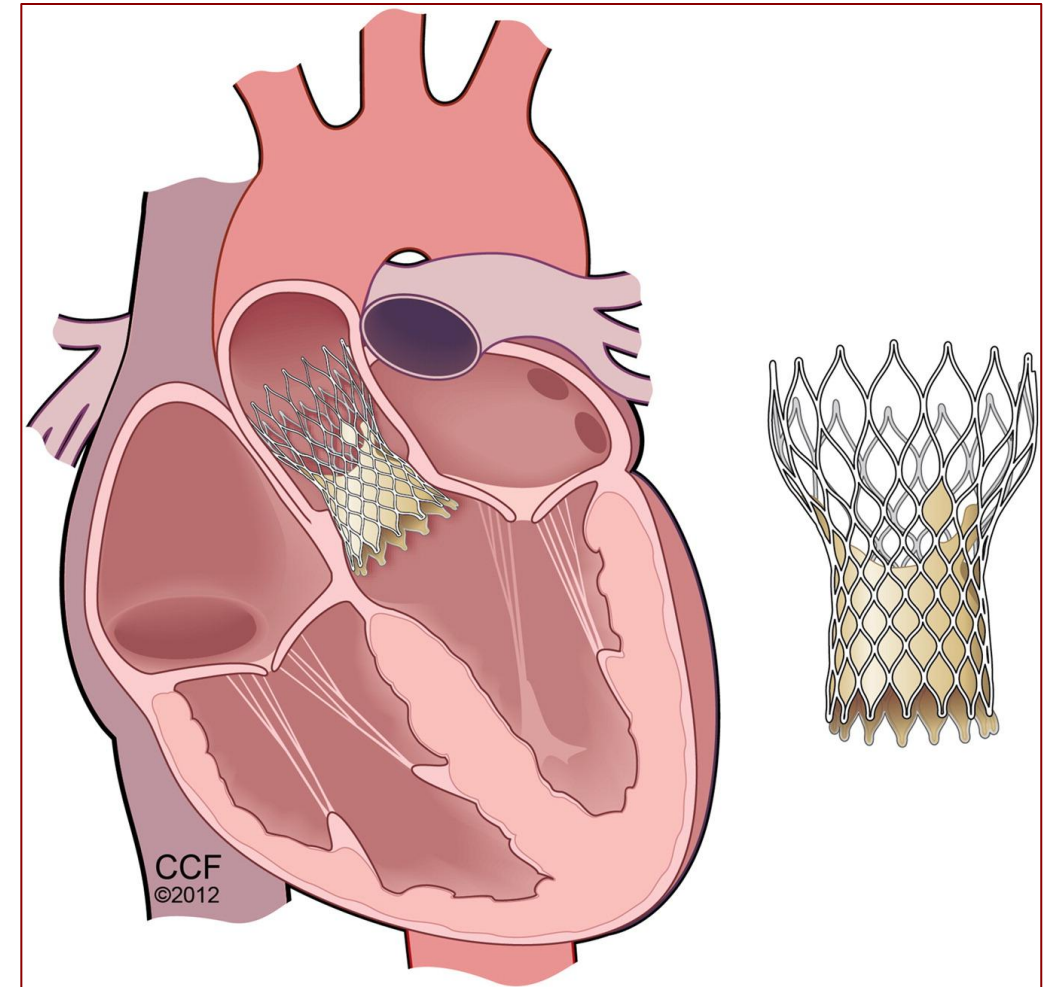
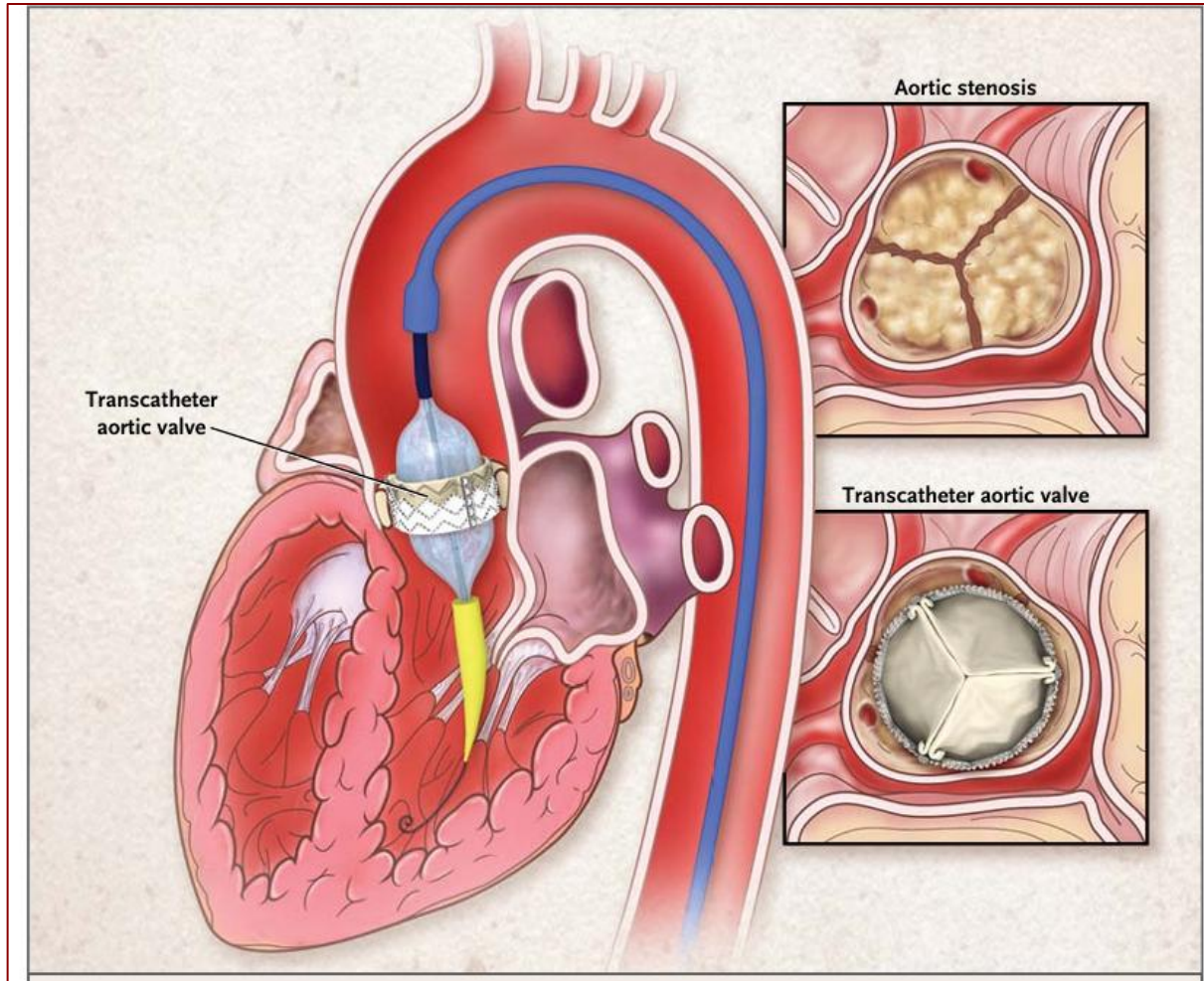


# Implantation percutanée de la valve aortique: standard du remplacement valvulaire aortique

Marina Urena

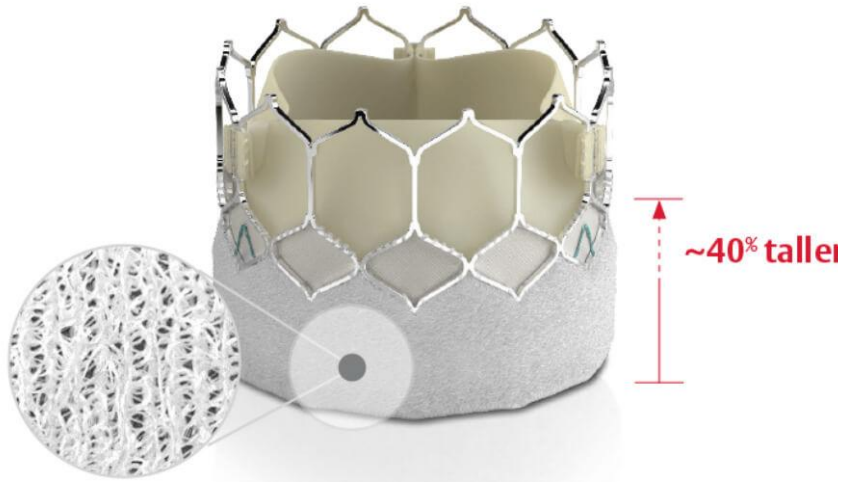
Bichat Hospital, Paris City University, INSERM 1148

# Transcatheter valve implantation:TAVI

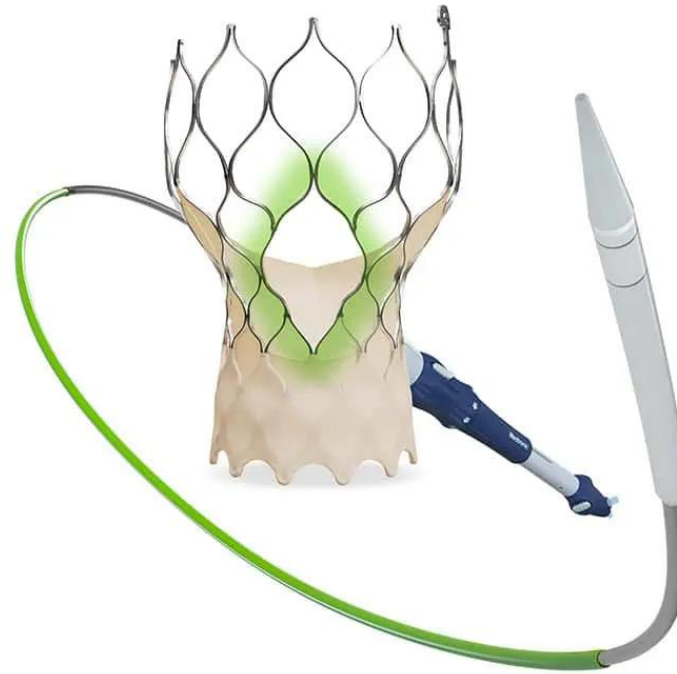


# Transcatheter heart valves

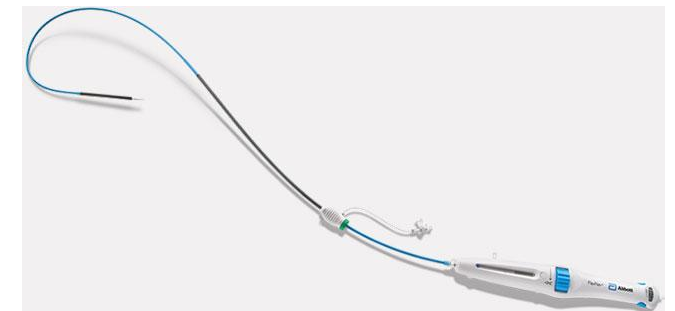
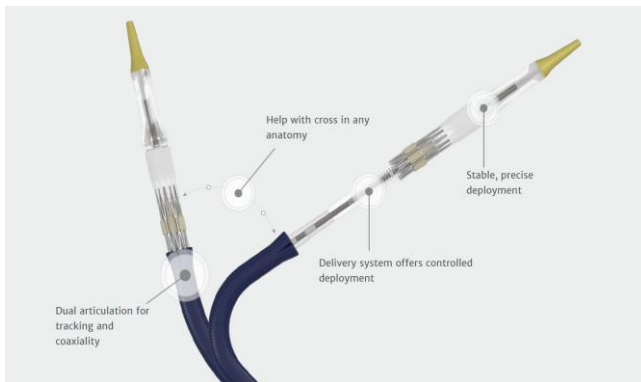
Sapien 3 ultra



Evolut Fx+

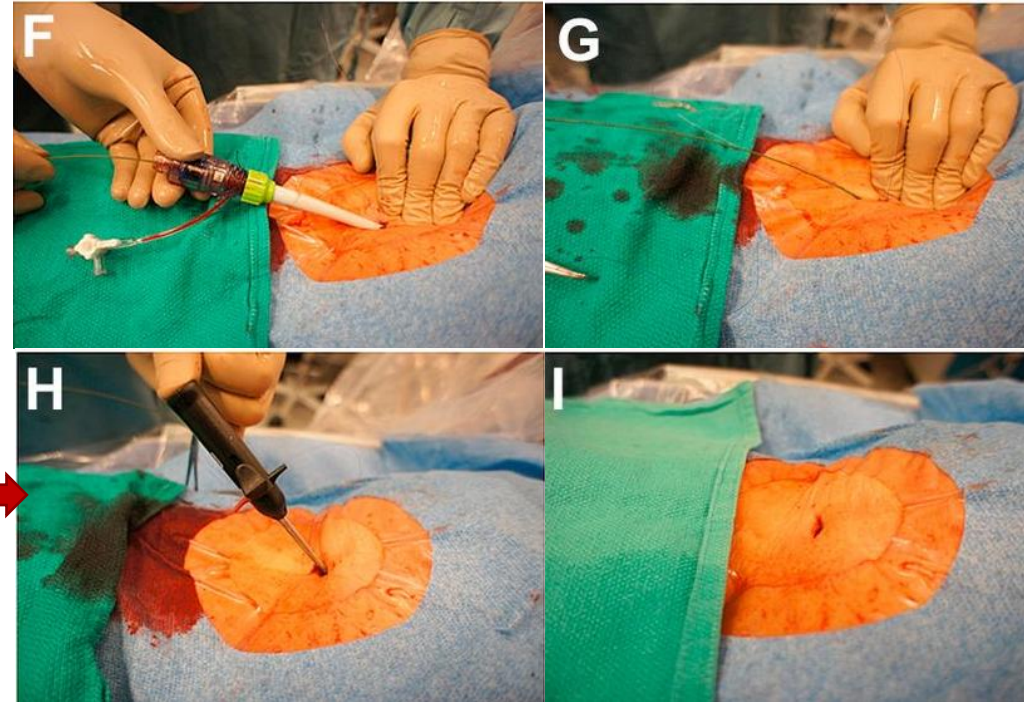
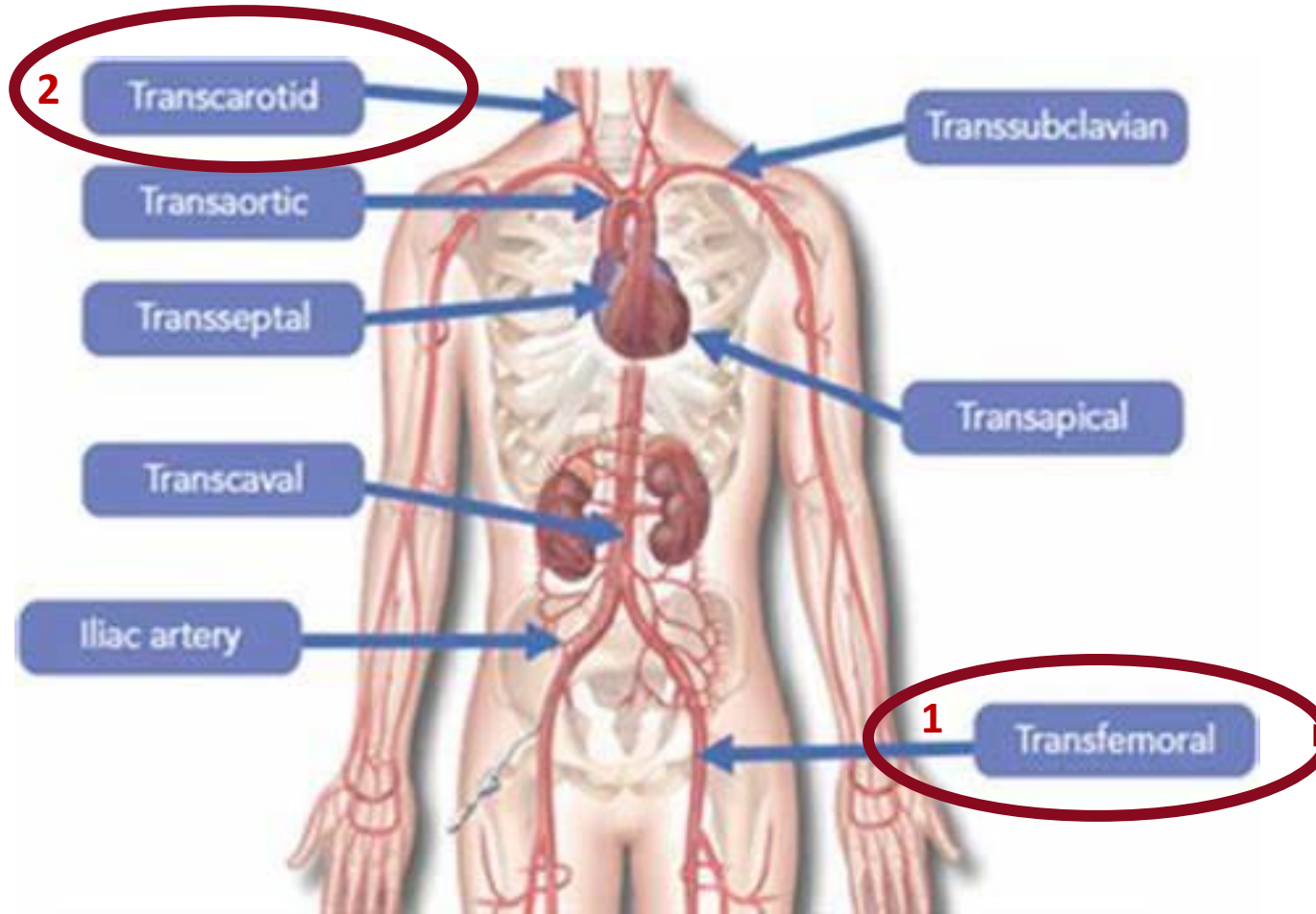


Navitor



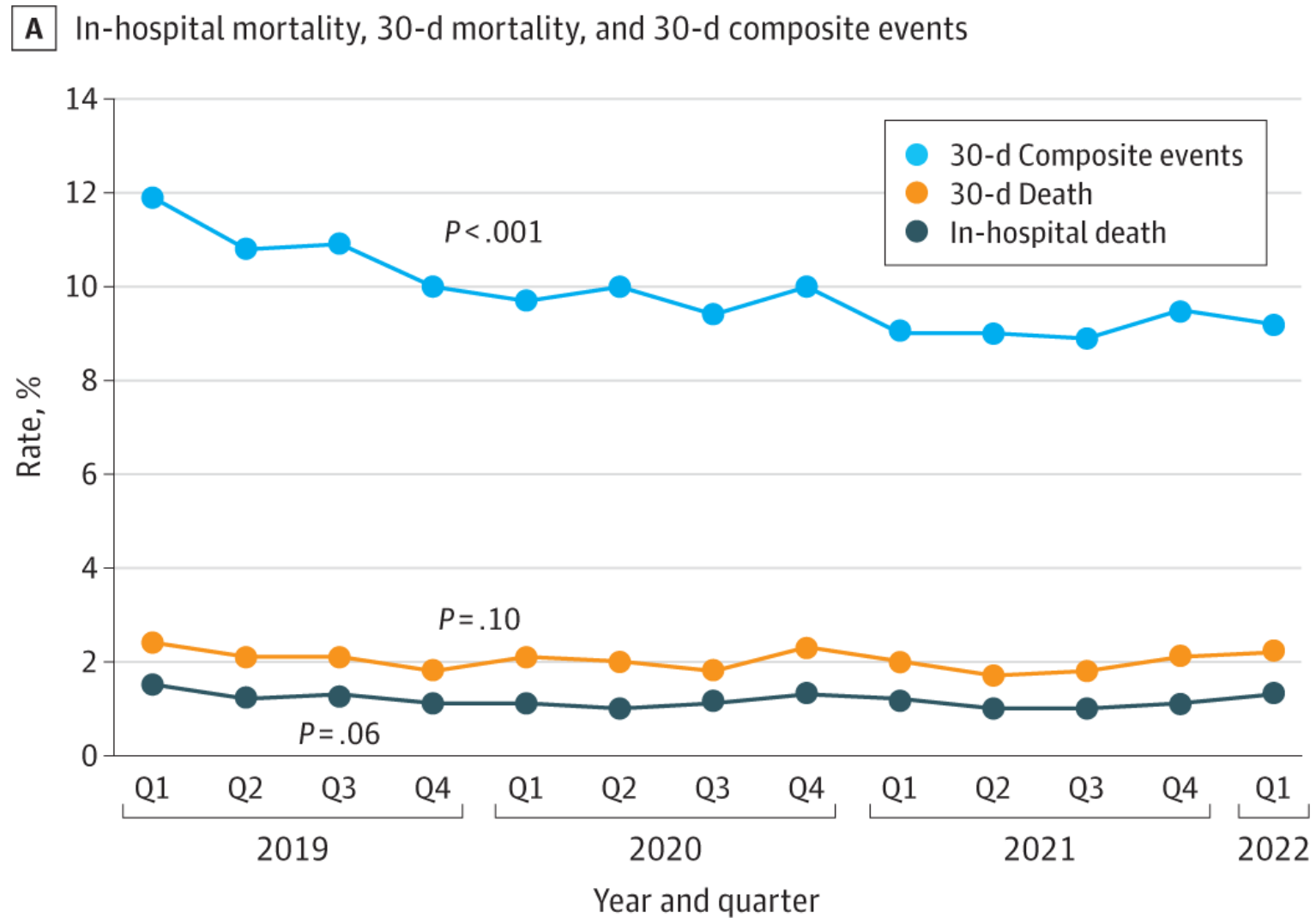
# Approach

- Local anesthesia (+/-sedation)



