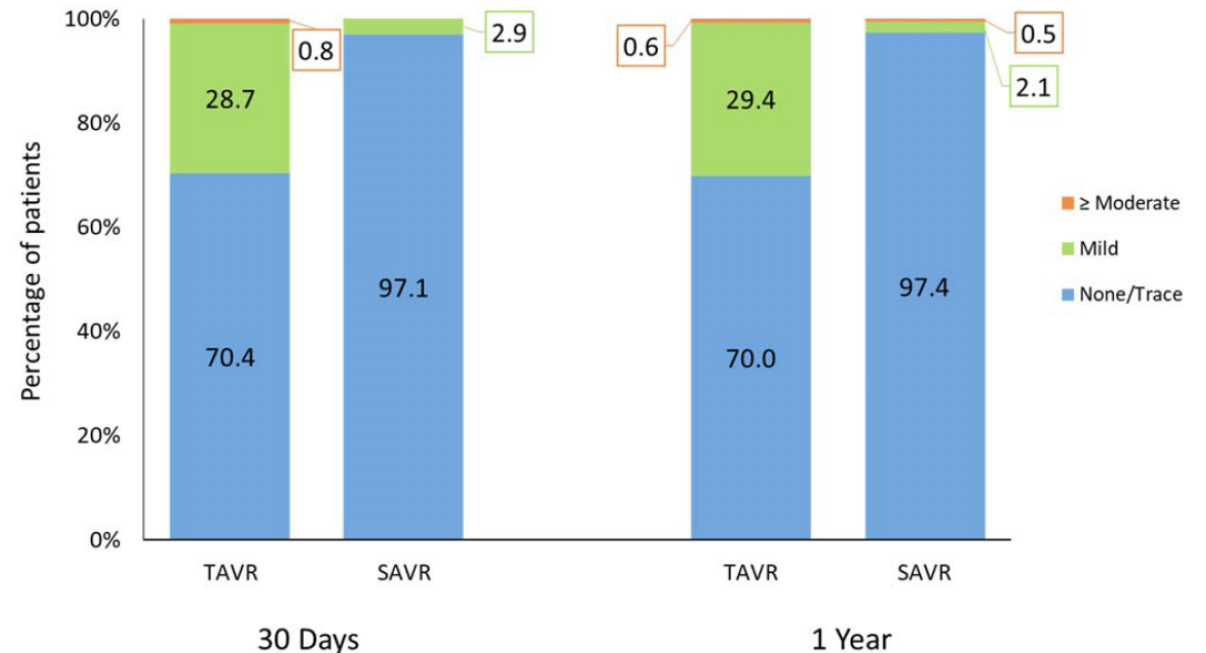
ORIGINAL ARTICLE

## Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. \ and C.R. Smith, for the PARTNER 3 Investigators\*



### Paravalvular Regurgitation





# Risco Baixo: TAVI vs. cirurgia

The NEW ENGLAND JOURNAL of MEDICINE

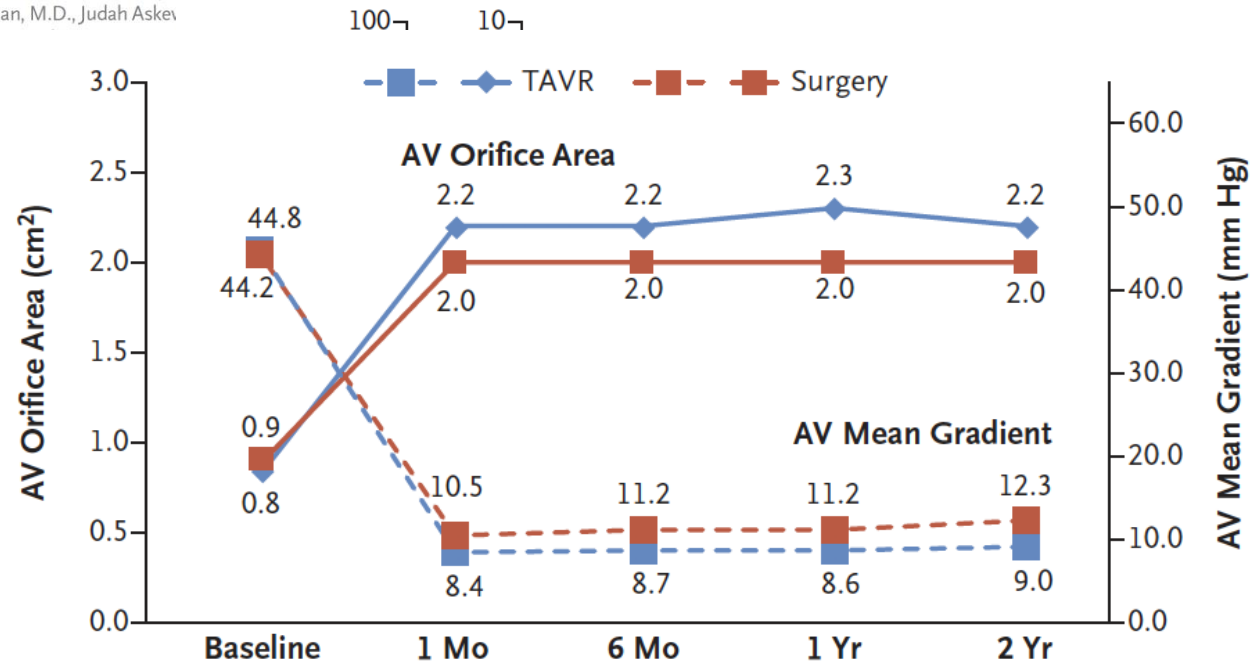
ORIGINAL ARTICLE

## Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M. Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajw John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askev Paul Sorajja, M.D., Joshua Rovin, M.D., David H. Adams, M.D., Paul S. Teirstein, M John K. Forrest, M.D., Didier Tchétché, M.D., Jon I Nicolò Piazza, M.D., Ph.D., Basel Ramlawi, I George Petrossian, M.D., Thomas G. Glea Michael J. Boulware, Ph.D., Hongyan Qiao, Ph and Michael J. Reardon, M.D., for the Evolut



### B Incidence of Primary End Point



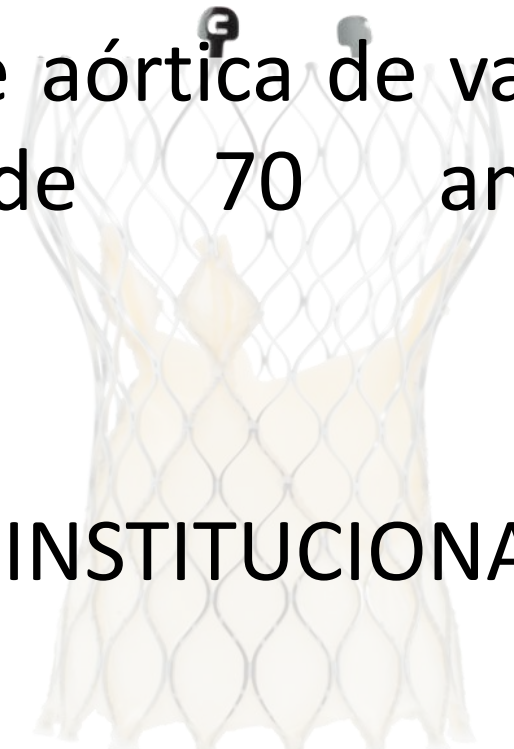
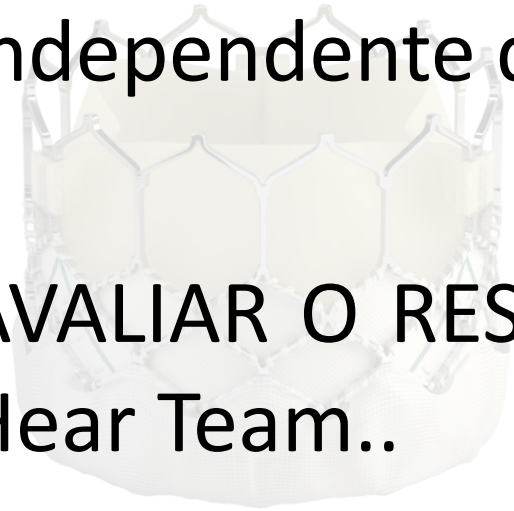
# TAVI VS. Cirurgia em 2019

- Menos AVC
- Menor mortalidade
- Menos fibrilação atrial
- Recuperação mais rápida
- Melhor hemodinâmica
- Sem cicatriz



# *Para quem eu indico TAVI em 2019?*

- Pacientes com estenose aórtica de valva tricúspide, acima de 70 anos, independente do risco.
- **AVALIAR O RESULTADO INSTITUCIONAL!!**  
Hear Team..



# TAVI em 2019

**Para quem?**

**Como realizar o procedimento?**

**Novas fronteiras**

# TAVI em 2019

**Para quem?**

**Como realizar o procedimento?**

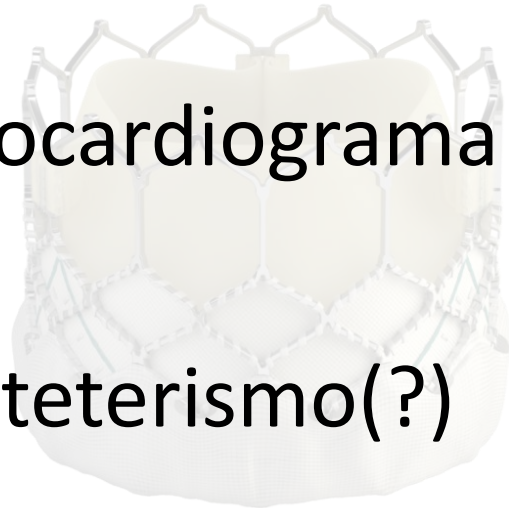
**Novas fronteiras**



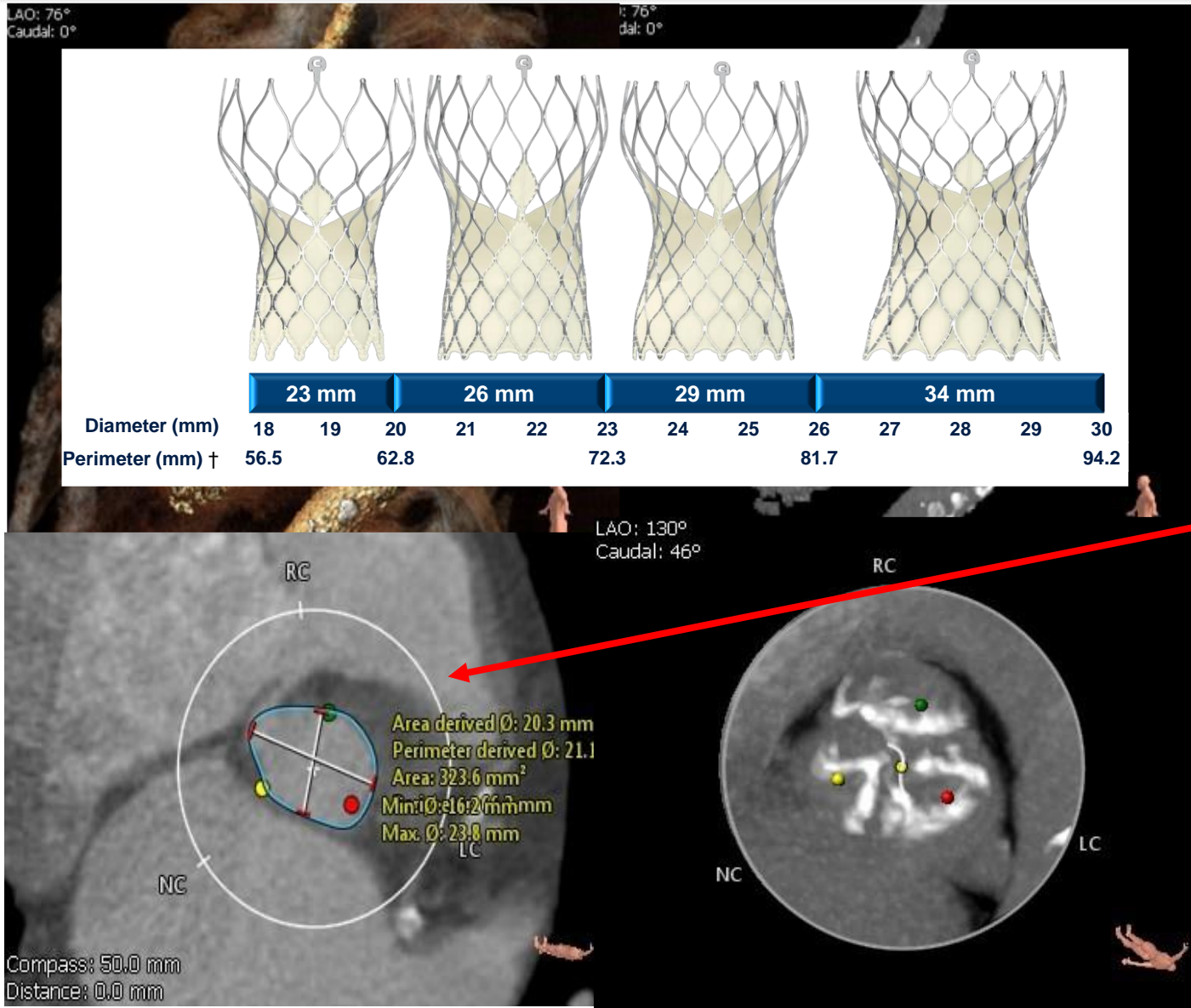
➤ Avaliação de risco(Heart Team)

➤ Ecocardiograma TT e Angiotomografia

➤ Cateterismo(?)



