

2023

11<sup>ème</sup>

SÉMINAIRE de CARDIOLOGIE  
INTERVENTIONNELLE de TROYES

01 & 02  
AVRIL



SALLE DU CONSEIL MUNICIPAL  
HOTEL DE VILLE de TROYES



*L'interventionnelle Valvulaire Percutanée*

## **Valve In Valve**

**Thierry Folliguet, Créteil**

# Déclaration de conflits d'intérêts

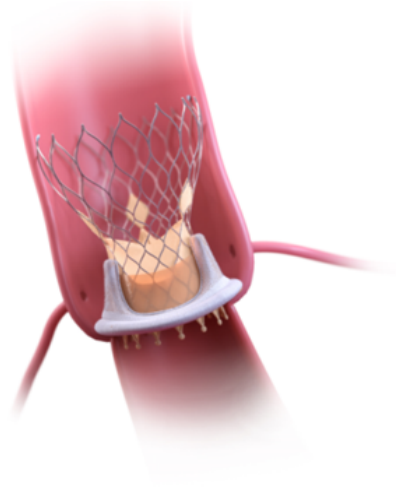
- Aucun

# 2017 AHA/ACC Guidelines

## TAVR Valve in Valve (VIV)

### VIV is reasonable for the following patients:

- ▶ severely symptomatic, tissue AVR stenosis, high or prohibitive risk of reoperation, and whom improvement in hemodynamics is anticipated – which is “only in patients with larger-sized prosthesis.”



Nishimura et al., 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2017;135:e1159–e1195.

## 2017 AHA/ACC Guidelines – continued

### Valve in Valve (VIV)

- ▶ **No Long Term Data** or extensive long-term follow-up of transcatheter valves [placed in a valve in valve procedure] is available.
- ▶ **Not all bioprostheses** are suitable for a future valve-in-valve procedure
- ▶ **VIV Requires** a smaller valve to be placed making PPM a potential problem
- ▶ **Root Enlargement** should be considered in patients with a small annulus to ensure that there is not an initial prosthesis patient mismatch
  - How often is a root enlargement performed by surgeons?



Nishimura et al., 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2017;135:e1159–e1195.

# Strategy for TAVR VIV

## Reoperative SAVR Bioprosthetic

**Perception:** As *younger* patients' tissue valve wears out, a transcatheter VIV is a good option.

**Reality:** Transcatheter valve-in-valve (VIV) insertion is an attractive but unproven long-term strategy<sup>1</sup>

- ▶ **Primarily for high risk AVR patients, but targeting low/intermediate risk now**
- ▶ **Procedure includes several efficacy and safety concerns, such as:**
  - Elevated post-procedural **gradients** in the setting of small bioprostheses,
  - A high **malposition** rate in inexperienced hands [...],
  - The potential for **coronary obstruction**.<sup>2</sup>
- ▶ **Additional considerations:**
  - Structural Valve Deterioration<sup>4</sup>
  - Paravalvular leaks<sup>5</sup>
  - Restricted Leaflet Motion<sup>4</sup>
  - Pacemaker implantation<sup>5</sup>



Asymmetric  
Degeneration 5 yrs  
after TAVI<sup>3</sup>

1. Suri R and Schaff H. Circulation. 2013;128:1372-80. 2. Dvir D and Webb J. Circ J. 2015;79:695-703. 3. Dvir D. First look at long-term durability of transcatheter heart valves: Assessment of valve function up to 10-years after implantation. EuroPCR 2016 presentation. 4. Laschinger J et al, N Engl J Med. 2015; 373:1996-8. 5. Dvir D et al, JAMA. 2014;312:162-70.

# Strategy for TAVR VIV

How many SAVR bioprosthetic valves are “large”?

**Perception:** The majority of SAVR (surgical aortic valve replacement) tissue valves implanted prior to a VIV are “large” valves.