# TAVI Outcomes

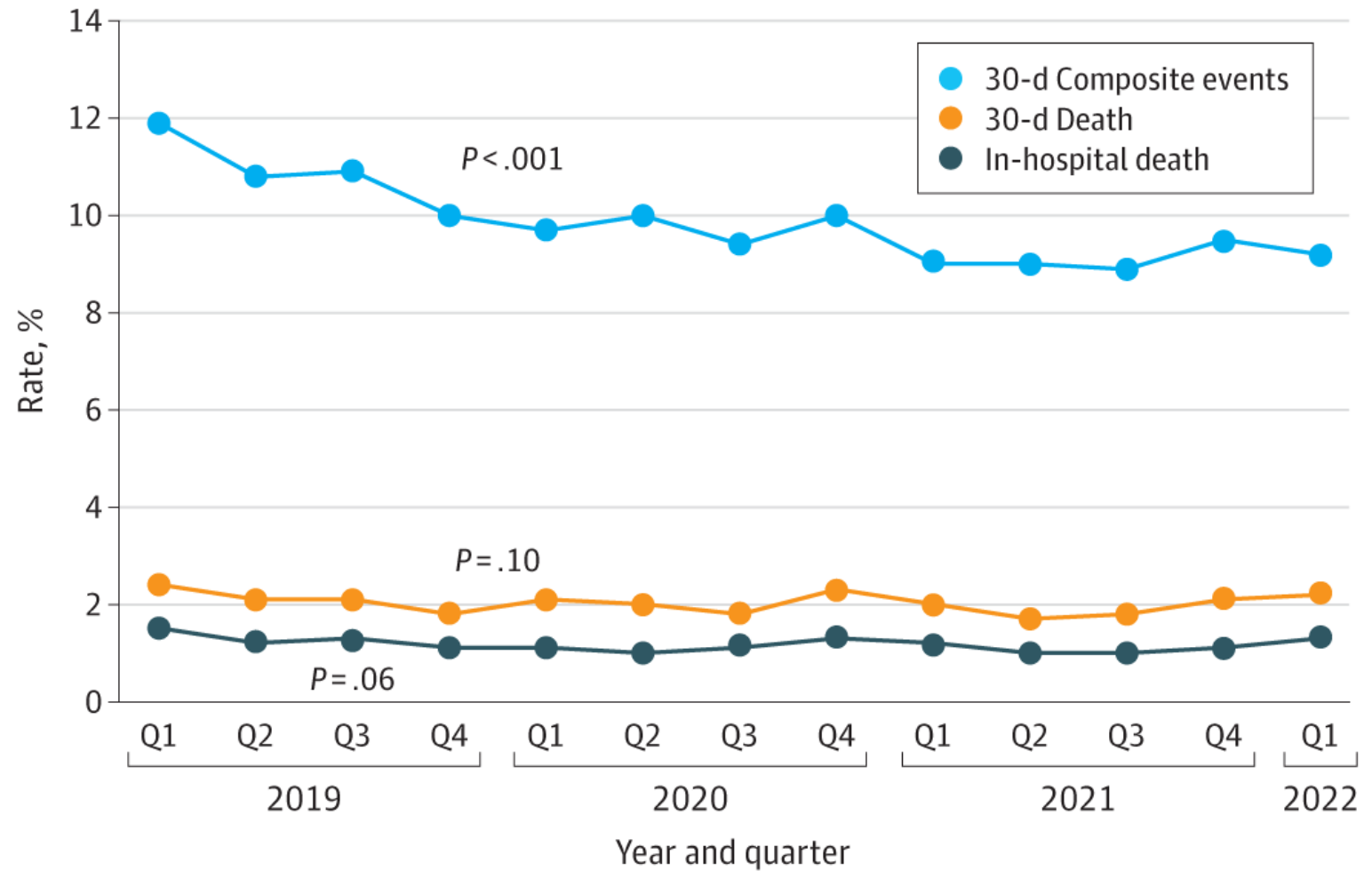
n=210 495 pts  
median age 79 (73-85) yrs,  
43% were female  
STS 3.3%



# TAVI Outcomes

n=210 495 pts  
median age 79 (73-85) yrs,  
43% were female  
STS 3.3%

**A** In-hospital mortality, 30-d mortality, and 30-d composite events



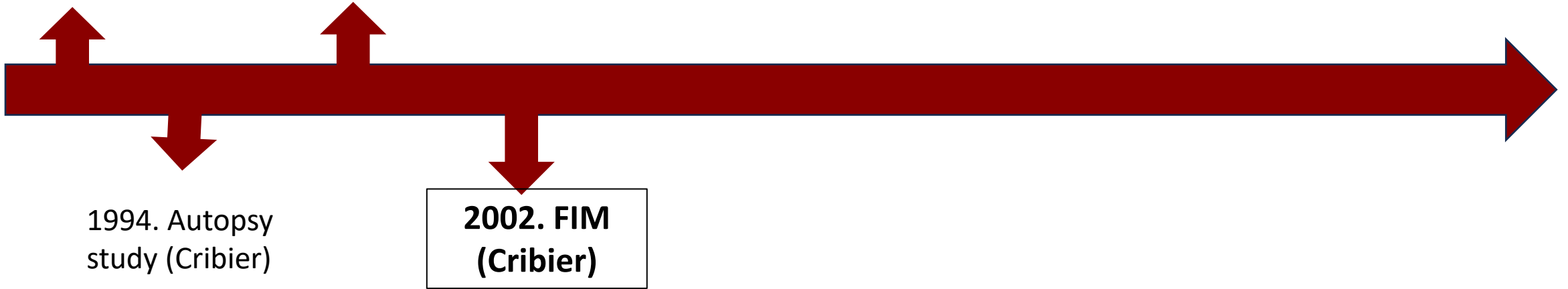
# A brief history..

1985. 1<sup>st</sup>  
implantation in a  
pig aorta  
(Andersen)

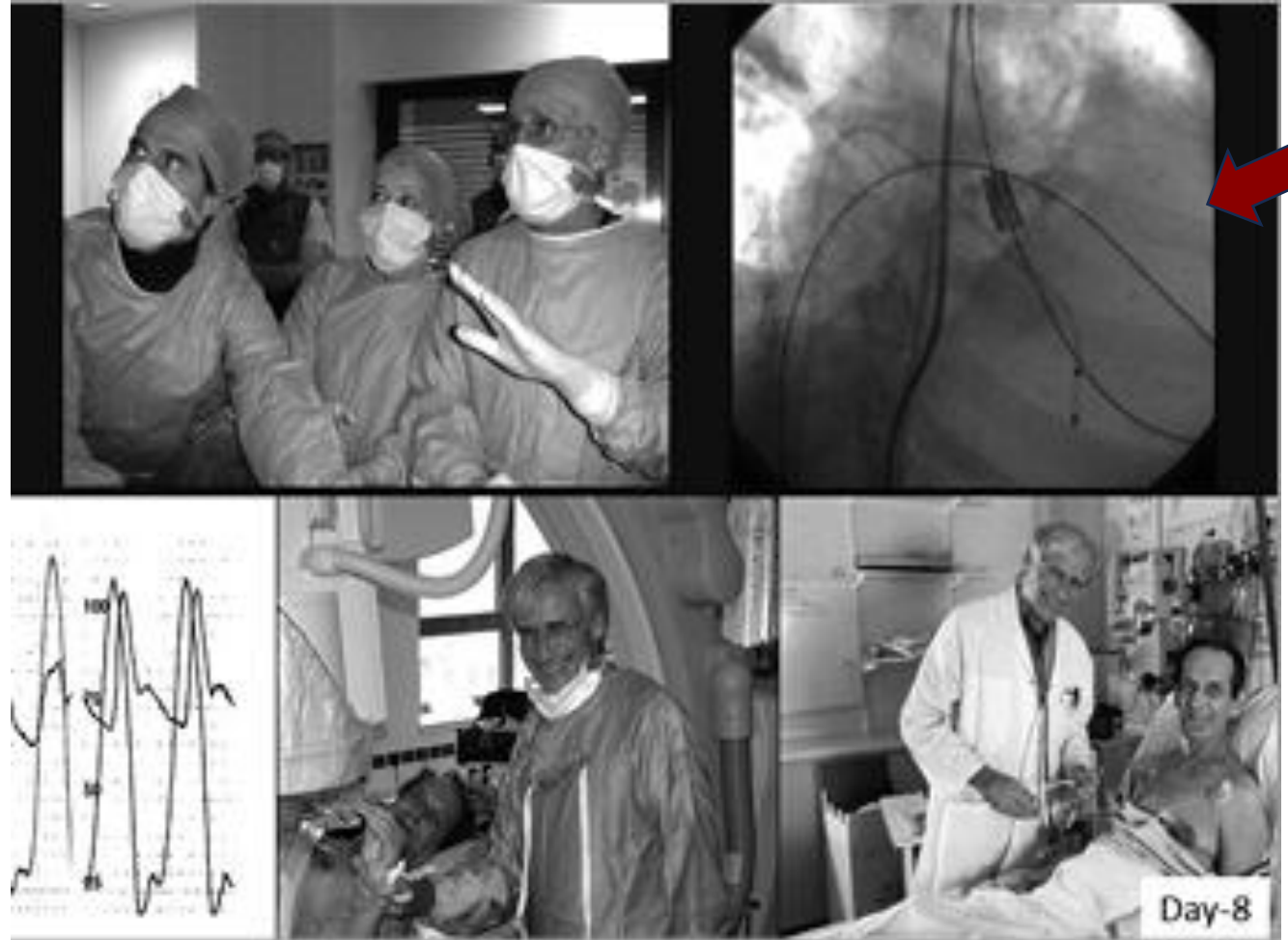
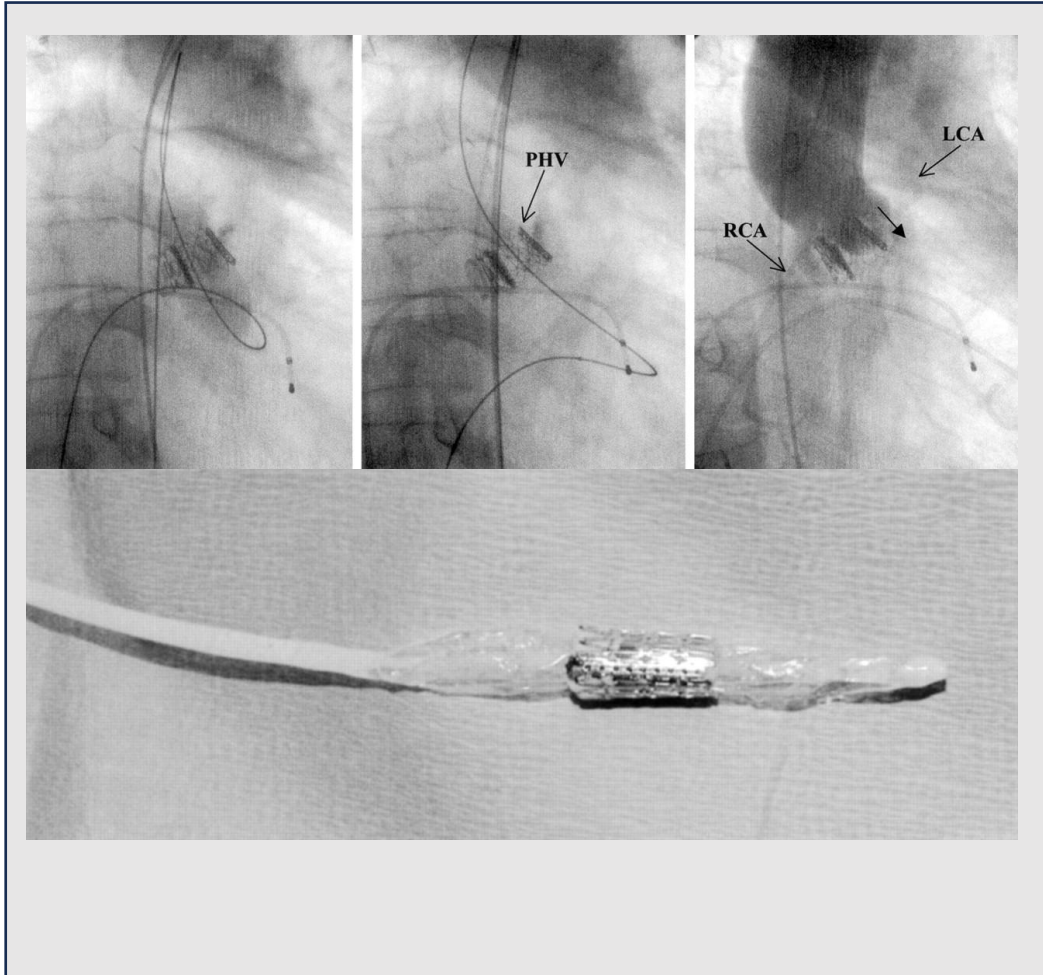
1999. 1erePVT  
2000. Animal  
study

1994. Autopsy  
study (Cribier)

**2002. FIM  
(Cribier)**



# TAVI, « proof of concept »



Bicuspid valve  
Transseptal approach  
Cardiogenic shock

Cribier et al. *Circulation*. 2002

# A brief history..

1985. 1<sup>st</sup>  
implantation in a  
pig aorta  
(Andersen)

1999. 1erePVT  
2000. Animal  
study

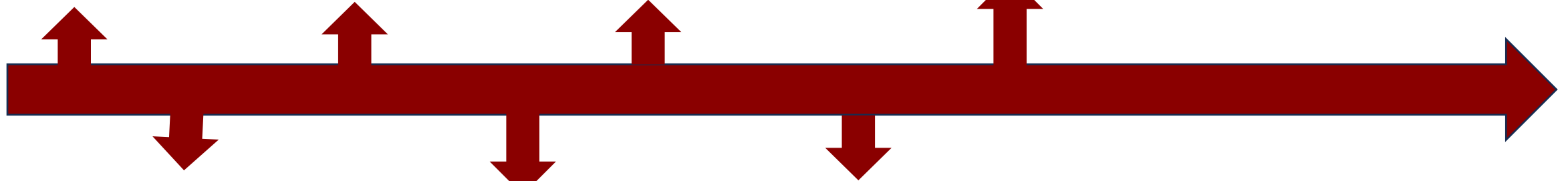
2004. 1<sup>st</sup> TF TAVI  
(Webb)  
2004. FIM Corevalve

**2010. Inoperable**  
**2011. High risk**

1994. Autopsy  
study (Cribier)

**2002. FIM**  
**(Cribier)**

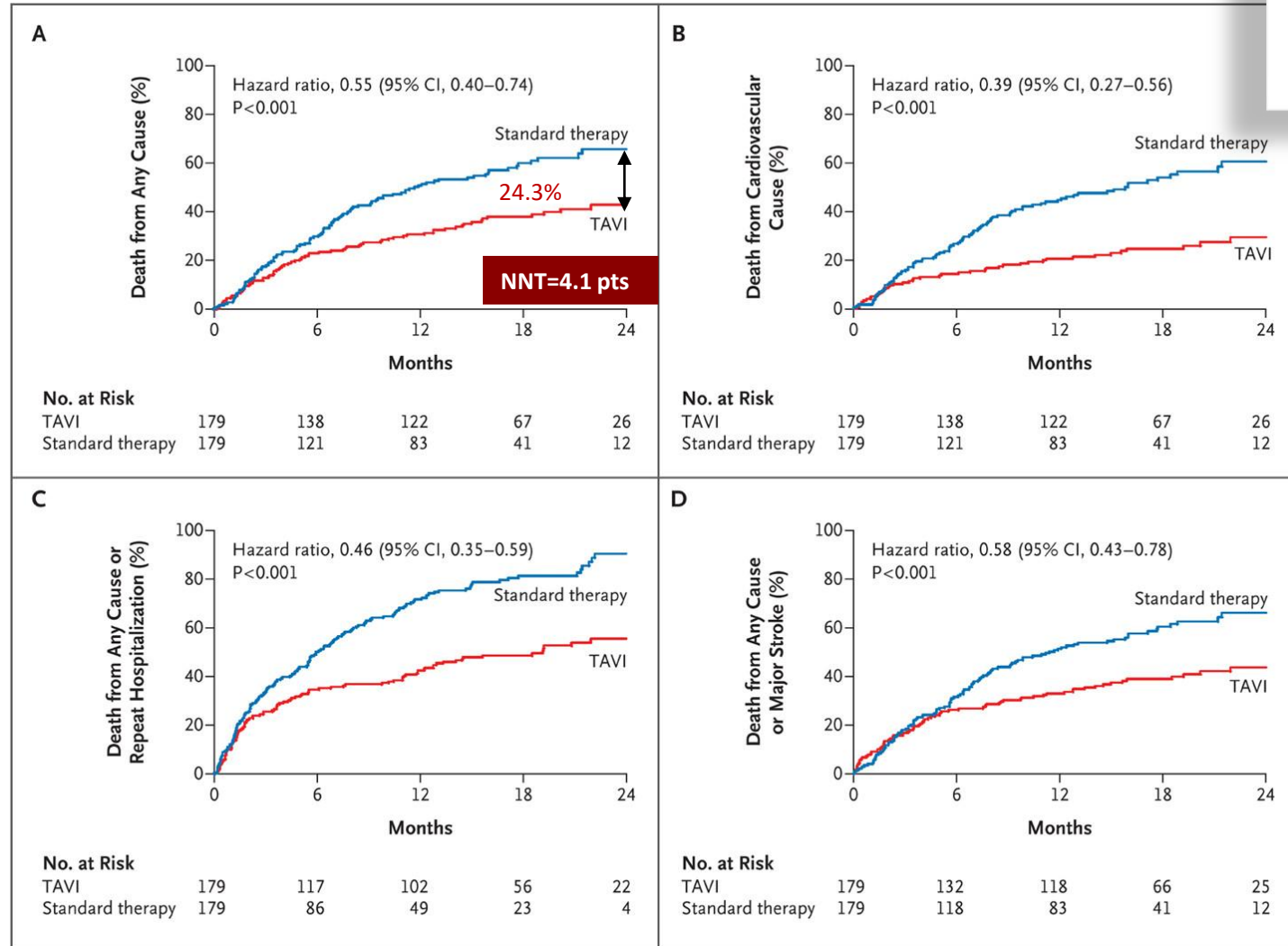
2007 CEE Mark



# TAVI in inoperable patients

## 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\*



*Standard therapy included balloon aortic valvuloplasty*

# TAVI in high risk patients

The NEW ENGLAND  
JOURNAL of MEDICINE

ESTABLISHED IN 1812

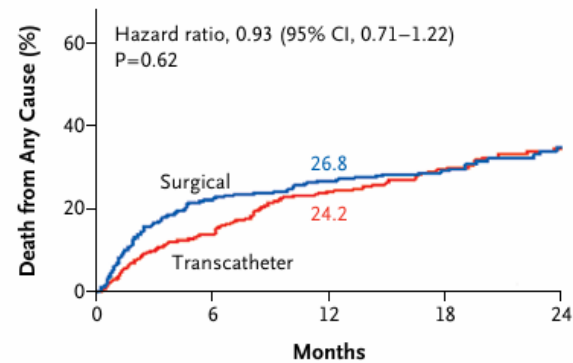
JUNE 9, 2011

VOL. 364 NO. 23

## Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. 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., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators\*

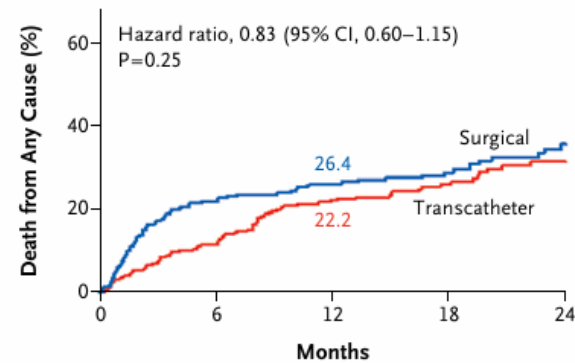
### A Death from Any Cause, All Patients



#### No. at Risk

Transcatheter	348	298	260	147	67
Surgical	351	252	236	139	65

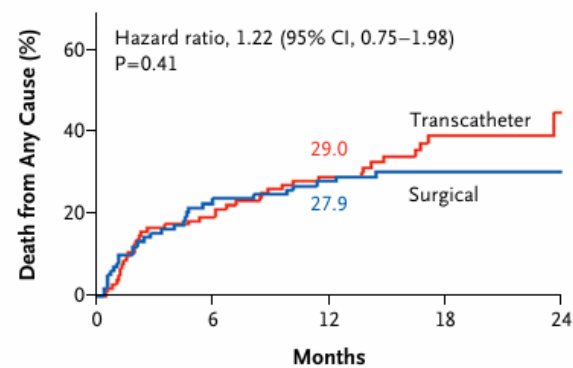
### B Death from Any Cause, Transfemoral-Placement Cohort



#### No. at Risk

Transcatheter	244	215	188	119	59
Surgical	248	180	168	109	56

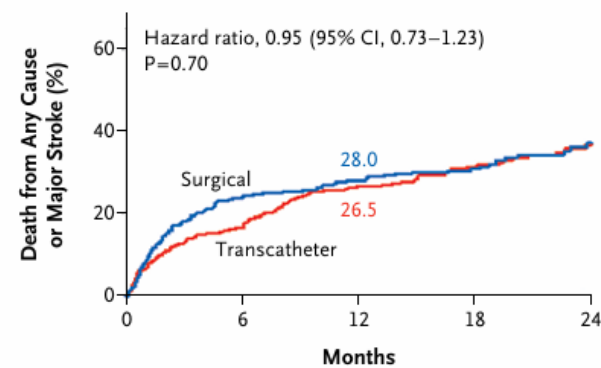
### C Death from Any Cause, Transapical-Placement Cohort



