

# Estado actual de la implantación de válvula mitral transcatéter

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¿Necesidad de tratamiento transcatóter de la insuficiencia mitral?

Reparación vs. Sustitución transcatóter de la válvula mitral

Tipos de sustitución percutánea de la válvula mitral

- Prótesis aórticas en posición mitral

- Prótesis mitrales específicas

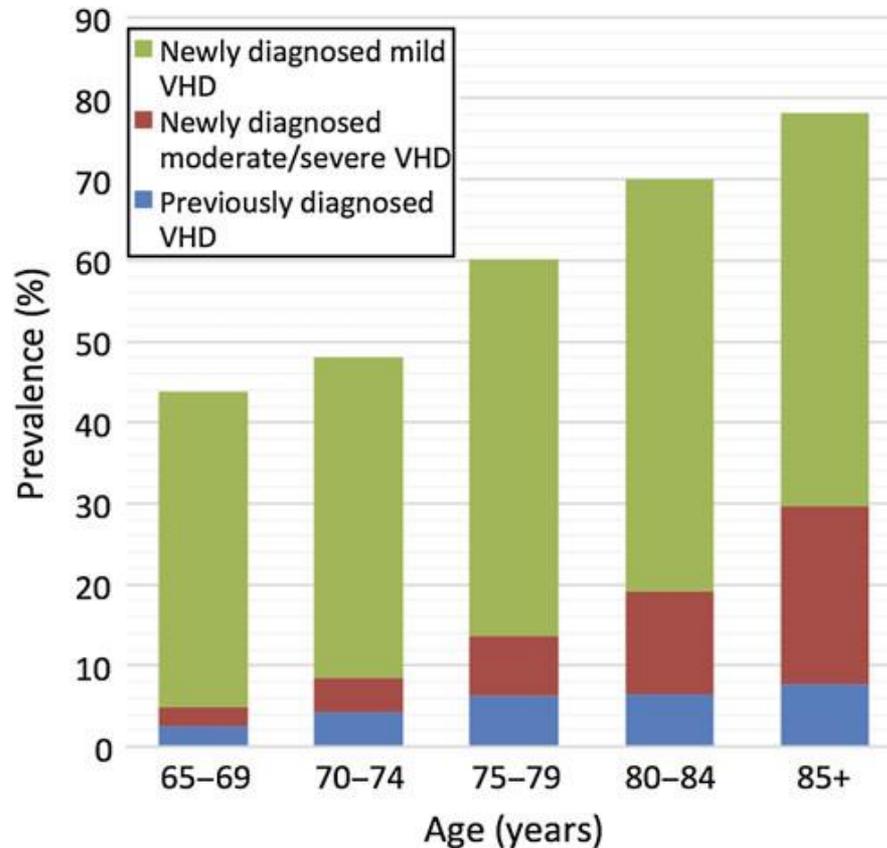
Retos para el desarrollo de una prótesis mitral transcatóter

Clasificación de las prótesis

Experiencia actual

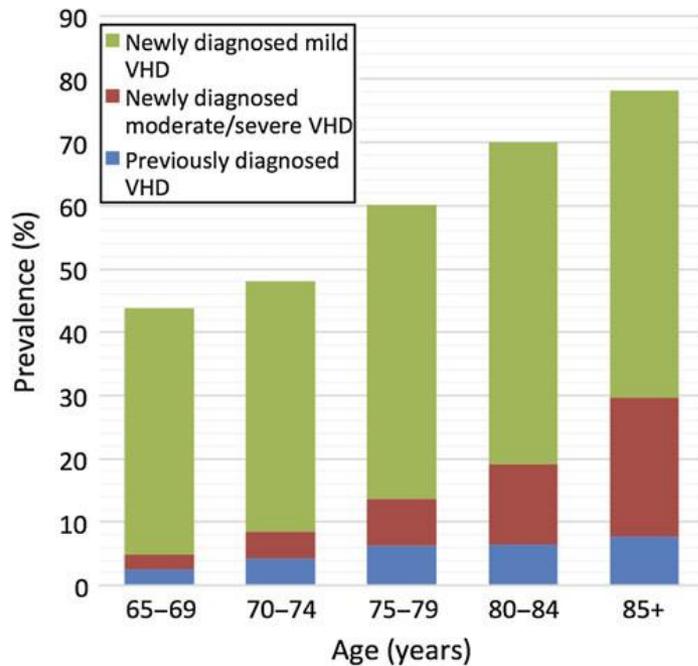
# ¿Necesidad de tratamiento percutáneo de la insuficiencia mitral?

# Prevalencia de valvulopatías

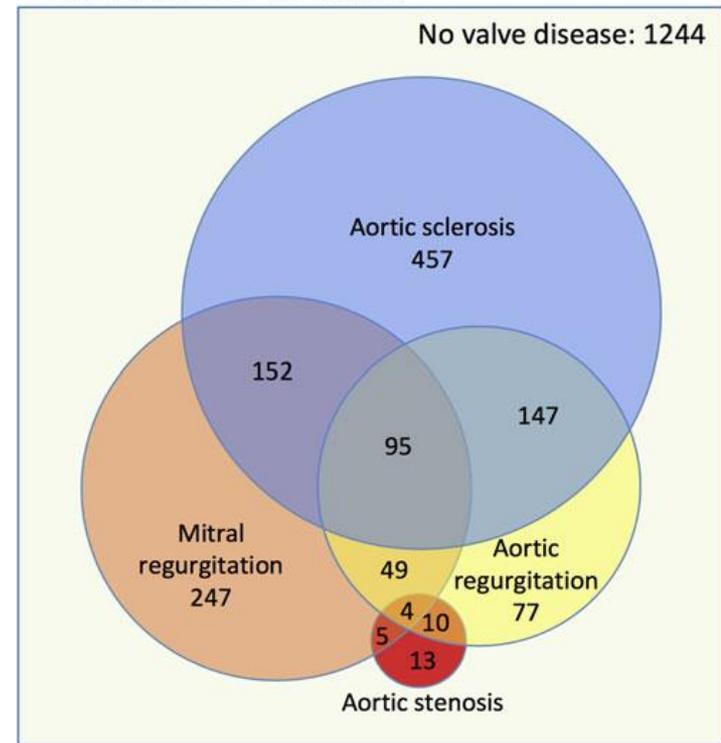


D'Arcy J, et al. Eur Heart J 2016; 37:3515-22

# Prevalencia de valvulopatías



Total cohort: 2500 (rectangle)



D'Arcy J, et al. Eur Heart J 2016; 37:3515-22

# Prevalencia de insuficiencia mitral

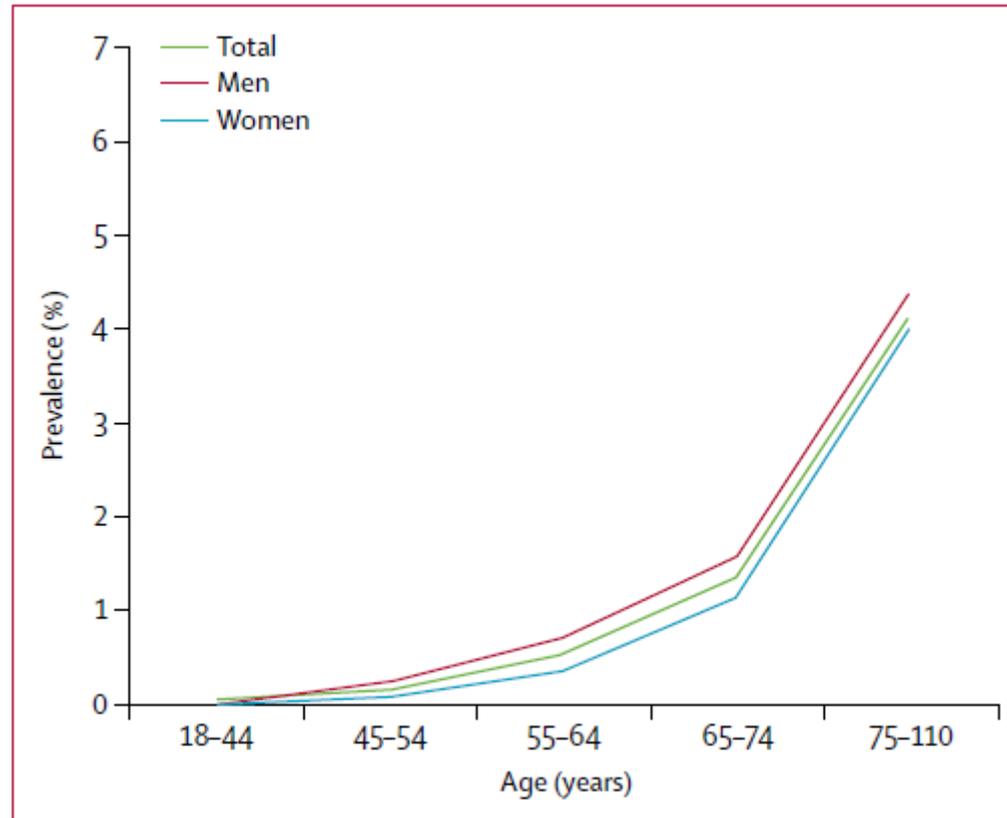
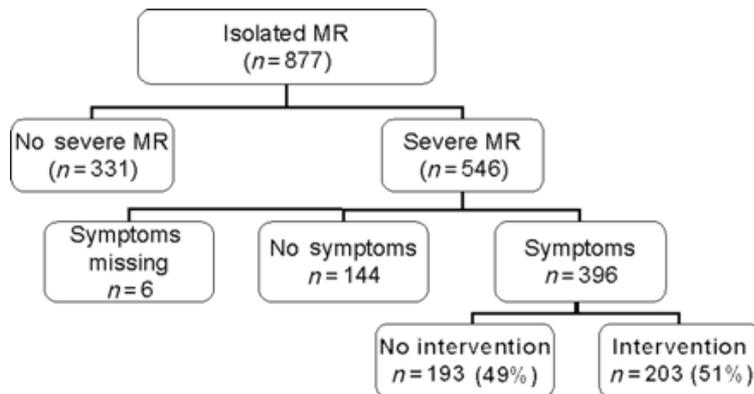
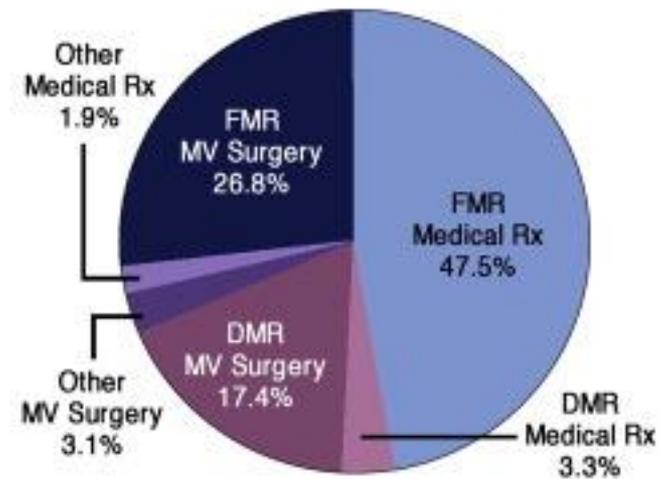