# ANGIO TC DE AORTA E RAMOS



## Anel valvar:

Perímetro deriv: 21.1 mm

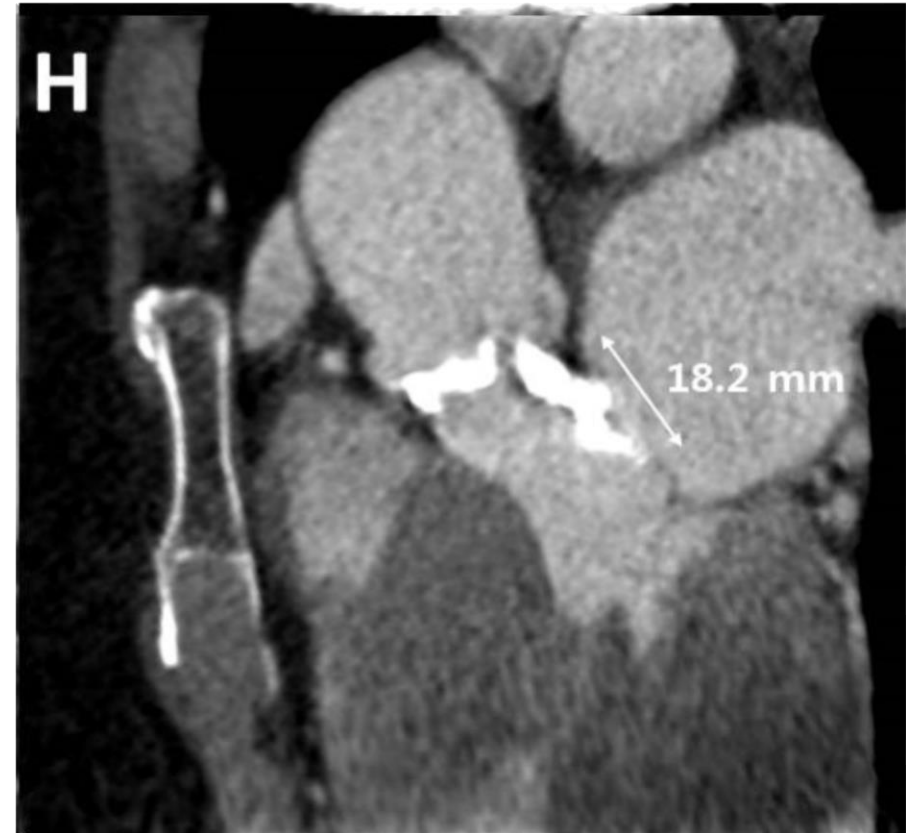
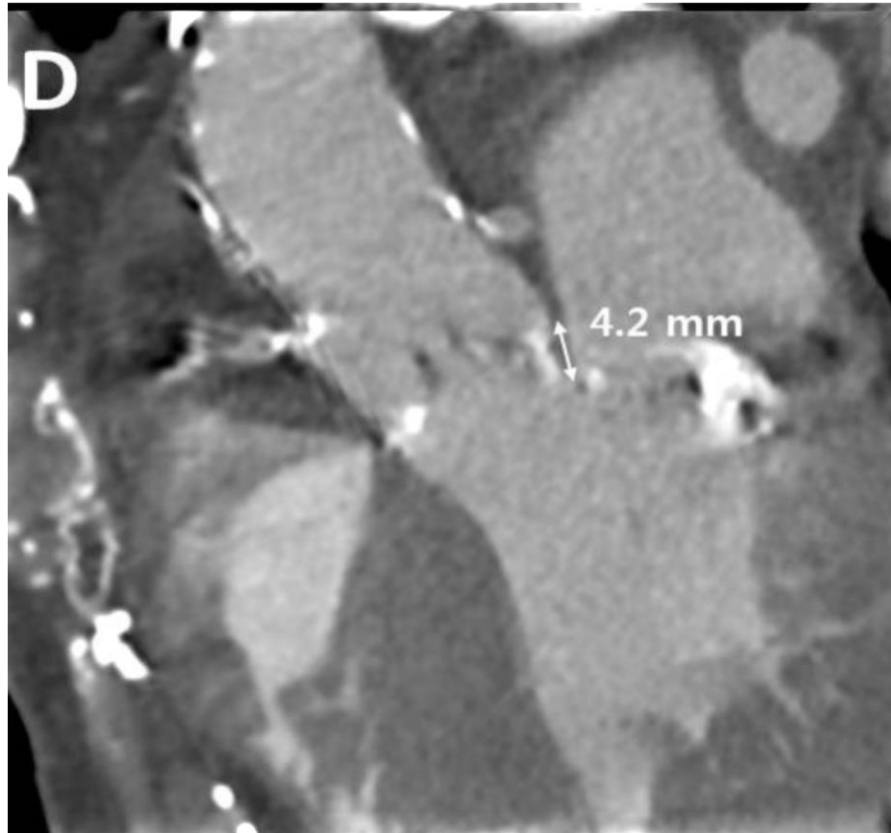
Diam. mínimo= 16.2 mm

Diam. Máximo=23.8 mm



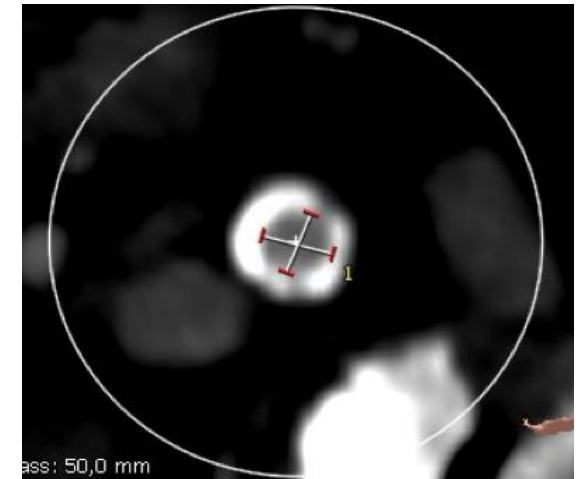
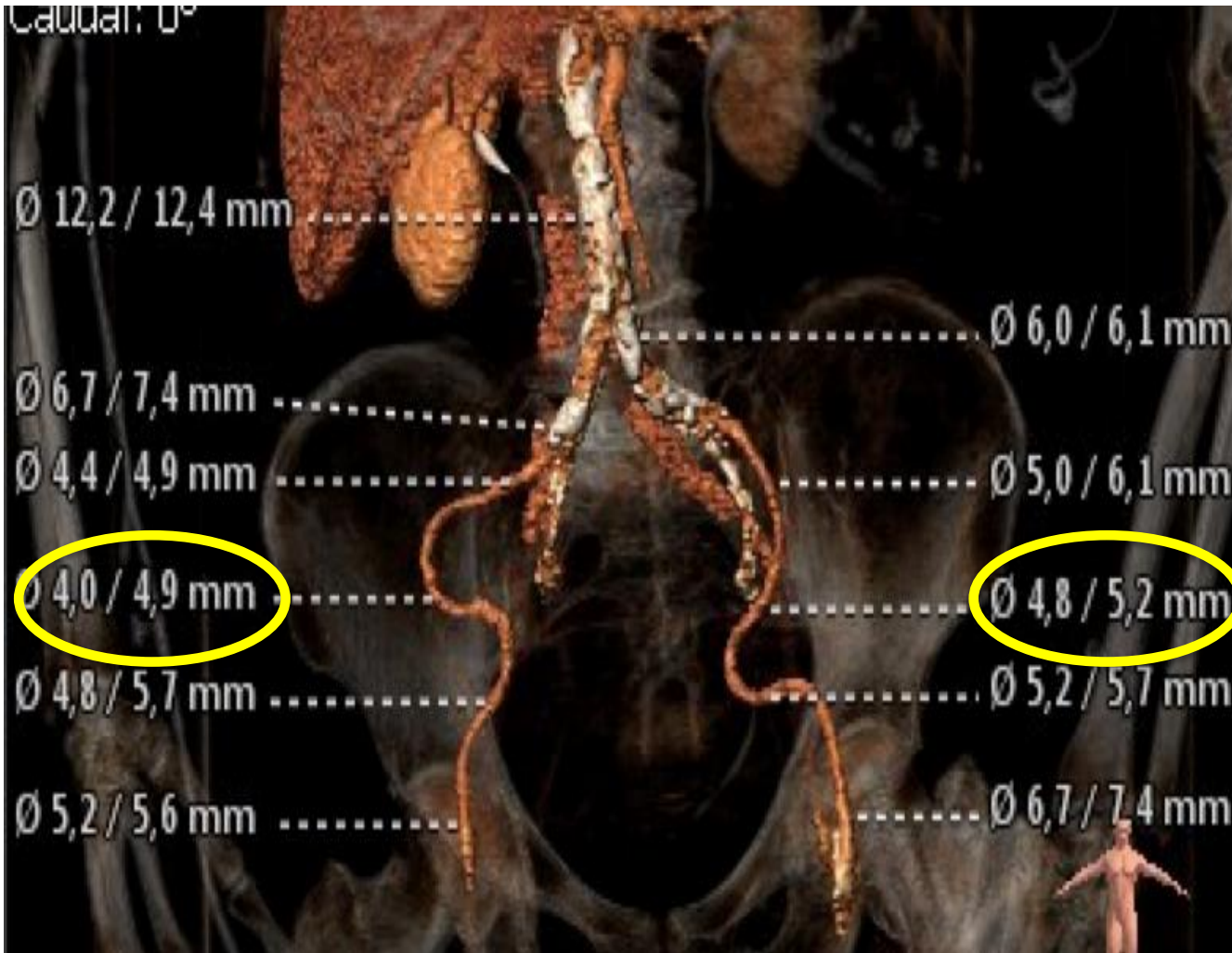
# ANGIO TC DE AORTA E RAMOS

## Calcificação da via de saída do VE



# ANGIO TC DE AORTA E RAMOS

Feminina, 84 anos / STS: 11,8% / 48 kg / Frágil / Cirurgia Prévia



• *Para todos?* **Não**

- *Pacientes com angina*
- *Histórico de DAC*
- *Lesões proximais à angio TC*
- ***Indicação seletiva***





# Qual prótese utilizar?

Interações diferentes de cada device com VAo

1. Durabilidade
2. Acesso coronário
3. Alinhamento de comissuras
4. Custo



A escolha deve ser individualizada!