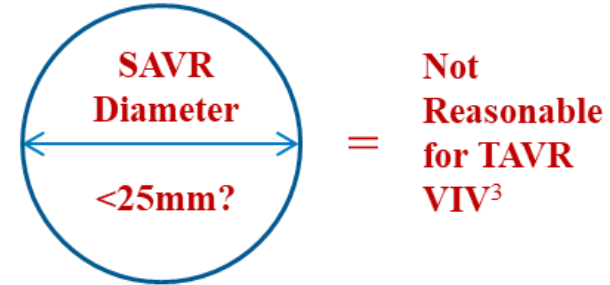
**Reality:** In the largest VIV registry to date, 69% of patients had “intermediate” or “small” valves.<sup>1</sup>

## SAVR Valve Sizes Defined for VIV:<sup>1</sup>

- ▶ Large =  $\geq 25$ mm (31%)
- ▶ Intermediate =  $> 21$  to  $< 25$ mm (39%)
- ▶ Small =  $\leq 21$ mm (30%)

## PERIMOUNT<sup>®</sup> Tissue Valves Sold in US:<sup>2</sup>

67% are Small and Intermediate Sizes ( $\leq 21$  to  $< 25$ mm)



Do patients considering a SAVR tissue valve know that they do not reasonably qualify for VIV when they receive a tissue valve  $< 25$ mm?

1. Dvir. JAMA. 2014;312:162-70.  
2. IMS US Sales Report, Q4, 2010 to Q3, 2016. Perimount models 2700, 2800, and 3300. Report run by CryoLife Marketing, 04/10/2017. Data on file.  
3. Nishimura et al., Circulation. 2017;135:e1159–e1195.

# Strategy for TAVR VIV

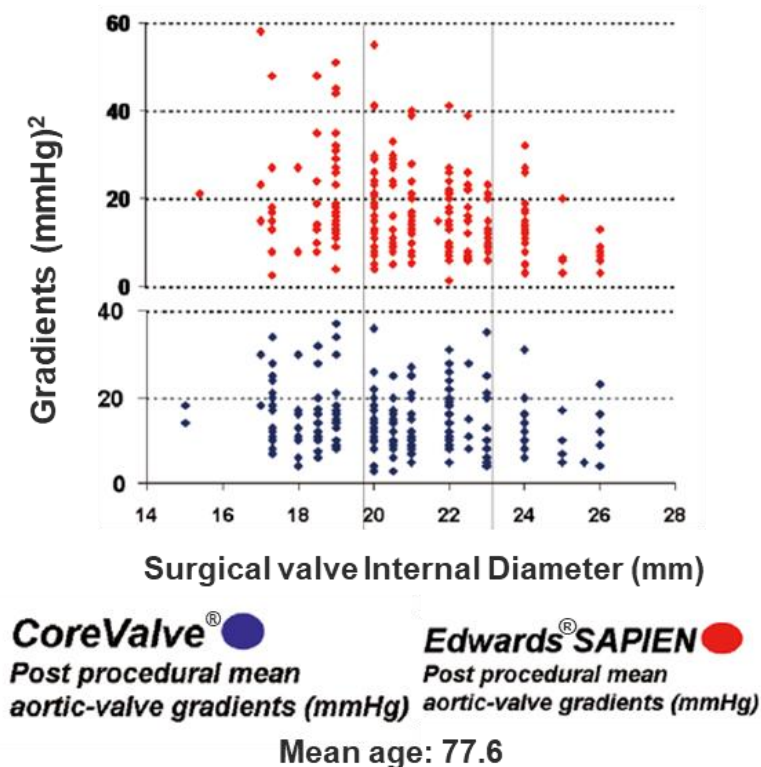
## Prosthesis Patient Mismatch (PPM), Gradients, and Mortality

**Perception:** The outcomes of VIV are equivalent to a de novo TAVR procedure

**Reality:** VIV hemodynamics are poor and mortality is excessive in  $\leq 21$  mm SAVR valves.

### PPM and Gradients from VIV Registry Data:<sup>1</sup>

- ▶ 62% PPM\*
- ▶ 31.8% Severe PPM
- ▶ Gradients in many patients:  $\geq 20$  mmHg to  $\geq 40$  mmHg
- ▶ Excess Mortality at  $\leq 1$  year was correlated with small surgical bioprosthesis ( $\leq 21$  mm; hazard ratio, 2.04; 95%CI, 1.14-3.67;  $P = .02$ )



1. Dvir D et al., JAMA. 2014;312:162-70.

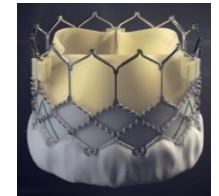
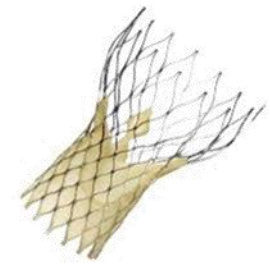
\*Calculation from descriptive statistics with PPM as iEOA  $< 0.85 \text{m}^2/\text{m}^2$