Figure 1: Prevalence of isolated mitral regurgitation in the community by age

# Elección del tratamiento

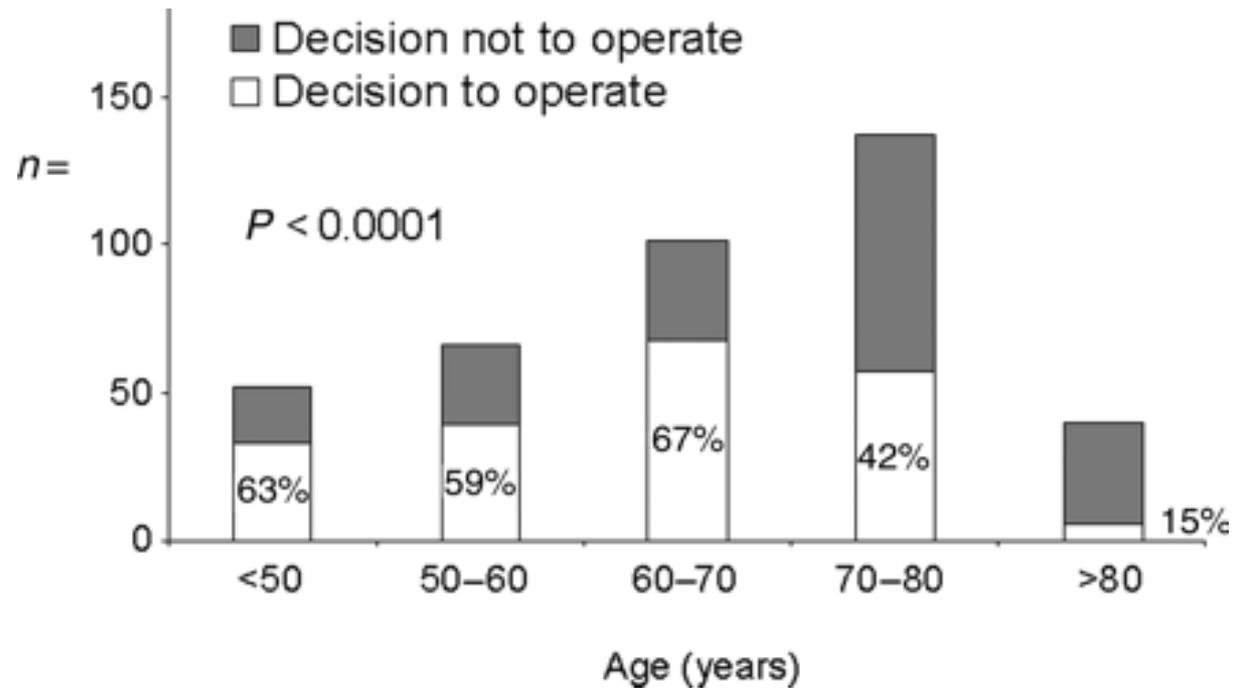


## Medically treated patients with severe MR



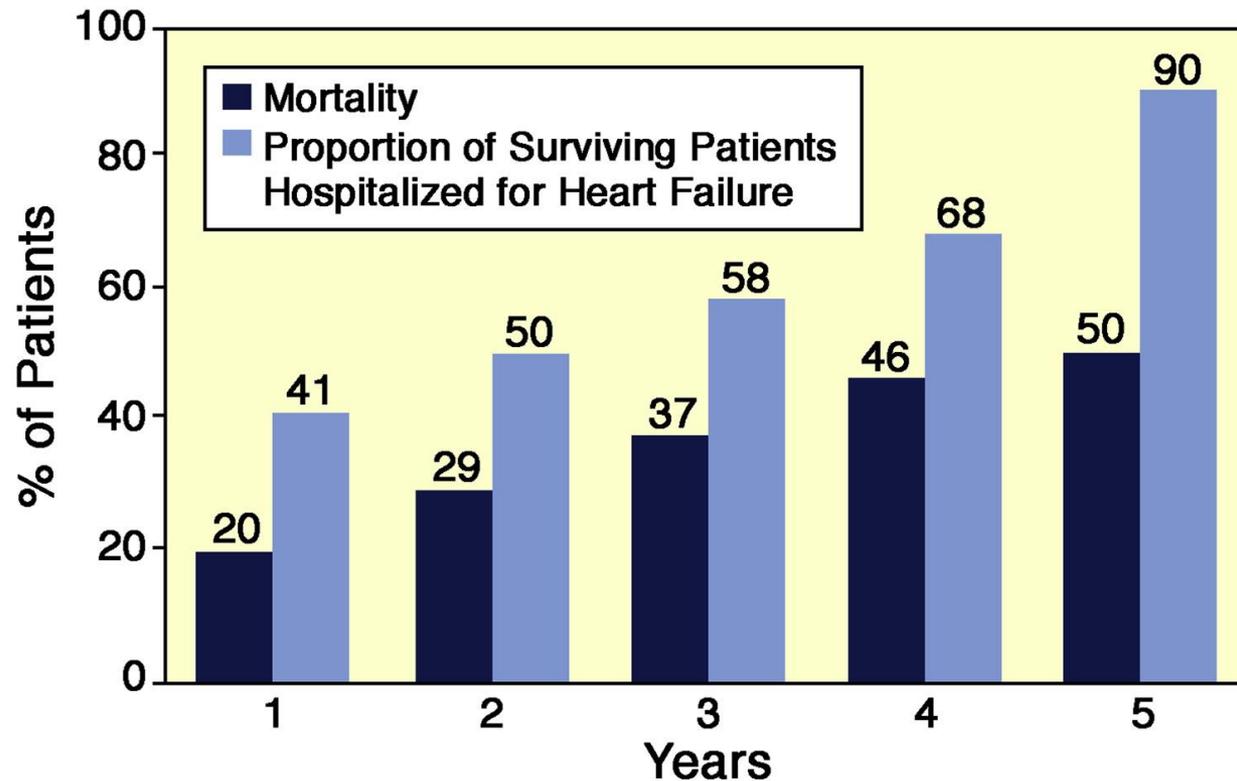
Goel SS, et al. J Am Coll Cardiol. 2014;63:185-6  
Mirabel M, et al. Eur Heart J 2007;28:1358-65

# Elección del tratamiento



Mirabel M, et al. Eur Heart J 2007;28:1358-65

# Pronóstico IM no tratada



Goel SS, et al. J Am Coll Cardiol. 2014;63:185-6

# Pronóstico IM no tratada

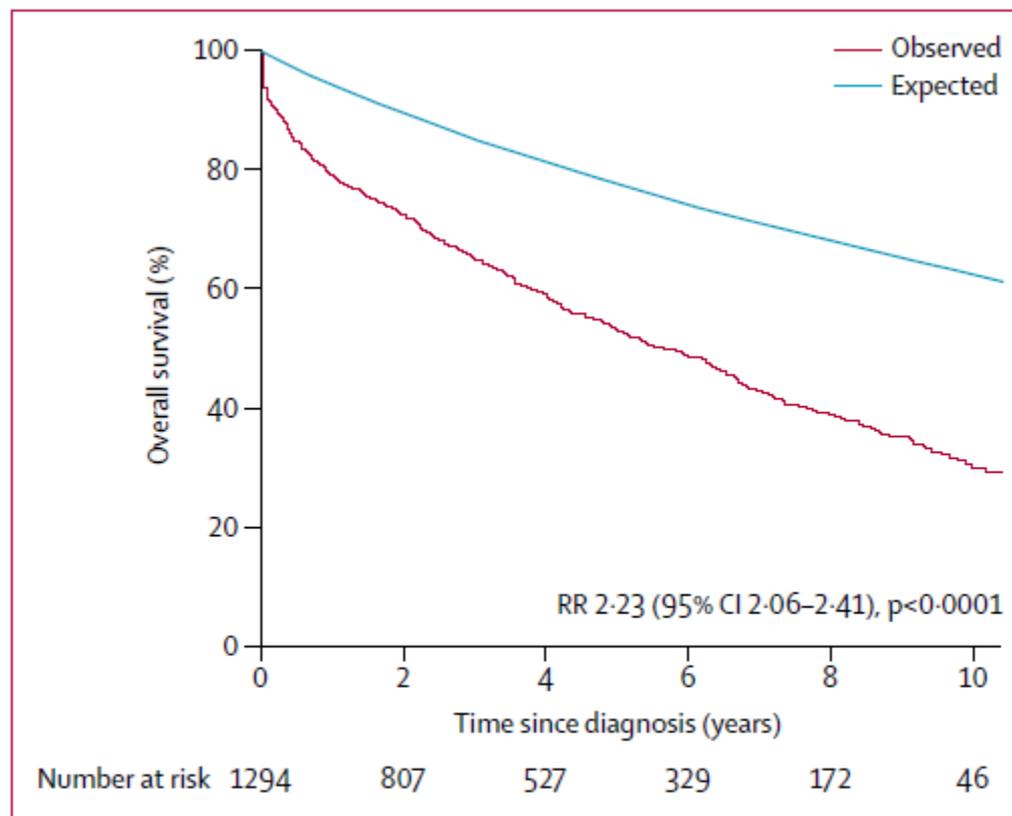
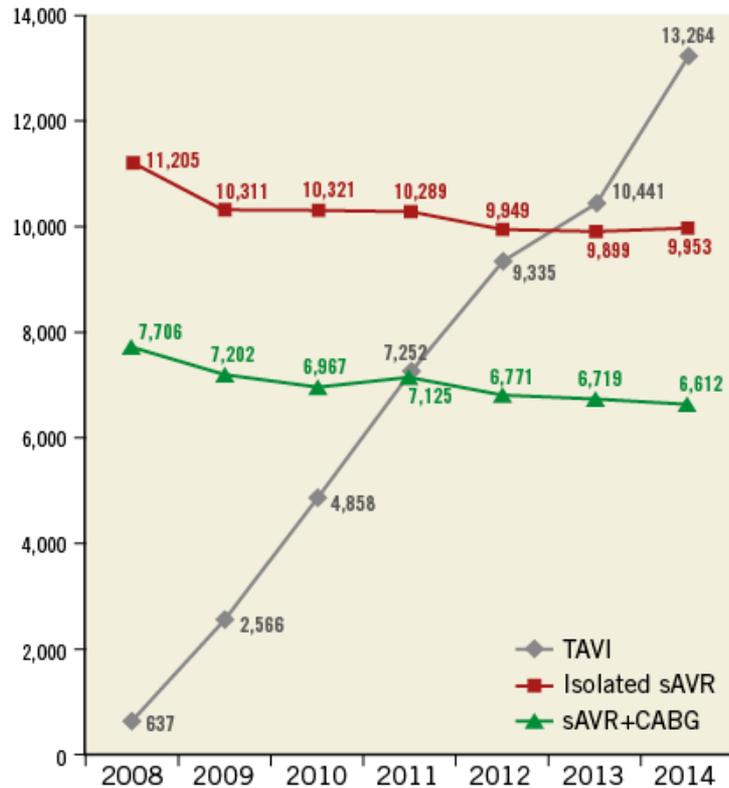
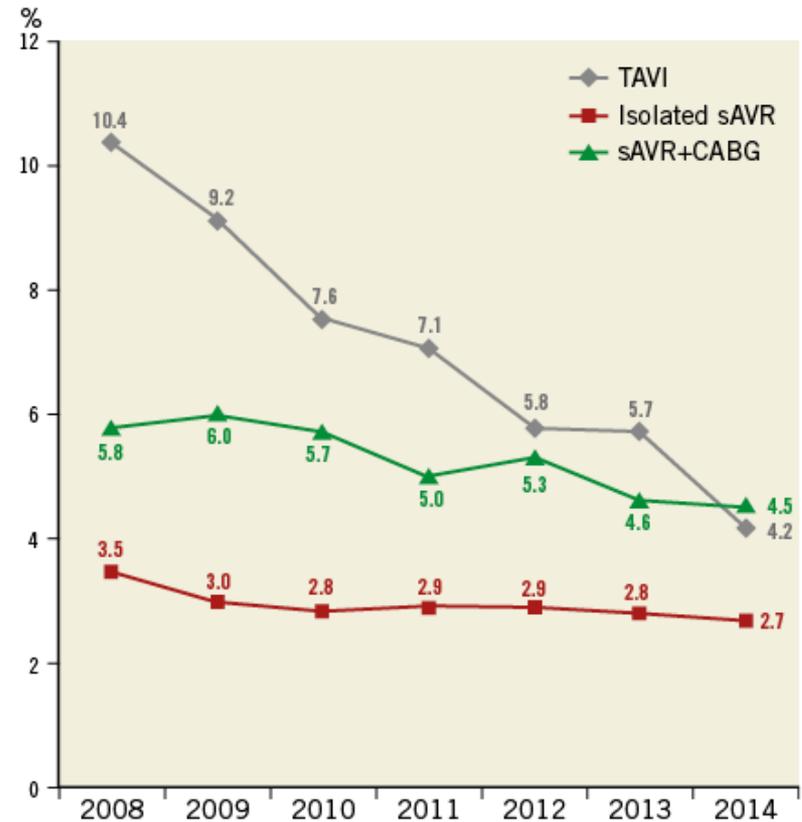