# Estratégia minimalista deve ser o padrão

Rev Bras Cardiol Invasiva. 2015;23(4):285-287

Relato de Caso

Estratégia minimamente invasiva para o implante percutâneo de bioprótese aórtica de segunda geração Lotus™

2009

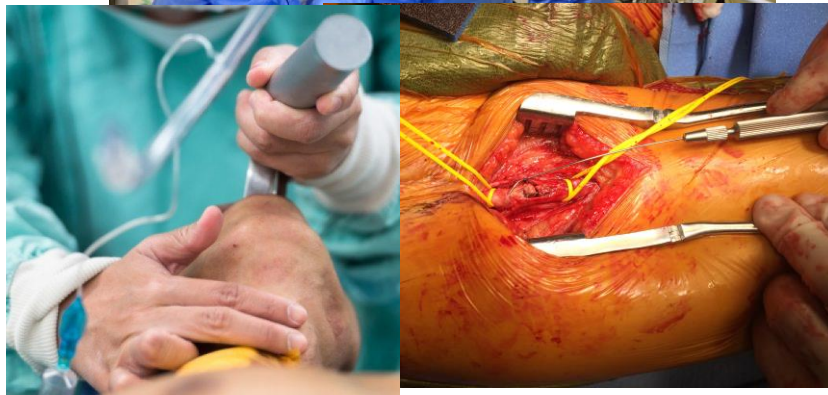
Marden André Tebet<sup>a,\*</sup>, Vinicius Borges Cardoso Esteves<sup>a</sup>, Sergio Kreimer<sup>a</sup>, Cleverson Zukowski<sup>b</sup>, Felipe Maia<sup>b</sup>, Maurício Oliveira<sup>b</sup>, Jorge Lorena<sup>c</sup>, Pedro Beraldo de Andrade<sup>d</sup>, Luiz Alberto Piva e Mattos<sup>a</sup>

<sup>a</sup> Rede D'OR Hospital São Luiz São Paulo, Hospitais Brasil (Santo André) e Morumbi, São Paulo, SP, Brasil

<sup>b</sup> Rede D'OR Hospital São Luiz Rio de Janeiro, Hospitais Copa e Quinta D'OR, Rio de Janeiro, RJ, Brasil

<sup>c</sup> Rede D'OR Hospital São Luiz Recife, Hospital Esperança, Recife, PE, Brasil

2019



# TAVI em 2019

**Para quem?**

**Como realizar o procedimento?**

**Novas fronteiras**

# TAVI em 2019

**Para quem?**

**Como realizar o procedimento?**

**Novas fronteiras**

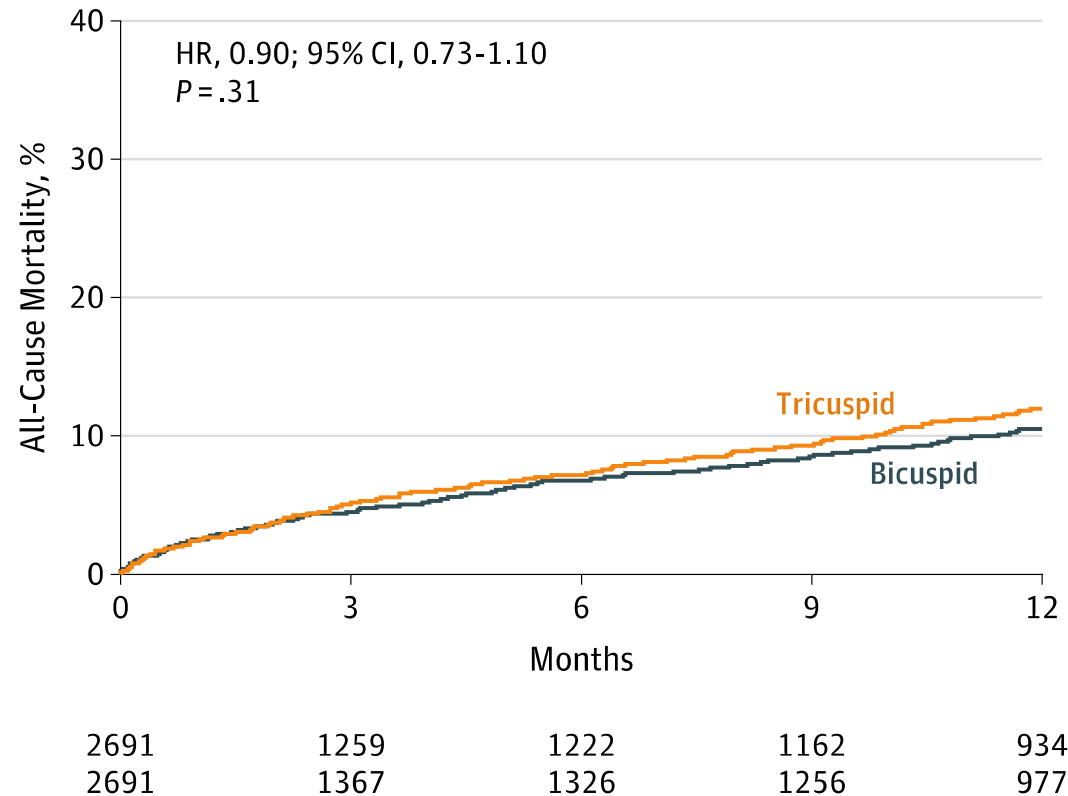


# Estenose Aórtica Bicúspide

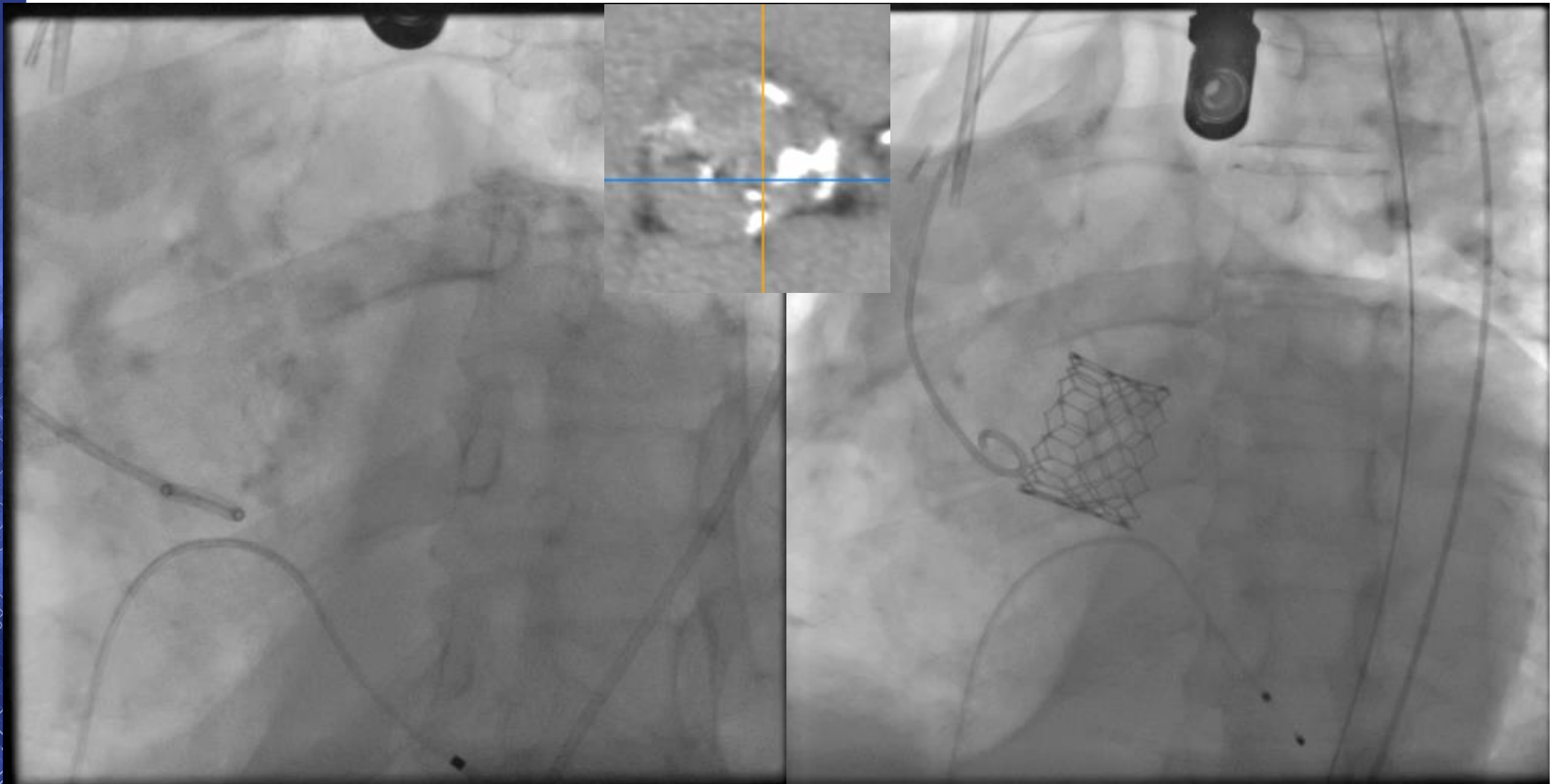
JAMA | Preliminary Communication

## Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid Aortic Stenosis and Mortality or Stroke

Raj R. Makkar, MD; Sung-Han Yoon, MD; Martin B. Leon, MD; Tarun Chakravarty, MD; Michael Rinaldi, MD; Pinak B. Shah, MD; Eric R. Skipper, MD; Vinod H. Thourani, MD; Vasilis Babaliaros, MD; Wen Cheng, MD; Alfredo Trento, MD; Sreekanth Vemulapalli, MD; Samir R. Kapadia, MD; Susheel Kodali, MD; Michael J. Mack, MD; Gilbert H. L. Tang, MD, Msc, MBA; Tsuyoshi Kaneko, MD



# Estenose Aórtica Bicúspide



ORIGINAL INVESTIGATIONS

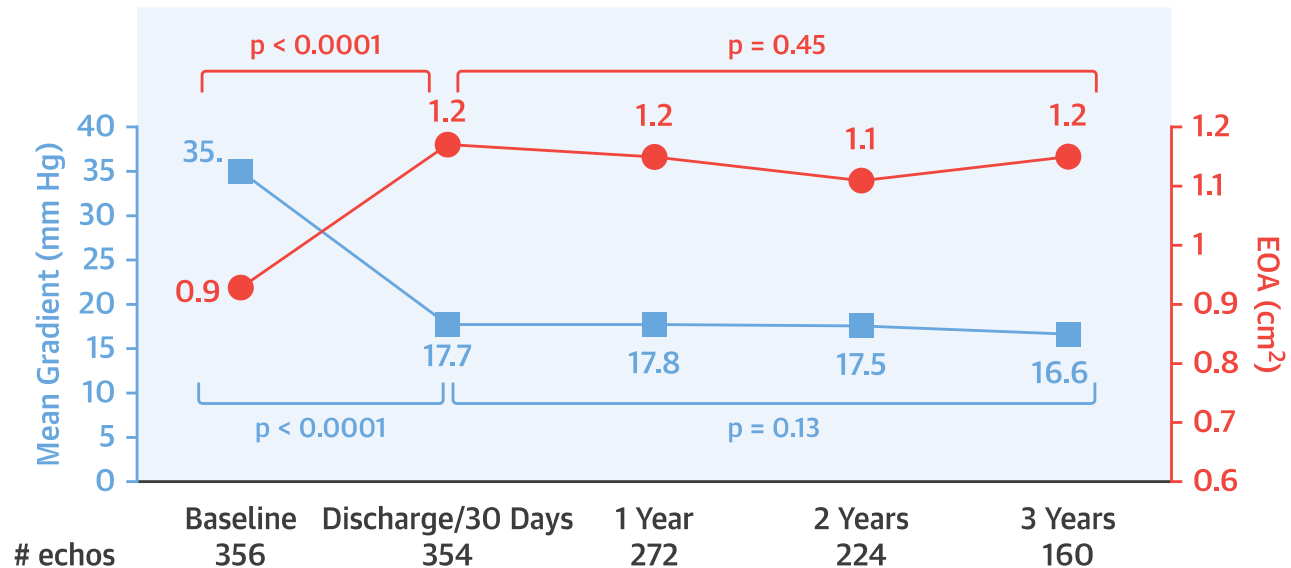
## 3-Year Outcomes After Valve-in-Valve Transcatheter Aortic Valve Replacement for Degenerated Bioprostheses



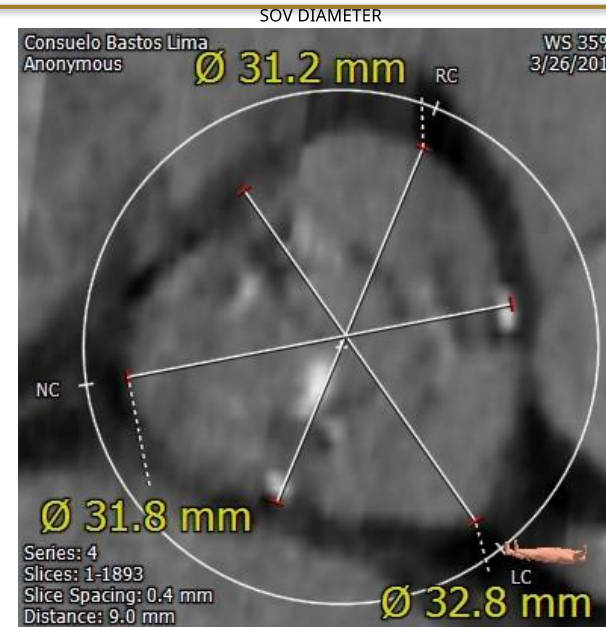
The PARTNER 2 Registry

John G. Webb, MD,<sup>a</sup> Dale J. Murdoch, MBBS,<sup>b</sup> Maria C. Alu, MS,<sup>b</sup> Anson Cheung, MD,<sup>a</sup> Aaron Crowley, MA,<sup>c</sup> Danny Dvir, MD,<sup>d</sup> Howard C. Herrmann, MD,<sup>e</sup> Susheel K. Kodali, MD,<sup>b</sup> Jonathon Leipsic, MD,<sup>b</sup> D. Craig Miller, MD,<sup>f</sup> Philippe Pibarot, PhD, DVM,<sup>g</sup> Rakesh M. Suri, MD, DPhM,<sup>h</sup> David Wood, MD,<sup>a</sup> Martin B. Leon, MD,<sup>b,c</sup> Michael J. Mack, MD<sup>i</sup>