#### No. at Risk

Transcatheter	104	83	72	28	8
Surgical	103	72	68	30	9

### D Death from Any Cause or Major Stroke



#### No. at Risk

Transcatheter	348	289	252	143	65
Surgical	351	247	232	138	63

Smith et al. NEJM 2011

# A brief history..

1985. 1<sup>st</sup>  
implantation in a  
pig aorta  
(Andersen)

1999. 1erePVT  
2000. Animal  
study

2004. 1<sup>st</sup> TF TAVI  
(Webb)  
2004. FIM Corevalve

**2010. Inoperable**  
**2011. High risk**

2016.  
Intermediate  
risk patients

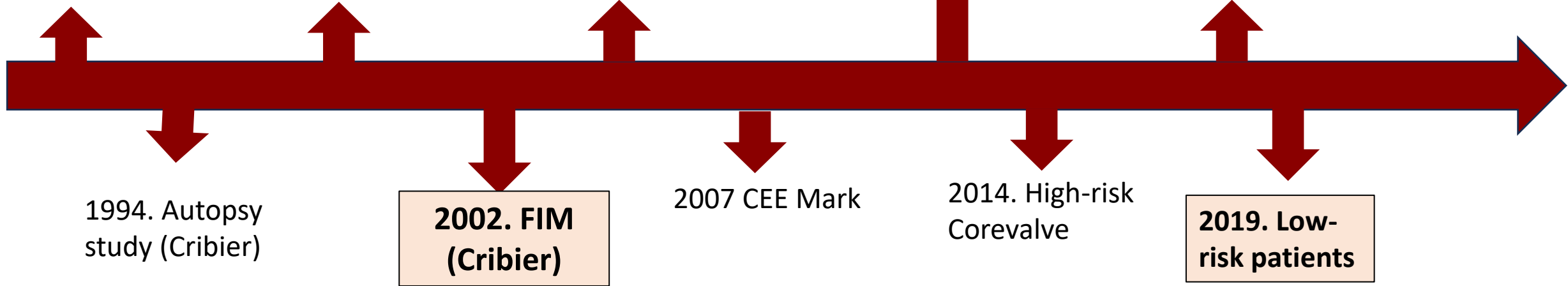
1994. Autopsy  
study (Cribier)

**2002. FIM**  
**(Cribier)**

2007 CEE Mark

2014. High-risk  
Corevalve

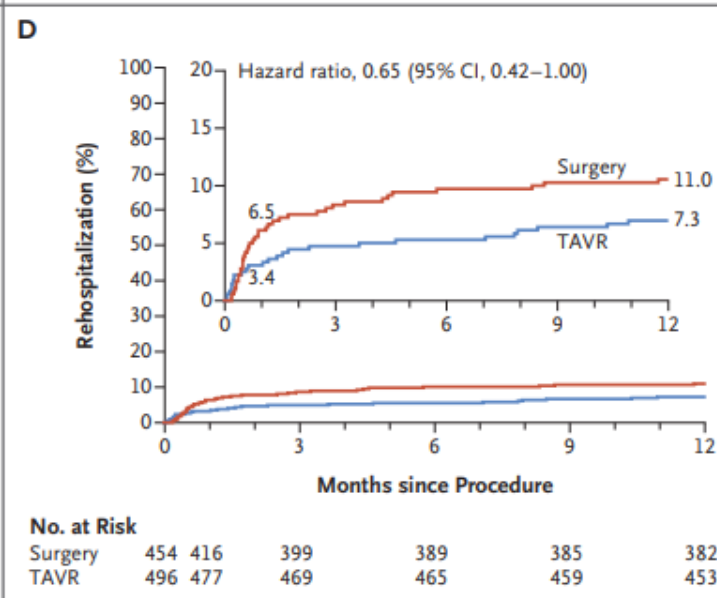
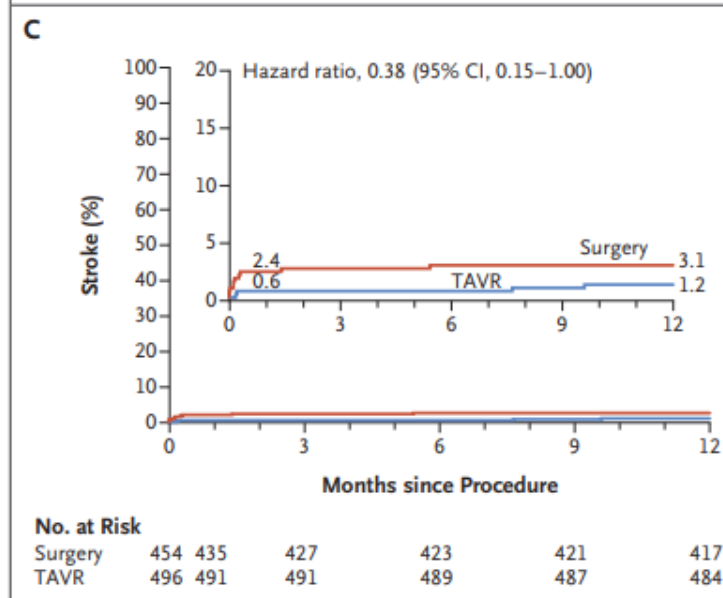
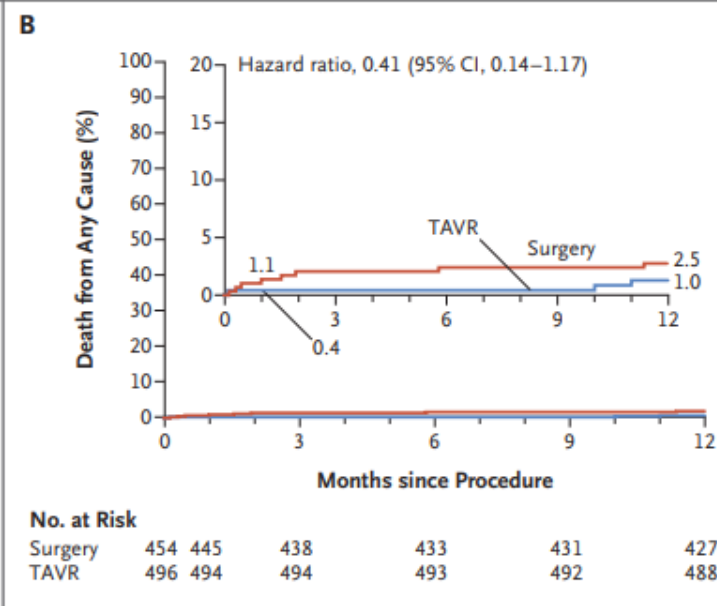
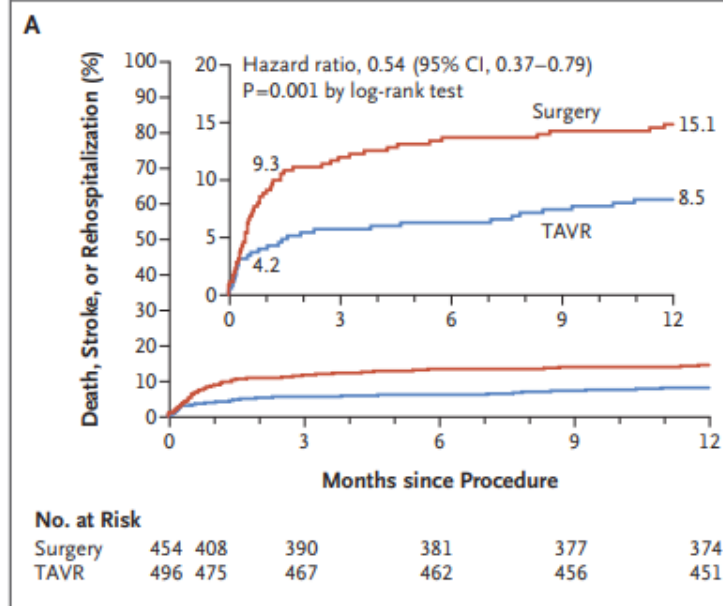
**2019. Low-**  
**risk patients**



# Low-risk patients-*BEV*

## 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\*



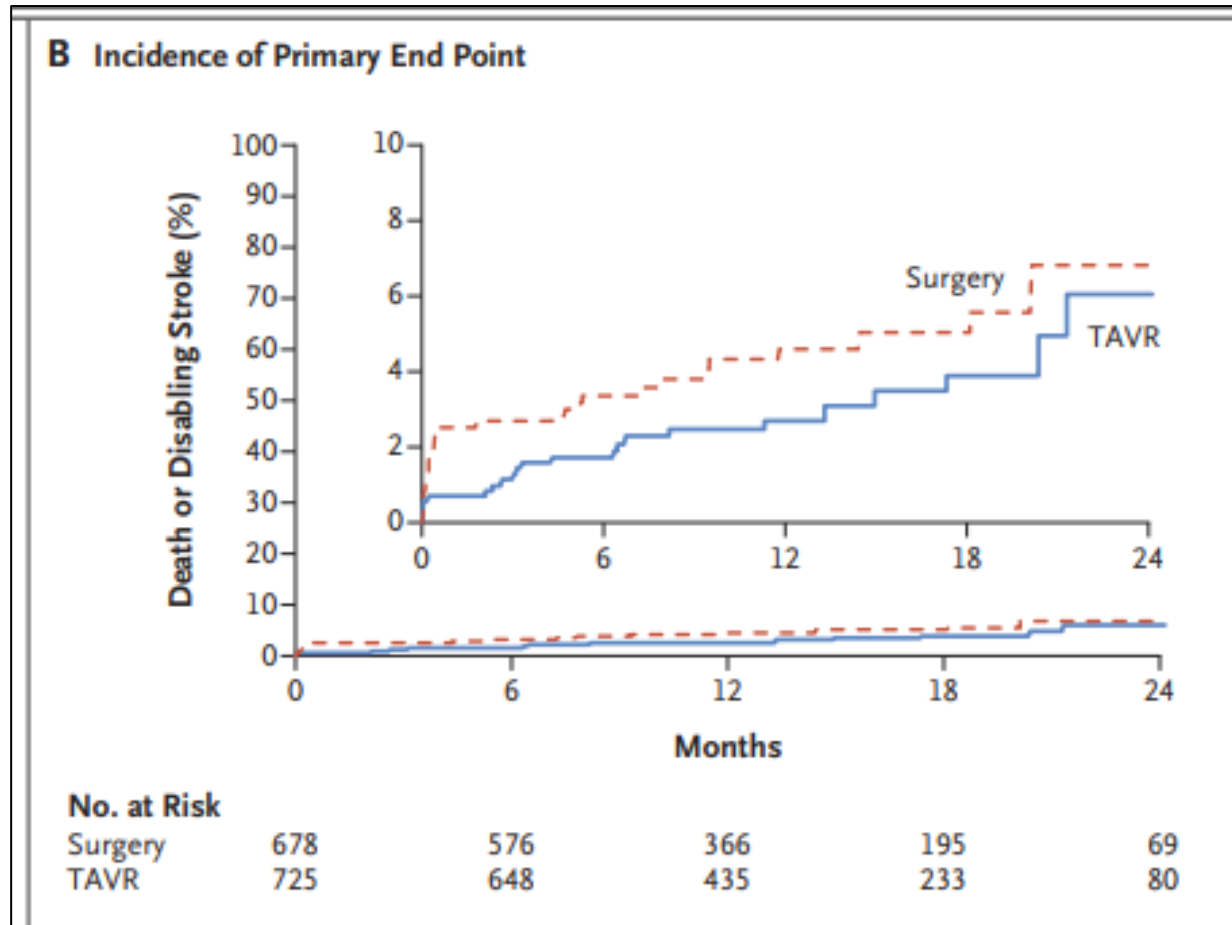


# Low-risk patients-SEV

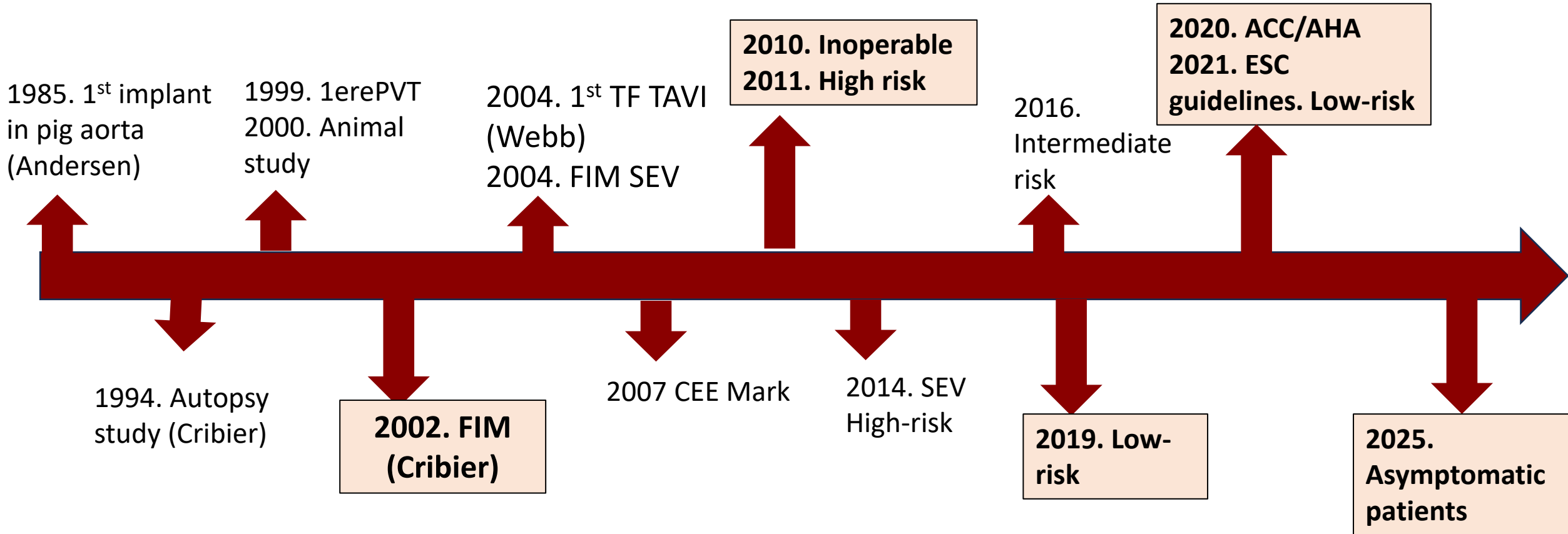
ORIGINAL ARTICLE

## 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.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn III, M.D., John K. Forrest, M.D., Didier Tchétché, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators\*




# A brief history..



# TAVI: randomized trials

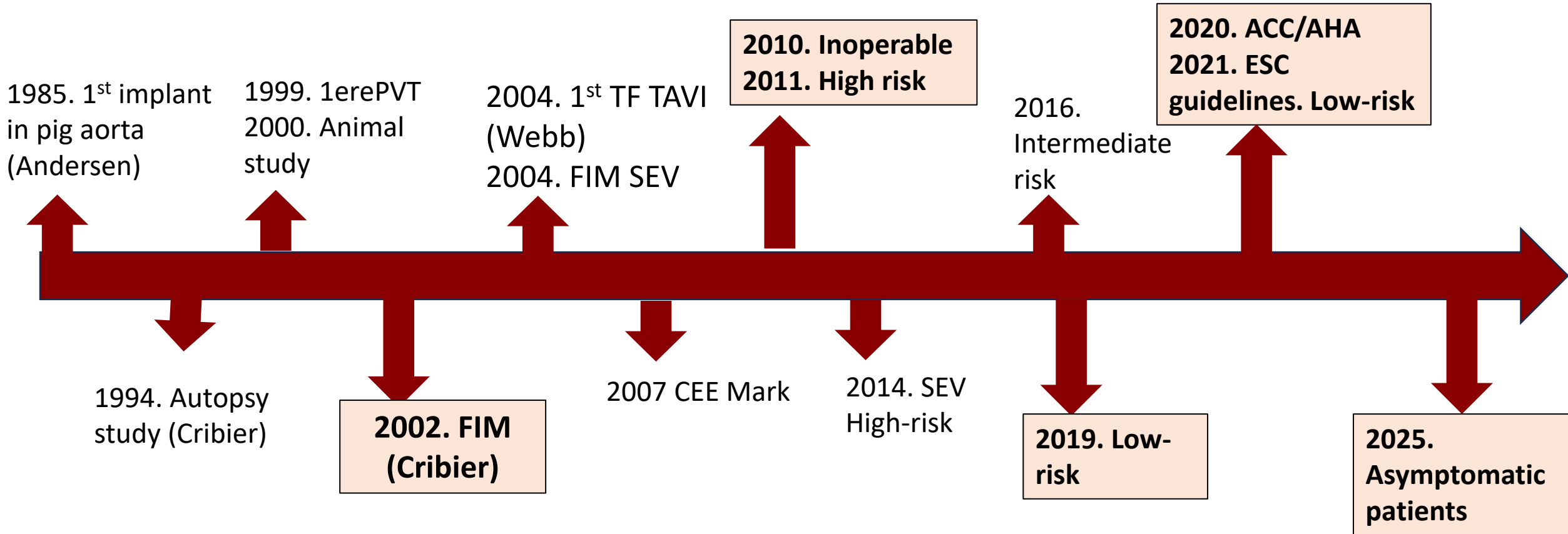
	STS score	Age
<b>Inoperable</b>		
PARTNER IB (2010)	11.6	83
<b>High risk</b>		
PARTNER IA (2011)	11.8	84
CoreValve US Pivotal Trial (2014)	7.4	83
<b>Intermediate risk</b>		
PARTNER II (2016)	5.8	82
SURTAVI (2017)	4.5	80
<b>Low risk</b>		
NOTION (2015)	3.0	79
PARTNER III (2019)	1.9	73
Evolut Low Risk (2019)	1.8	74



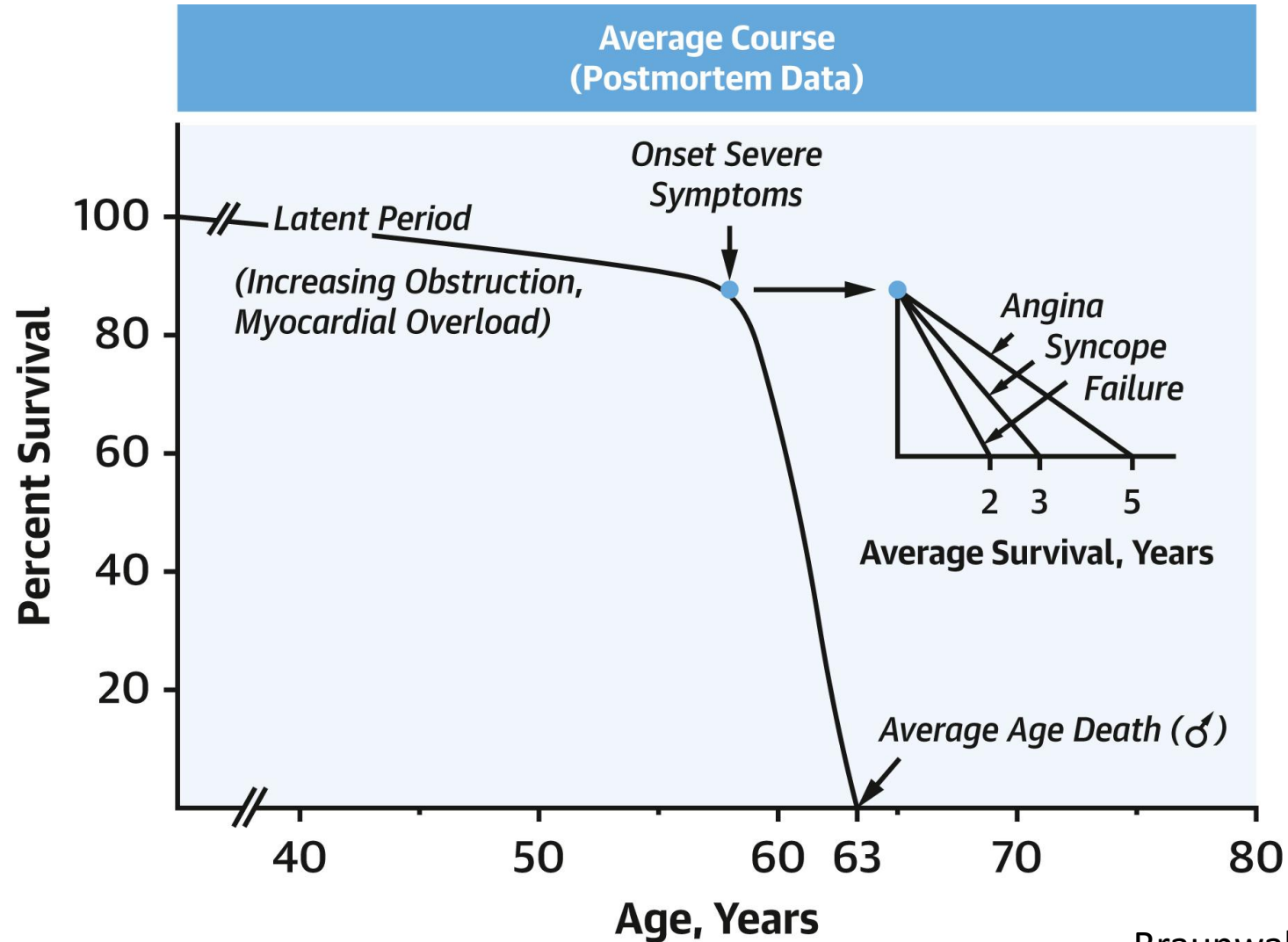
# Recommandations 2021

Choix RVA chirurgical vs TAVI		
Classe	ACC/AHA	ESC/EACTS
I	La chirurgie est recommandée chez les patients symptomatiques ou asymptomatiques ayant un RA sévère et une indication de RVA < 65 ans ou qui ont une espérance de vie > 20 ans	La chirurgie est recommandée chez les patients jeunes et à faible risque chirurgical (<75 ans et STS-PROM/EuroSCORE II <4%) ou opérables et non éligibles au TAVI transfémoral
I	Chez les patients symptomatiques ayant un RA sévère et âgés entre 65 et 80 ans, sans contre-indication anatomique à un TAVI transfémoral, un RVA chirurgical ou un TAVI transfémoral peuvent être recommandés après discussion commune de la balance entre la longévité attendue du patient et la durabilité de la valve	Le TAVI est recommandé chez les patients âgés (≥75 ans) ou à haut risque (STS-PROM /EuroSCORE II >8%) ou inopérables
I	Le TAVI est recommandé de préférence à la chirurgie pour les patients symptomatiques ayant un RA sévère, > 80 ans ou plus jeunes mais avec une espérance de vie < 10 ans et sans contre-indication à un TAVI transfémoral	La chirurgie ou le TAVI sont recommandés chez les autres patients en fonction des caractéristiques individuelles cliniques, anatomiques et procédurales