2. Chart from Dvir D and Webb J. Circ J. 2015;79:695-703.

# Valve Aortique

## Valve in Valve

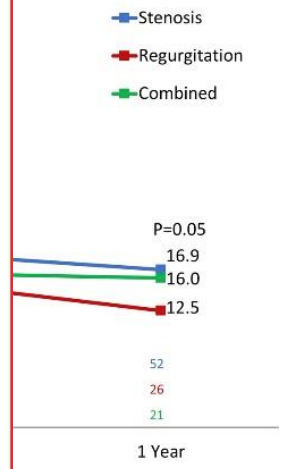
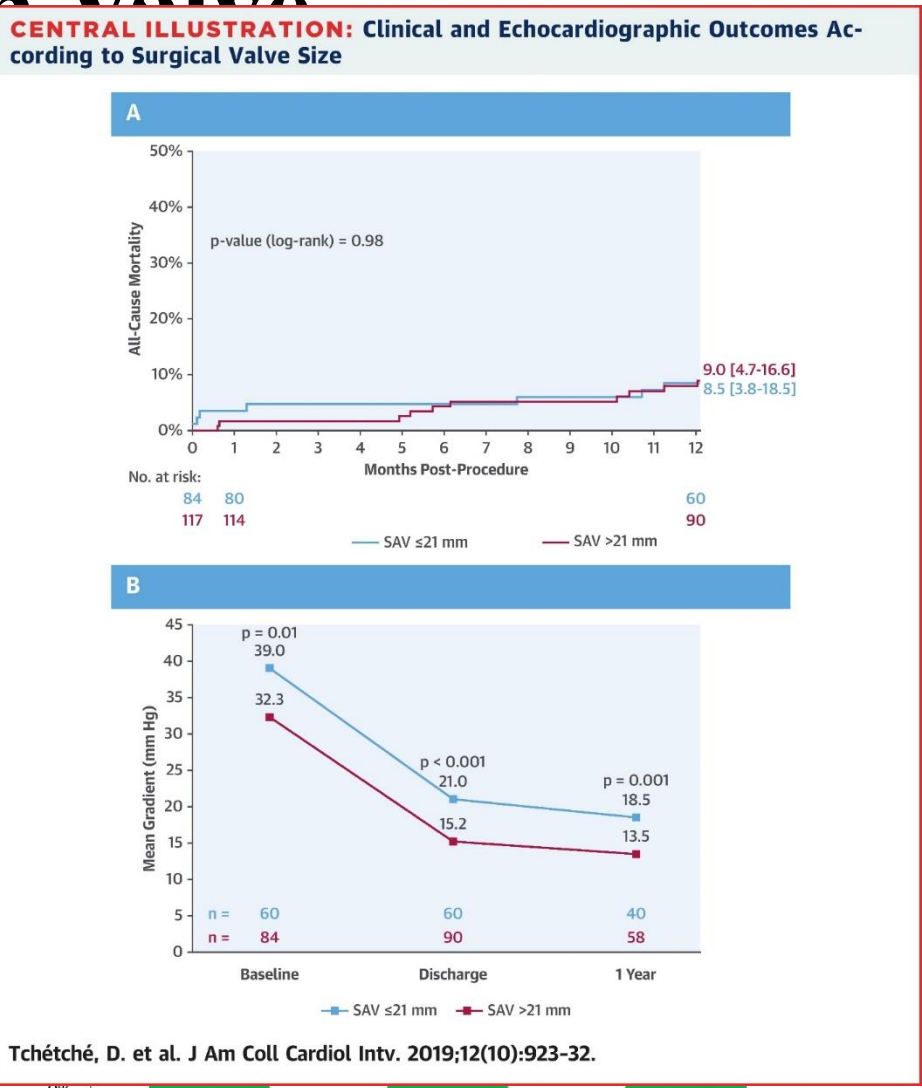
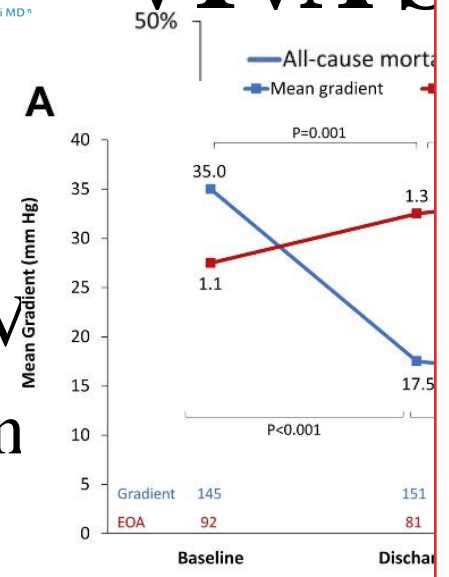
### VIVA S