Figure 2: Survival after diagnosis of isolated moderate or severe mitral regurgitation

# Estenosis aórtica



Trends in TAVI and sAVR



Trends in unadjusted in-hospital mortality rates after TAVI and sAVR

**¿Porqué el tratamiento  
percutáneo de la  
insuficiencia mitral no ha  
ido a la par de la estenosis  
aórtica (TAVI)?**

# Estenosis aórtica ≠ Insuficiencia mitral

*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 D. 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\*

**Septiembre 2005**

*The* NEW ENGLAND  
JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

OCTOBER 21, 2010

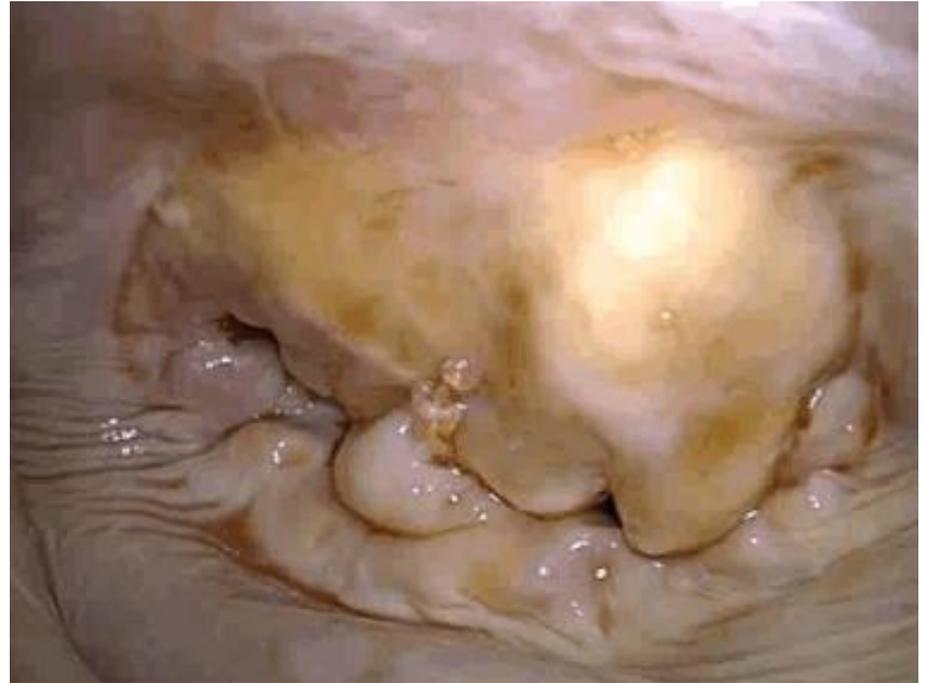
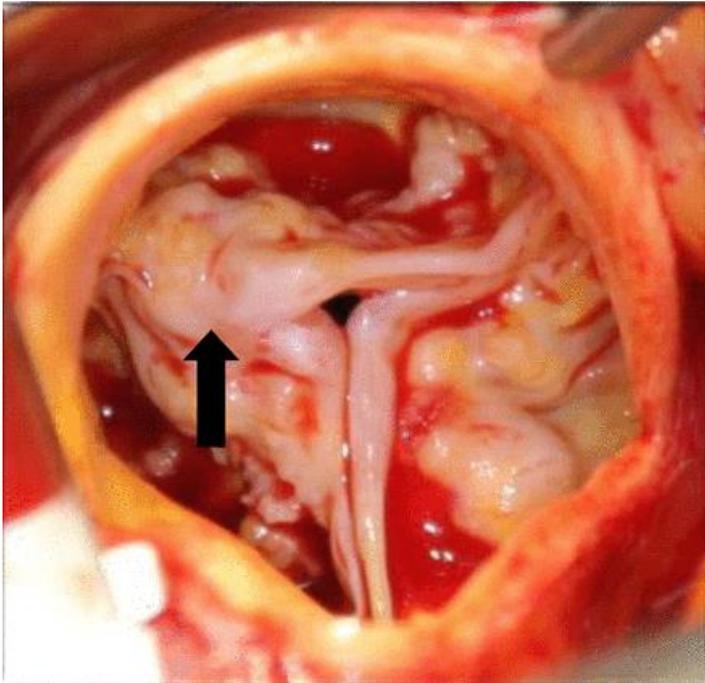
VOL. 363 NO. 17

## Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators\*

**Mayo 2007**

# Estenosis aórtica ≠ Insuficiencia mitral

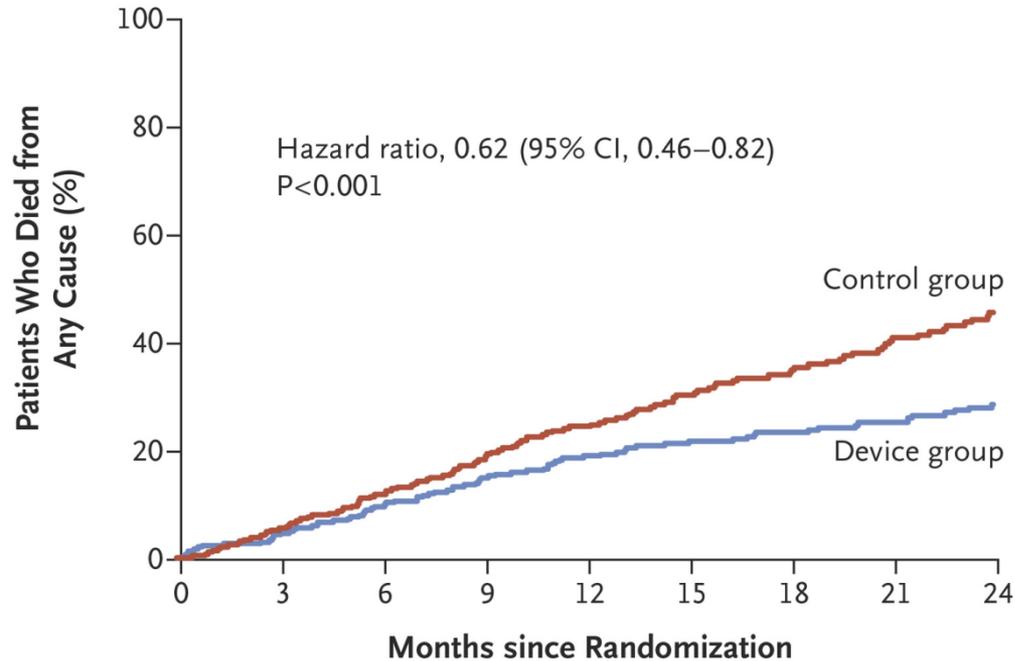


## Falta de evidencia para el tratamiento de la insuficiencia mitral funcional

Falta de evidencia para el  
tratamiento de la  
insuficiencia mitral funcional

# Estenosis aórtica ≠ Insuficiencia mitral

## C Death from Any Cause



### No. at Risk

Control group	312	294	271	245	219	176	145	121	88
Device group	302	286	269	253	236	191	178	161	124

Stone GW, et al. NEJM 2018; doi.10.1056/NEJMoa1806640

# Tratamiento transcatéter de la insuficiencia mitral

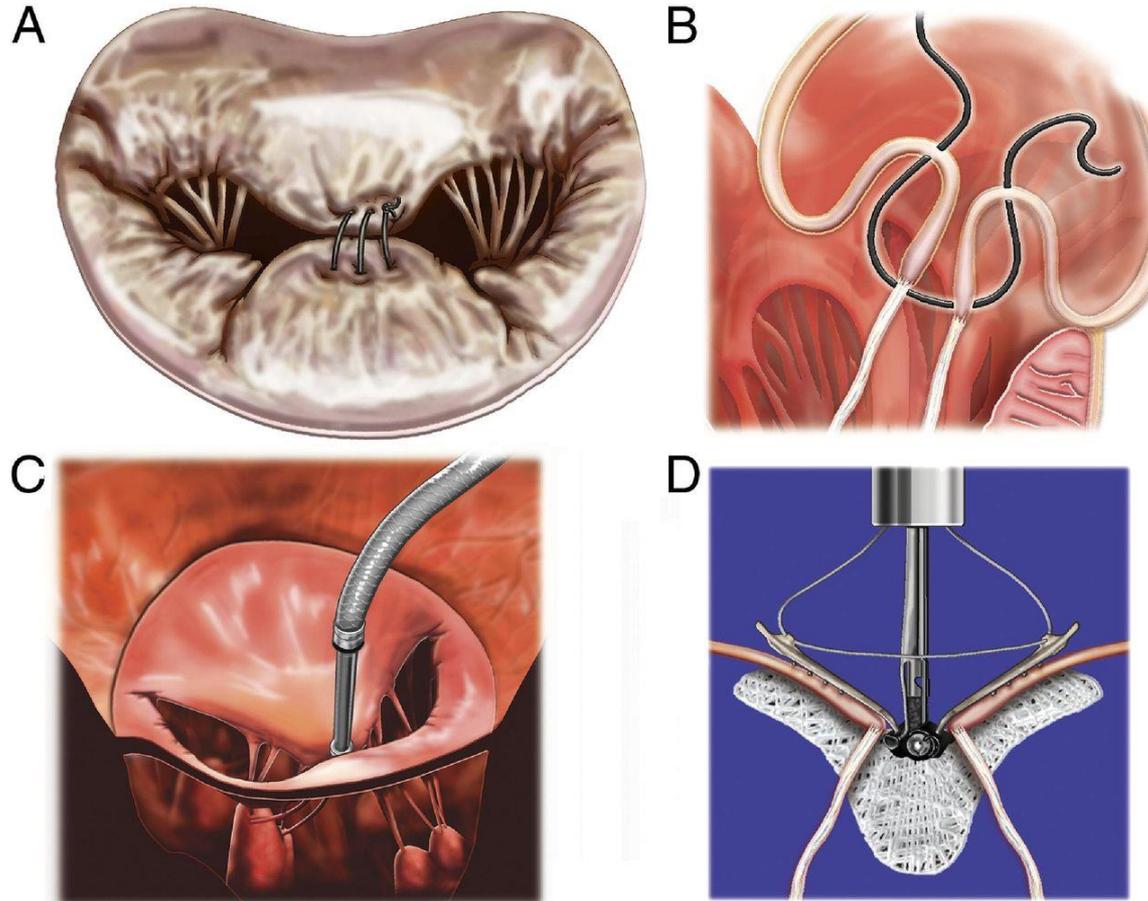
## ¿Reparación vs. Sustitución?