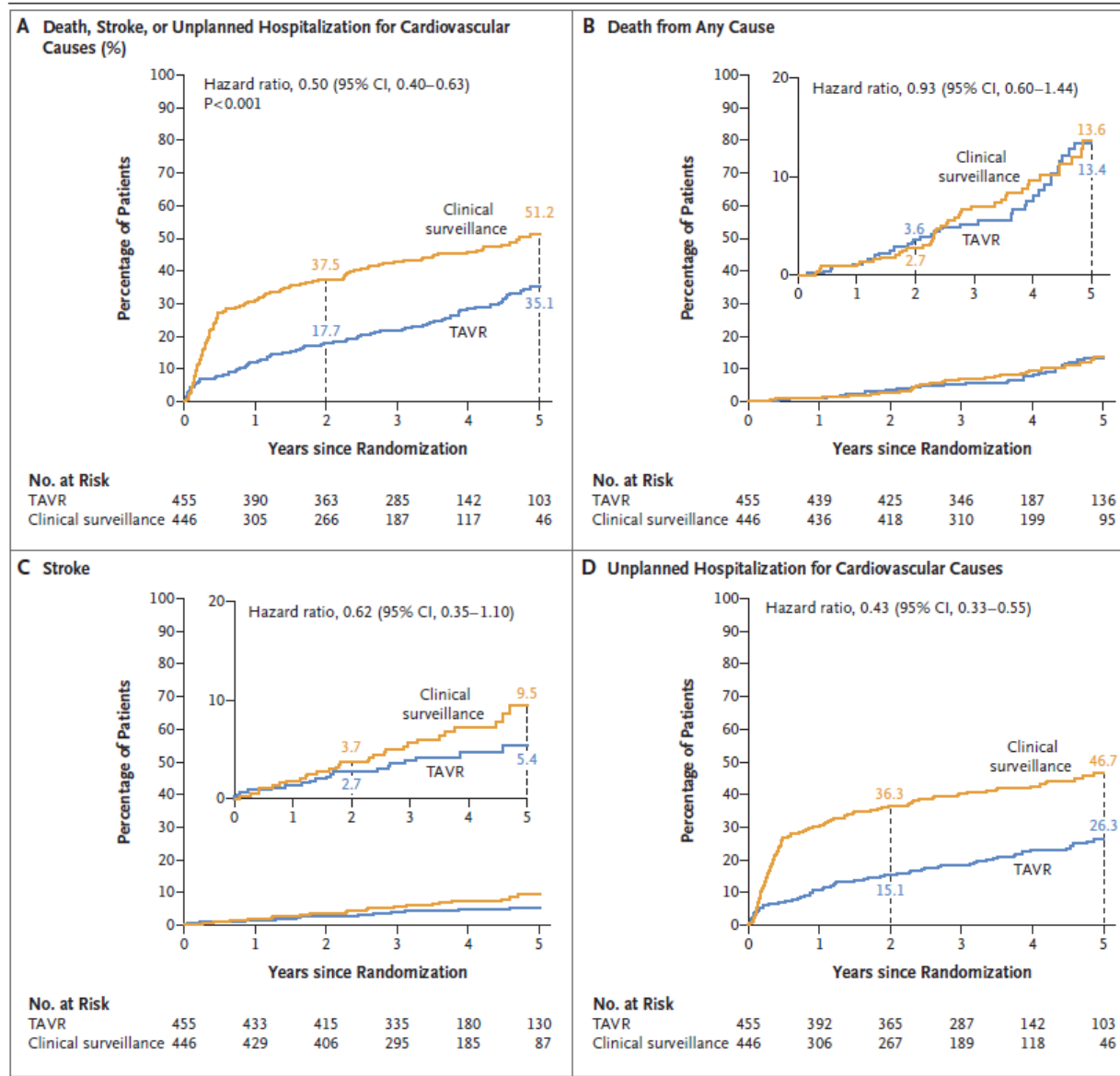
# A brief history..



# Natural evolution of AS



# Asymptomatic patients



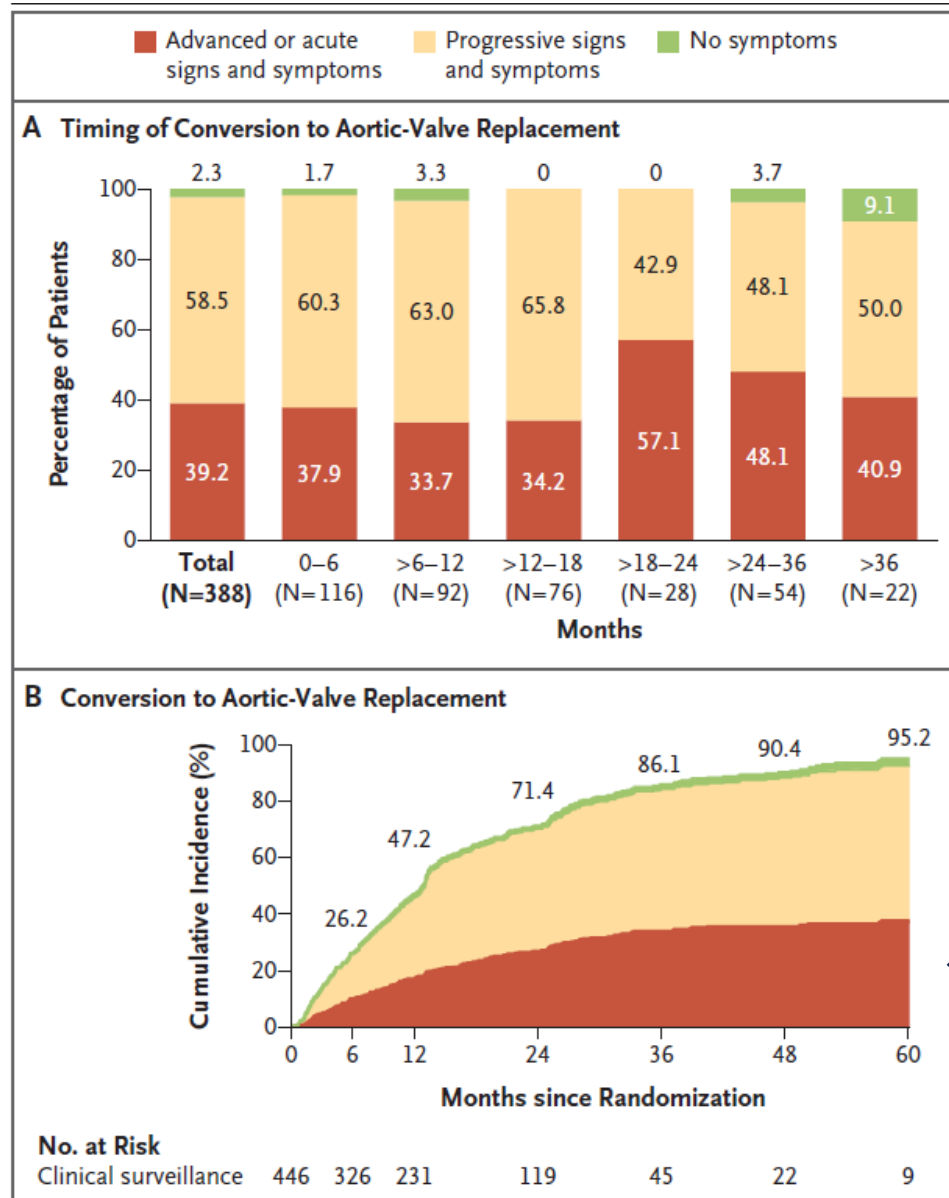
ORIGINAL ARTICLE

## Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis

P. Généreux, A. Schwartz, J.B. Oldemeyer, P. Pibarot, D.J. Cohen, P. Blanke, B.R. Lindman, V. Babaliaros, W.F. Fearon, D.V. Daniels, A.K. Chhatriwalla, C. Kavinsky, H. Gada, P. Shah, M. Szerlip, T. Dahle, K. Goel, W. O'Neill, T. Sheth, C.J. Davidson, R.R. Makkar, H. Prince, Y. Zhao, R.T. Hahn, J. Leipsic, B. Redfors, S.J. Pocock, M. Mack, and M.B. Leon, for the EARLY TAVR Trial Investigators\*

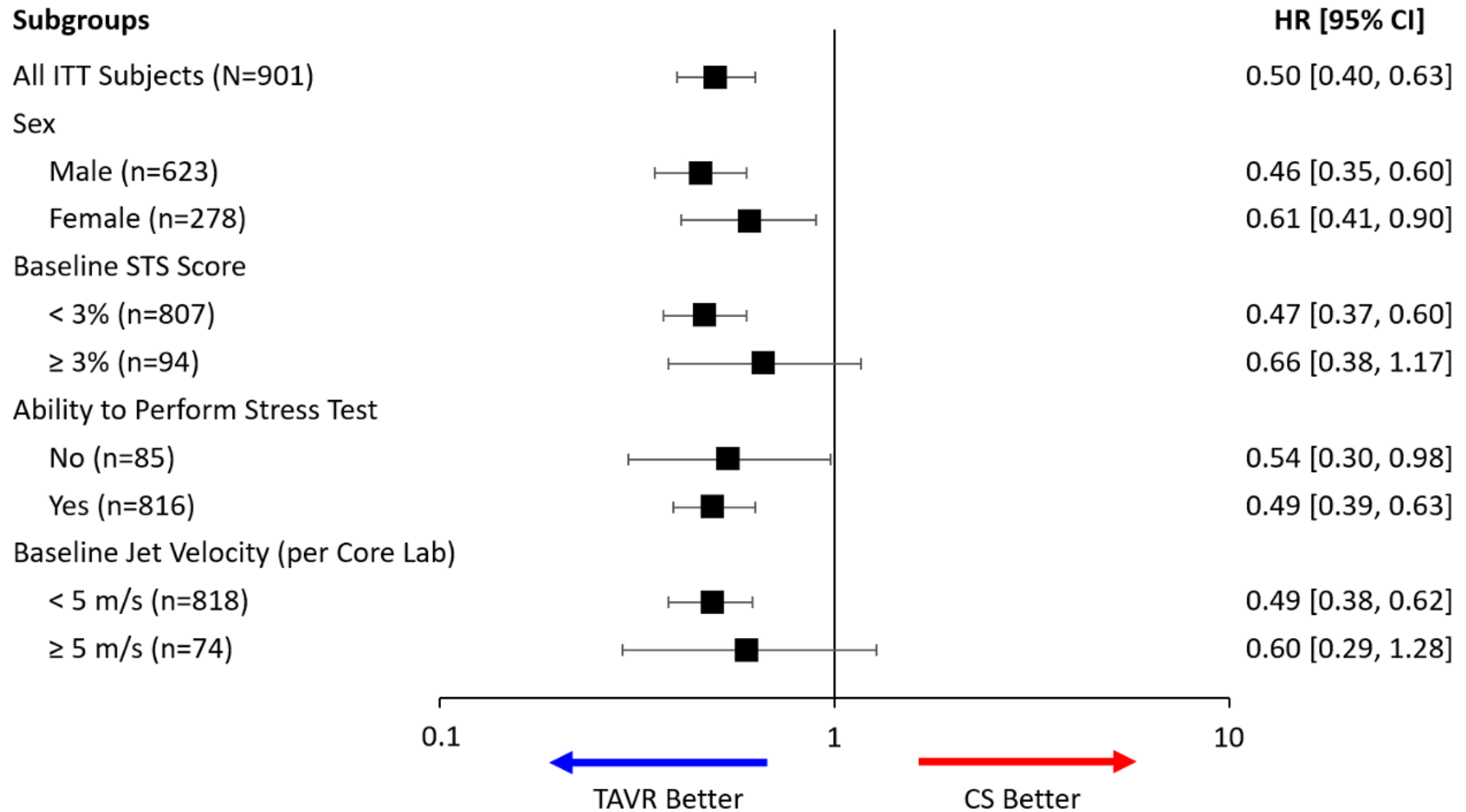
Généreux et al. NEJM 2025

# Asymptomatic patients



Acute valve syndrome

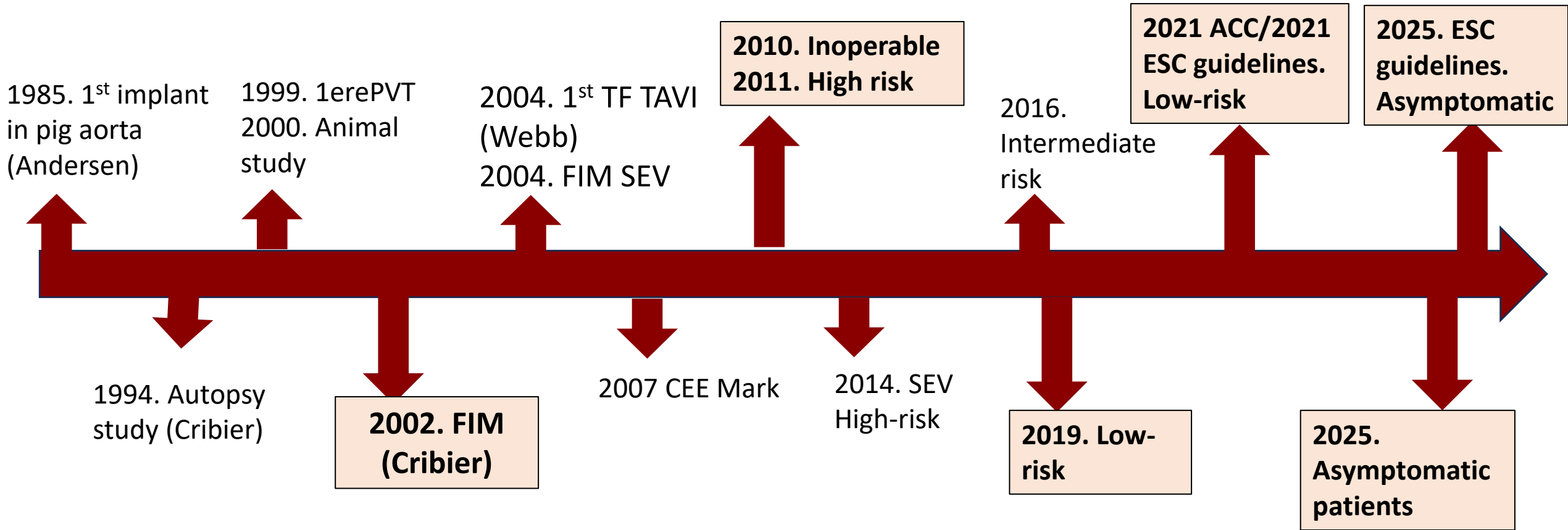
# Asymptomatic patients



CS denotes clinical surveillance, ITT intent-to-treat population, STS Society of Thoracic Surgeons, TAVR transcatheter aortic valve replacement. There was a median follow-up of 3.8 years; patients had a minimum follow-up of 2 years.

The widths of the confidence intervals have not been adjusted for multiple comparisons and should not be used in place of a hypothesis test.

# A brief history..



# 2025 ESC/EACTS Guidelines for the management of HVD

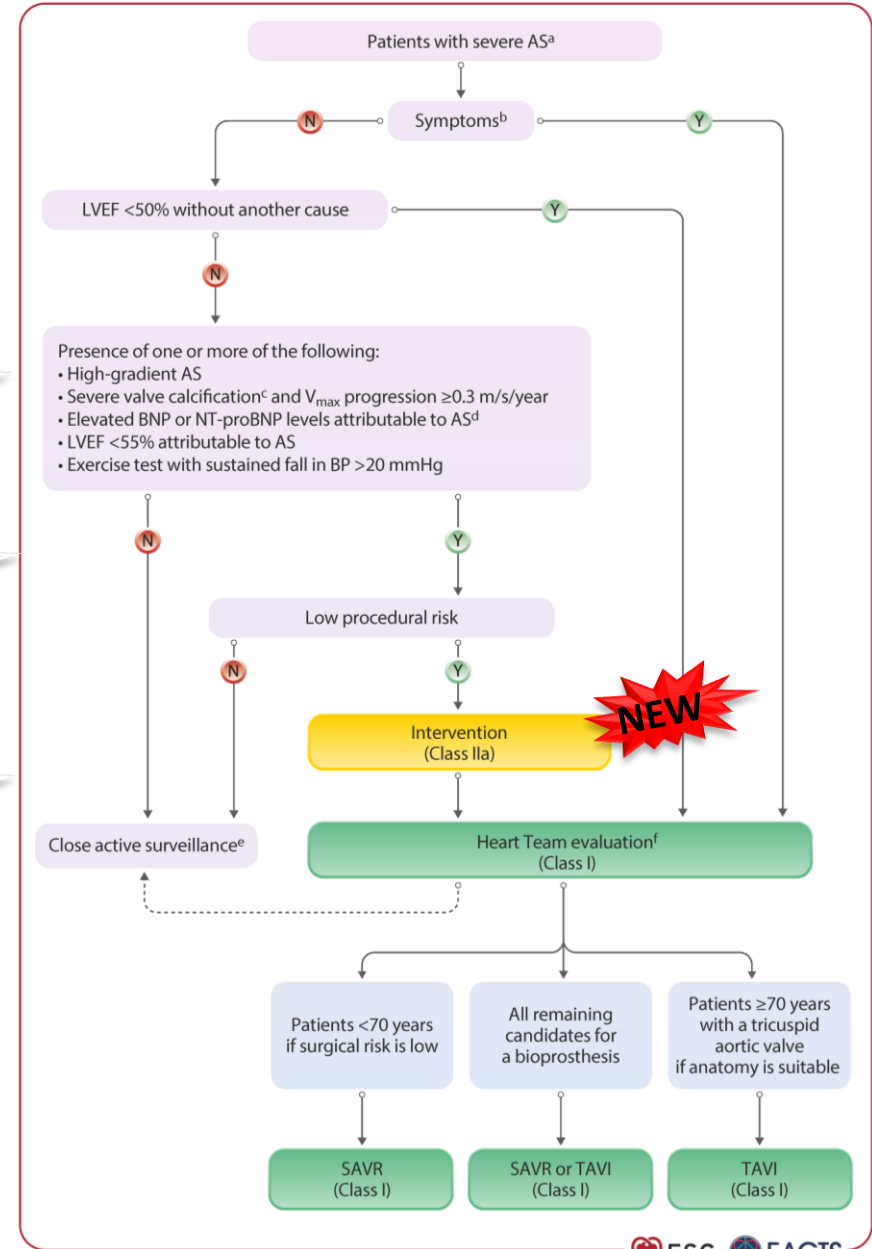
irrespective of the surgical risk score

Recommendations	Class	Level
TAVI is recommended in patients $\geq 70$ years of age with tricuspid AV stenosis, if the anatomy is suitable.	I	A
SAVR is recommended in patients $< 70$ years of age, if the surgical risk is low.	I	B
SAVR or TAVI are recommended for all remaining candidates for an aortic BHV according to Heart Team assessment.	I	B

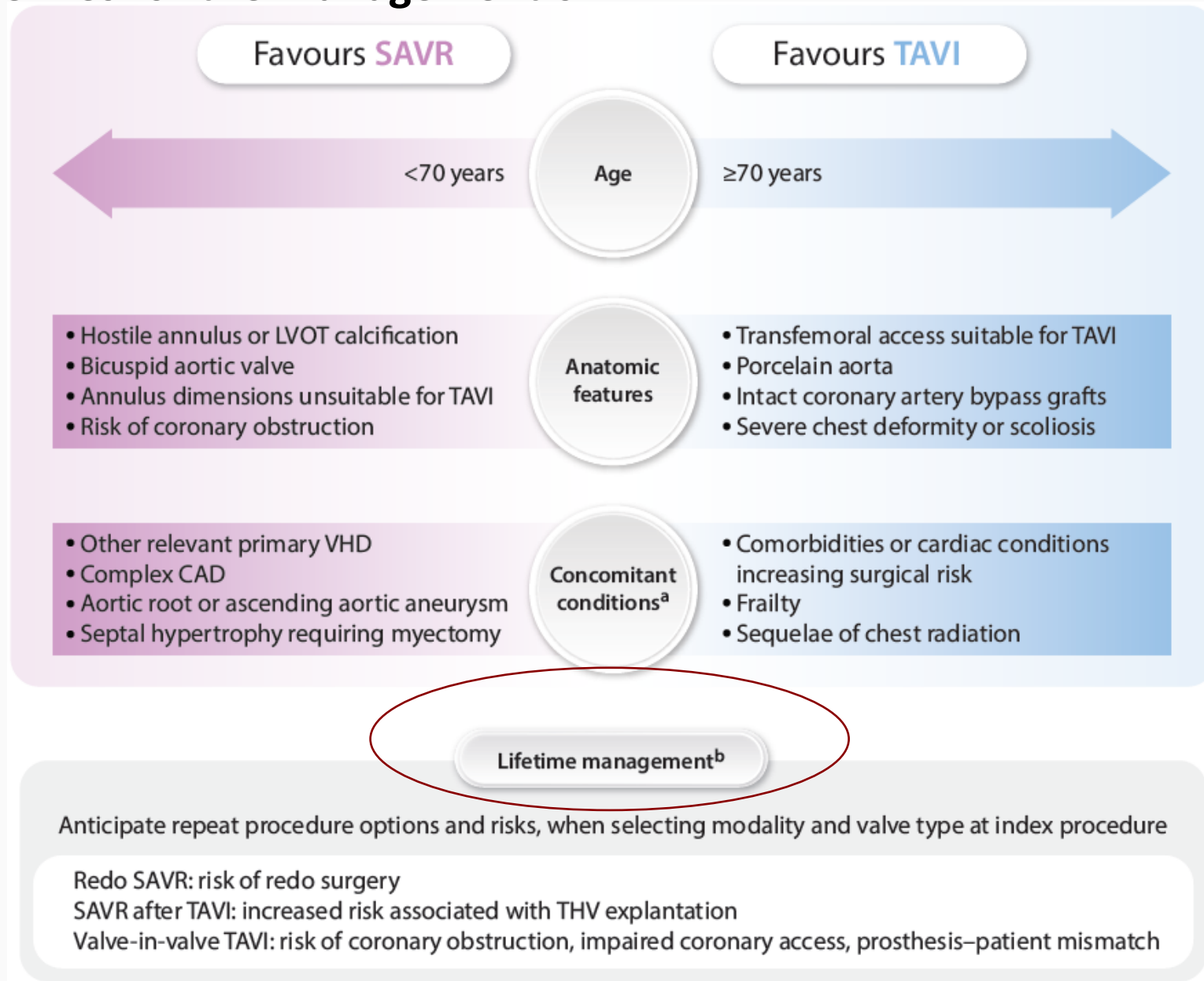
REV.