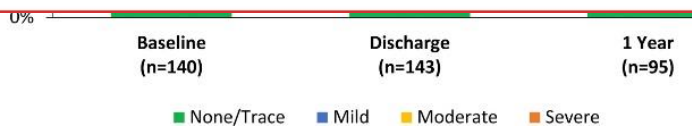
Focus on TAVR Special Cohorts  
TAVR for Failed Surgical Aortic Bioprostheses  
Using a Self-Expanding Device: 1-Year Results  
From the Prospective VIVA Postmarket Study

Didier Tchétché MD <sup>1,2,3,4</sup>, Bernard Chevalier MD <sup>5</sup>, David Holzhey MD <sup>6</sup>, Axel Harnath MD <sup>4</sup>, Ulrich Schäfer MD <sup>7</sup>,  
Emmanuel Teiger MD, PhD <sup>1</sup>, Thibaut Manigold MD <sup>8</sup>, Thomas Modine MD <sup>9</sup>, Geraud Souteyrand MD <sup>1</sup>, Didier  
Champagnac MD <sup>1</sup>, Jae K. Oh MD <sup>5</sup>, Shuzhen Li PhD <sup>1</sup>, Jean-Philippe Verhoye MD <sup>10</sup>, Ran Kornowski MD <sup>11</sup>  
VIVA Investigators

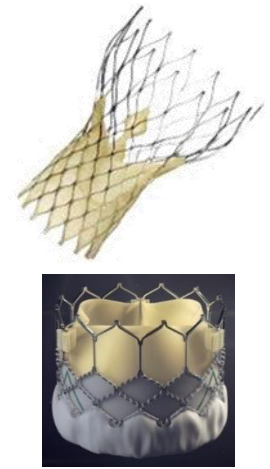
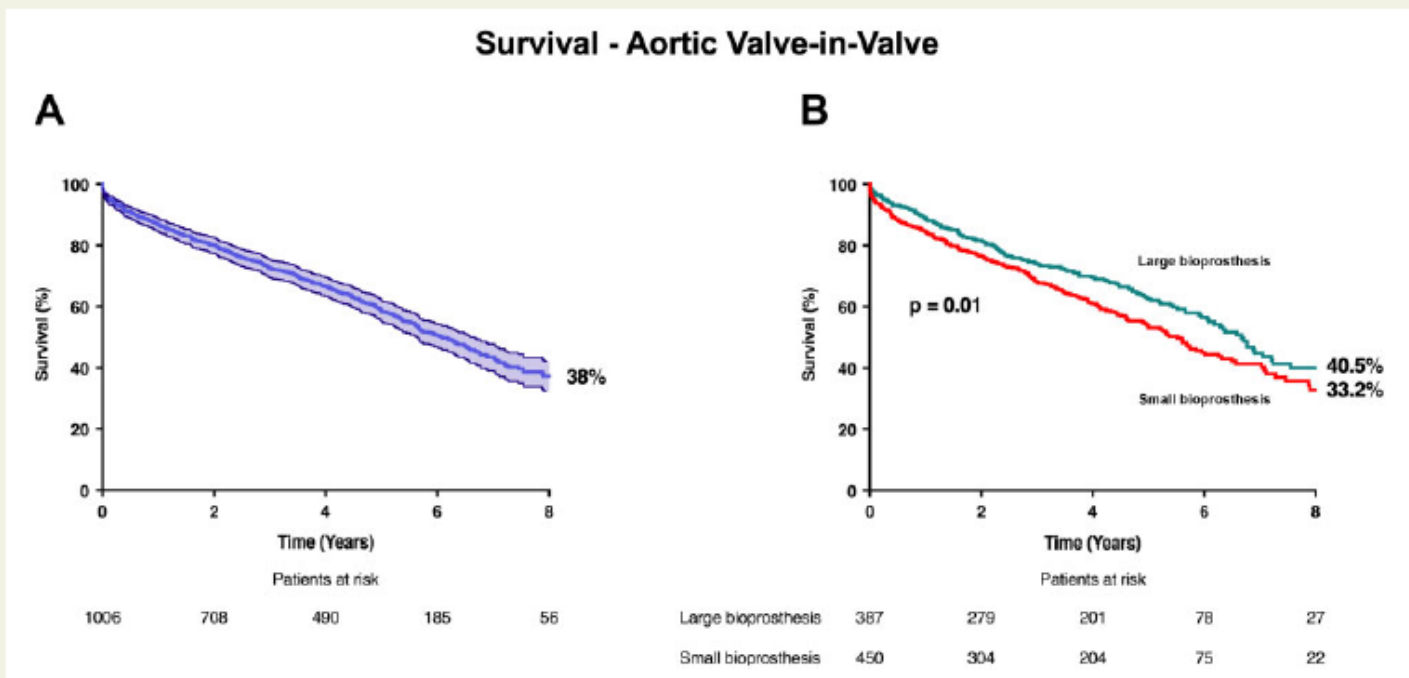
- VIV
- # en