### A Aortic Valve Gradient and Area

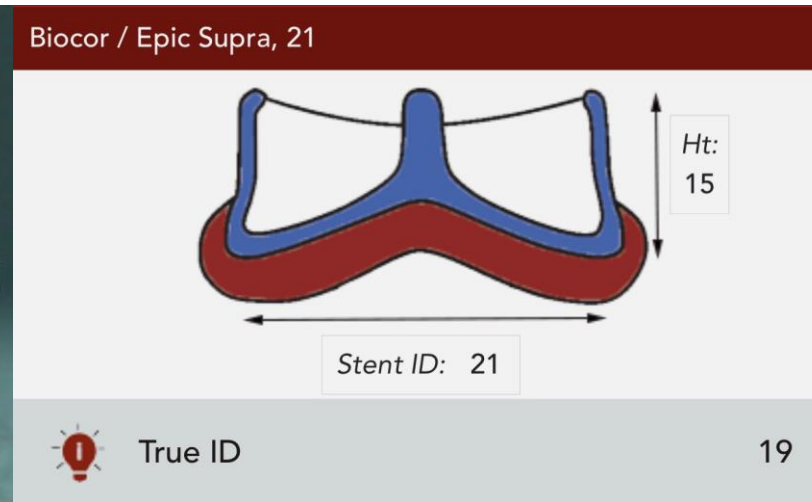


# Valve-in-Valve (ViV)



“MISMATCH”

SAV inner diameter measures < 18 mm

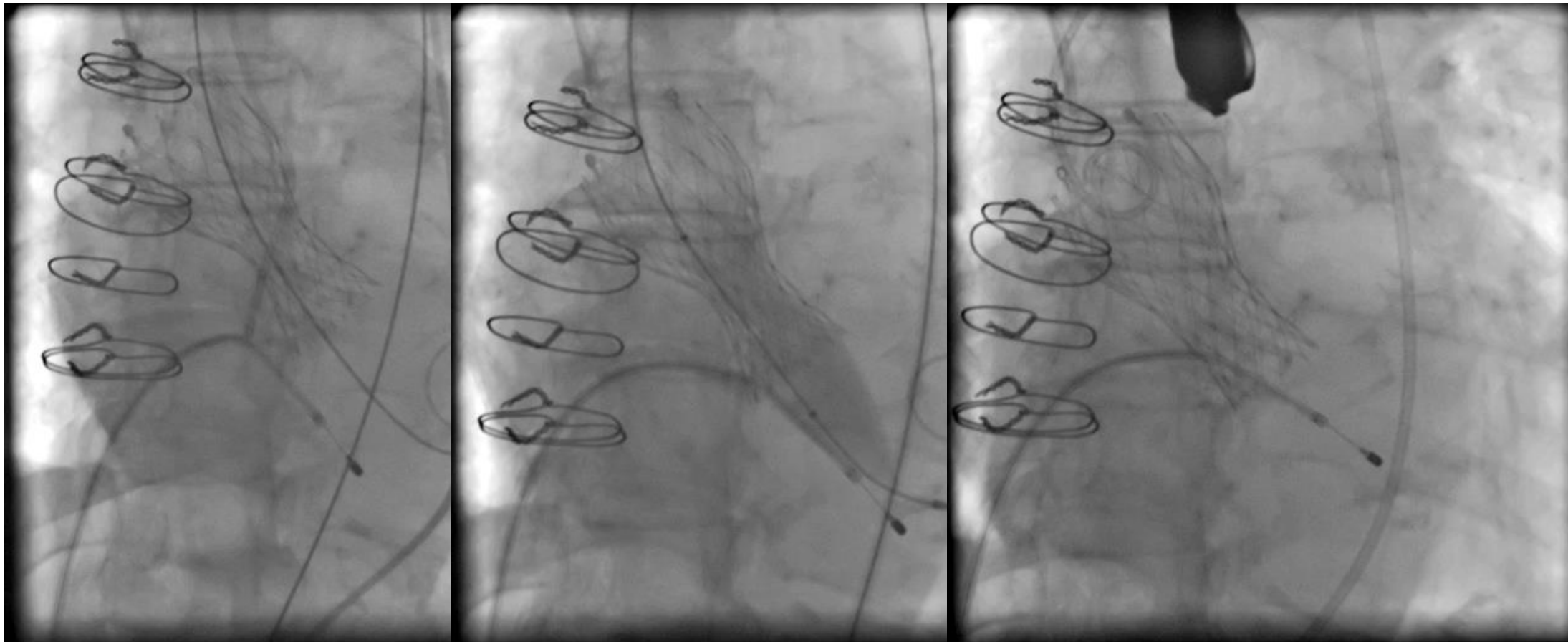




# Valve-in-Valve(ViV)

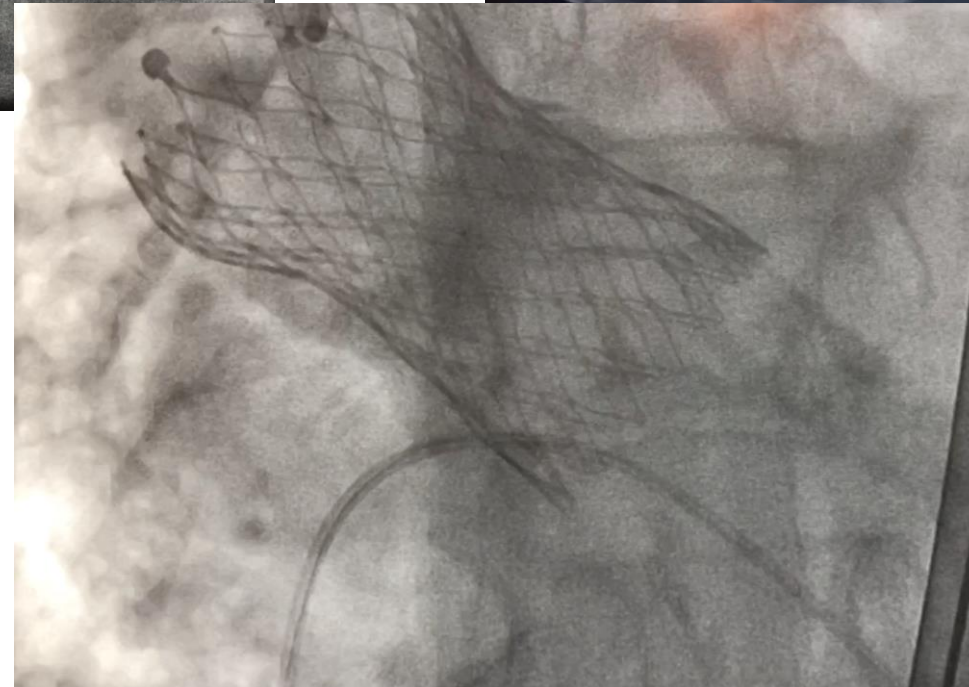
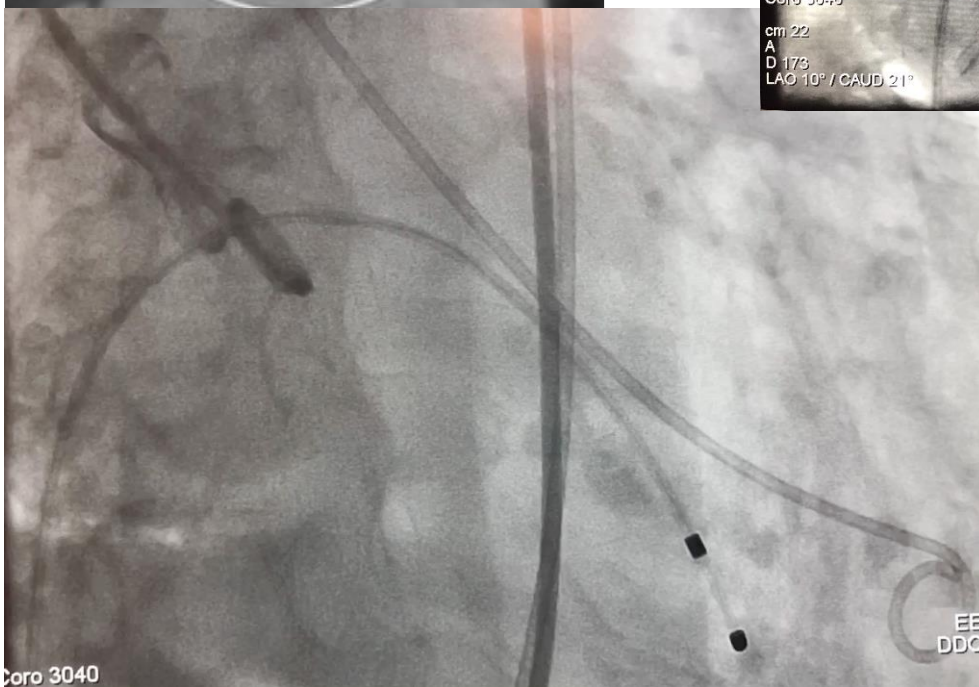
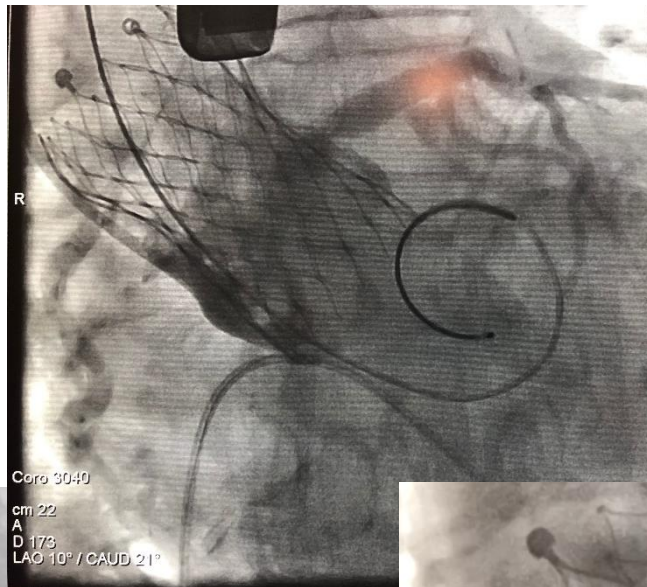
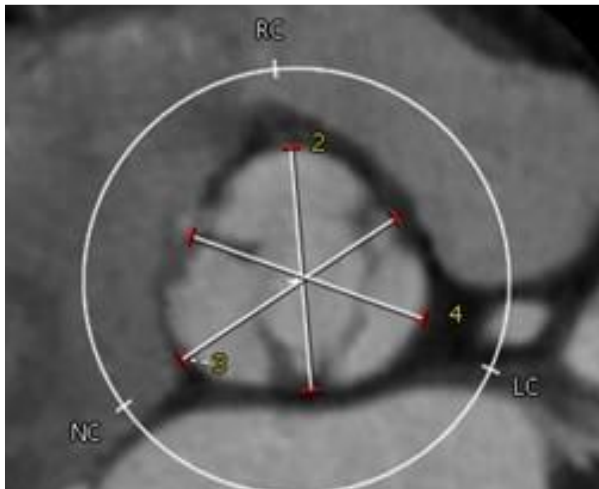
VE/Ao=19 mmHg

VE/Ao= 4 mmHg





# TAVI em IAO pura





# THE EARLY TAVR TRIAL

**Pending FDA Submission/Approval**

**Asymptomatic Severe, Calcific AS**

**Screening**  
Not eligible if <65, has Class 1 indication for AVR, bicuspid valve, not suitable for TF access or STS > 10