REV.

REV.



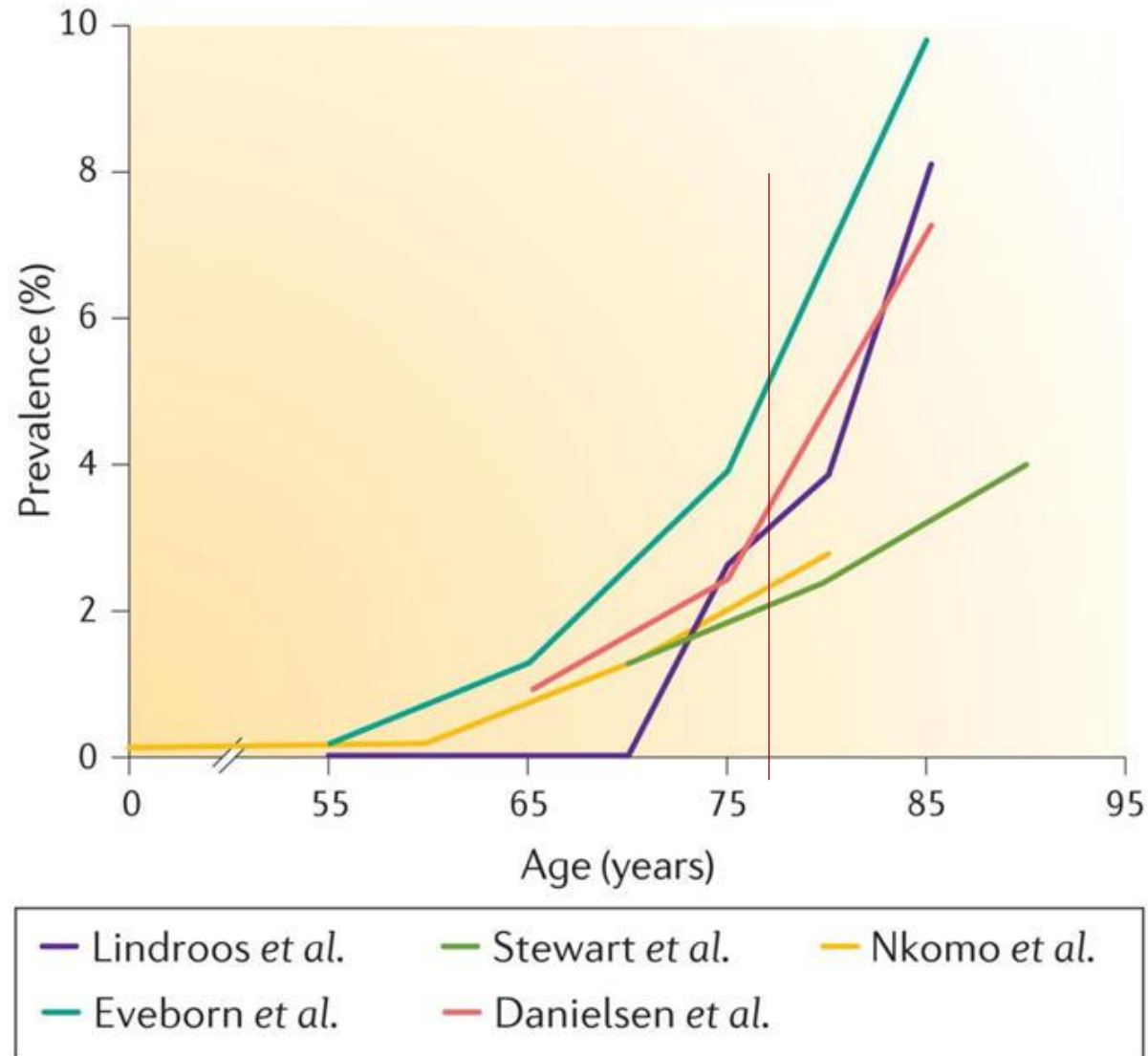
# 2025 ESC/EACTS Guidelines for the management of HVD



# 2025 ESC/EACTS Guidelines for the management of HVD

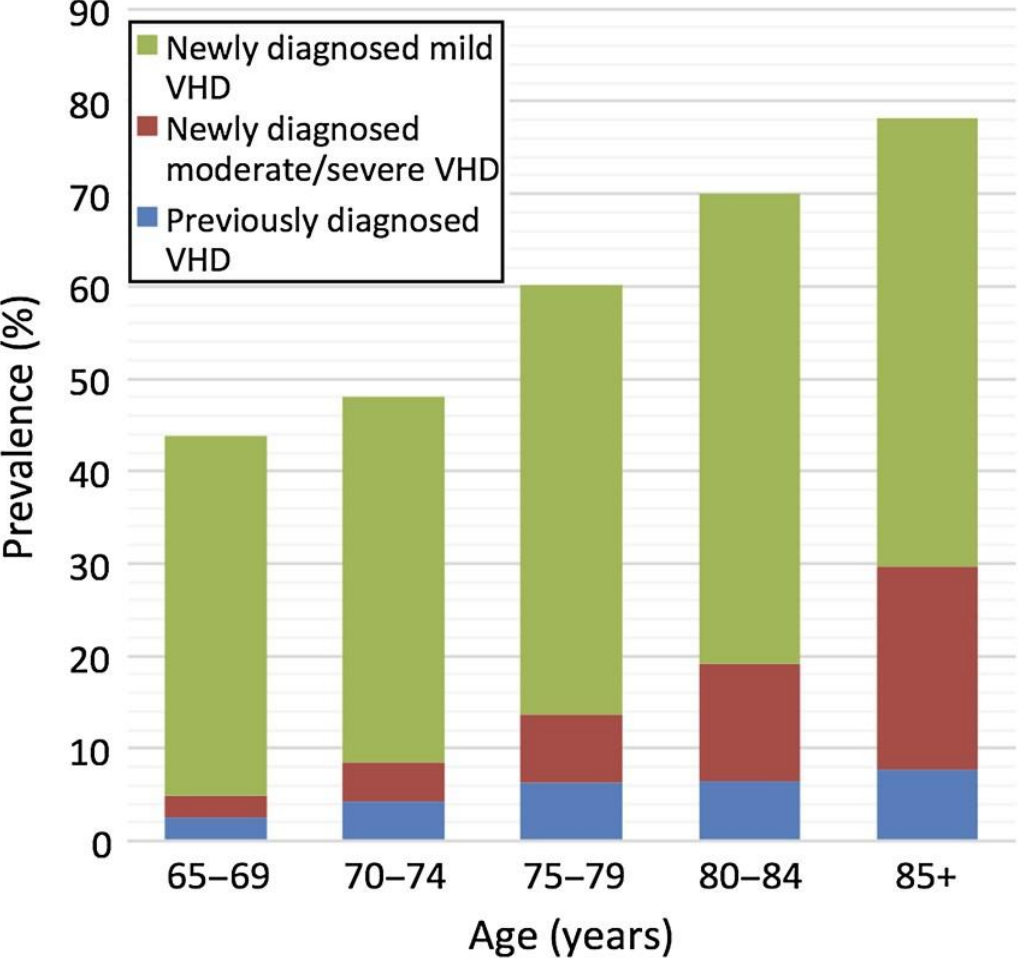
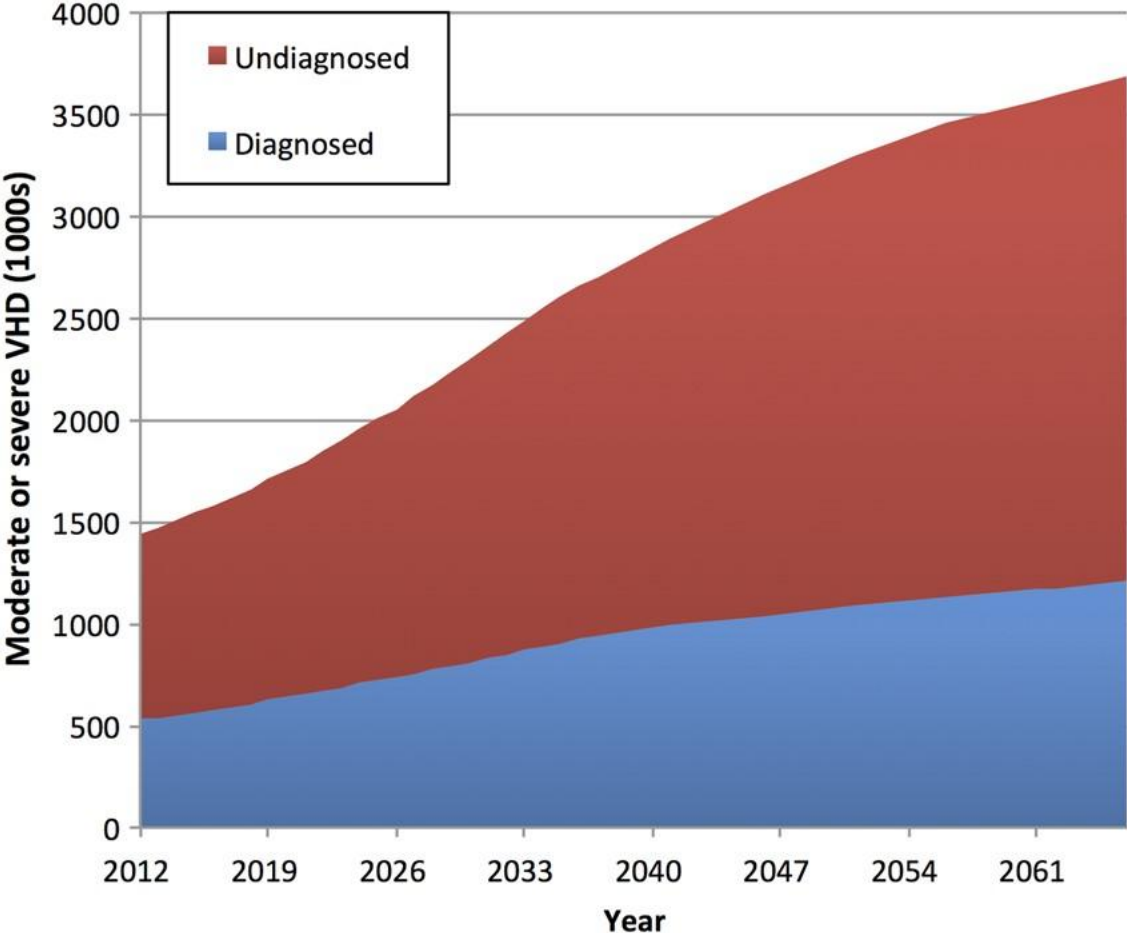
Recommendations	Class	Level
It is recommended that the mode of intervention is based on Heart Team assessment of individual clinical, anatomical, and procedural characteristics, <b>incorporating lifetime management considerations and estimated life expectancy.</b>	I	C