# Reparación mitral percutánea

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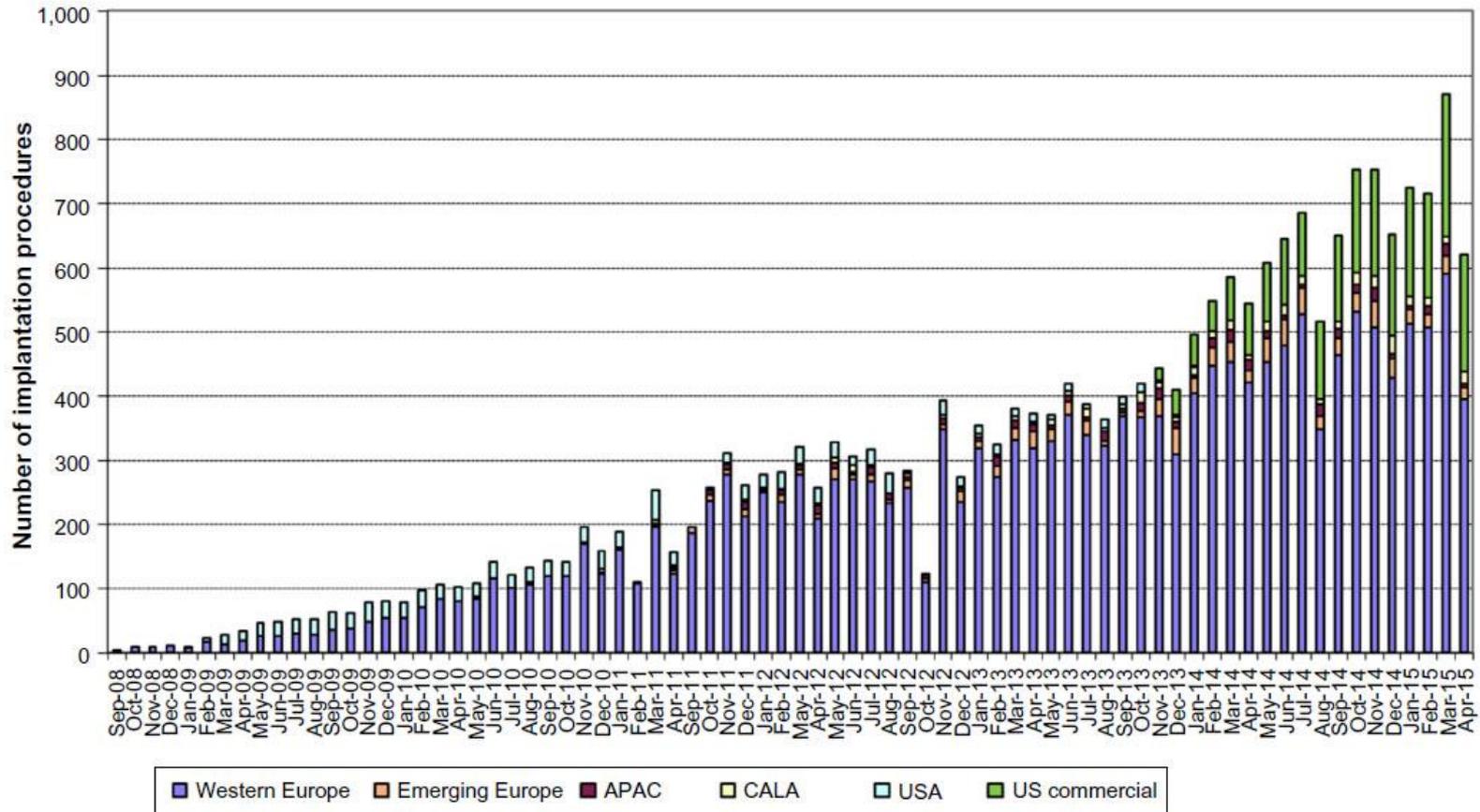


# Reparación mitral percutánea

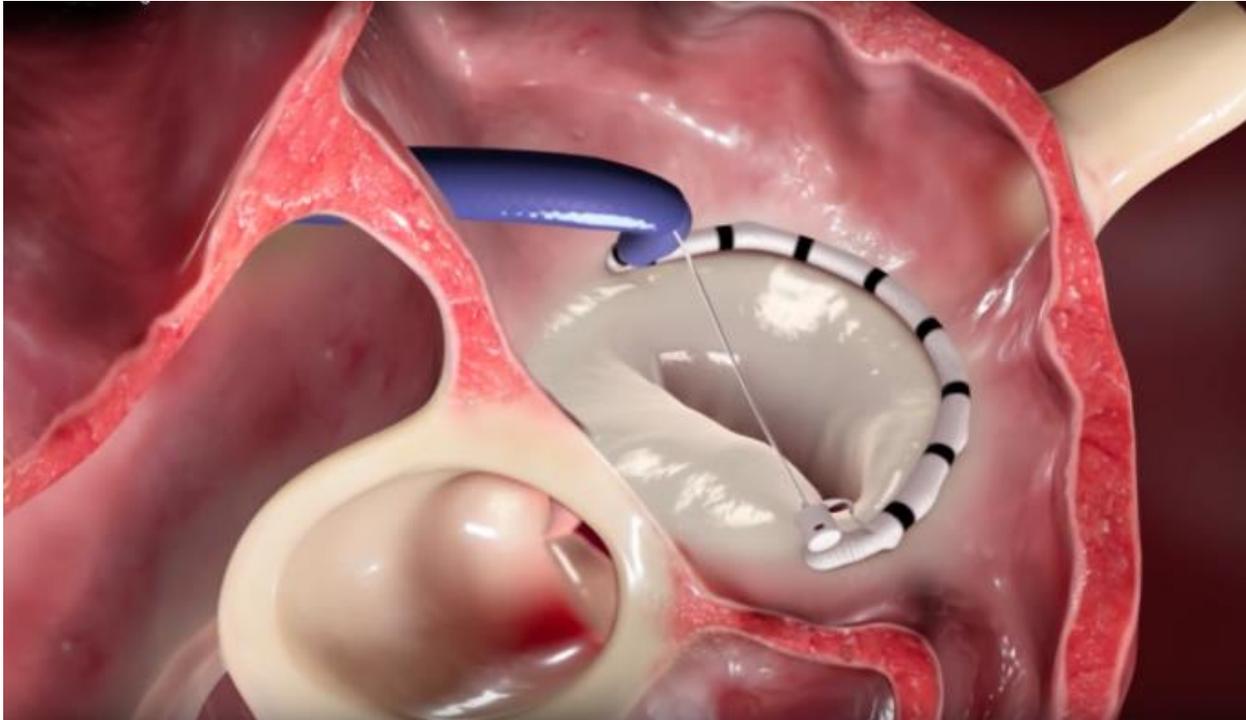


Maisano F, et al. JACC 2011;58

# Reparación mitral percutánea



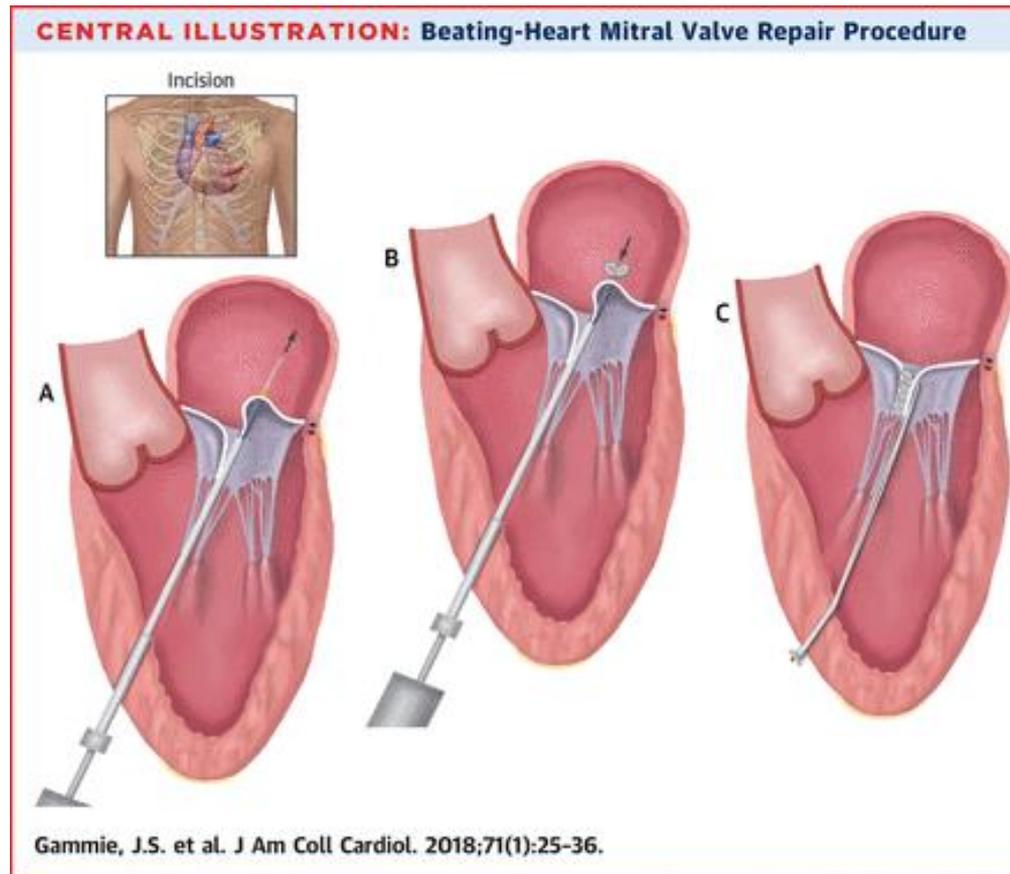
# Reparación mitral percutánea



**Implante de válvula mitral percutánea**

Sesión GREG IMIM, Hospital del Mar. 09/11/2018

# Reparación mitral percutánea



La insuficiencia mitral es una entidad compleja y heterogénea

En la cirugía existen múltiples técnicas de reparación

Desarrollar técnicas percutáneas para tratar todas las variaciones anatómicas y tipos de pacientes sería complejo

# Ventajas teóricas

## Sustitución (percutáneo vs. quirúrgico)

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Preserva el aparato subvalvular (insuficiencia mitral secundaria)

Acceso transeptal (insuficiencia mitral secundaria con disfunción sistólica grave)

# Ventajas teóricas

## Sustitución vs. reparación

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Idealmente la sustitución percutánea sería un concepto **más universal** con resultados **más predecibles** en un procedimiento **menos invasivo** (vs. cirugía) y técnicamente **menos complejo**

# Tipos de sustitución valvular mitral transcatéter

Prótesis aórticas en posición mitral

Bioprótesis

Anillo mitral

Calcificación extrema del anillo mitral

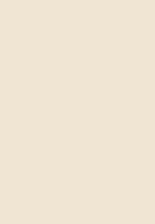
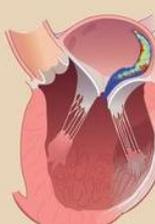
**Prótesis mitrales específicas**

**Válvula nativa**

# Sustitución valvular mitral transcatéter en válvula nativa

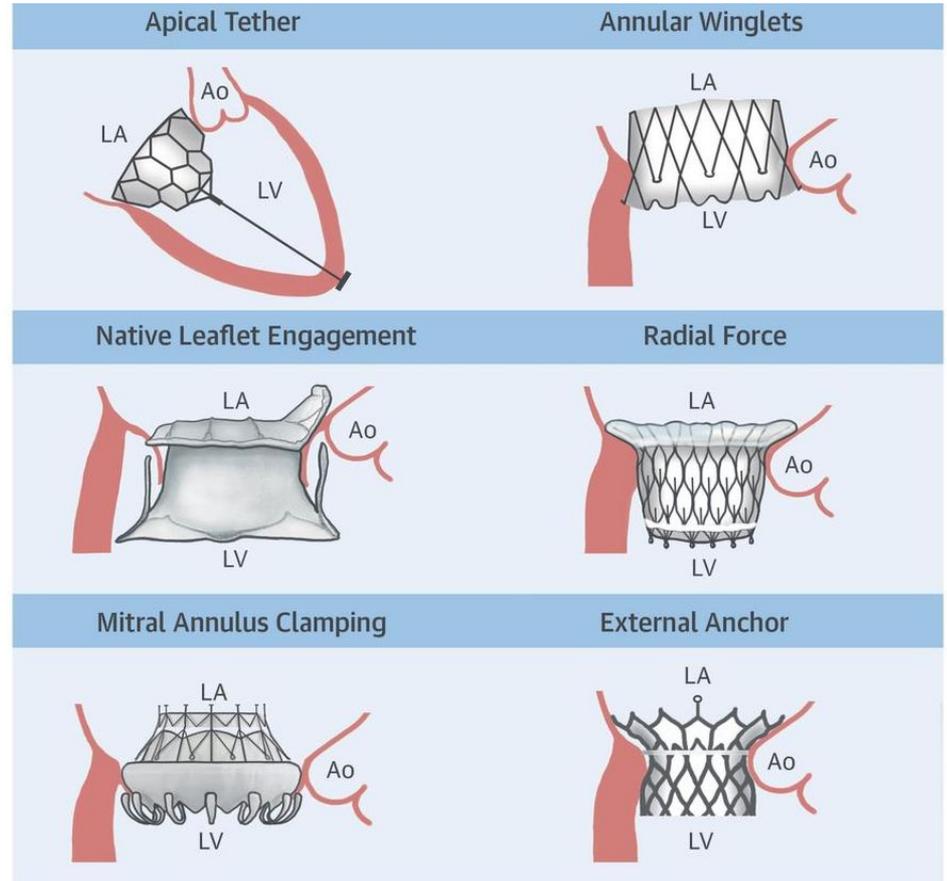
# Retos para el desarrollo de una prótesis mitral transcatéter