**Asymptomatic**  
*Negative stress test OR confirmation via history\**

**Symptomatic**  
*Positive stress test*

**Randomization 1:1**  
Stratified by ability to perform stress test

**Registry**

**TF- TAVR**

**Clinical Surveillance**

**Commercial AVR (TAVR or SAVR),  
Clinical Trial (P3), etc.**

**Clinical and Echo Follow-up:**  
30 days (TAVR only), 1, 2, 3 and 5 years

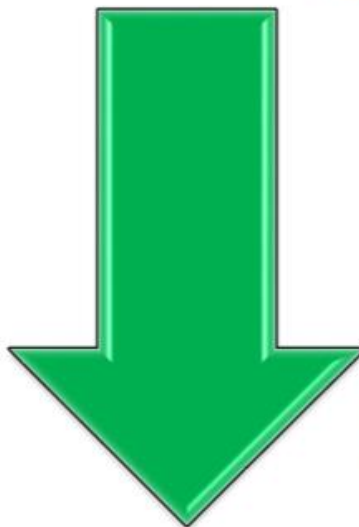
**Telephone Follow-up:**  
1, 2, 3 and 5 years

**Proposed Primary Endpoint (superiority):**  
2-year composite of all-cause death, all stroke, and unplanned cardiovascular hospitalization

# Mitraclip em 2019



**INTERVENÇÕES  
TRANSCATETER  
PARA VALVA MITRAL**

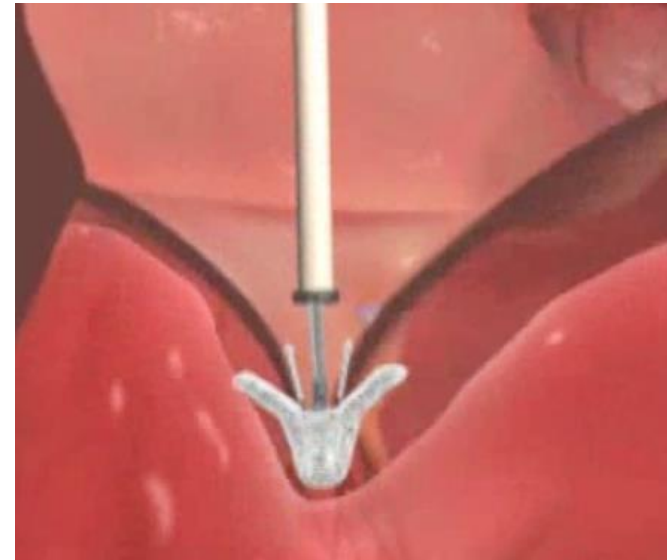
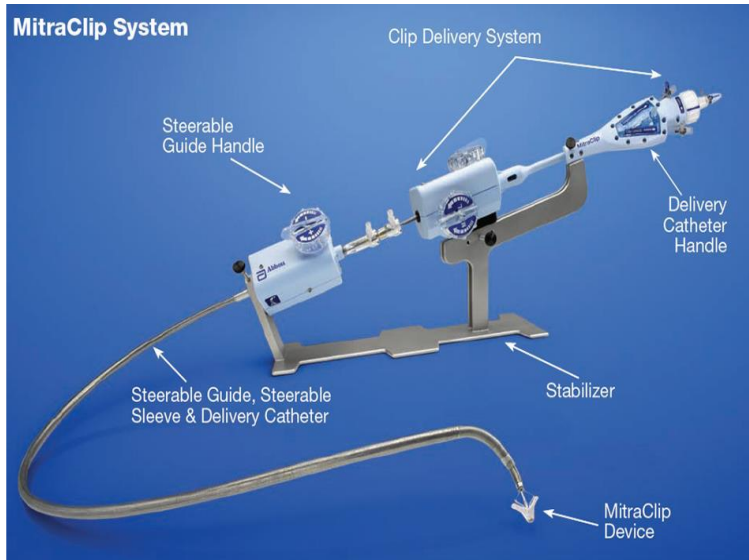