# Epidemiology of calcific AS



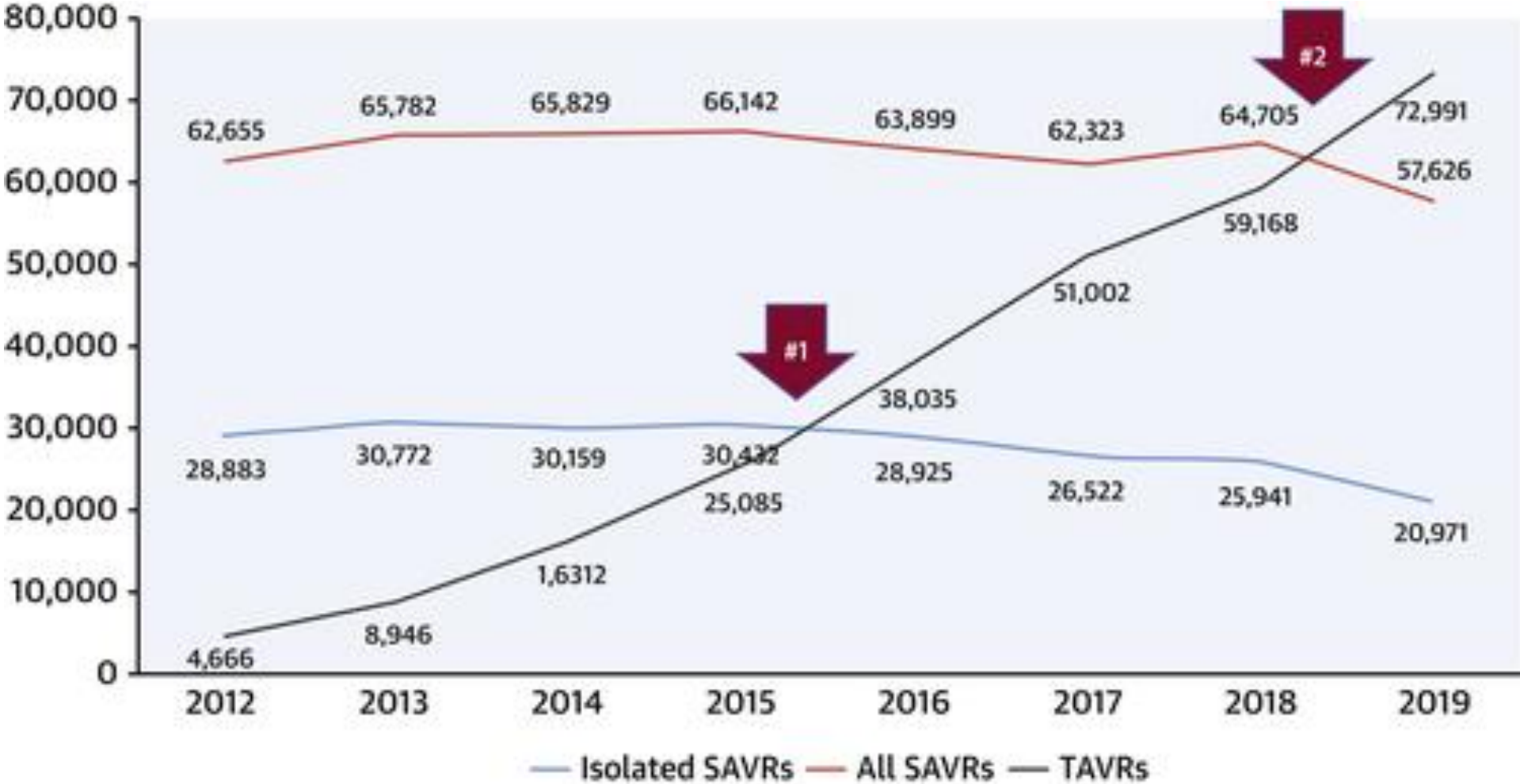
# Epidemiology of calcific AS

## OxVALVE Population Cohort Study

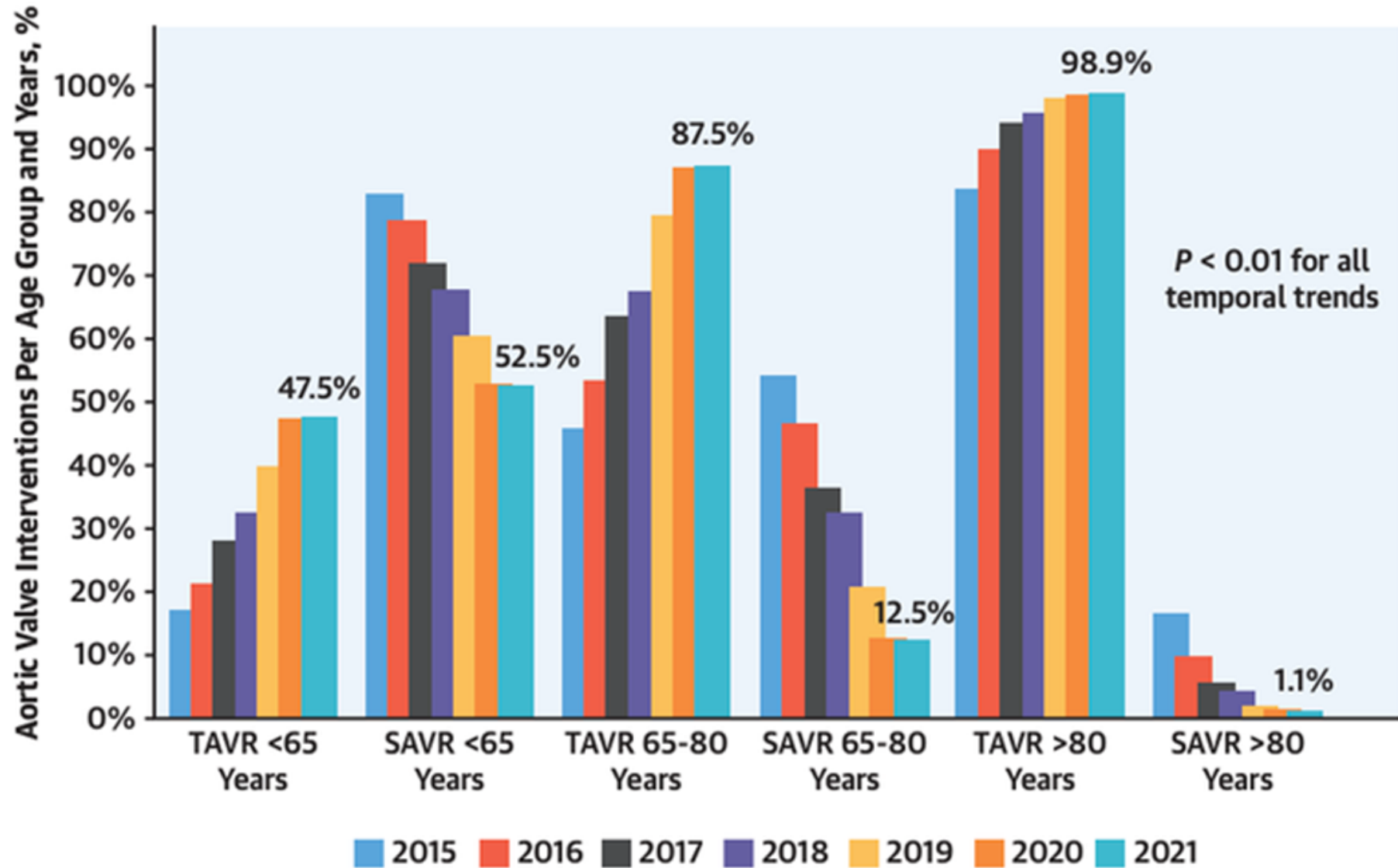


# TAVI vs SAVR

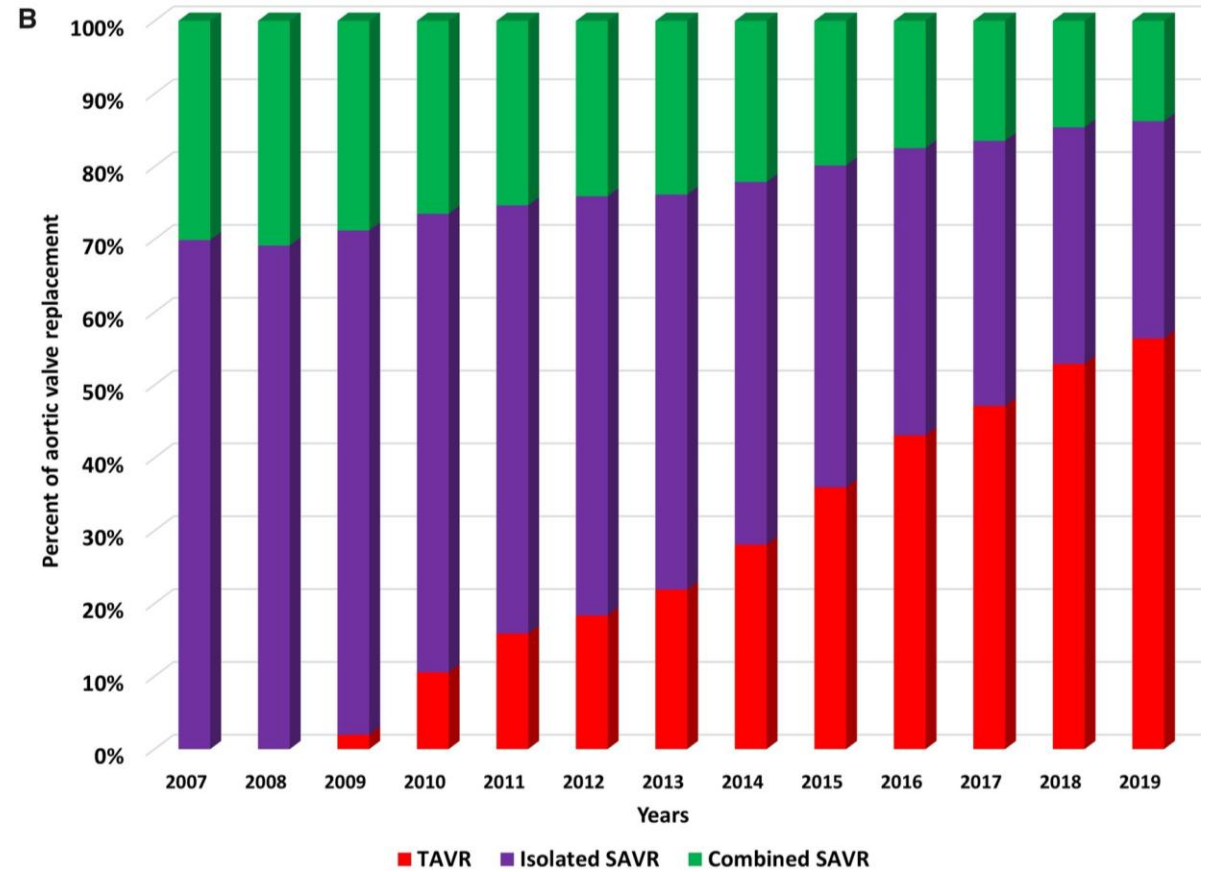
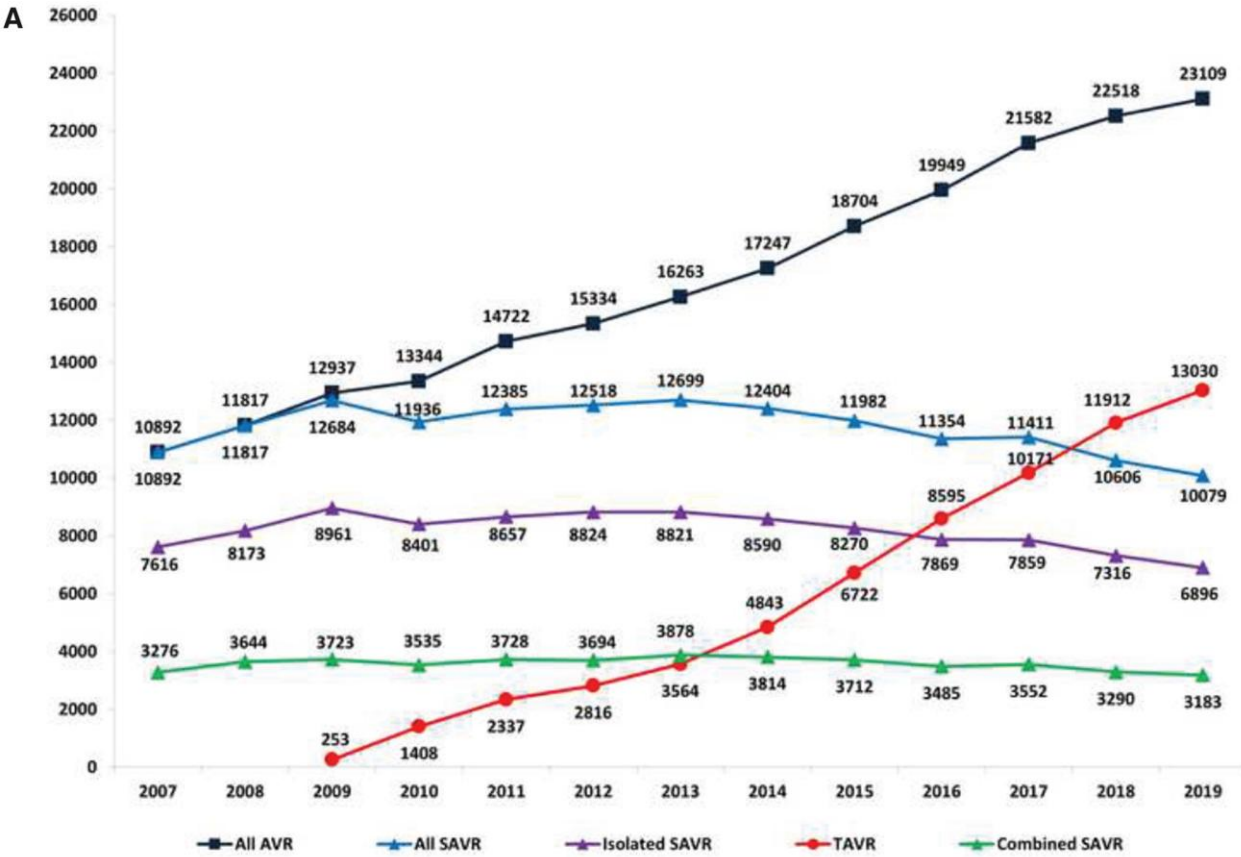
TVT registry (US)



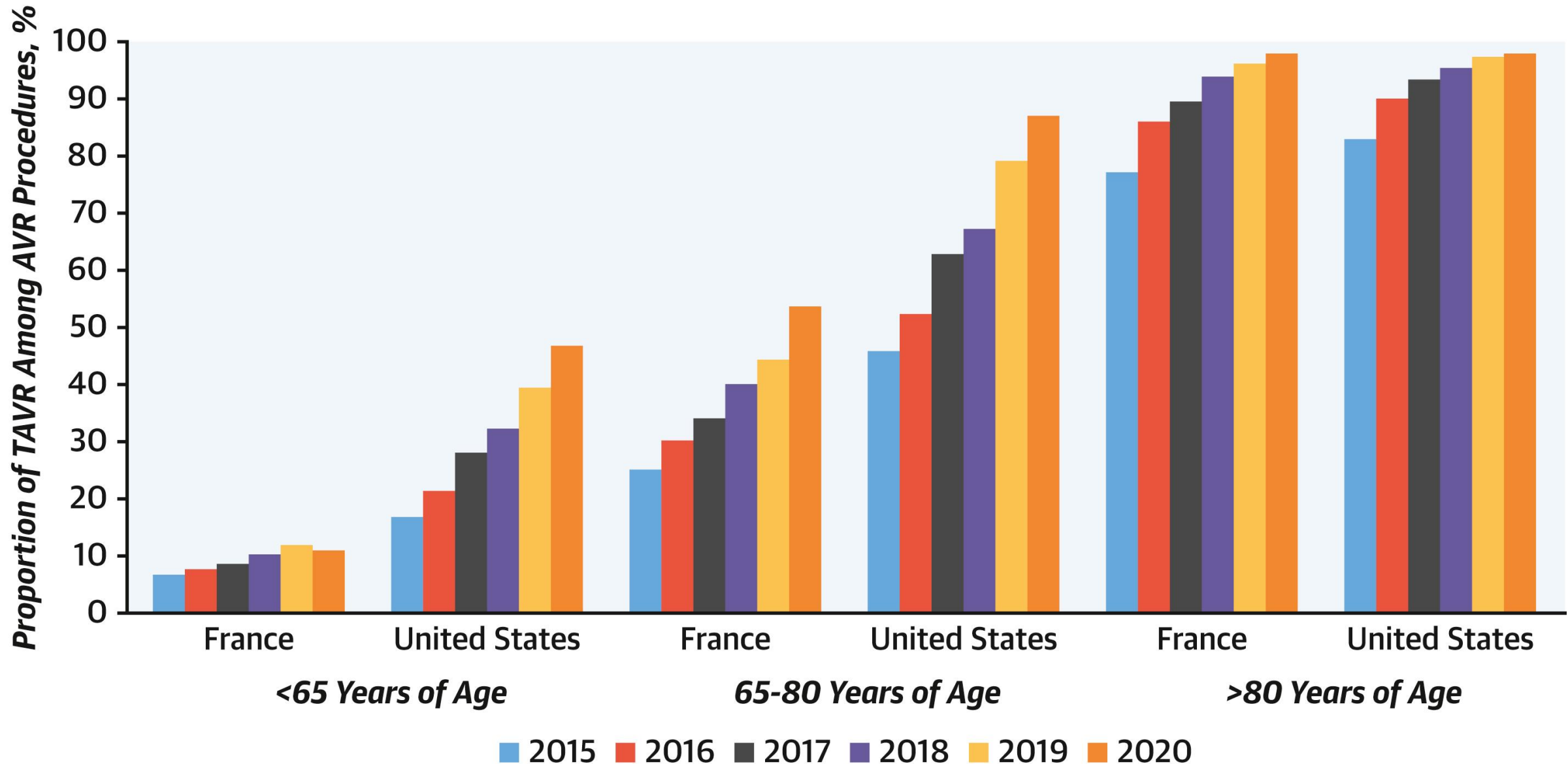
# TAVI vs SAVR



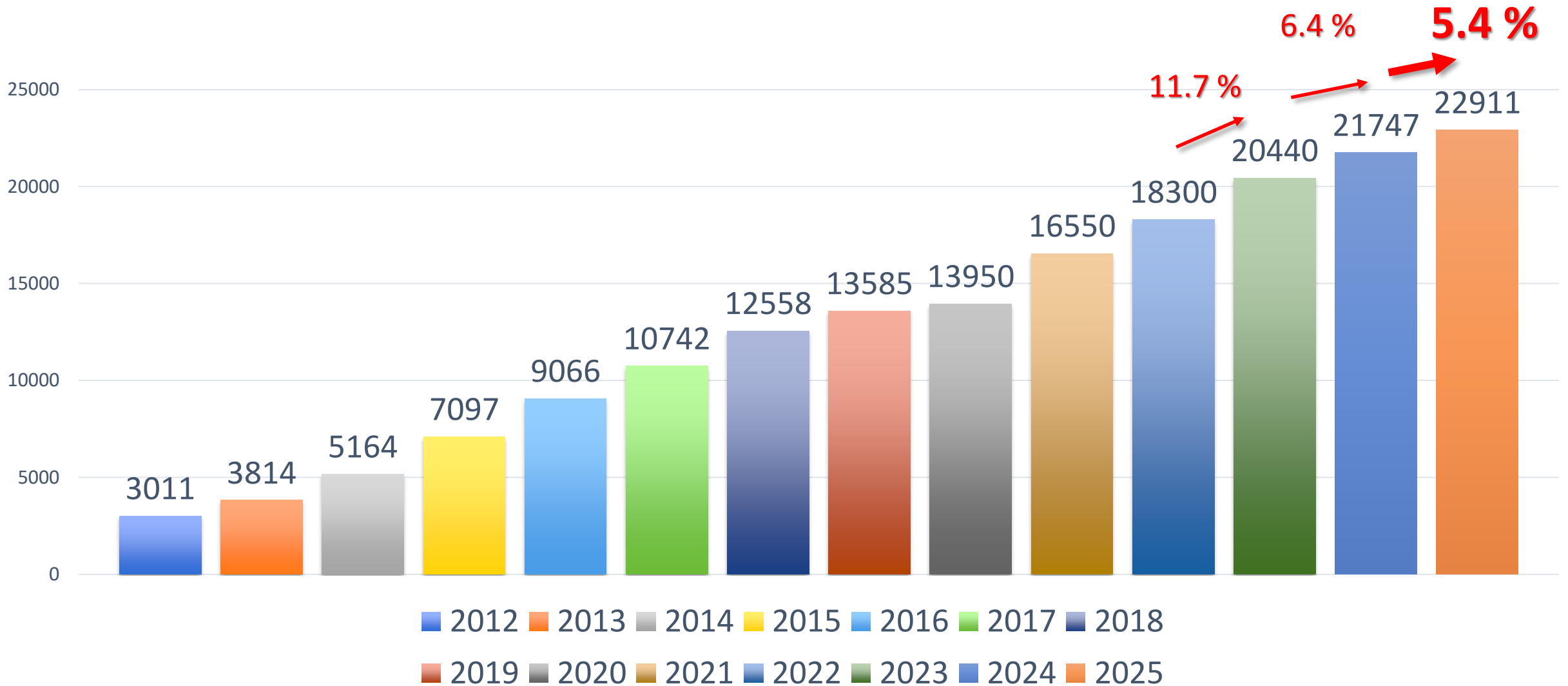
# TAVI in France



# TAVI in France compared to US



# TAVI in France



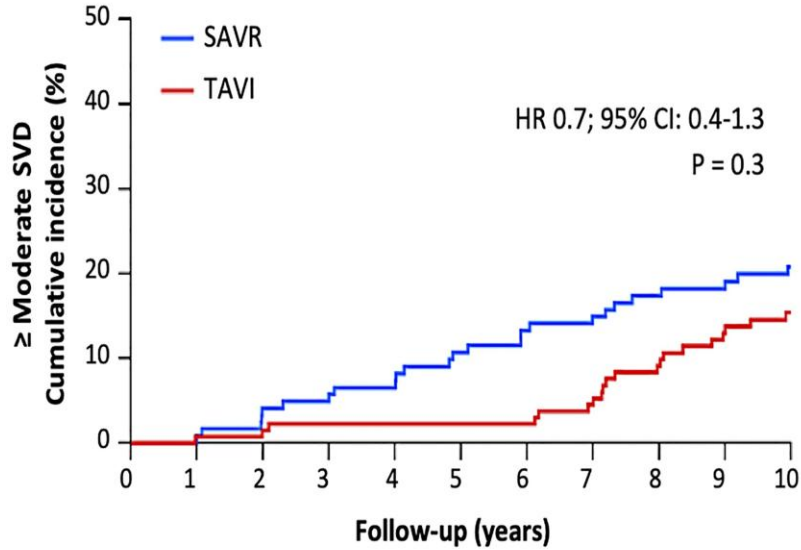
Source: industriels

# Challenges

- **Valve durability**
- **Reintervention**
- **Bicuspid valves**
- **Valve thrombosis**
- **Expansion of indications**

# Valve durability

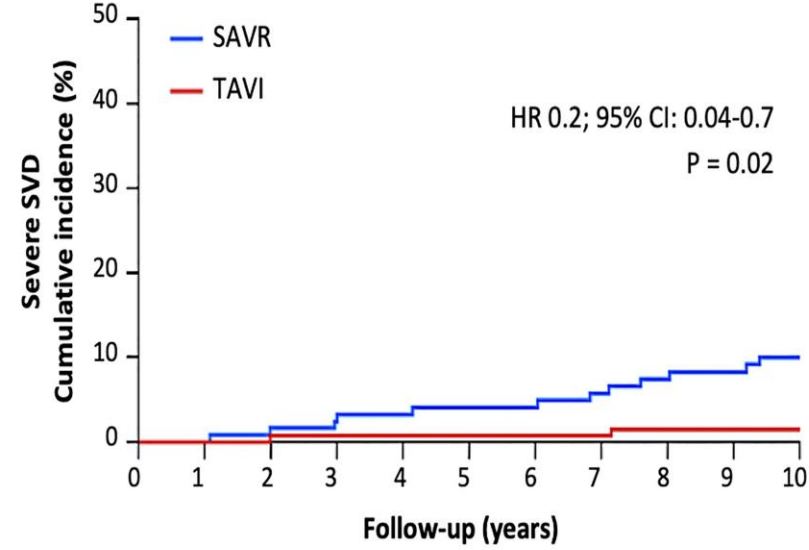
N=280



Patients at risk

TAVI	134	131	128	117	109	96	82	71	56	44	30
SAVR	123	122	116	107	96	84	69	61	48	41	32

	TAVI	SAVR	p value
<b>≥ Moderate SVD</b>	<b>15.4%</b>	<b>20.8%</b>	<b>0.2</b>
Mean gradient ≥ 20 mmHg; AND Increase in mean gradient ≥ 10 mmHg <sup>§</sup>	12.3%	20.8%	0.05
Moderate/severe intraprosthetic AR	4.6%	0	0.02



Patients at risk

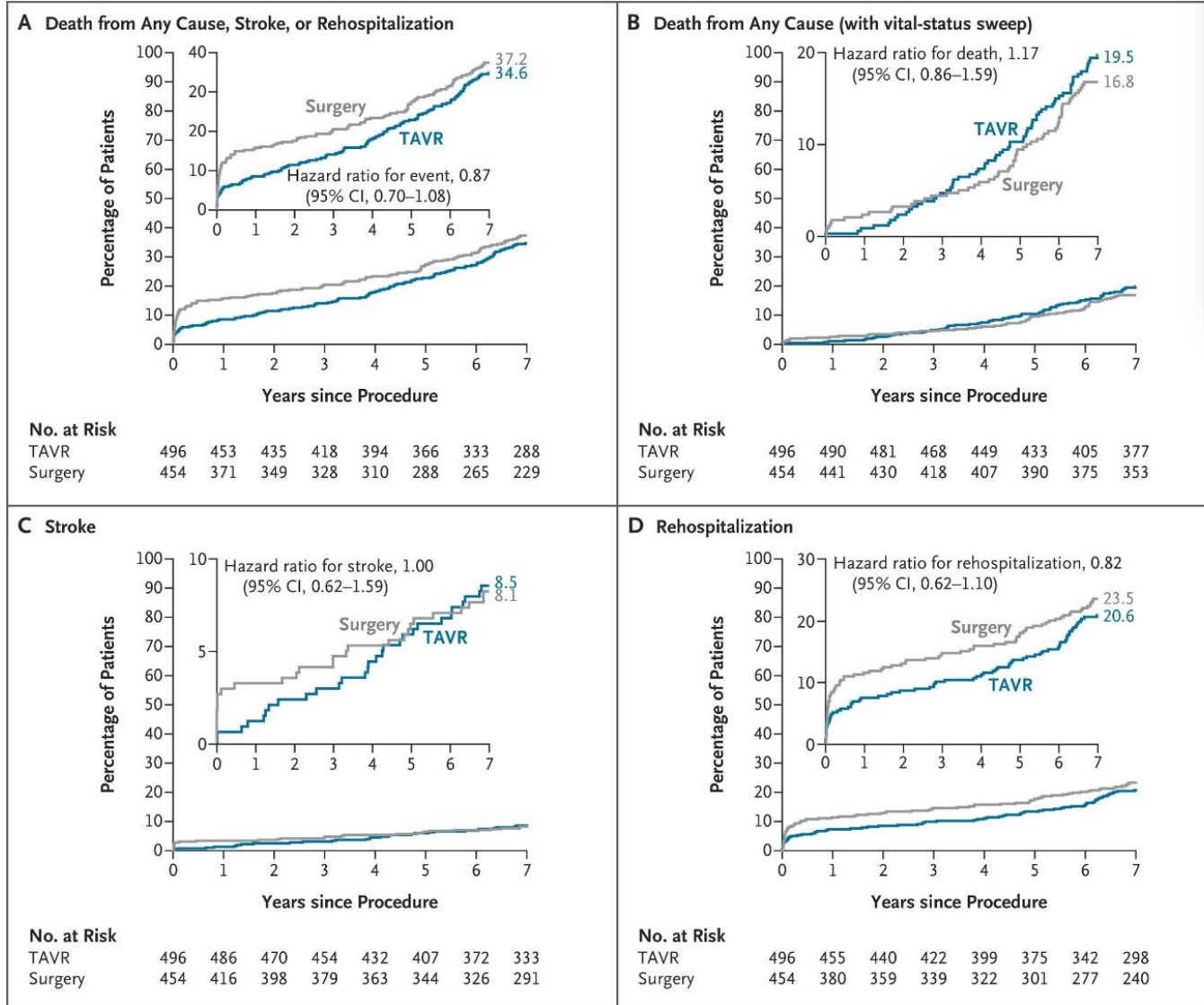
TAVI	134	132	129	118	109	96	82	73	62	51	40
SAVR	123	122	119	110	100	91	79	70	58	50	39

	TAVI	SAVR	p value
<b>Severe SVD</b>	<b>1.5%</b>	<b>10.0%</b>	<b>0.004</b>
Mean gradient ≥ 30 mmHg; AND Increase in mean gradient ≥ 20 mmHg <sup>§</sup>	1.5%	10.0%	0.004
Severe intraprosthetic AR	0	0	-