Tchétché, D. et al. J Am Coll Cardiol Intv. 2019;12(10):923-32.

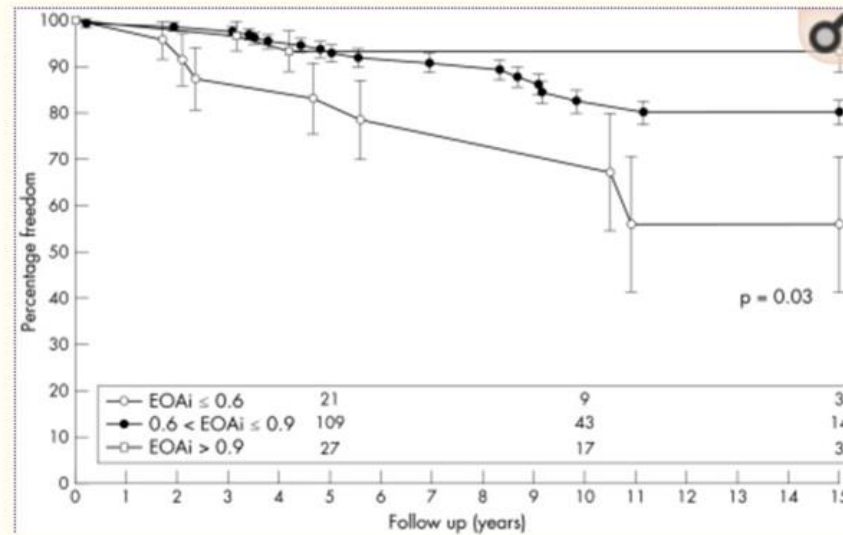






**Figure 1** Kaplan–Meier model of survival after aortic valve-in-valve. (A) All patients included in the analysis. (B) Patients with small bioprostheses (i.e. true internal diameter  $\leq 20$  mm) had worse survival at 8 years. Note that bioprosthetic valves without a known standard for internal diameter size, such as homografts, were not included (from Bleiziffer S, Simonato M, Webb JG, Rodés-Cabau J, Pibarot P, Kornowski R, Kornowski S, Erlebach M, Duncan A, Seiffert M, Unbehaun A, Freker C, Conzelmann L, Wijesundera H, Kim W-K, Montorfano M, Latib A, Tchetché D, Allali A, Abdel-Wahab M, Orvin K, Stortecky S, Nissen H, Holzamer A, Urena M, Testa L, Agrifoglio M, Whisenant B, Sathananthan J, Napodano M, Landi A, Fiorina C, Zittermann A, Veulemans V, Sinning J-M, Saja F, Brecker S, Presbitero P, De Backer O, Søndergaard L, Bruschi G, Franco LN, Petronio AS, Barbanti M, Cerillo A, Spargias K, Schofer J, Cohen M, Muñoz-García A, Finkelstein A, Adam M, Serra V, Teles RC, Champagnac D, Iadanza A, Chodor P, Eggebrecht H, Welsh R, Caixeta A, Salizzoni S, Dager A, Auffret V, Cheema A, Ubben T, Ancona M, Rudolph T, Gummert J, Tseng E, Noble S, Bunc M, Roberts D, Kass M, Gupta A, Leon LB, Dvir D. Long-term outcomes after transcatheter aortic valve implantation in failed bioprosthetic valves. See pages 2731–2742).