**INTERVENÇÕES  
TRANSCATETER PARA  
VALVA AÓRTICA**





# Mitraclip em 2019



# CRITÉRIOS ANATÔMICOS PARA IMPLANTE DO MITRACLIP NA IM PRIMÁRIA

Patologia central no segmento 2

Sem calcificação no folheto

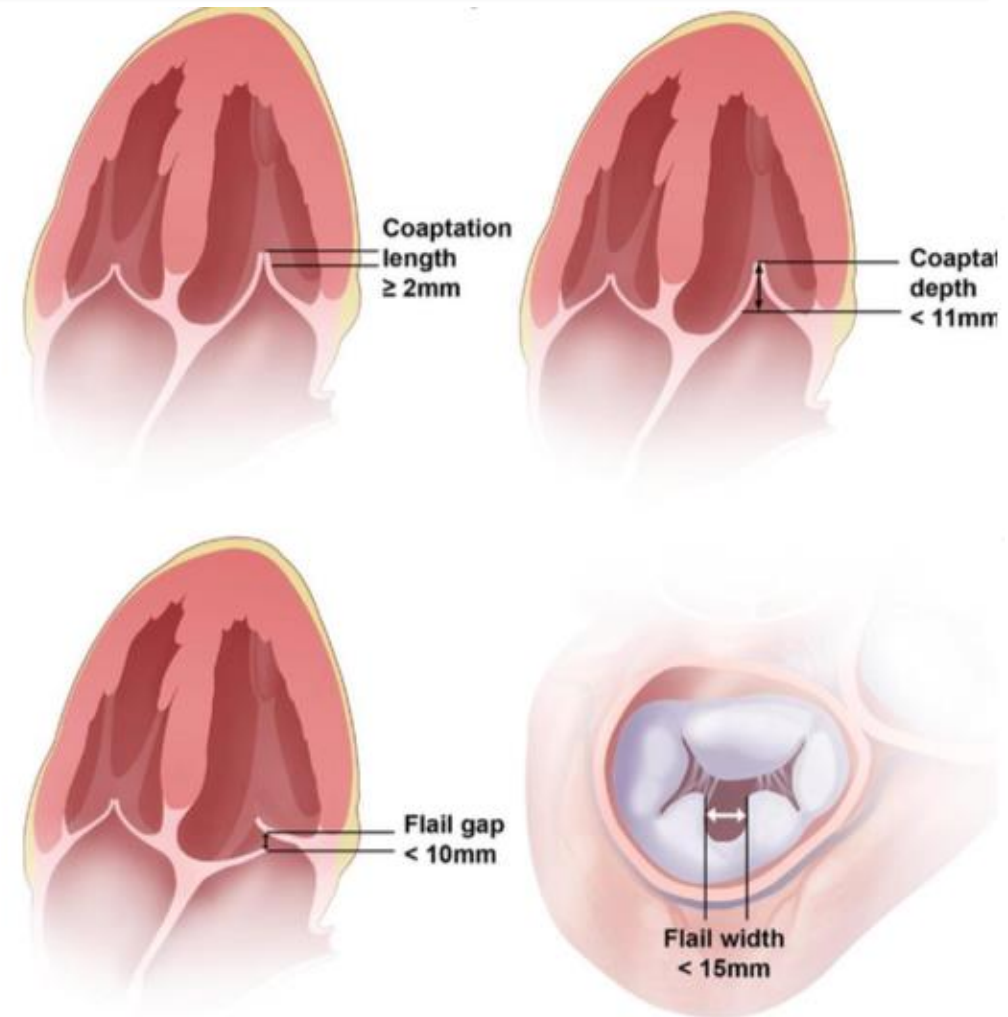
Abertura da válvula > 4cm<sup>2</sup>

Parte móvel do folheto posterior >10 mm

Falha de coaptação < 11 mm

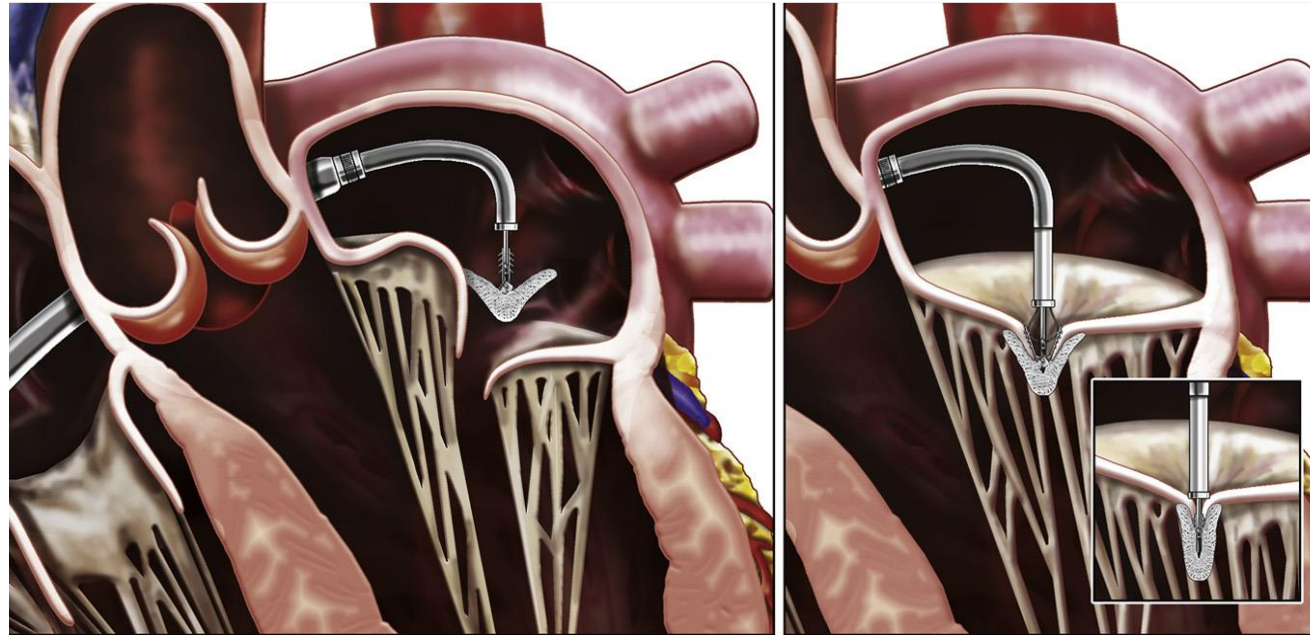
Mobilidade preservada

Largura do Flail < 15 mm e Gap < 10 mm





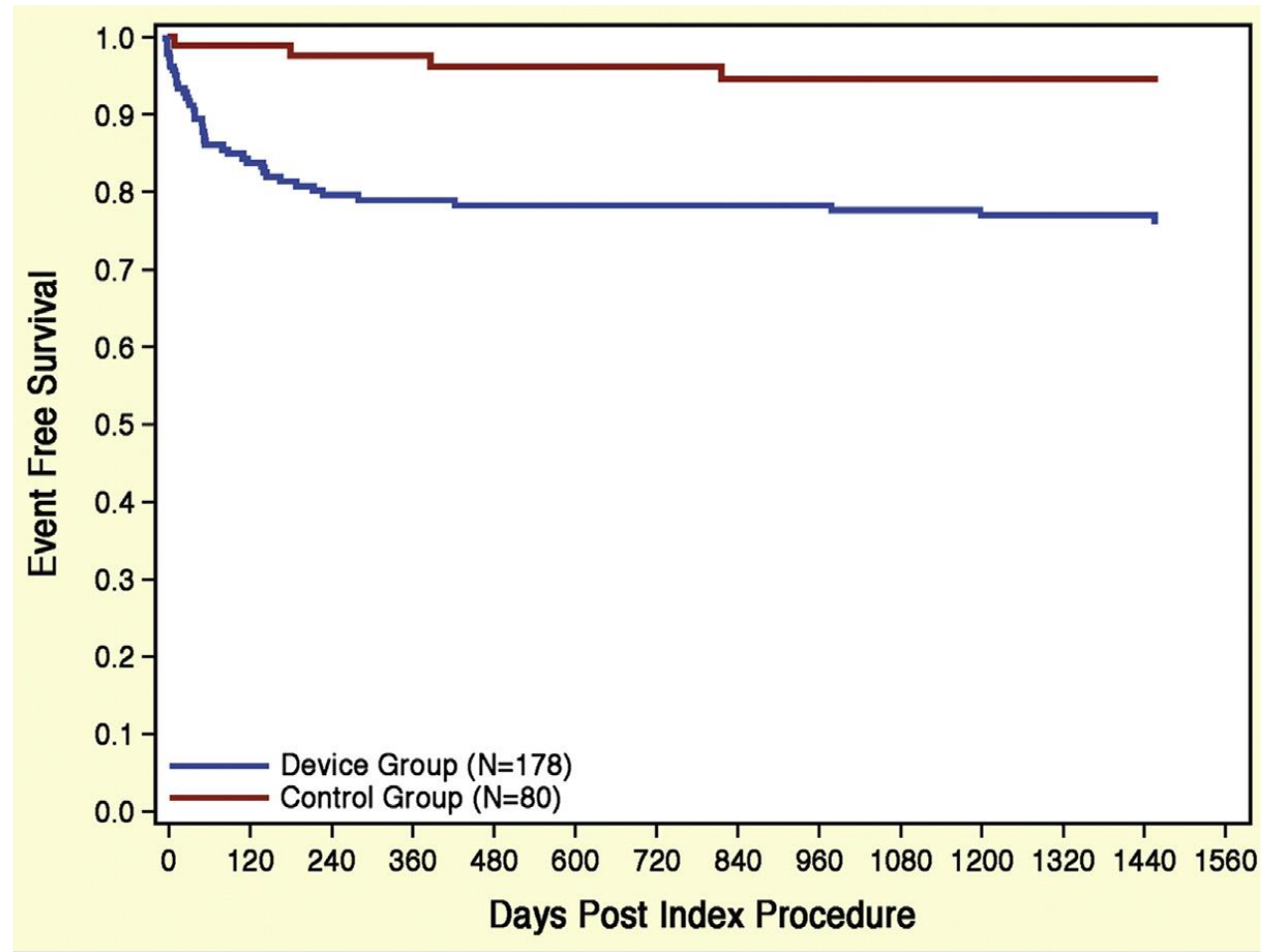
# Mitraclip em 2019



**Ins. Mitral Degenerativa**

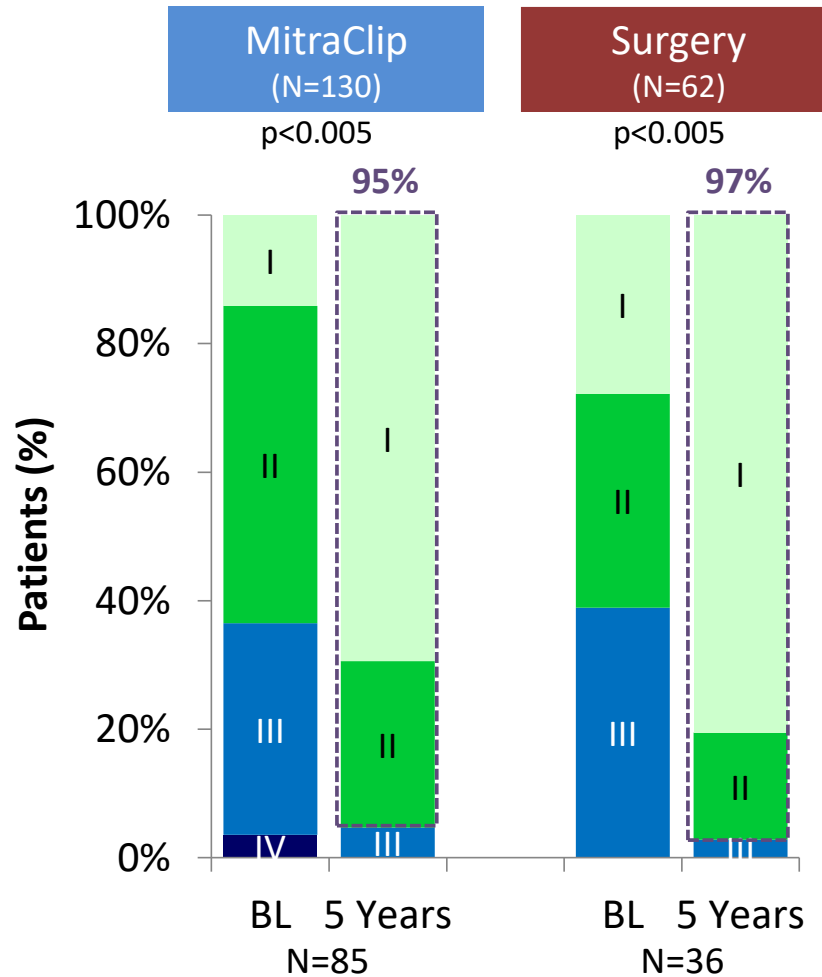
**Ins. Mitral Funcional**

# EVEREST II: inferioridade em relação a necessidade de cirurgia

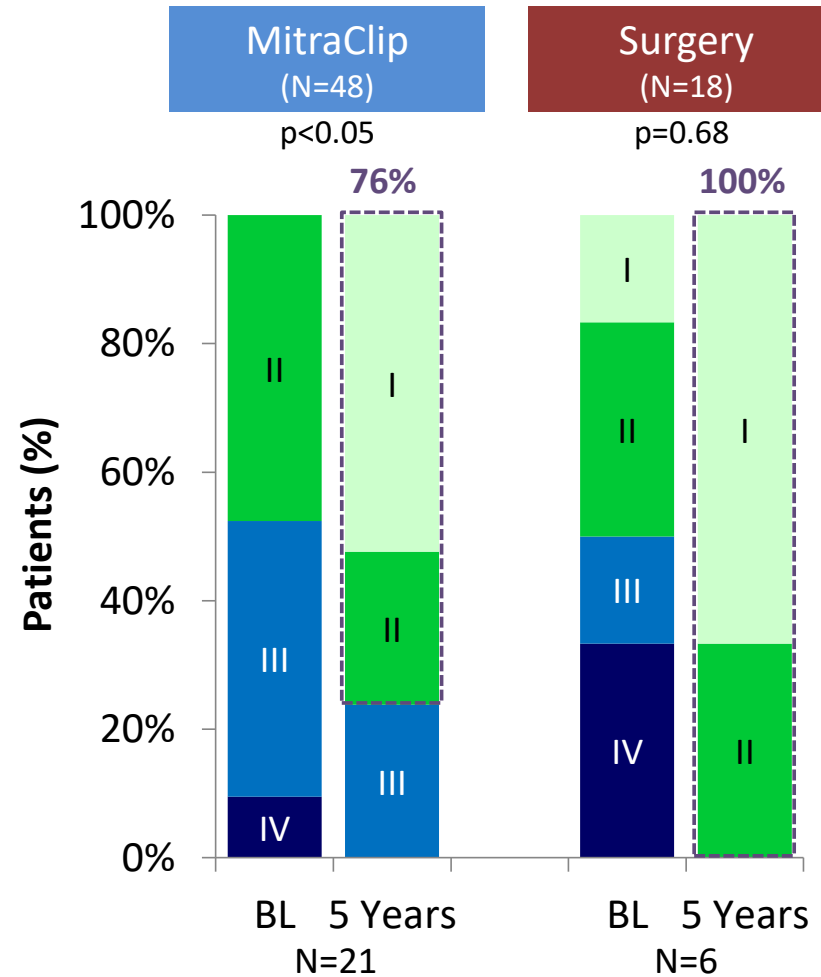


# EVEREST II: MELHORA DA CLASSE FUNCIONAL

## Degenerativa

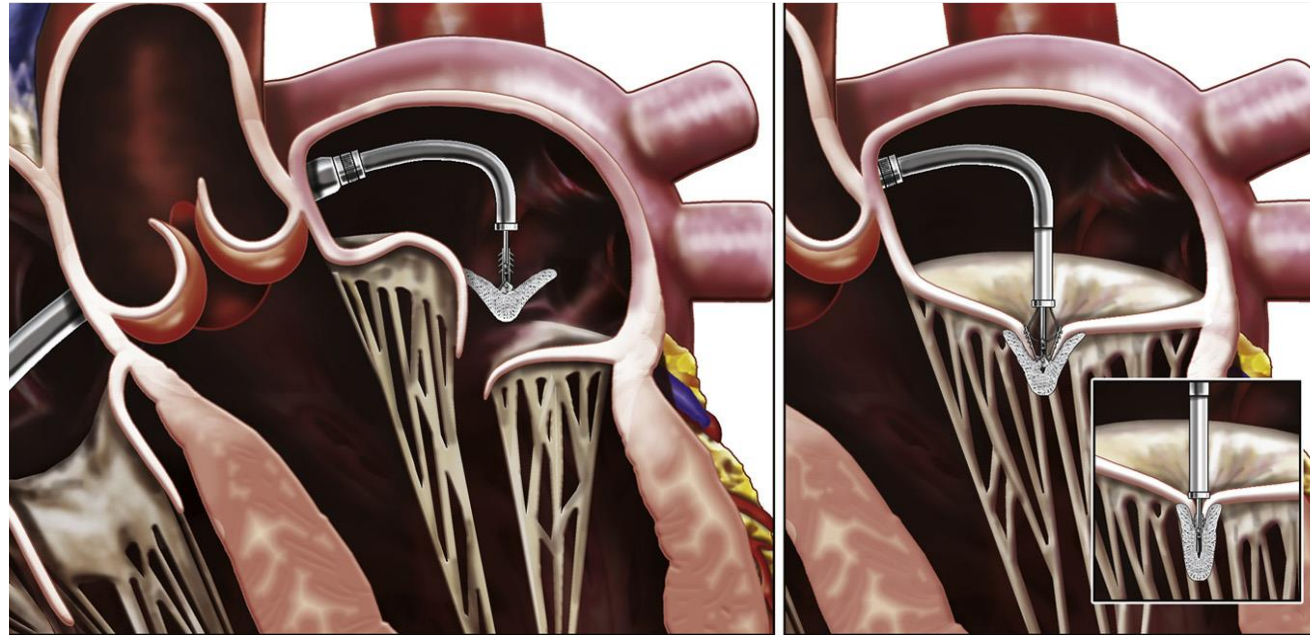


## Funcional



N = survivors with paired data; p-values for descriptive purposes only

# Mitraclip em 2019



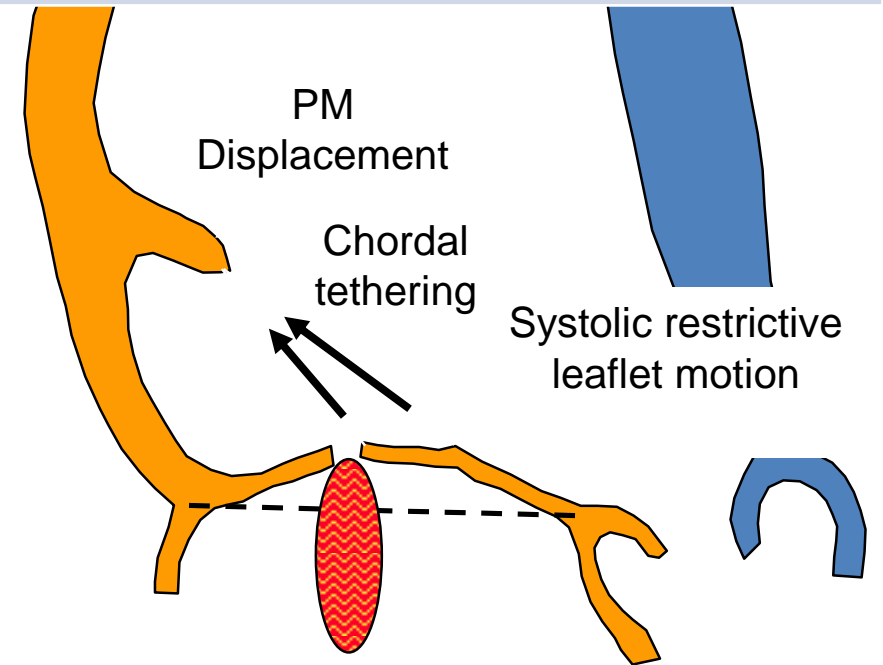
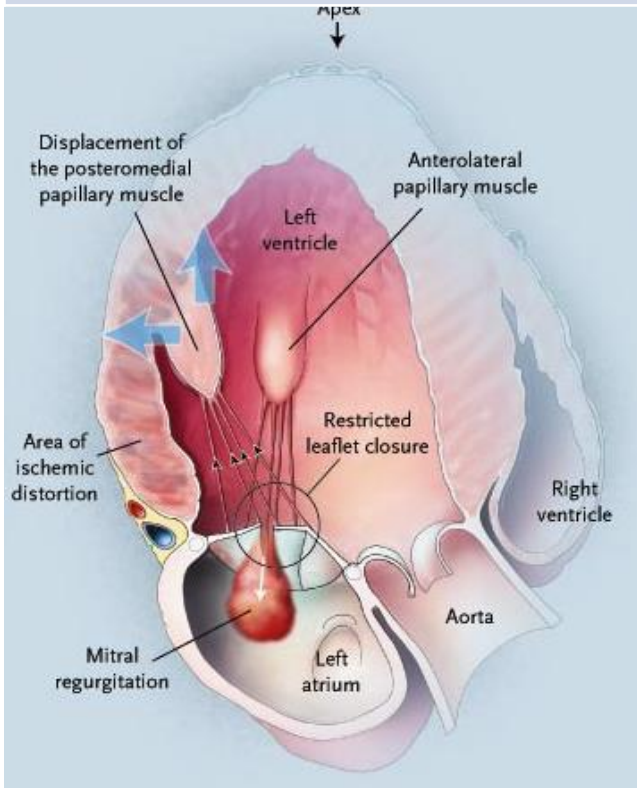
**Ins. Mitral Degenerativa**