# Durability of BEVs

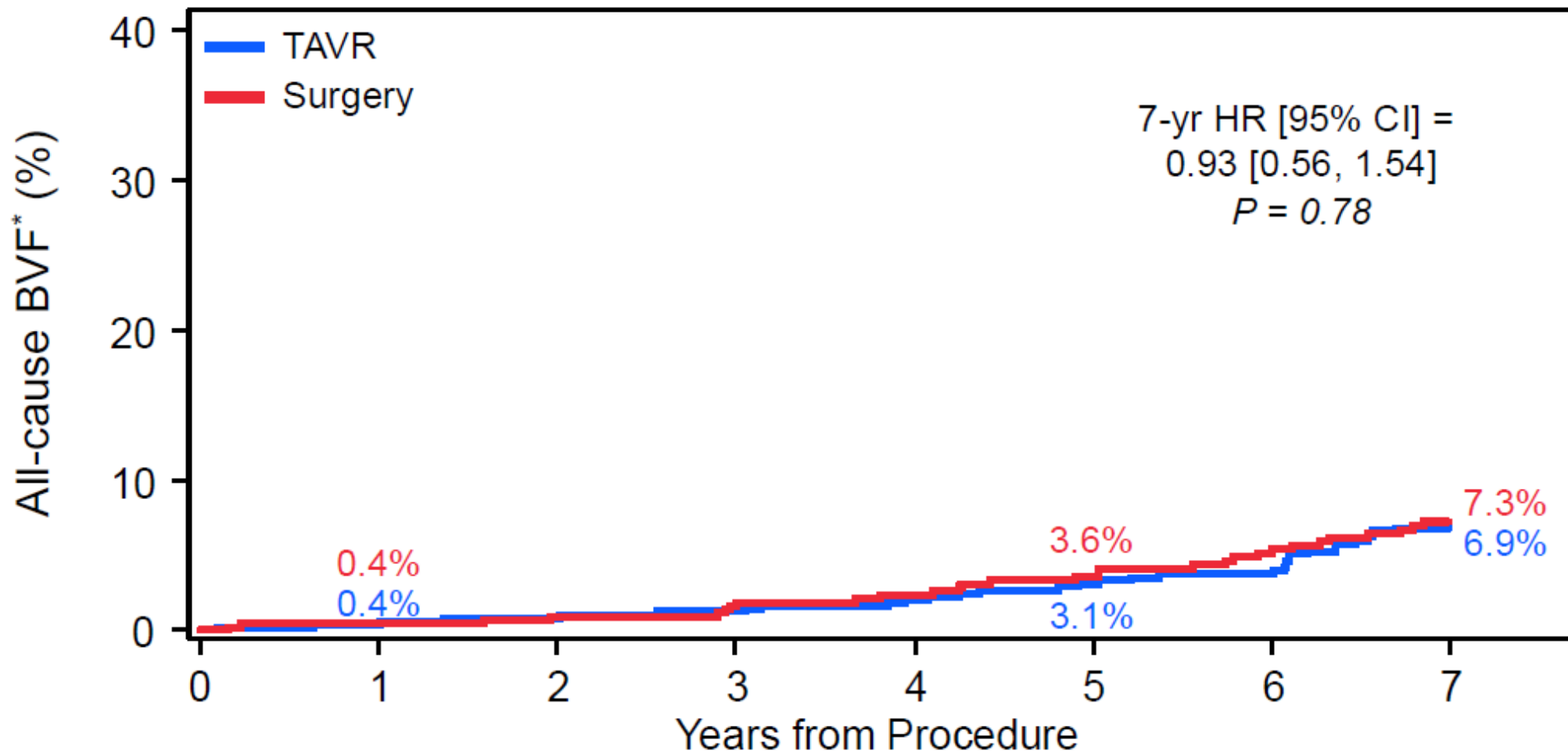
## Transcatheter or Surgical Aortic-Valve Replacement in Low-Risk Patients at 7 Years

Martin B. Leon, M.D.,<sup>1,2</sup> Michael J. Mack, M.D.,<sup>3</sup> Philippe Pibarot, D.V.M., Ph.D.,<sup>4</sup> Rebecca T. Hahn, M.D.,<sup>1,2</sup> Vinod H. Thourani, M.D.,<sup>5</sup> S.H. Kodali, M.D.,<sup>1,2</sup> Philippe G n reux, M.D.,<sup>6</sup> Samir R. Kapadia, M.D.,<sup>7</sup> David J. Cohen, M.D.,<sup>2,8</sup> Stuart J. Pocock, Ph.D.,<sup>2,9</sup> Yiran Zhang, M.S.,<sup>10</sup> Molly Szerlip, M.D.,<sup>3</sup> Julien Ternacle, M.D., Ph.D.,<sup>11</sup> S. Chris Malaisrie, M.D.,<sup>12</sup> Howard C. Herrmann, M.D.,<sup>13</sup> Wilson Y. Szeto, M.D.,<sup>13</sup> Mark J. Russo, M.D.,<sup>14</sup> Vasilis Babaliaros, M.D.,<sup>15</sup> Tamim Nazif, M.D.,<sup>1,2</sup> John G. Webb, M.D.,<sup>16</sup> and Raj R. Makkar, M.D.,<sup>17</sup> for the PARTNER 3 Investigators\*



Leon et al NEJM 2025

# All-cause BVF (VARC-3)

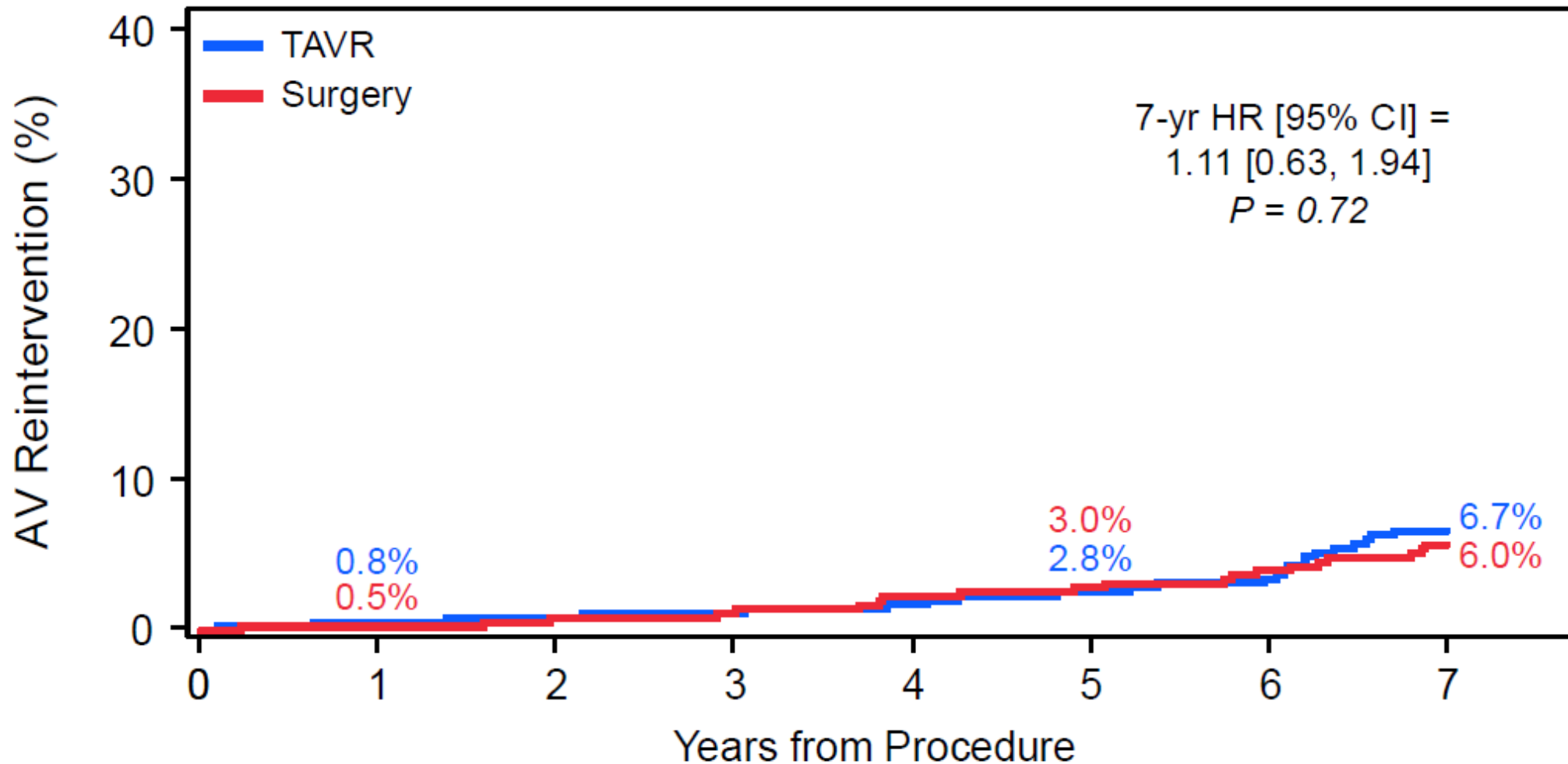


Number at risk:

TAVR	496	488	476	459	433	408	374	330
Surgery	454	426	407	390	372	348	327	288

\*Cumulative incidence with death as a competing risk; HR estimated using the Fine and Gray method

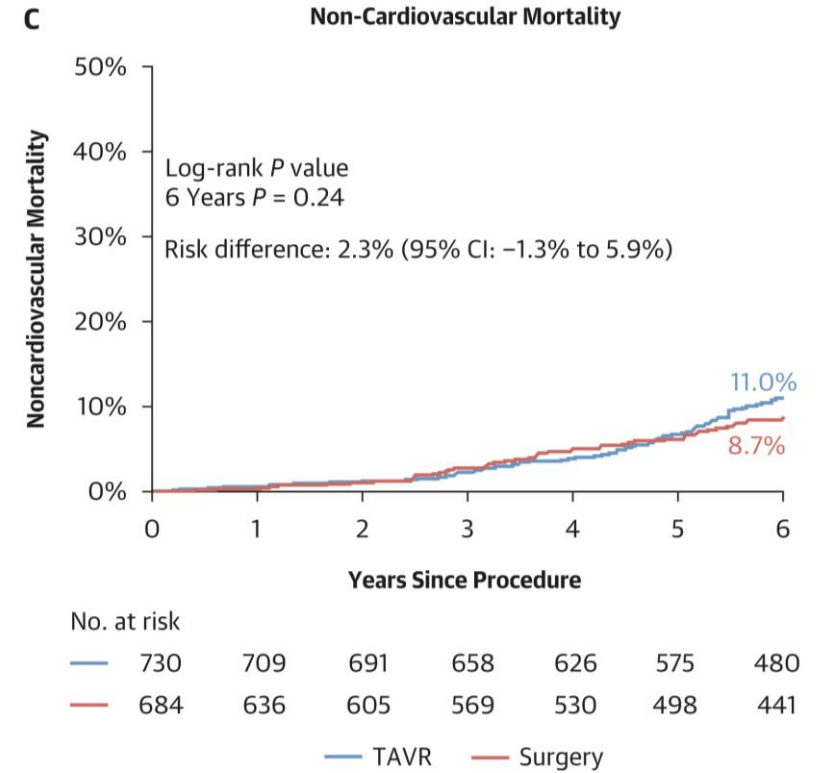
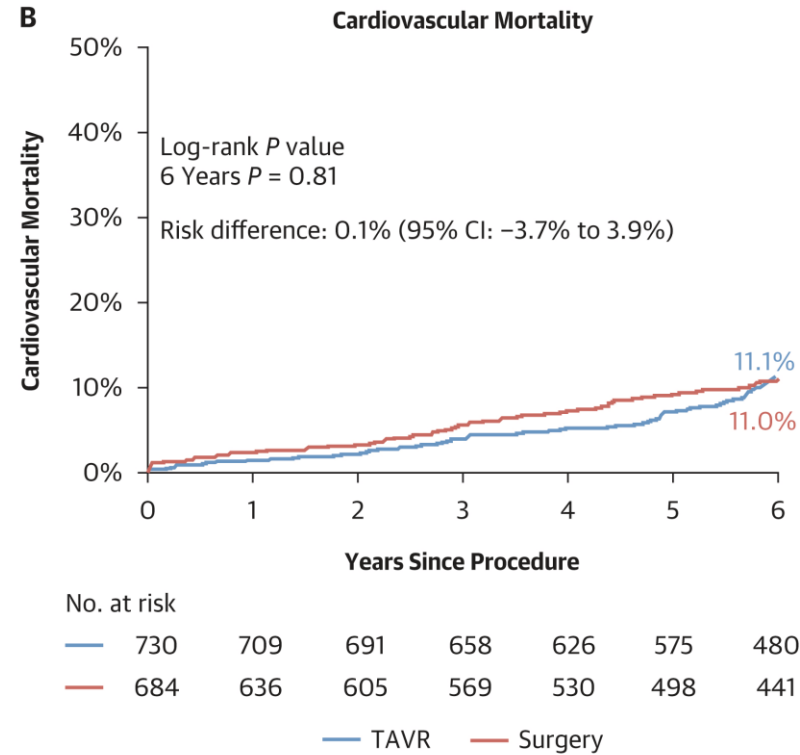
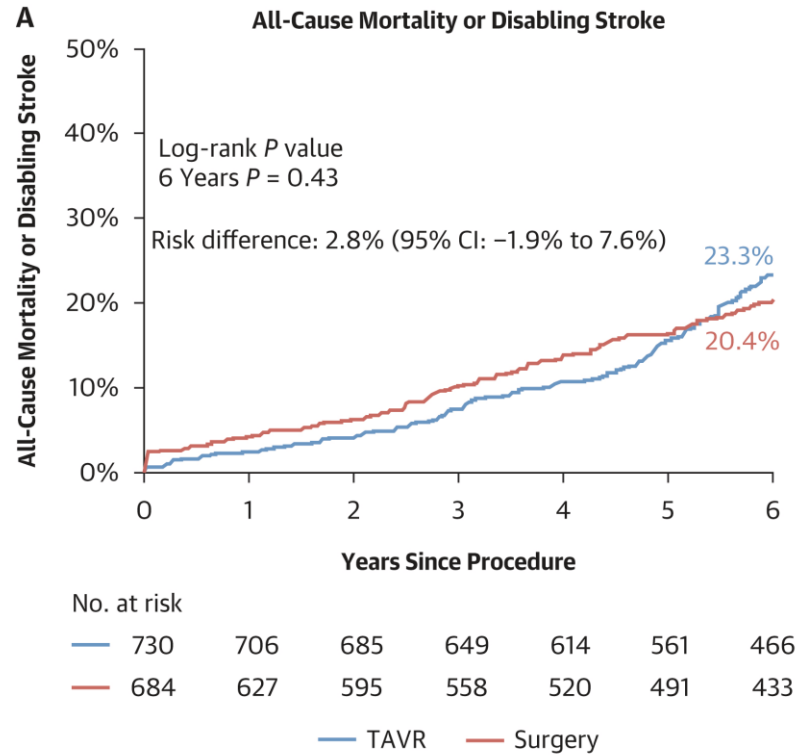
# Aortic Valve Reintervention



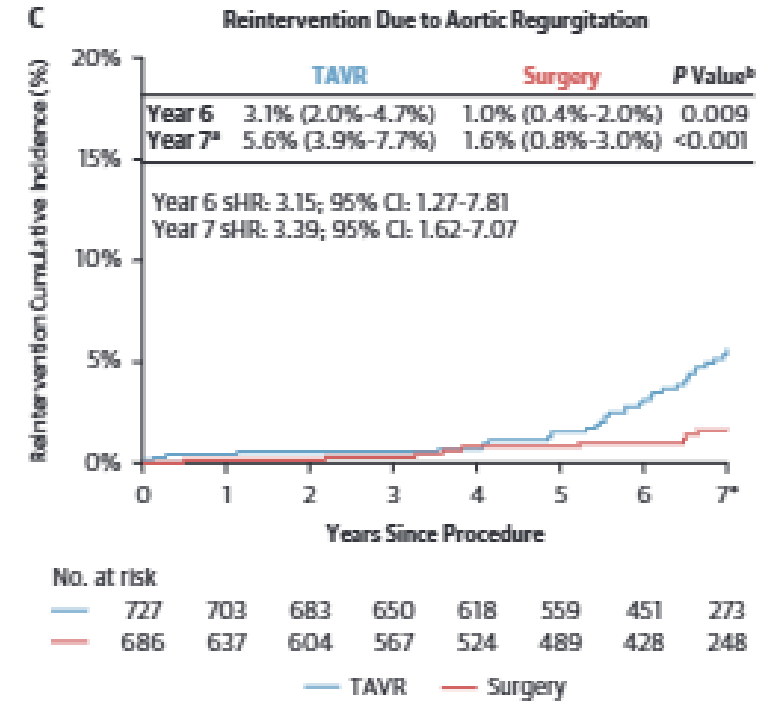
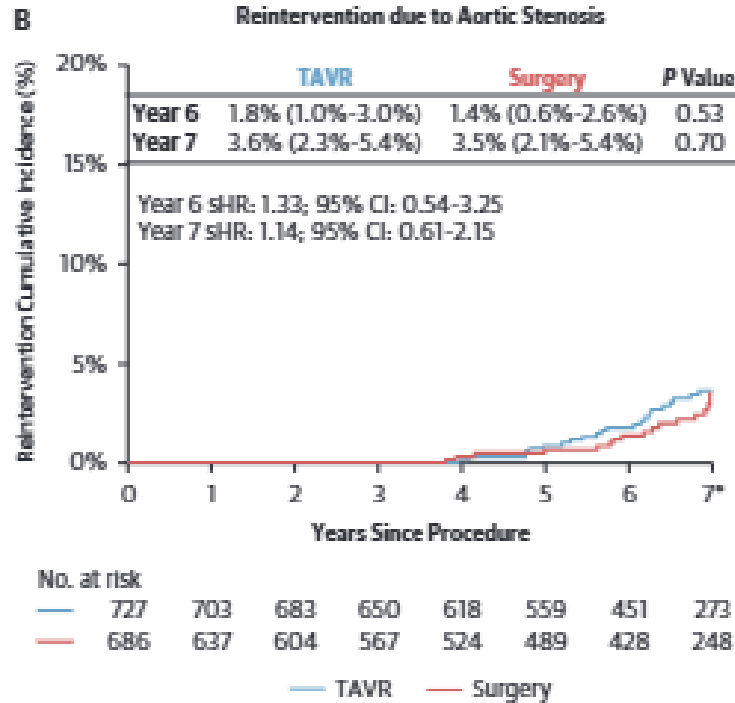
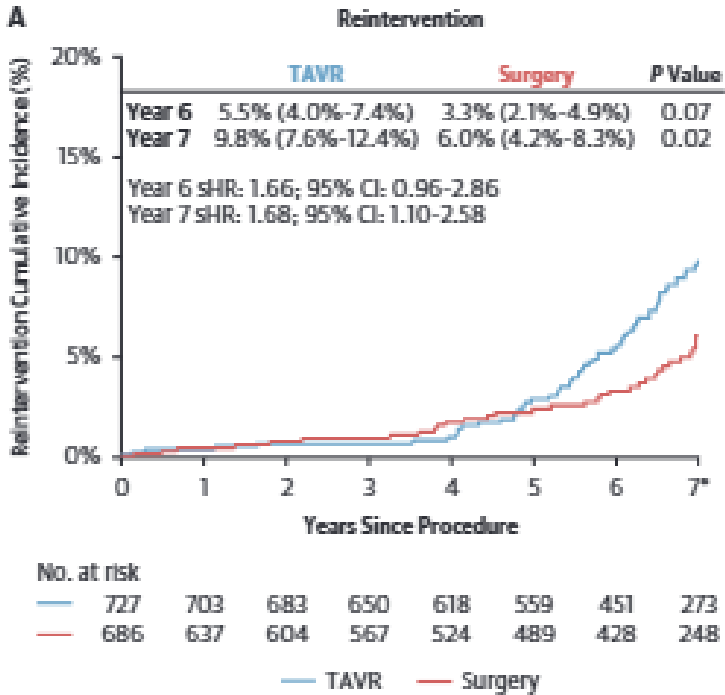
Number at risk:

	0	1	2	3	4	5	6	7
TAVR	496	488	477	461	437	413	378	333
Surgery	454	426	407	391	373	352	332	294