## Heterogeneidad del trastorno de la válvula mitral

	Carpentier Type I (normal leaflet motion and position)	Carpentier Type II (excess leaflet motion)	Carpentier Type IIIa (restricted leaflet motion in systole and diastole)	Carpentier Type IIIb (restricted leaflet motion in systole)
<b>PRIMARY MR</b>	 <p>Leaflet Perforation Cleft</p>	 <p>Mitral Valve Prolapse</p>	 <p>Rheumatic Valve Disease Mitral Annular Calcification Drug Induced MR</p>	
<b>SECONDARY MR</b>	 <p>Atrial MR</p>	 <p>Nonischemic Cardiomyopathy</p>		 <p>Ischemic Cardiomyopathy</p>

El Sabbagh, et al. JACC Imag 2018;11:628-43

## Anclaje de la prótesis



Regueiro A, et al. J Am Coll Cardiol 2017;69:2175-92

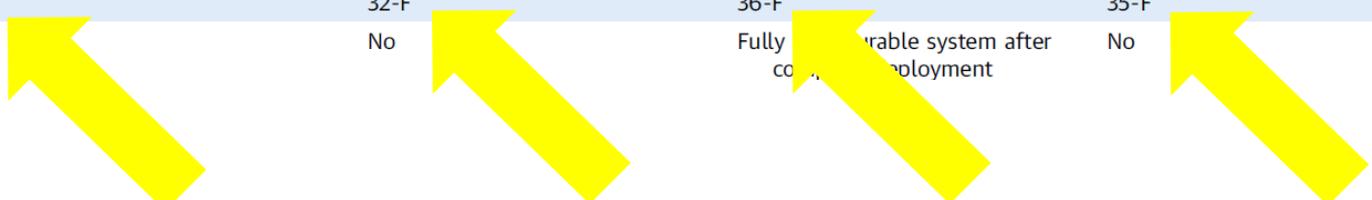
## Obstrucción del tracto de salida



Regueiro A, et al. J Am Coll Cardiol 2017;69:2175-92

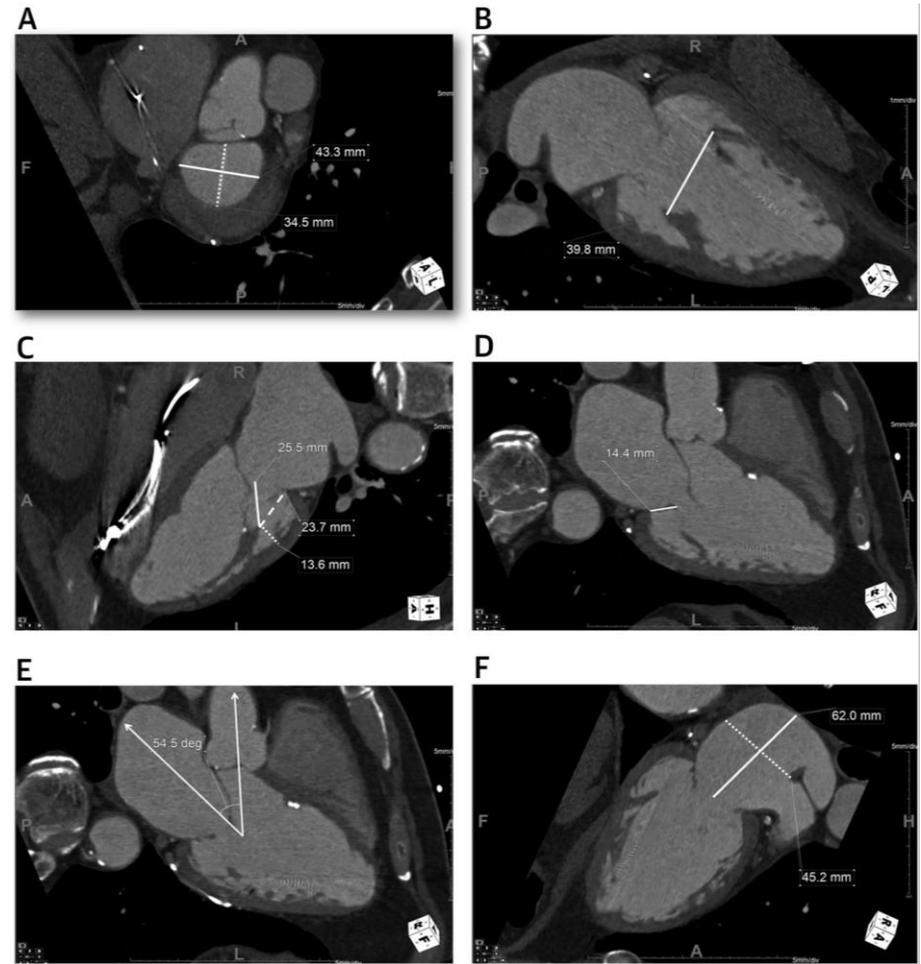
## Acceso: Transeptal vs. transapical

	<b>CardiaQ-Edwards</b>	<b>Neovasc Tiara</b>	<b>Tendyne</b>	<b>Intrepid TMVR</b>
Valve shape	Circular	D-shaped	D-shaped (outer stent) Circular (inner frame)	Circular
Frame	Nitinol, self-expandable	Nitinol, self-expandable	Nitinol, double frame; Self-expandable	Nitinol, double stent; Self-expandable
Anchoring mechanism	Mitral annulus capture with native leaflet engagement	Fibrous trigone capture with native leaflet engagement	Apical tether	Radial force and subannular cleats
Leaflets	Trileaflet Bovine pericardium	Trileaflet Bovine pericardium	Trileaflet Porcine pericardium	Trileaflet Bovine pericardium
Valve position	Supra-annular	Intra-annular	Intra-annular	Intra-annular
Access	Transapical Transseptal	Transapical	Transapical	Transapical
Delivery system size	33-F	32-F	36-F	35-F
Recapture	No	No	Fully retrievable system after complete deployment	No



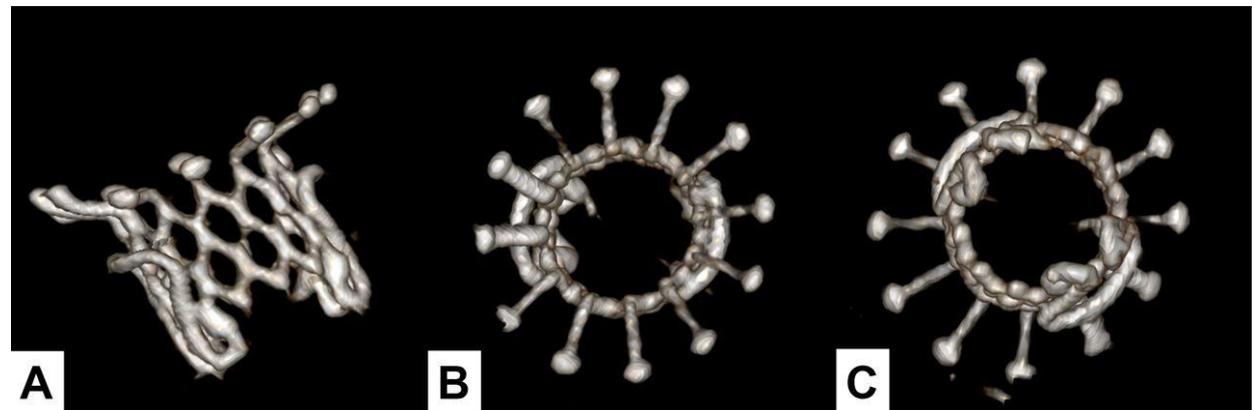
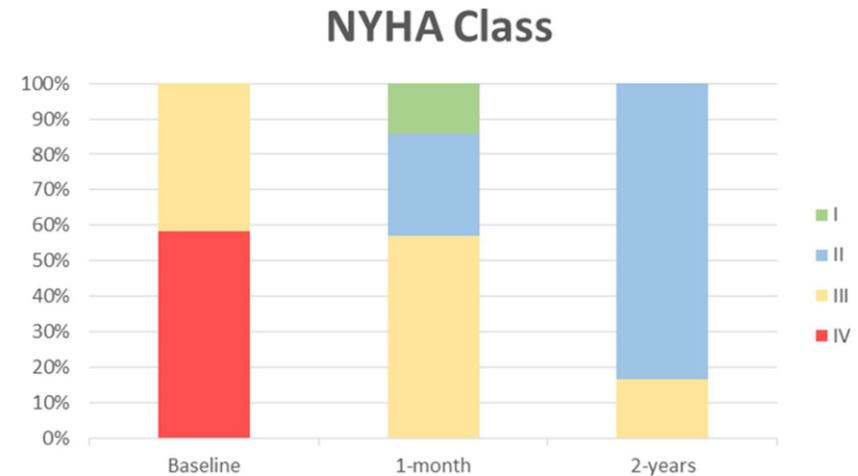
Regueiro A, et al. J Am Coll Cardiol 2017;69:2175-92

## Planeación



Regueiro A, et al. J Am Coll Cardiol 2017;69:2175-92

## Degeneración protésica



Regueiro A, et al. JACC Cardiovasc Interv 2017; 10:1671-78

# Prótesis mitrales transcatéter

Tiara



CardiAQ



Intrepid



CardiAQ TF



Mvalve



Caisson



Sapien M3



2012

2014

2015

2016

2018



CardiAQ



Fortis



Tendyne



Navigate



HighLife



Cardiovalve

**Implante de válvula mitral percutánea**

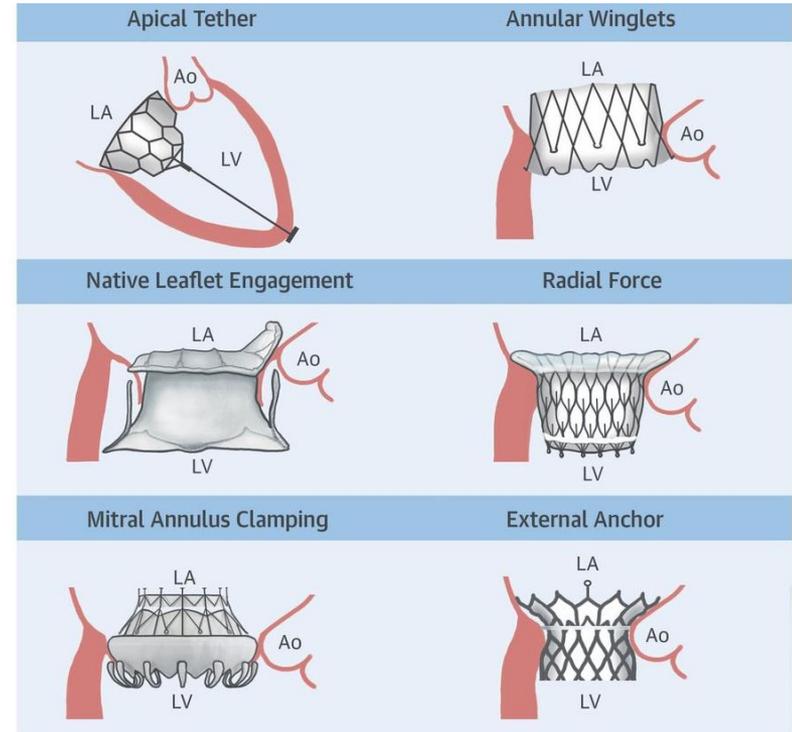
Sesión GREG IMIM, Hospital del Mar. 09/11/2018

## Acceso

- **Transapical**  
Tendyne, Intrepid, Tiara
- **Transeptal**  
Caisson, SAPIEN M3, CardioValve
- **Ambos**  
Highlife, CardiAQ

## Anclaje

- **Cuerda apical**  
Tendyne
- **Velos**  
Tiara, CardiAQ
- **Velos y anillo**  
Intrepid, Cardiovalve
- **Anclaje externo (subanular)**  
Caisson, M3, Highlife



# Tendyne (Abbott)

Plataforma transapical  
Fijación con cuerda y almohadilla apical  
Reposicionable y recapturable  
Múltiples tamaños