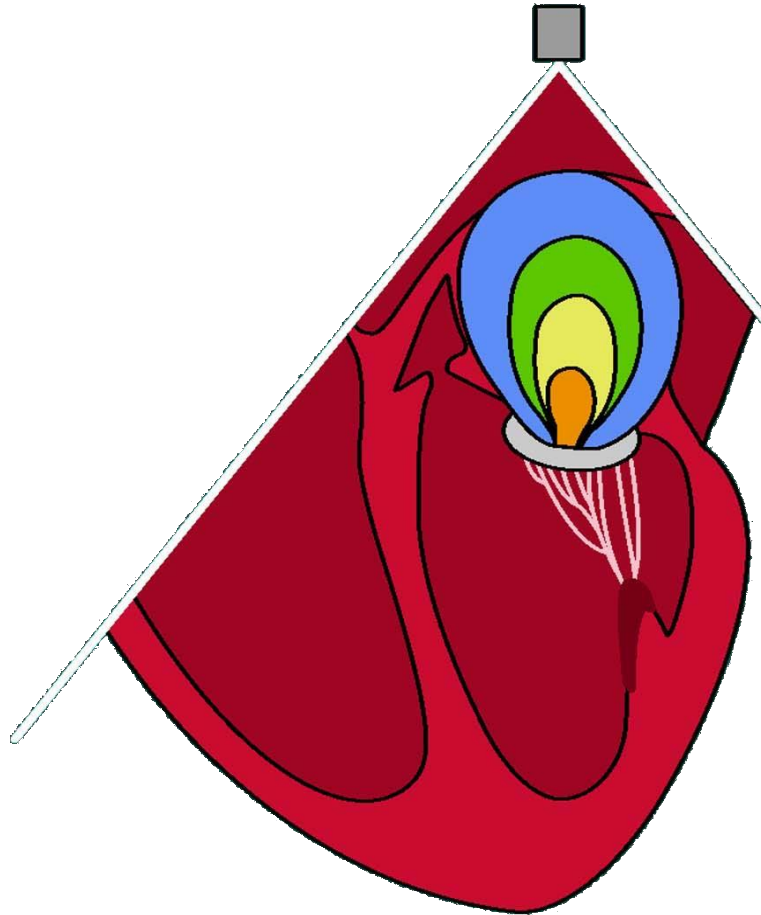
**Ins. Mitral Funcional**



# IM FUNCIONAL: DA LESÃO A DISFUNÇÃO

Thetering	Disfunção contrátil
<ul style="list-style-type: none"> <li>➤ Dilatação do VE e esfericidade</li> </ul>	<ul style="list-style-type: none"> <li>➤ Redução contratilidade VE</li> </ul>
<ul style="list-style-type: none"> <li>➤ Deslocamento do musculo</li> </ul>	<ul style="list-style-type: none"> <li>➤ Dissincronia</li> </ul>
<ul style="list-style-type: none"> <li>➤ Dilatação anular</li> </ul>	<ul style="list-style-type: none"> <li>➤ Redução da contração anular</li> </ul>





**”Classificar um paciente com IM secundária(funcional) como candidato a Mitraclip requer antes de tudo, terapia médica otimizada, ressincronização quando apropriada e revascularização coronária quando indicada”.**

*(Grayburn J Am Coll Cardiol 2014;64:2792-801)*

# Study funding

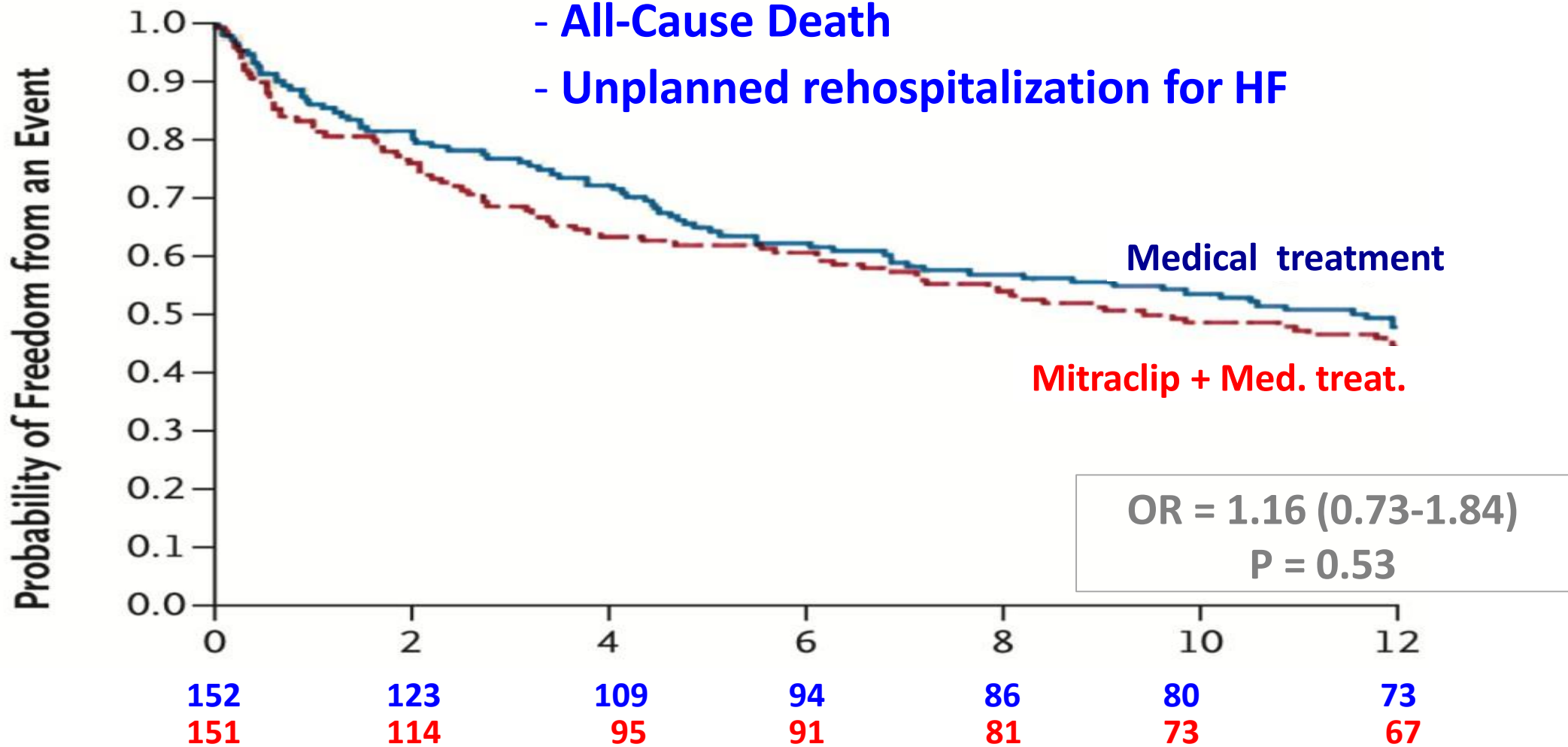
- **Study Sponsor:** Hospices Civils de Lyon Academic Study supported by a French Research Program grant from ministry of Health “PHRC”
- \* **Abbott Vascular involvement :**
  - Proctoring of the teams
  - Financing 84% of the clips



MITRA-FR

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

- All-Cause Death
- Unplanned rehospitalization for HF





# 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\*

```
graph TD; A[Randomize 1:1*] --> B[MitraClip + GDMT  
N=305]; A --> C[GDMT alone  
N=305];
```