# Durability of SEVs

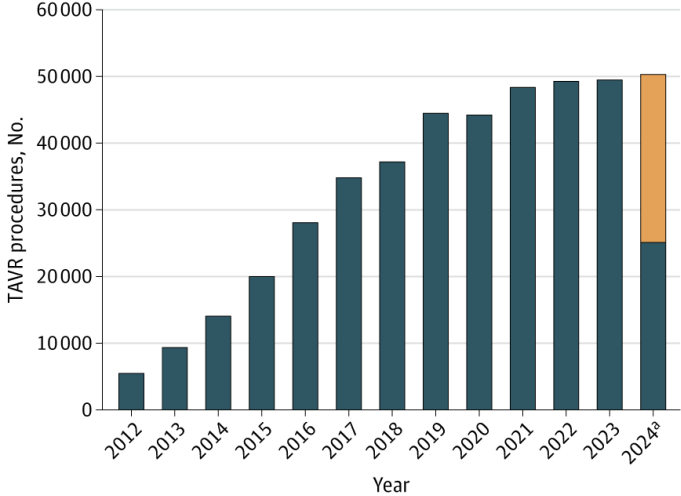


# Durability of SEVs

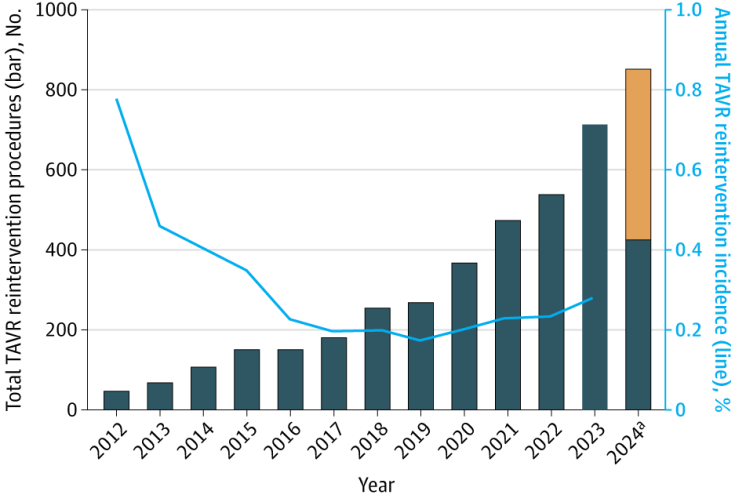


# Valve reintervention after TAVR

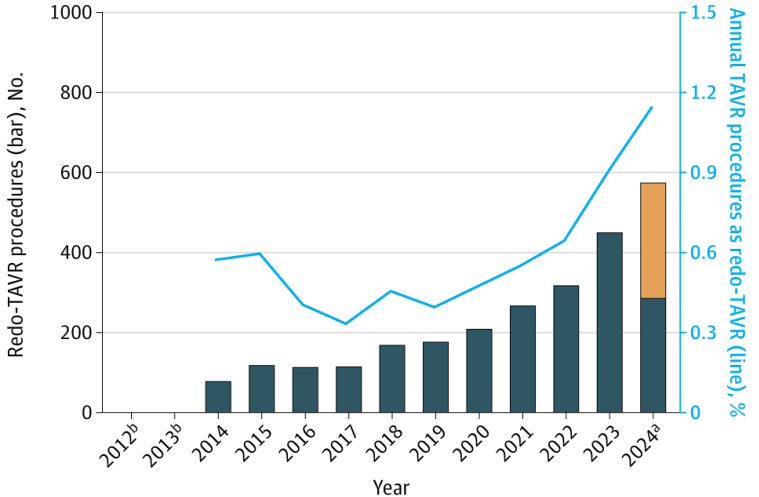
**A** TAVR procedures



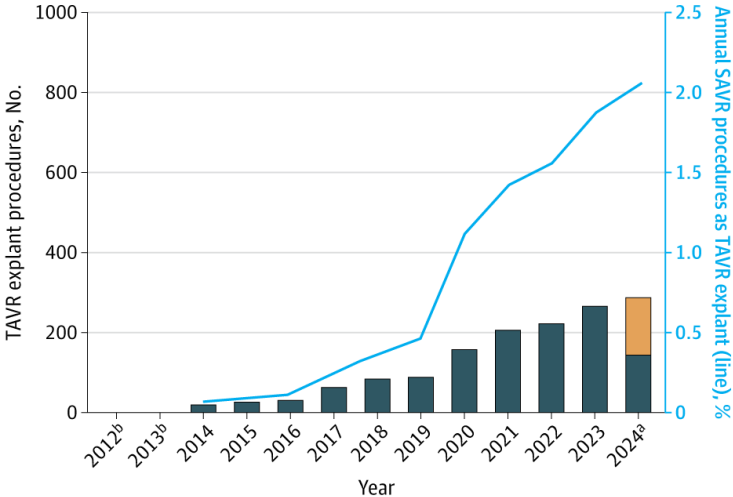
**B** Total TAVR reintervention procedures



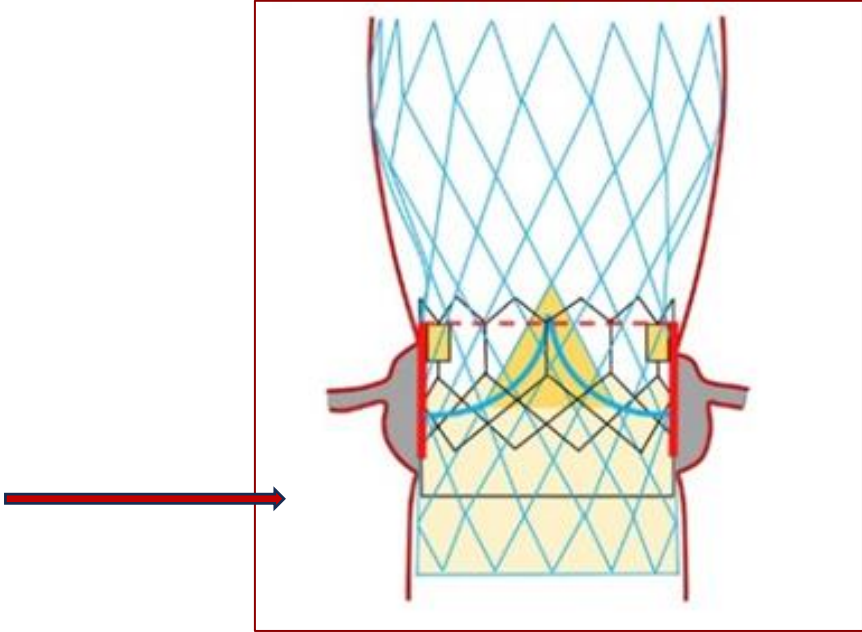
**C** Redo-TAVR procedures



**D** TAVR explant procedures

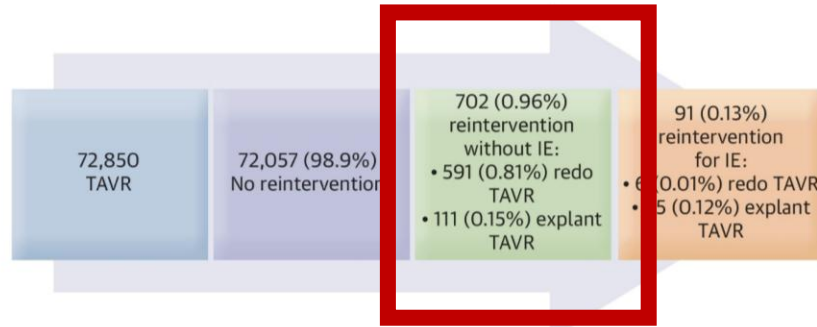


**N=410 726 patients**

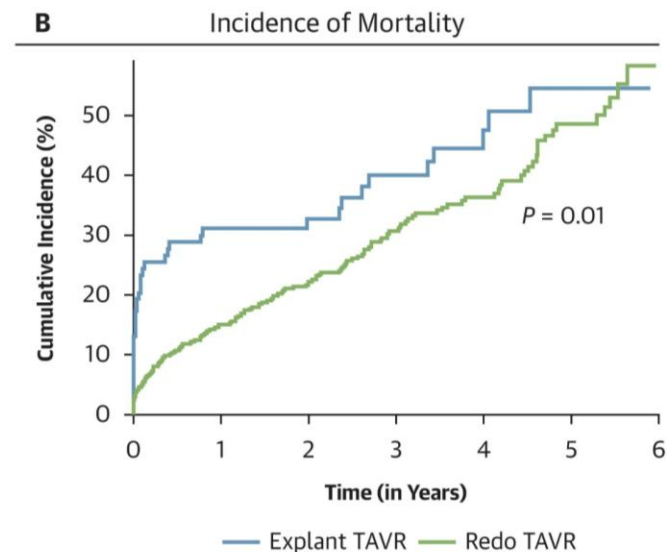
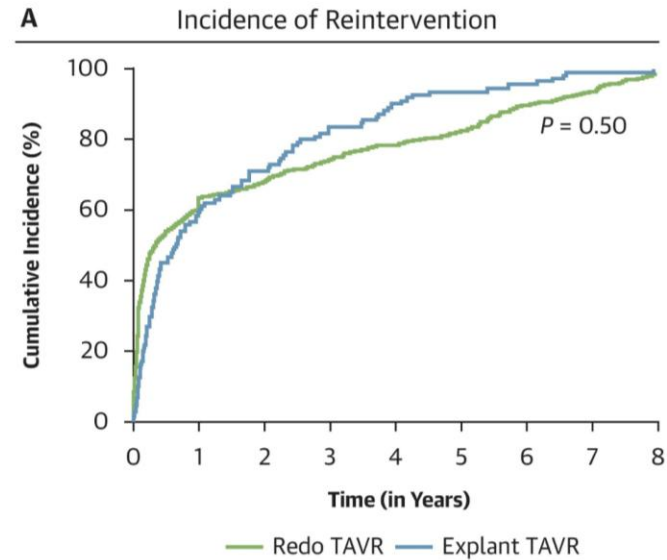


# Valve reintervention in France

Reintervention After TAVR: Data From French National Registries



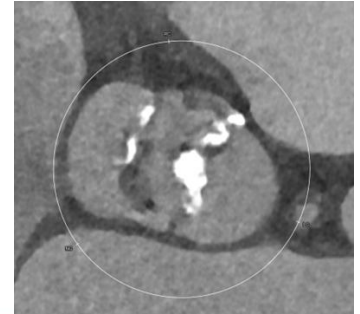
Predictive Factors of Reintervention			
	OR	95% CI	P Value
Age	0.95	0.94-0.97	<0.001
Dialysis	1.95	0.98-3.91	0.06
Mean Aortic Gradient Preimplantation	0.99	0.98-1.00	0.03
Mean Aortic Gradient >20 mm Hg After Implantation	2.70	1.82-4.00	<0.001
Aortic Regurgitation ≥ Grade 2	3.30	2.36-4.62	<0.001
PCI Post TAVR	2.56	1.04-6.30	0.04



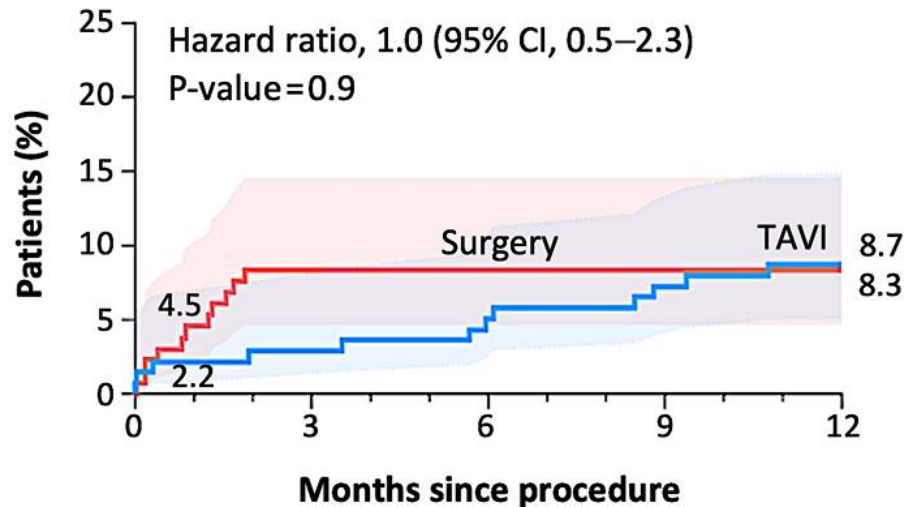
Durand et al, JACC 2025

# Bicuspid valves

NOTION II trial, N= 370, 100 bicuspid valves



**Primary endpoint  
Tricuspid cohort**

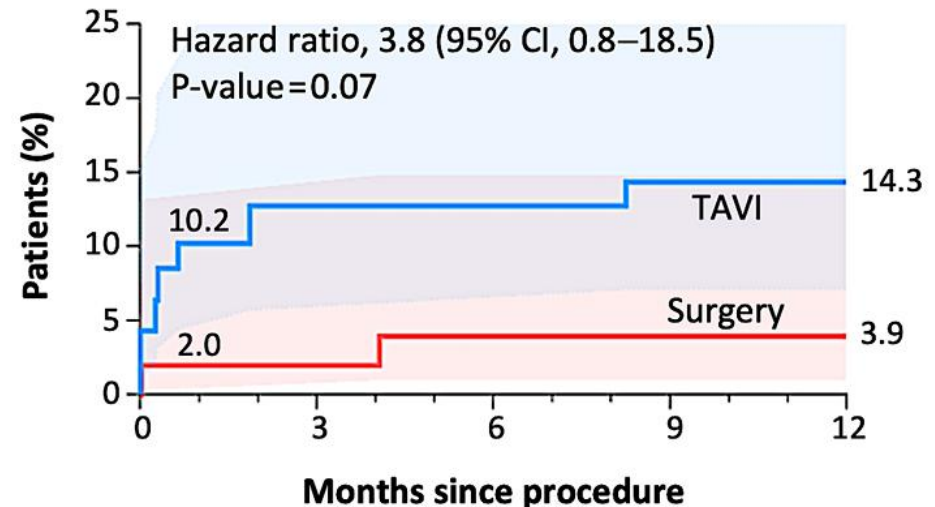


No. at Risk

	0	3	6	9	12
Surgery	132	121	121	121	121
TAVI	138	134	131	128	126

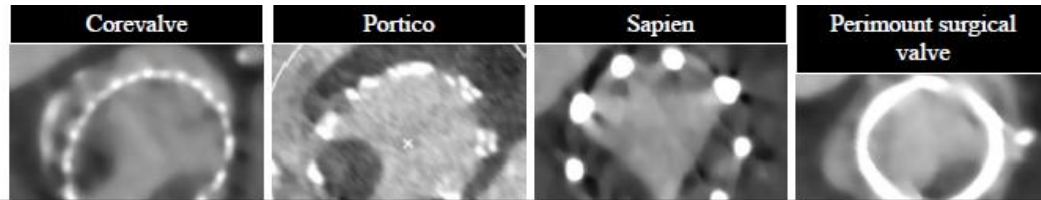


**Primary endpoint  
Bicuspid cohort**

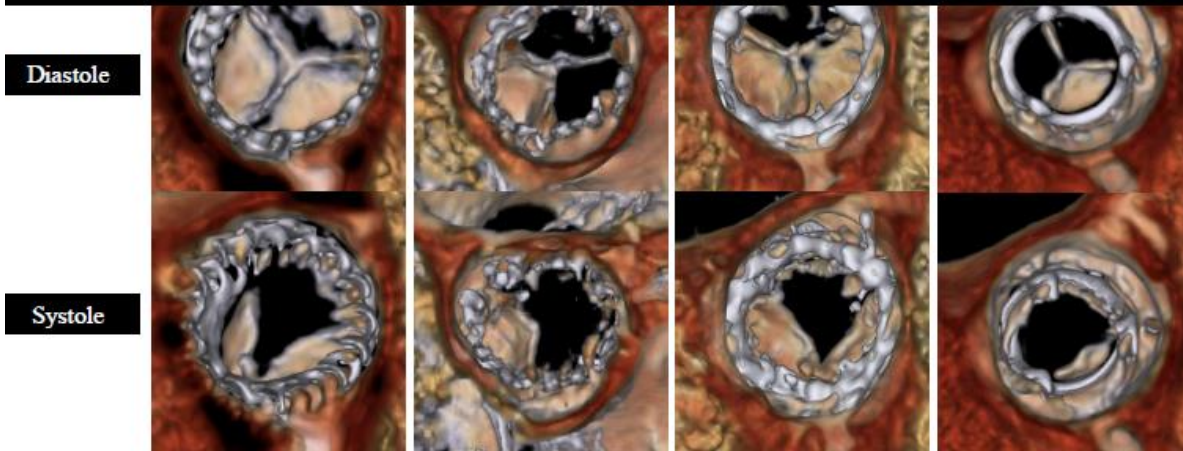


	0	3	6	9	12
TAVI	51	50	49	49	49
Surgery	49	43	43	42	42

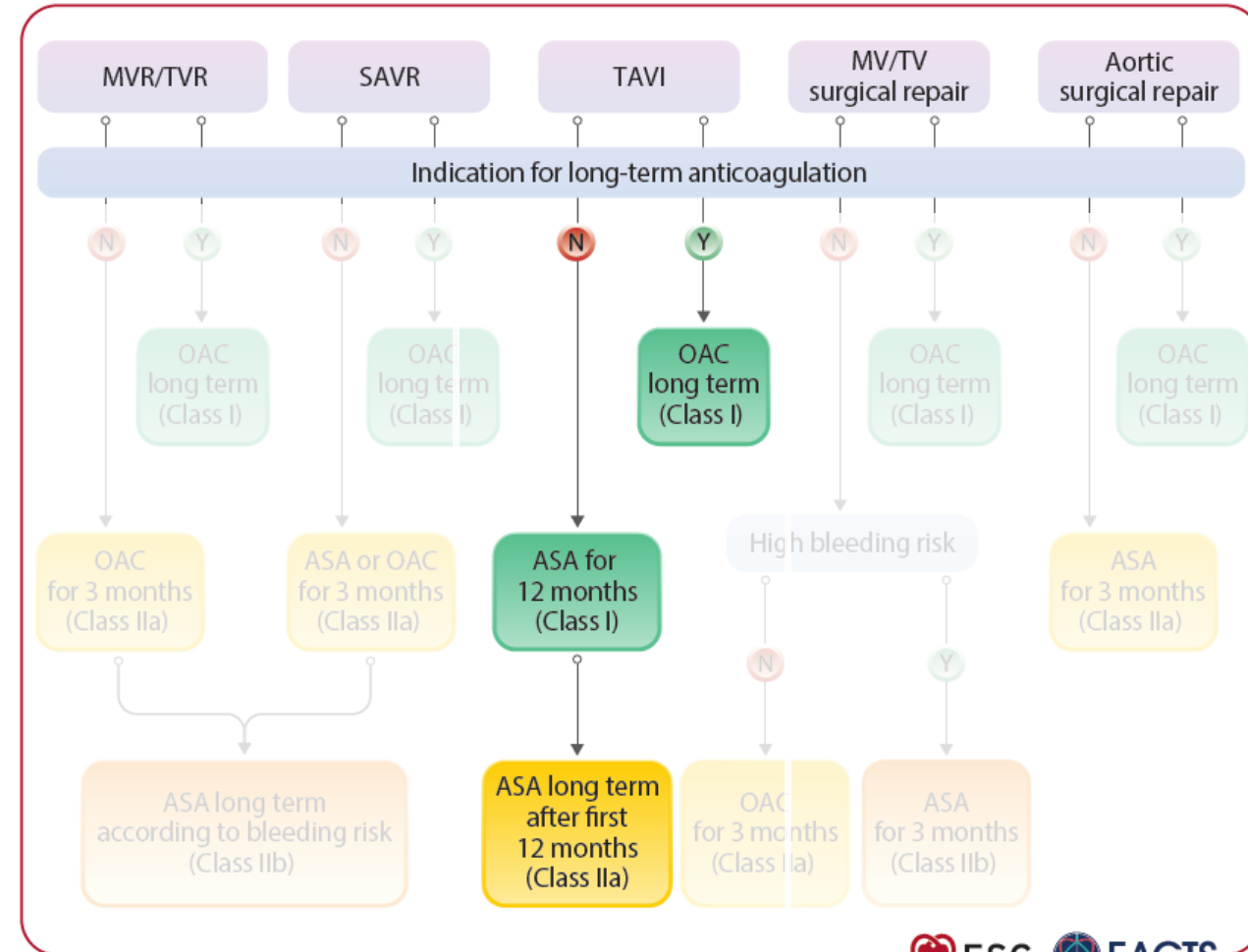
# Valve thrombosis



Prevalence was 13% in real life registries, 40% in a small IDE subset, overall 20% in 187 patients



## 2025 ESC/EACTS Guidelines for the management of HVD



# Expansion of indications

- **Bicuspid AS**

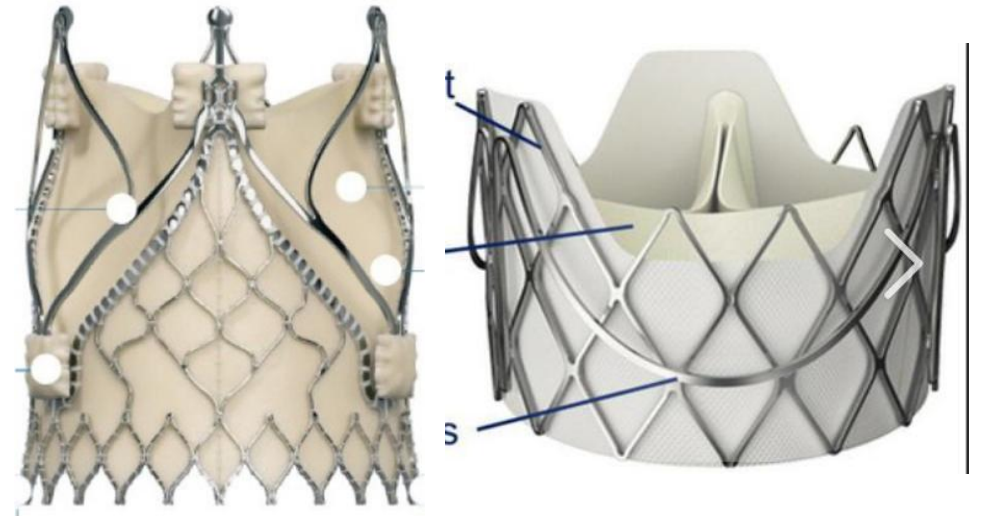
- NAVIGATE trial
- BELIEVERS trial
- Bicuspid TAVR vs Surgery Pilot Trial

- **Moderate AS**

- The PROGRESS trial
- EXPAND TAVR II
- TAVR UNLOAD

- **Aortic regurgitation**

- The JOURNEY trial
- JenaValve AR pivotal trial



# Conclusions

- TAVI est une révolution thérapeutique à l'échelle mondiale avec niveau de preuves élevé, plébiscité par les patients
  - Technologie rapidement évolutive
  - Elargissement des indications
- C'est aujourd'hui la thérapie de 1ere intention pour la majorité des patients avec un RAC
- Néanmoins, la durabilité des bioprothèses et les stratégies de réintervention restent des enjeux majeurs
- L'anticipation des options thérapeutiques futures dès la première intervention (lifetime management) est essentielle, en particulier chez les patients jeunes
- La place du TAVI dans la bicuspidie, l'insuffisance aortique et le RAC modéré reste à définir