# Impact of Prosthesis Patient Mismatch



**Figure 4** Freedom from late cardiac events in patients with non-significant (indexed EOA (EOAi) >0.9 cm<sup>2</sup>/m<sup>2</sup>; squares), moderate (EOAi >0.6 cm<sup>2</sup>/m<sup>2</sup> and ≤0.9 cm<sup>2</sup>/m<sup>2</sup>; solid circles), or severe (EOAi ≤0.6 cm<sup>2</sup>/m<sup>2</sup>; open circles) mismatch. Reproduced from Milano *et al*<sup>11</sup> with permission of the Society of Thoracic Surgeons.

Pibarot P and Dumesnil J: Prosthesis-patient mismatch: definition, clinical impact, and prevention. *Heart* 2006 Aug; 92(8) 1022-1029

# Valve-in-Valve Transcatheter Aortic Valve Replacement Versus Redo Surgical Aortic Valve Replacement

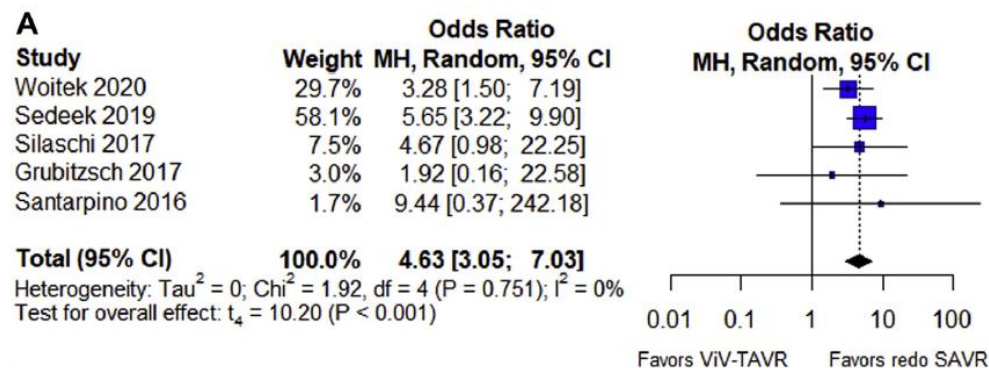
An Updated Meta-Analysis

Mortalité @ 1 an

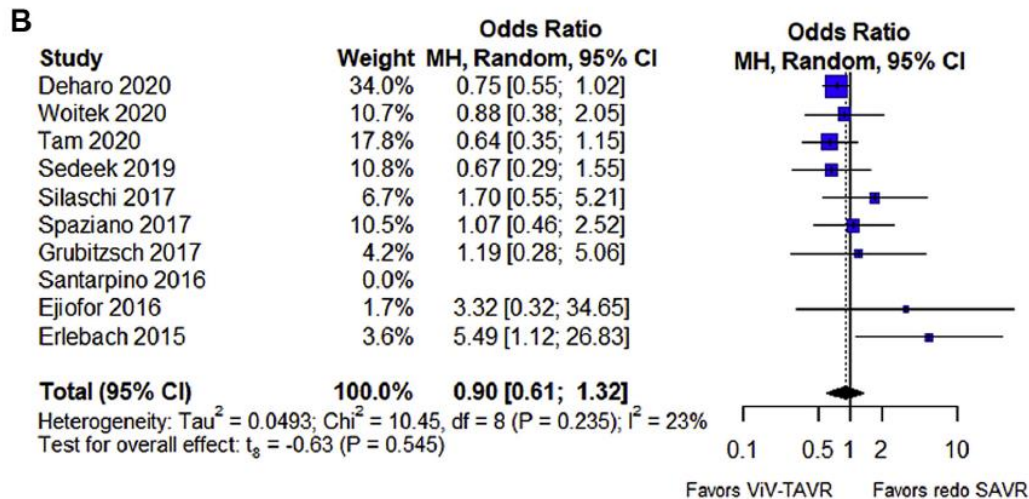
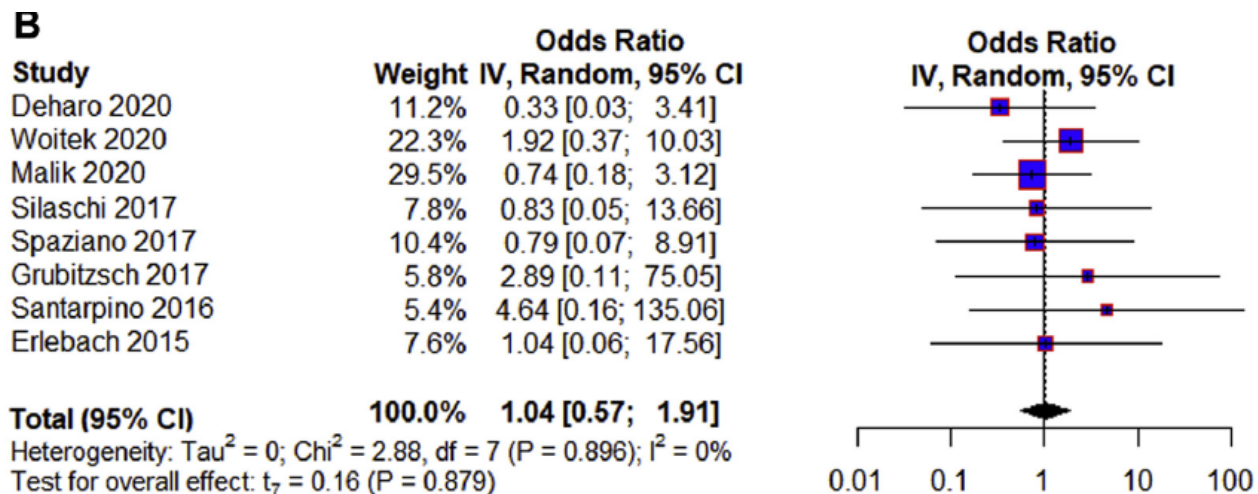