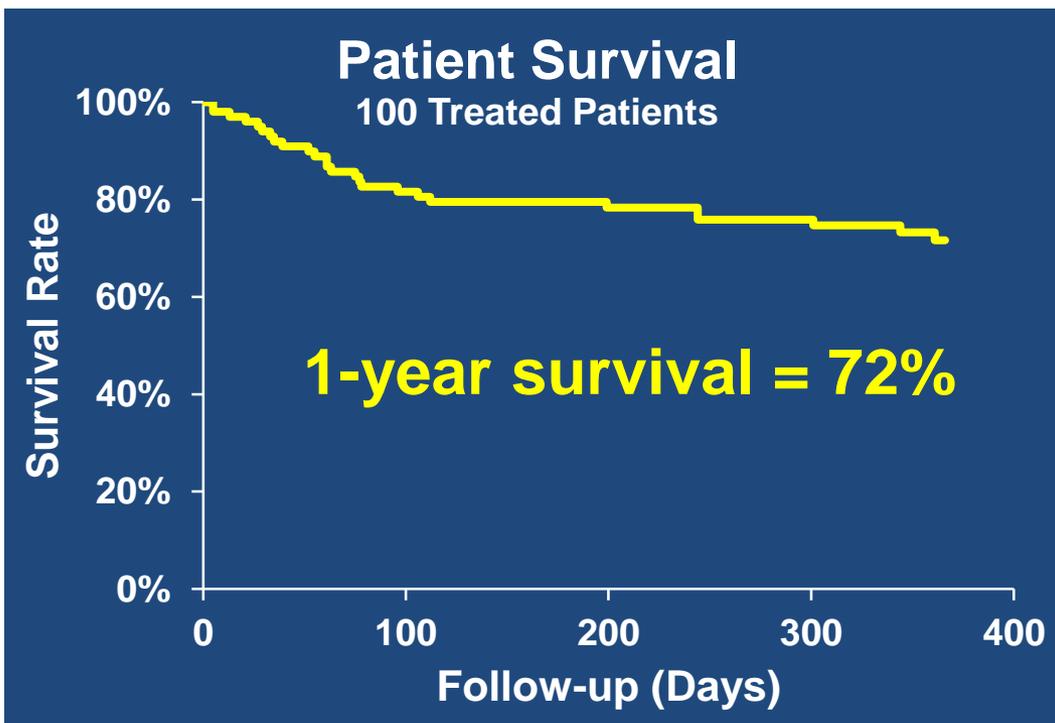


Sorajja P, TCT 2018

## Experiencia en más de 100 pacientes

	N=100
<b>Valve implanted</b>	<b>97 (97%)</b>
<b>Technical success</b>	<b>96 (96%)</b>
<b>Implant aborted</b>	<b>3 (3%)</b>
• Retrieved (SAM, LVOT obstruction)	
• Retrieved (non-orthogonal access)	
• Abandoned (pulmonary edema)	
<b>Procedural mortality</b>	<b>0 (0%)</b>
<b>Procedural strokes</b>	<b>0 (0%)</b>
<b>Emergency surgeries</b>	<b>0 (0%)</b>
<b>ECMO required</b>	<b>0 (0%)</b>
<b>Major apical bleeding</b>	<b>1 (1%)</b>
<b>30-day mortality</b>	<b>6 (6%)</b>

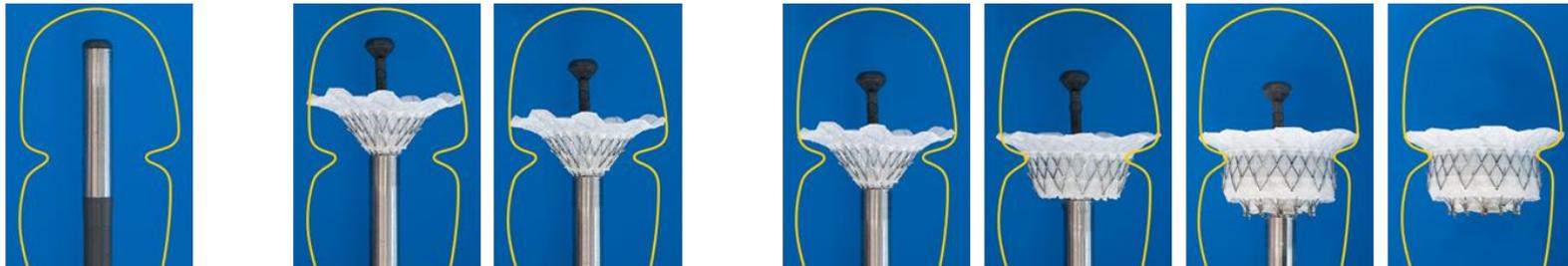
# Tendyne (Abbott)



Clinical Events Patients with 1-yr follow-up	N=86
All mortality	22 (26%)
CV death	18 (21%)
Disabling stroke	3 (3%)
Re-intervention for tether tensioning	3 (3%)
Embolization or late migration	0 (0%)
Endocarditis	1 (1%)
Thrombus*	6 (7%)