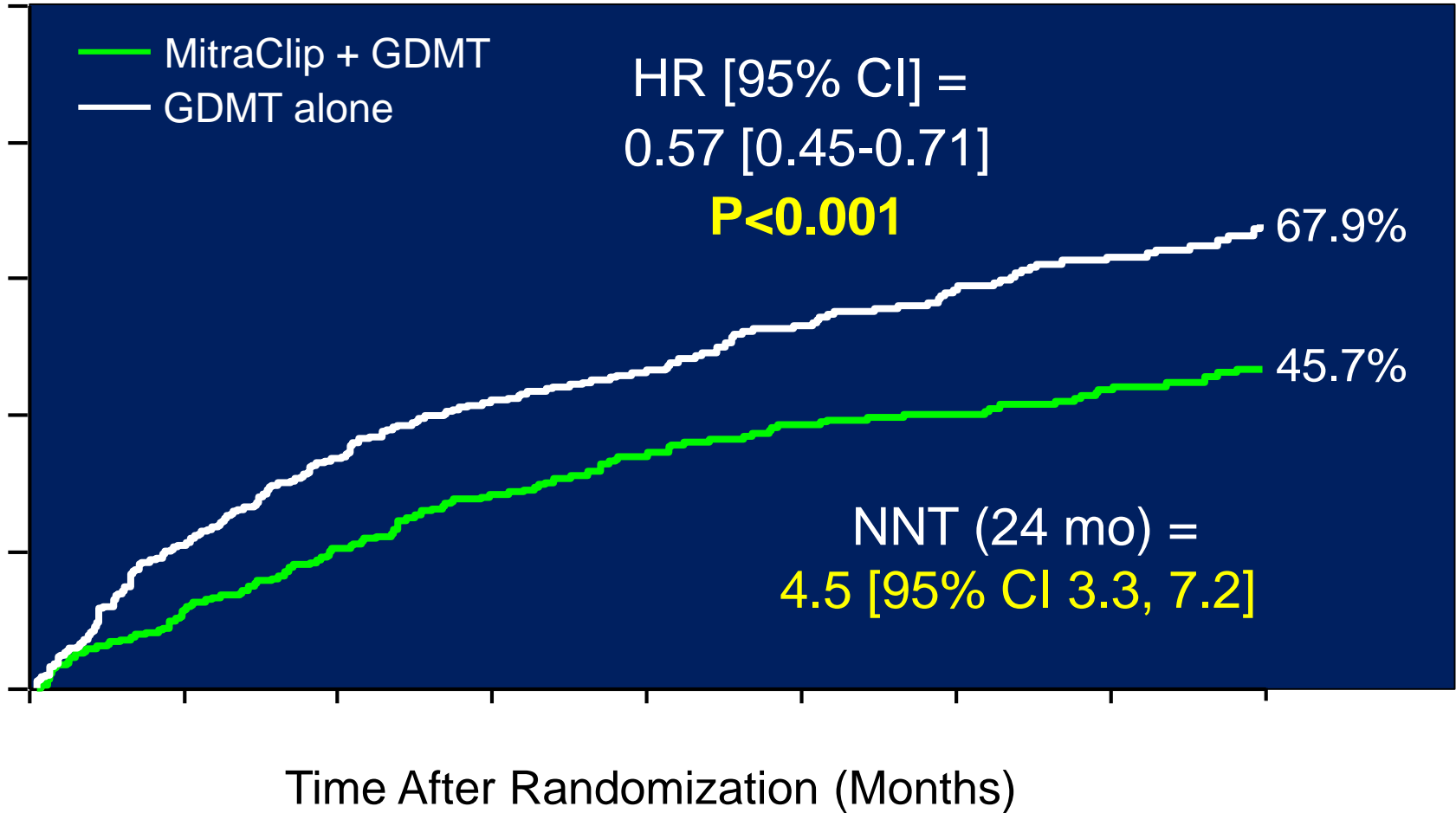
MitraClip + GDMT  
N=305

GDMT alone  
N=305

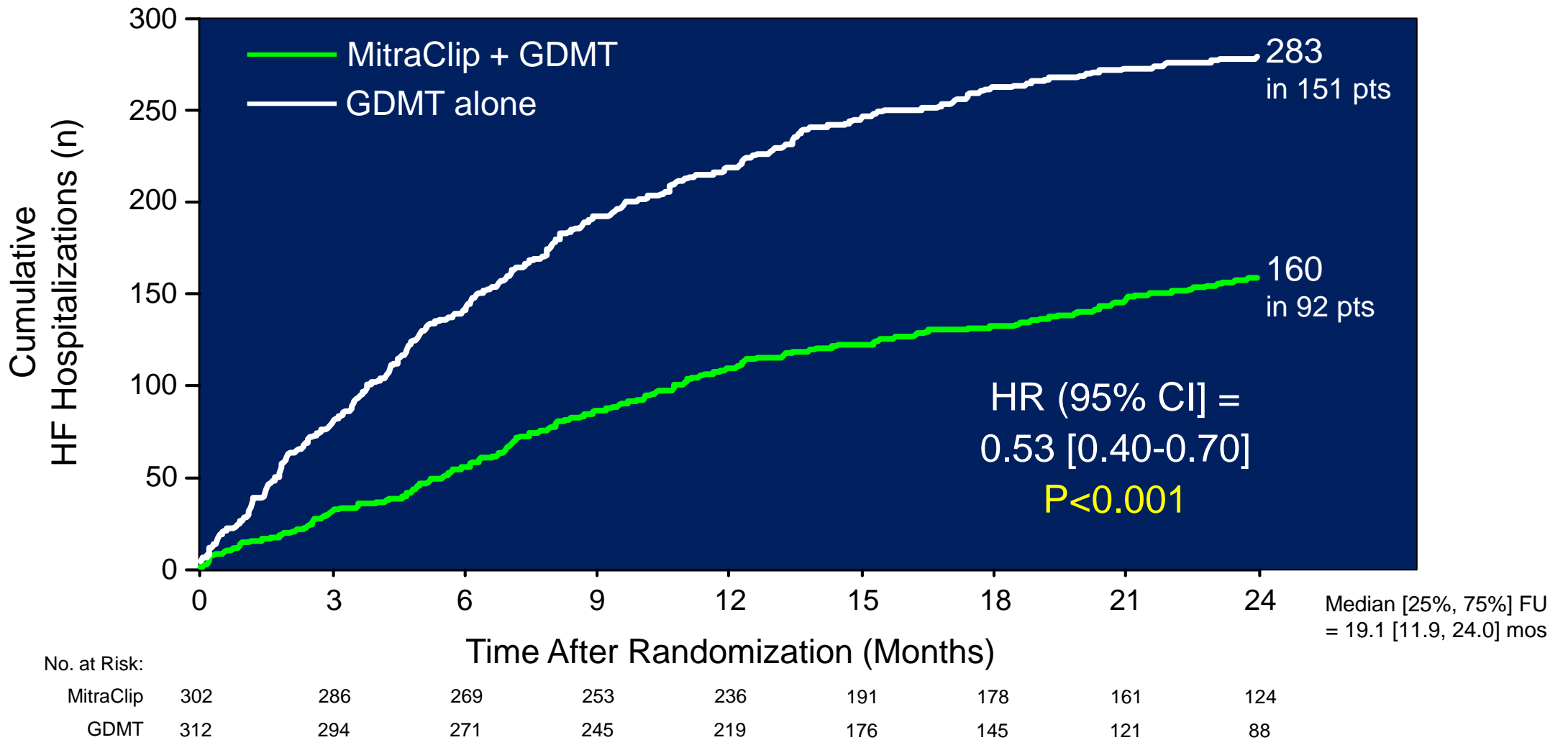
\*Stratified by cardiomyopathy etiology (ischemic vs. non-ischemic) and site

Morte e Rehospitalização

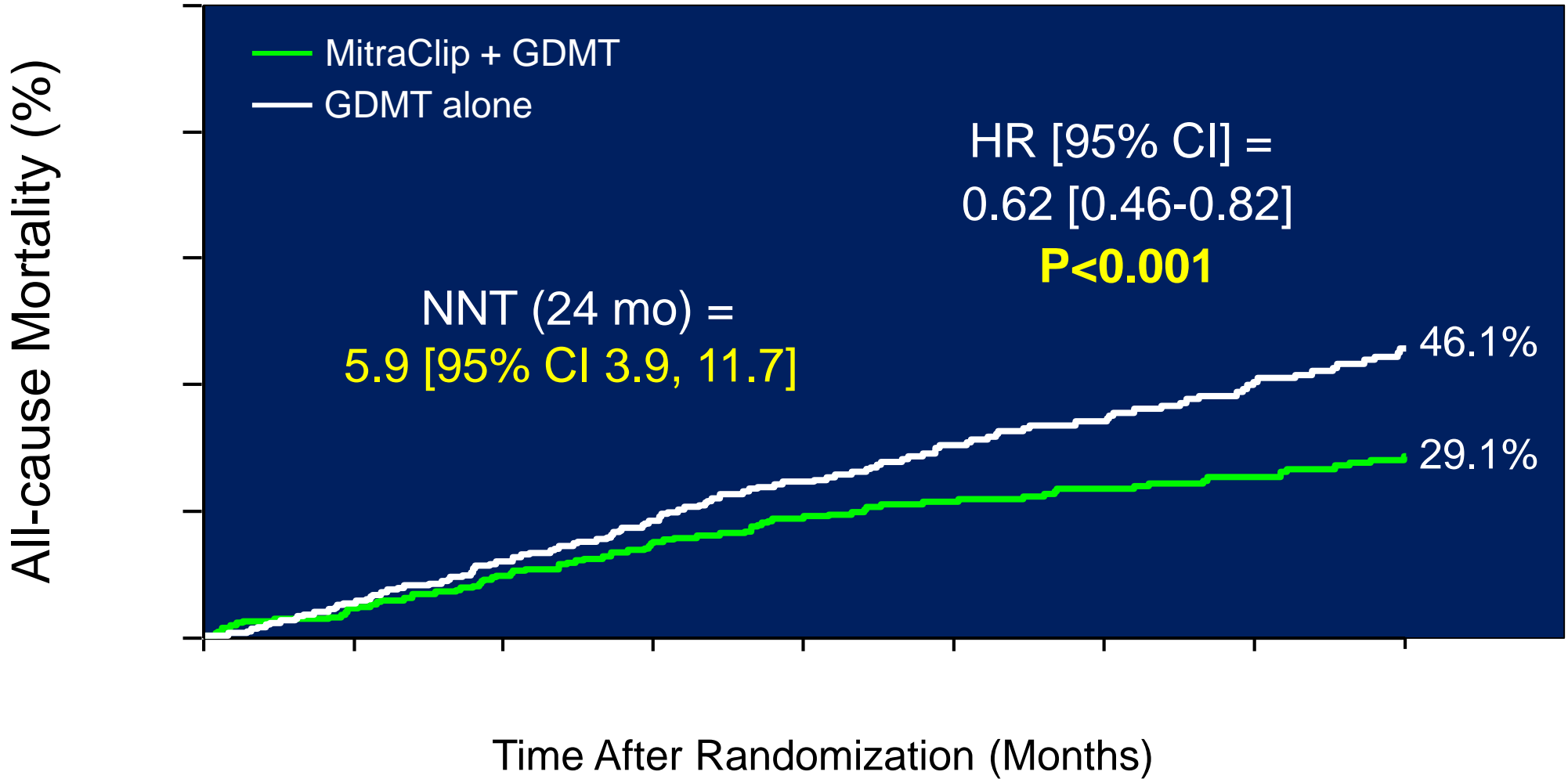
All-cause Mortality or  
HF Hospitalization (%)



# Rehospitalização por IC



Morte



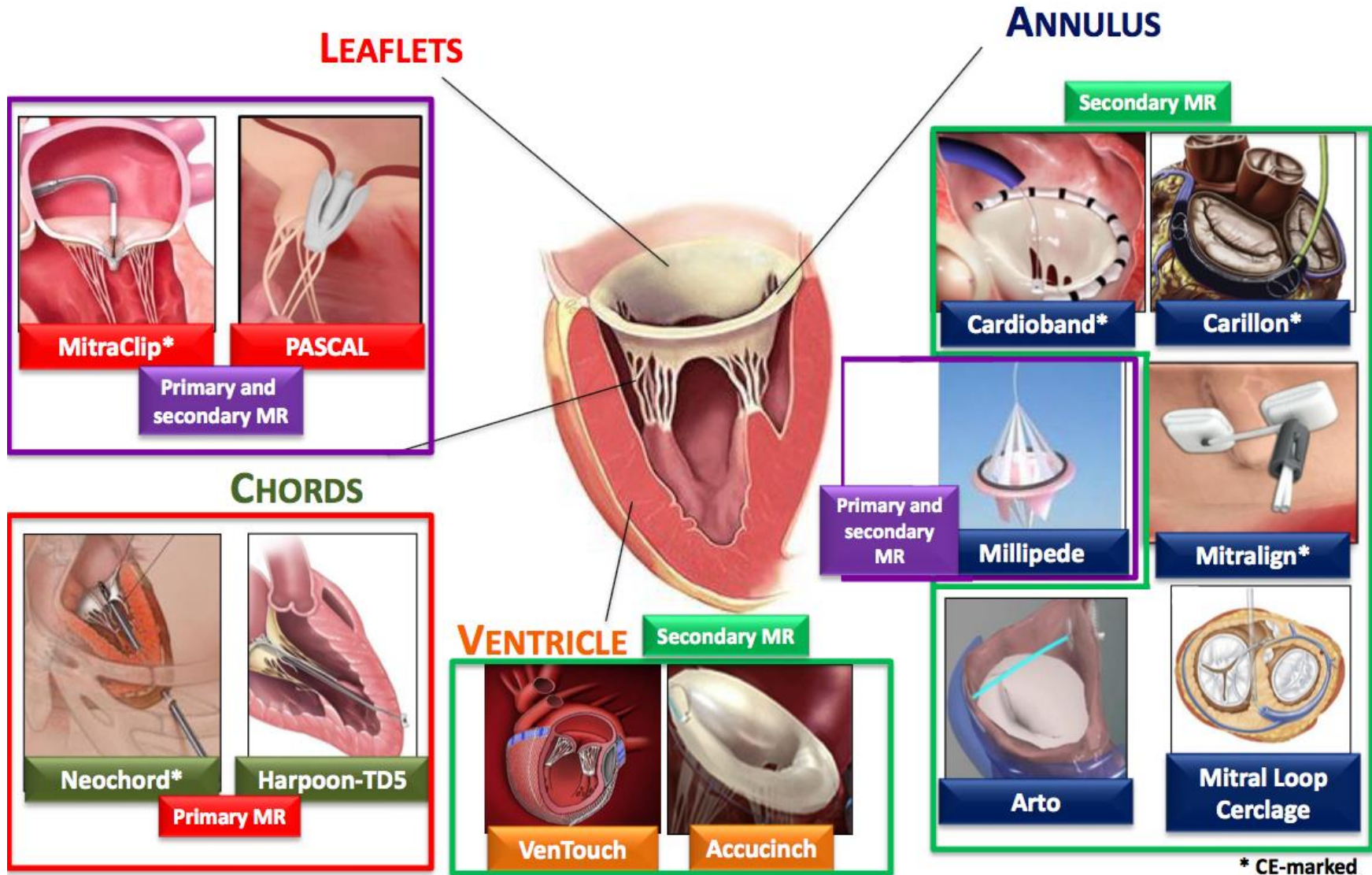


# Por que os resultados do COAPT trial são tão diferentes do MITRA-FR?

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

# SISTEMAS DE REPARO PARA APARATO VALVAR MITRAL



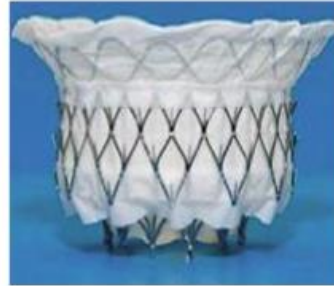
# PRÓTESES PERCUTÂNEAS PARA INSUFICIÊNCIA MITRAL

Apical Tether



**TENDYNE  
(ABBOTT)**

Radial Force



**INTREPID  
(MEDTRONIC)**

Native Leaflet  
Engagement



**TIARA  
(NEOVASC)**

Mitral Annulus Clamping



**CARDIAQ  
(EDWARDS)**

External Anchor



**CAISSON  
(CAISSON)**



**HIGHLIFE  
(HIGHLIFE)**



# Mensagem final

- O TAVI evoluiu em progressão geométrica com expansão de indicação para pacientes com estenose aórtica com idade >70 anos independente do risco.
- O Mitraclip deve ser reservado para pacientes com insuficiência mitral degenerativa de alto risco cirúrgico, e aqueles com insuficiência mitral funcional que não necessitam de revascularização associada.



# Obrigado!

Reunião Semanal  
**HEART TEAM**  
Copa D'Or

Discussão de casos complexos baseada em evidências, por cardiologistas clínicos, intervencionistas e cirurgiões

**15/05**  
12h às 13h



**CASO DA SEMANA:** Disfunção Precoce de Prótese Valvar Pulmonar

**Convidados:** Dr. Marcelo Machado Melo  
Coordenador da Divisão de Terapia Intensiva do INC

Dr. Francisco Chamé  
Coordenador do Departamento de Intervenção em Cardiopatias Congênitas do Hospital dos Servidores do Estado do Rio de Janeiro

Dr. Andrey José de Oliveira Monteiro  
Cirurgião Cardíaco do INC e Hospital Pró-Criança

**Público Alvo:** Corpo Clínico Interno e Médicos Externos Interessados

**Local:** Auditório Copa D'Or

**Endereço:** Rua Figueiredo de Magalhães, 875.  
Copacabana - RJ

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