## Severe Patient Prosthesis mismatch

FIGURE 4 Forest Plots for Severe Patient-Prosthesis Mismatch and Myocardial Infarction



## Infarctus



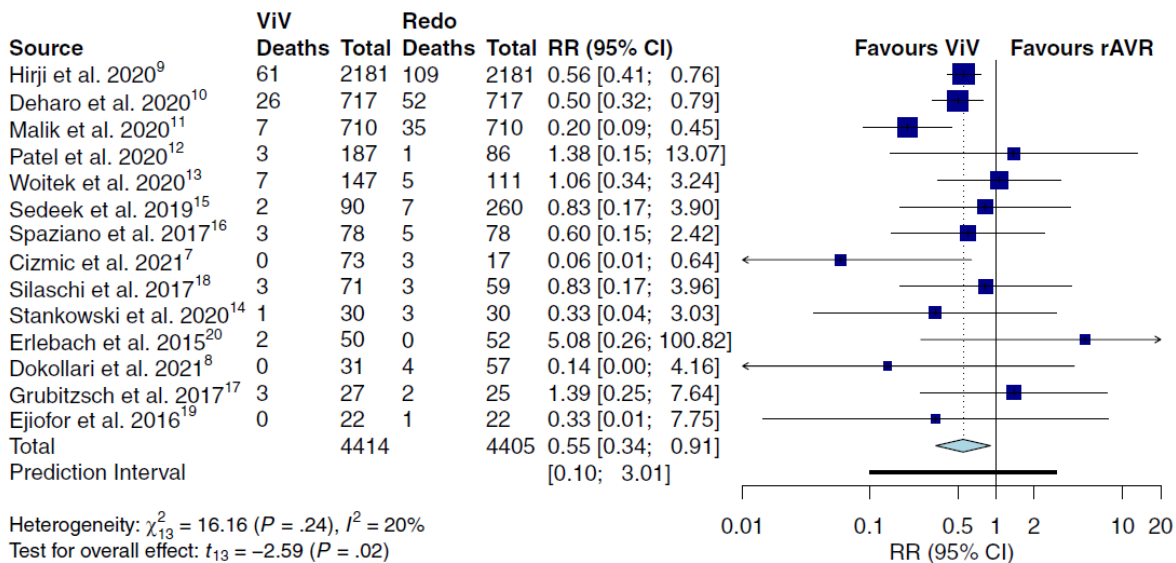
**SYSTEMATIC REVIEW AND META-ANALYSIS**

# Valve-in-Valve Transcatheter Aortic Valve Replacement Versus Redo Surgical Aortic Valve Replacement for Failed Surgical Aortic Bioprostheses: A Systematic Review and Meta-Analysis