# Intrepid (Medtronic)

Stent externo para fijación y sellado  
Stent interno con válvula tricúspide

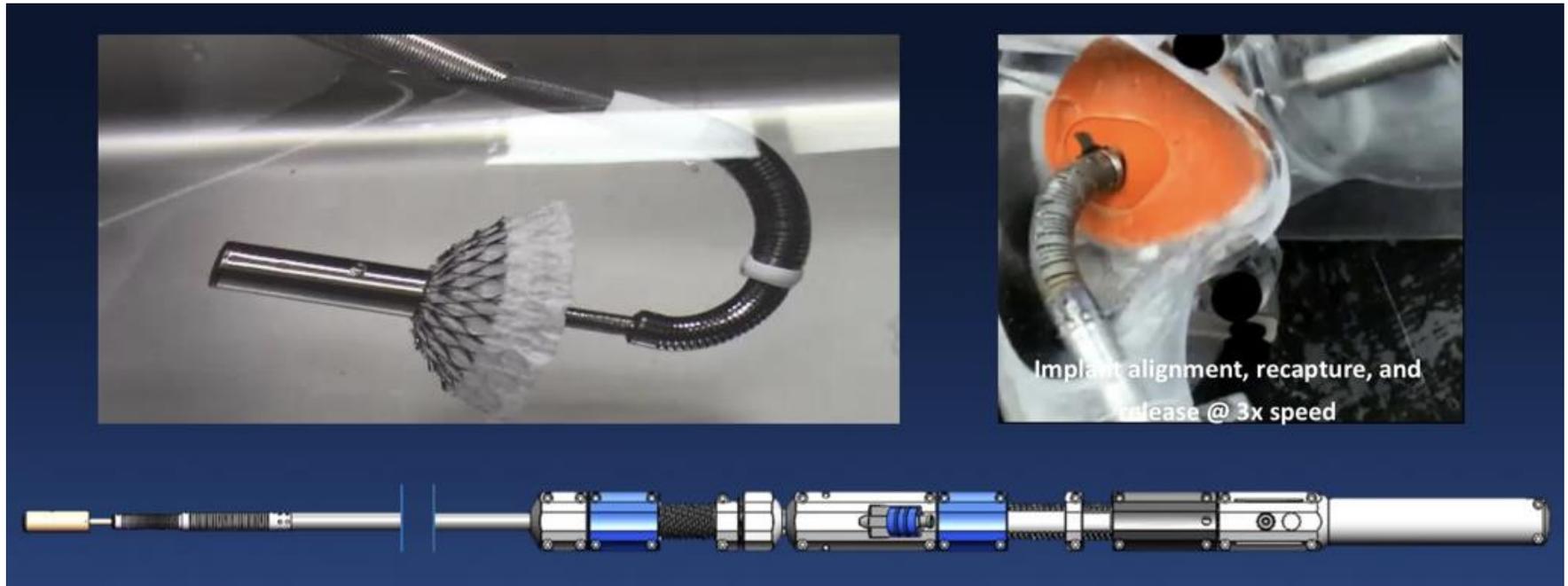


1. 60cm into D. 2. Expand from 5.5cm to 11cm. 3. Deploy and expand 3. Deploy



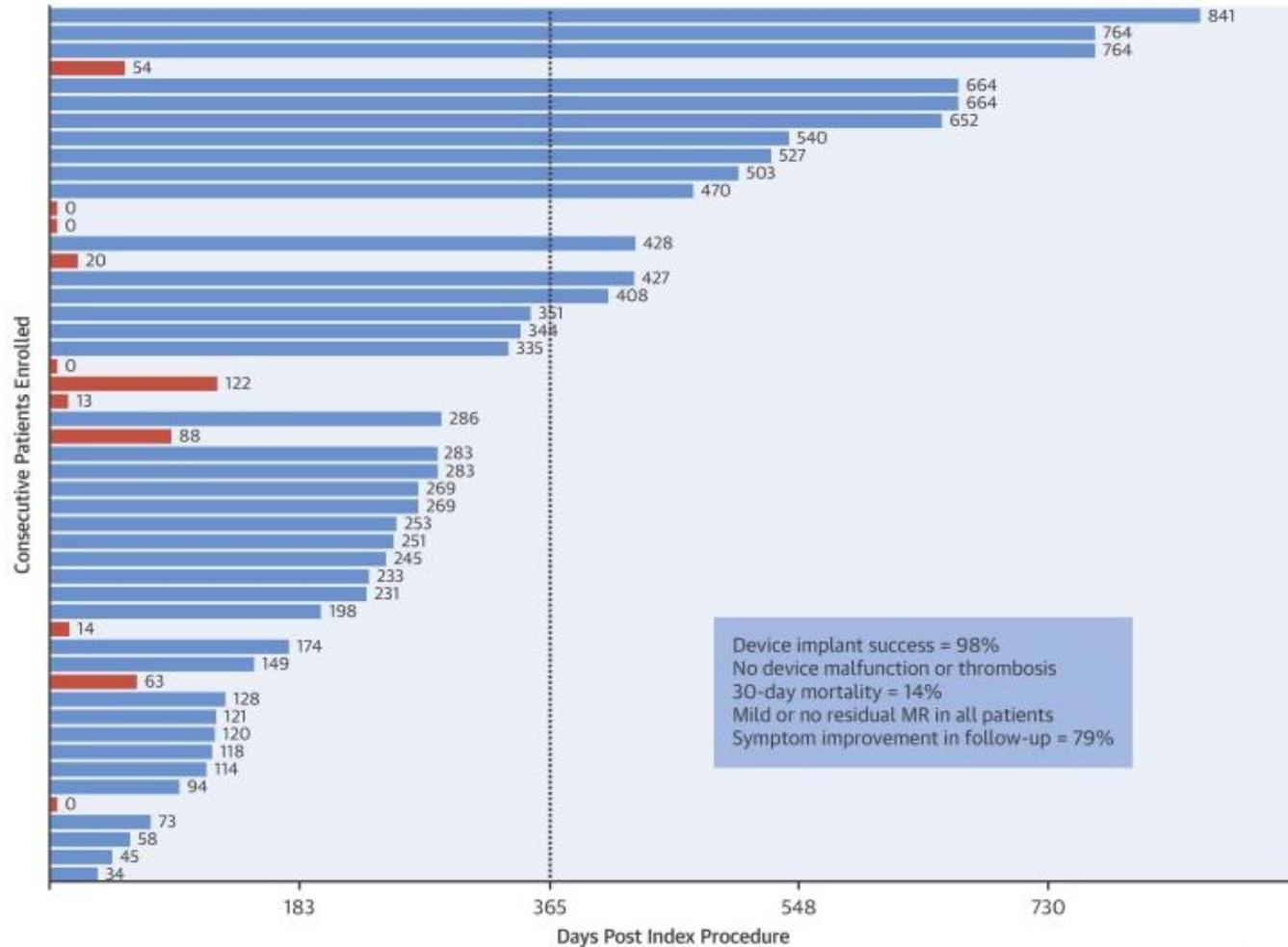
Reardon M, TCT 2018

# Intrepid (Medtronic)



Reardon M, TCT 2018

# Intrepid (Medtronic)

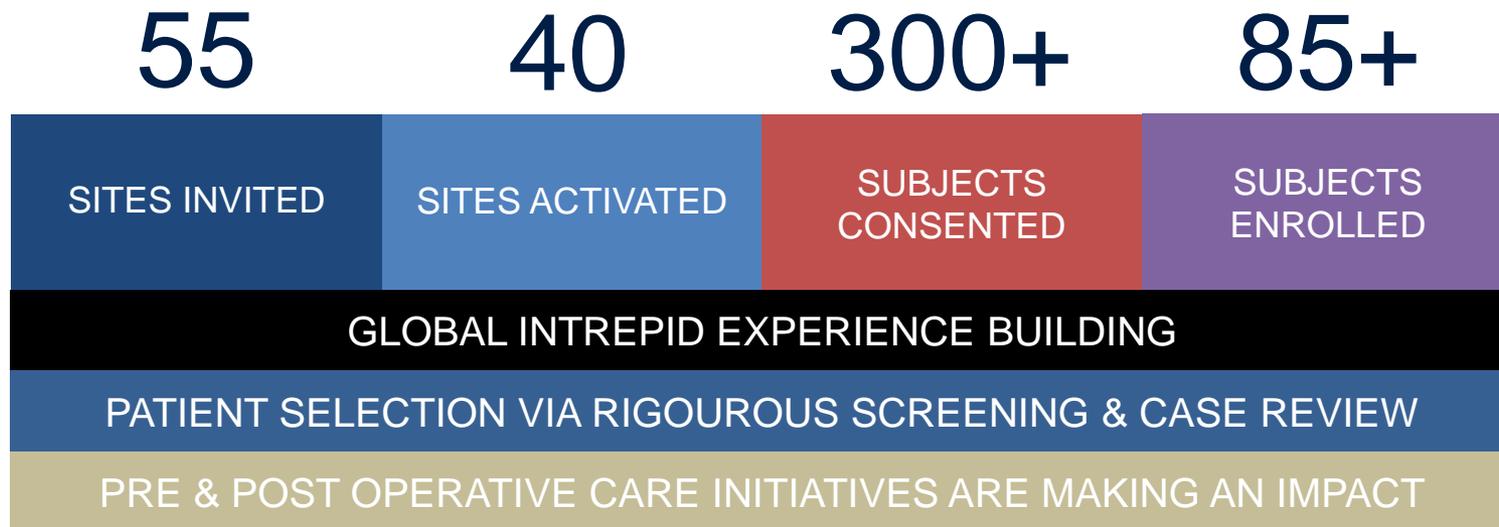


Bapat V, et al. J Am Coll Cardiol 2018;71:12-21

# Intrepid (Medtronic)

## APOLLO Trial By the numbers

### MEDTRONIC INTREPID™ TMVR APOLLO Trial



Reardon M, TCT 2018

# SAPIEN M3 (Edwards)

## Plataforma transseptal Prótesis SAPIEN 3 modificada

### Dock Delivery

SAPIEN M3 Dock

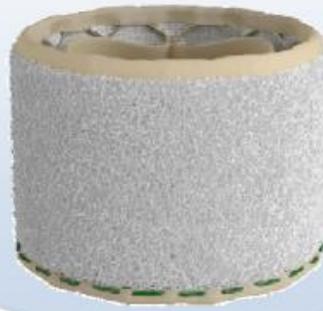


SAPIEN M3 Dock Delivery System



### Valve Delivery

SAPIEN M3 Valve



Commander Delivery System



### Final Implant



# SAPIEN M3 (Edwards)

Characteristic	N=15
Procedural duration (min)	189 ± 100
Transseptal puncture to dock release (min)	114 ± 84
Dock deployment duration (min)*	78 ± 70
Index hospitalization duration (days)	6.3 ± 3.2
Length of ICU stay (days)	2.6 ± 1.8
Post-dilatation	53.3 (8/15)

# SAPIEN M3 (Edwards)

30-Day Outcomes	n/15
All-cause mortality	0
All stroke	1*
Myocardial infarction	0
Rehospitalization (procedure- or device-related)	3 <sup>#</sup>
LVOT obstruction	0
Hemolysis	0
Device migration, embolization, or fracture	0
Endocarditis	0
Life-threatening bleeding	0
AKI (Stage 2-3)	1
Major vascular complications	0
Any valve-related dysfunction, migration, thrombosis requiring surgery or repeat intervention	1*

# CONCLUSIONES

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Existe una necesidad clínica para tratar por vía percutánea pacientes con insuficiencia mitral

El desarrollo ha sido lento debido a la complejidad de la válvula mitral

Existe evidencia que demuestra un aumento de sobrevida vs. el tratamiento médico (reparación) aunque no sería directamente trasladable a la sustitución en los diferentes escenarios clínicos

El tratamiento está limitado a pacientes con alto riesgo quirúrgico



**TABLE 5** Early Clinical Experience With TMVR in Native Severe MR (N = 115)\*

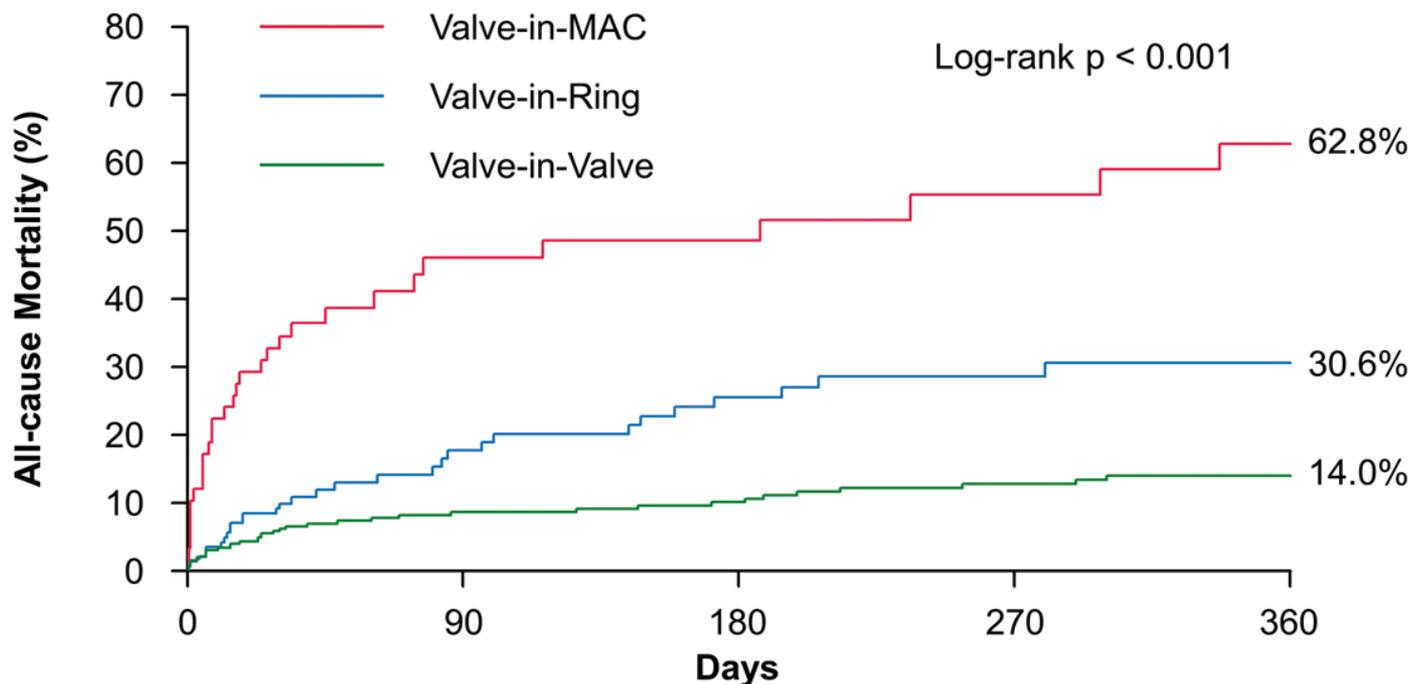
Procedural and 30-day outcomes	
Technical success	100/113 (88.4)
Procedural mortality	10/114 (8.8)
LVOT obstruction	1/96 (1.0)
Post-procedural $\geq$ moderate MR	1/77 (1.3)
30-day mortality	26/112 (23.2)

Regueiro A, J Am Coll Cardiol. 2017;69:2175-86

# **Sustitución valvular mitral transcatéter en prótesis valvular (Valve-in-Valve)**

# Valve-in-valve

**A**



**No. at Risk**

Valve-in-MAC  
Valve-in-Ring  
Valve-in-Valve

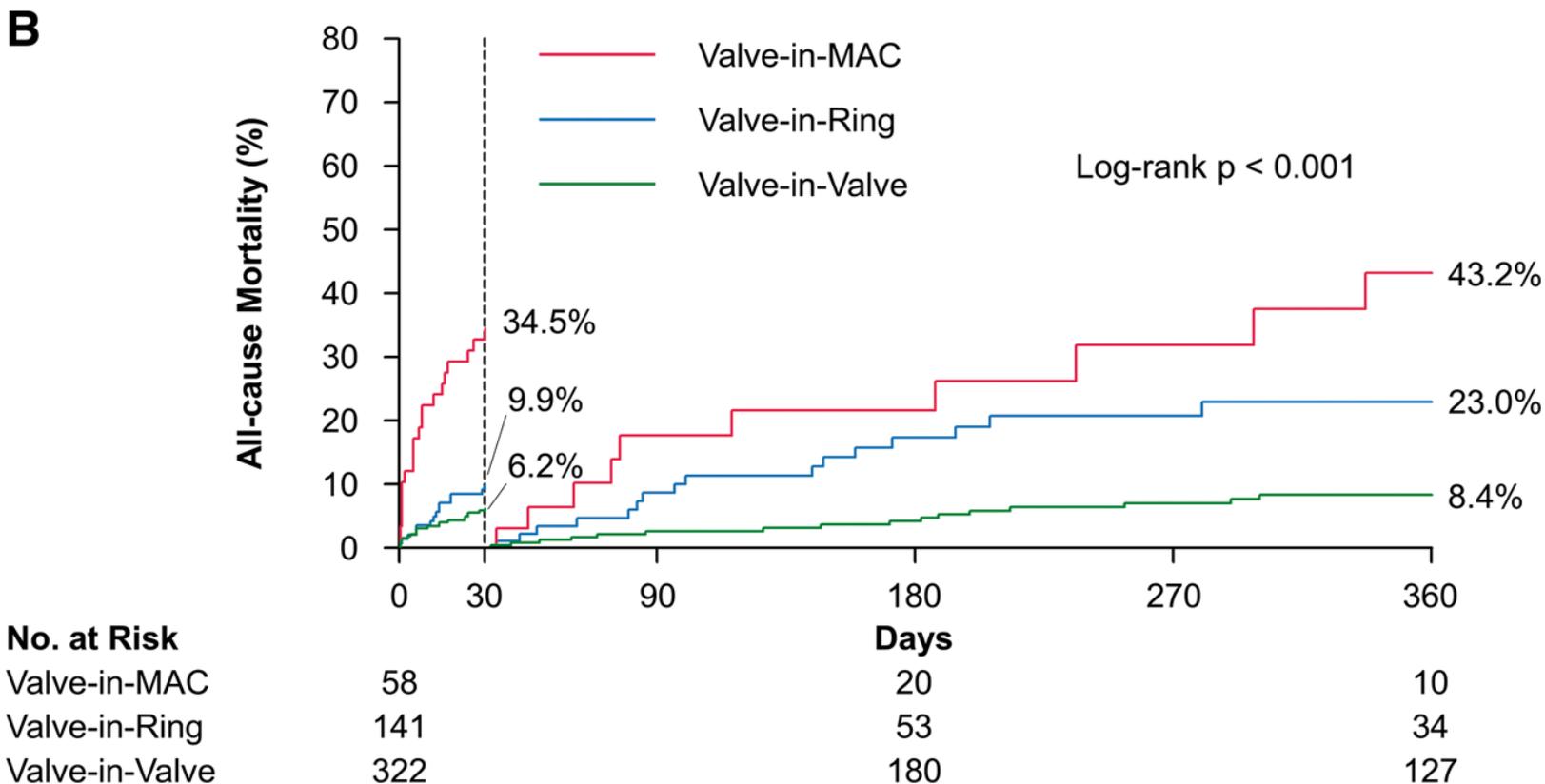
58  
141  
322

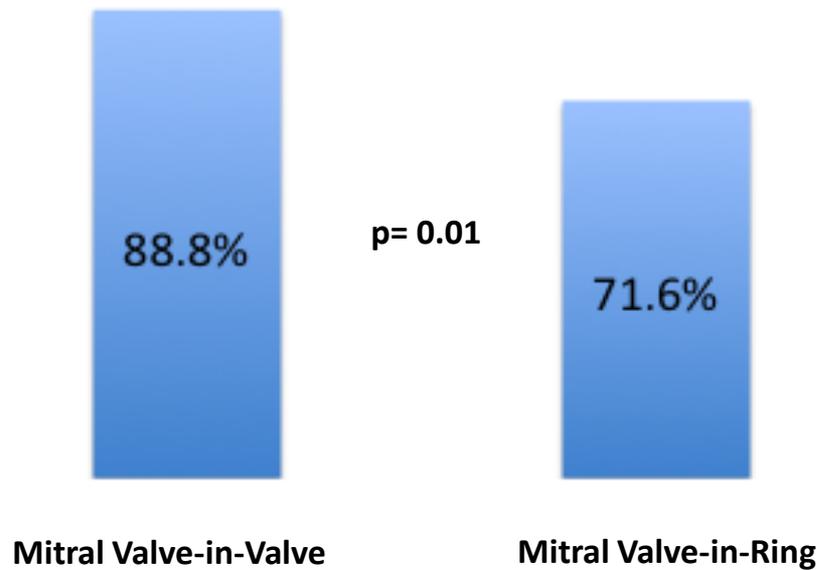
**Days**

20  
53  
180

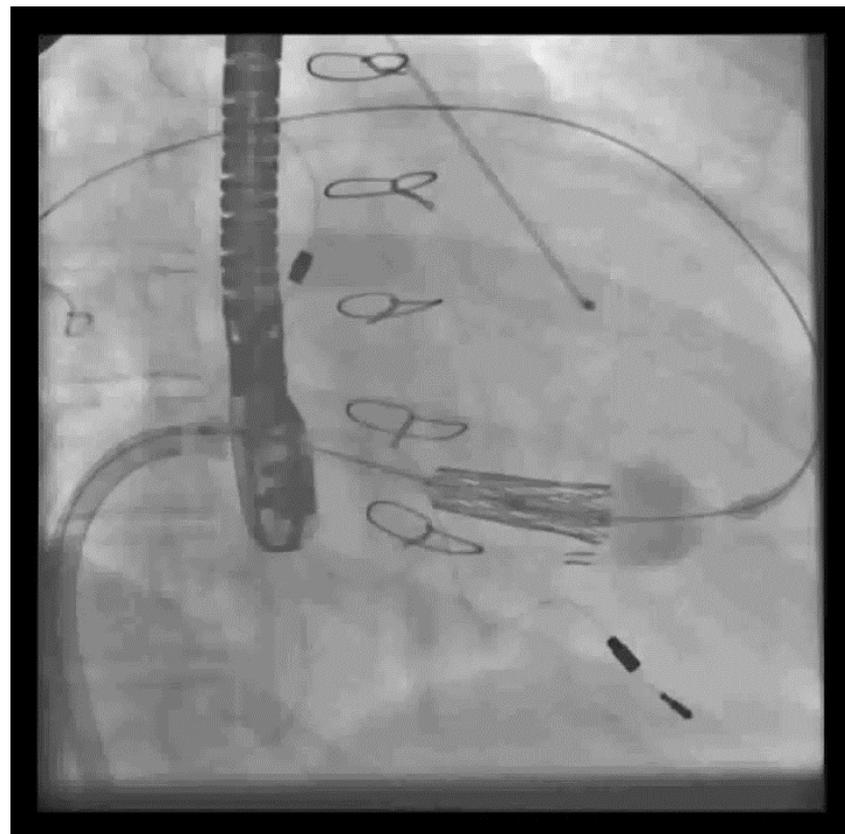
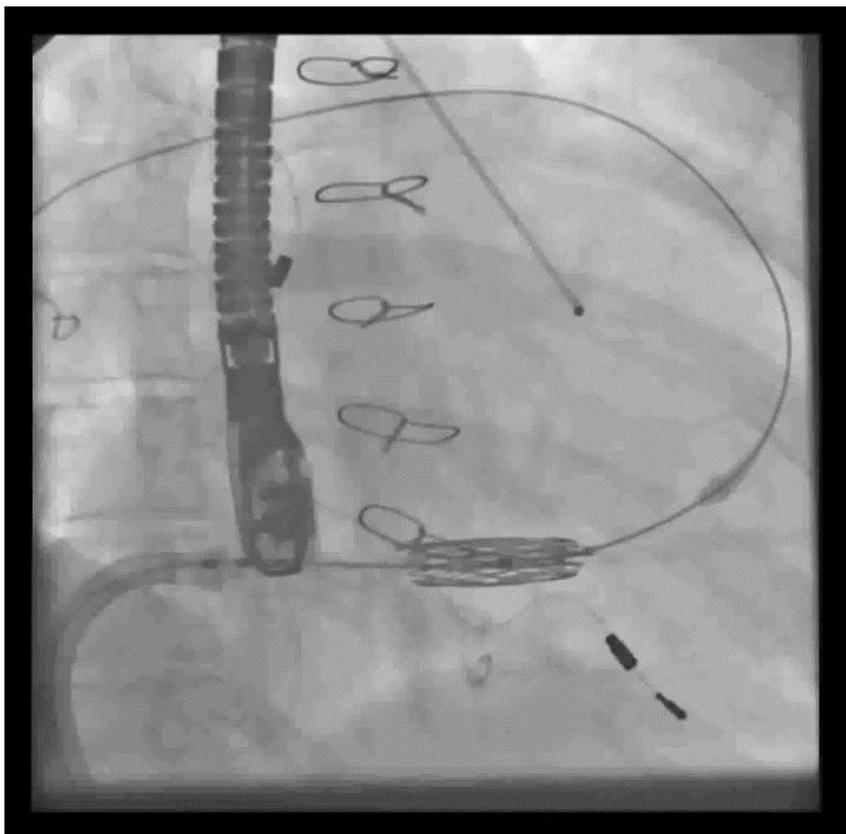
10  
34  
127

# Valve-in-valve





\*Composite end point included 30-day survival free from significant MR (moderate or more) or clinically-evident LVOT obstruction. The composite of adverse events occurred in 39 patients undergoing valve-in-valve and 25 patients that underwent valve-in-ring.



**Implante de válvula mitral percutánea**  
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# **Sustitución valvular mitral transcatéter en válvula calcificada (Valve-in-MAC)**

# Valve-in-MAC

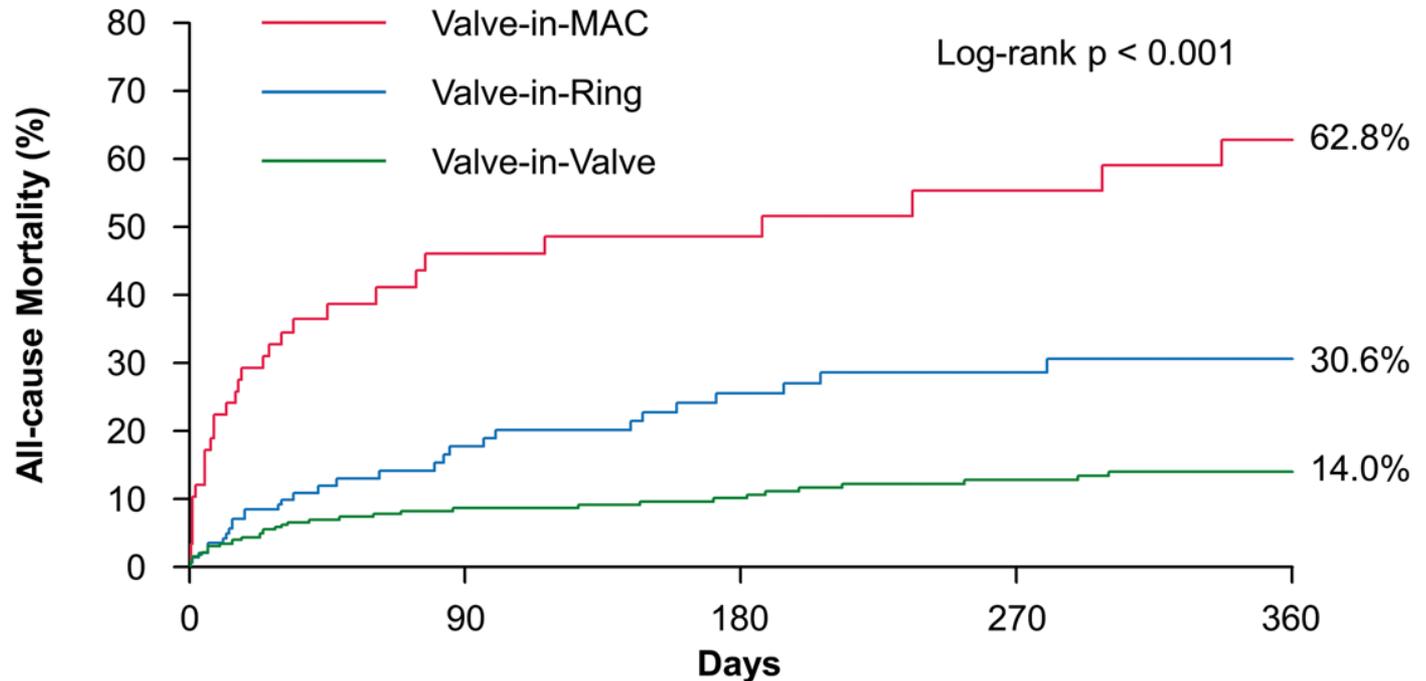
Overall (n = 521)    ViV (n = 322)    ViR (n = 141)    ViMAC (n = 58)    P-value

## Procedural outcomes

	Overall (n = 521)	ViV (n = 322)	ViR (n = 141)	ViMAC (n = 58)	P-value
Conversion to surgery	12 (2.3)	3 (0.9)	4 (2.8)	5 (8.6)	0.004 <sup>d</sup>
Valve embolization	9 (1.7)	3 (0.9)	2 (1.4)	4 (6.9)	0.01 <sup>d</sup>
Left ventricular perforation	4 (0.8)	4 (1.2)	0 (0.0)	0 (0.0)	0.58
Need for second valve implantation	28 (5.4)	8 (2.5)	17 (12.1)	3 (5.2)	<0.001 <sup>c</sup>
LVOT obstruction	37 (7.1)	7 (2.2)	7 (5.0)	23 (39.7)	<0.001 <sup>d,e</sup>
Technical success	454 (87.1)	304 (94.4)	114 (80.9)	36 (62.1)	<0.001 <sup>c,d,e</sup>
Re-intervention	73 (14.0)	35 (10.9)	25 (17.7)	13 (22.4)	0.02 <sup>c,d</sup>
Paravalvular leak closure	18 (3.5)	7 (2.2)	11 (7.8)	0 (0.0)	0.006 <sup>c,e</sup>
Atrial septal defect closure	36 (6.9)	23 (7.1)	7 (5.0)	6 (10.3)	0.38
Alcohol septal ablation	10 (1.9)	2 (0.6)	1 (0.7)	7 (12.1)	<0.001 <sup>d,e</sup>
Mitral valve replacement	10 (1.9)	6 (1.9)	3 (2.1)	1 (1.7)	0.98
Surgery	8 (1.5)	4 (1.2)	3 (2.1)	1 (1.7)	0.77
TMVR	2 (0.4)	2 (0.6)	0 (0.0)	0 (0.0)	>0.99
Device success	402 (77.2)	273 (84.8)	98 (69.5)	31 (53.4)	<0.001 <sup>c,d,e</sup>

# Valve-in-MAC

**A**



**No. at Risk**

	0	90	180	360
Valve-in-MAC	58	20	10	10
Valve-in-Ring	141	53	34	34
Valve-in-Valve	322	180	127	127