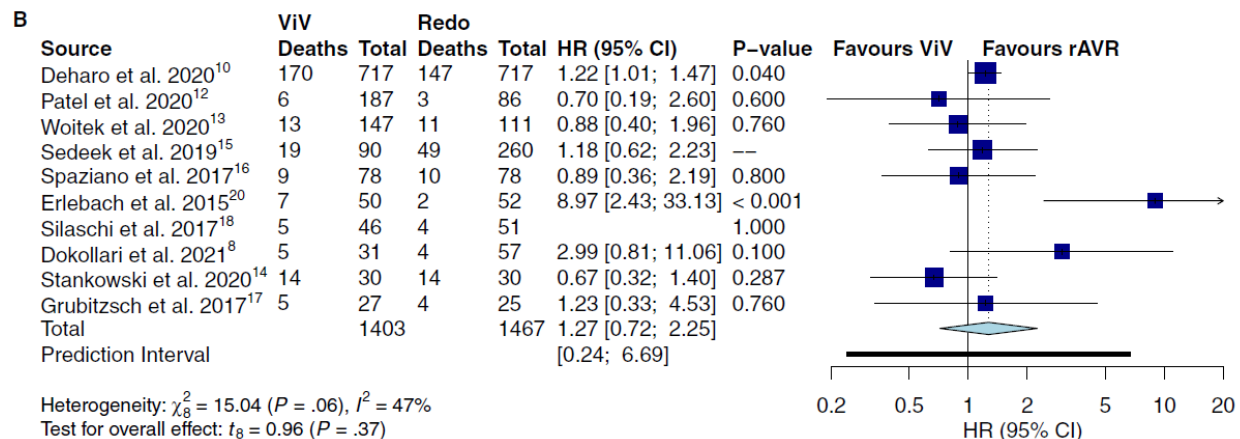
Matthias Raschpichler <sup>1</sup>, MD\*; Suzanne de Waha, MD\*; David Holzhey <sup>2</sup>, MD\*; Guido Schwarzer <sup>3</sup>, PhD; Nir Flint <sup>4</sup>, MD; Danon Kaewkes <sup>5</sup>, MD; Paul T. Bräuchle, MD; Danny Dvir <sup>6</sup>, MD; Raj Makkar, MD; Gorav Ailawadi, MD; Mohamed Abdel-Wahab <sup>7</sup>, MD; Holger Thiele <sup>8</sup>, MD\*; Michael A. Borger <sup>9</sup>, MD\*

*J Am Heart Assoc.* 2022;11:e7965. |

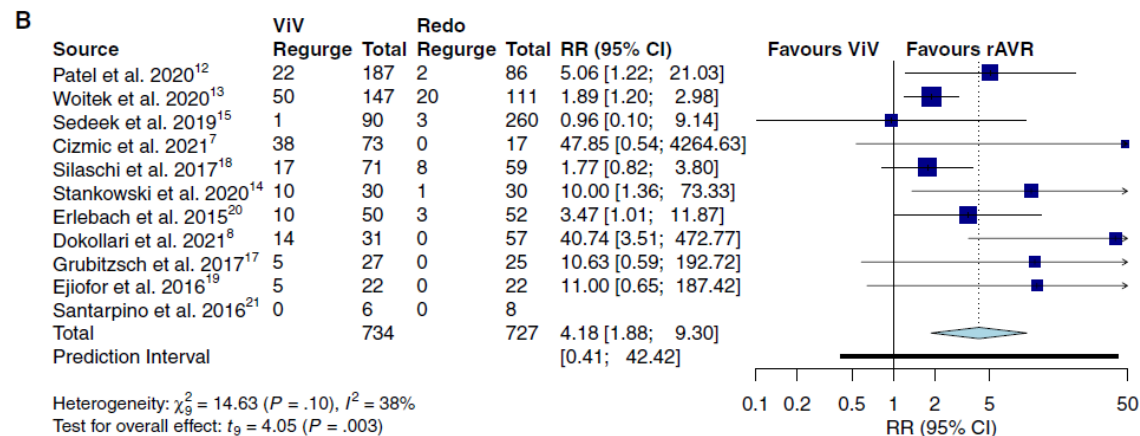
## Mortalité @ 30 J



## Mortalité @ moyen terme



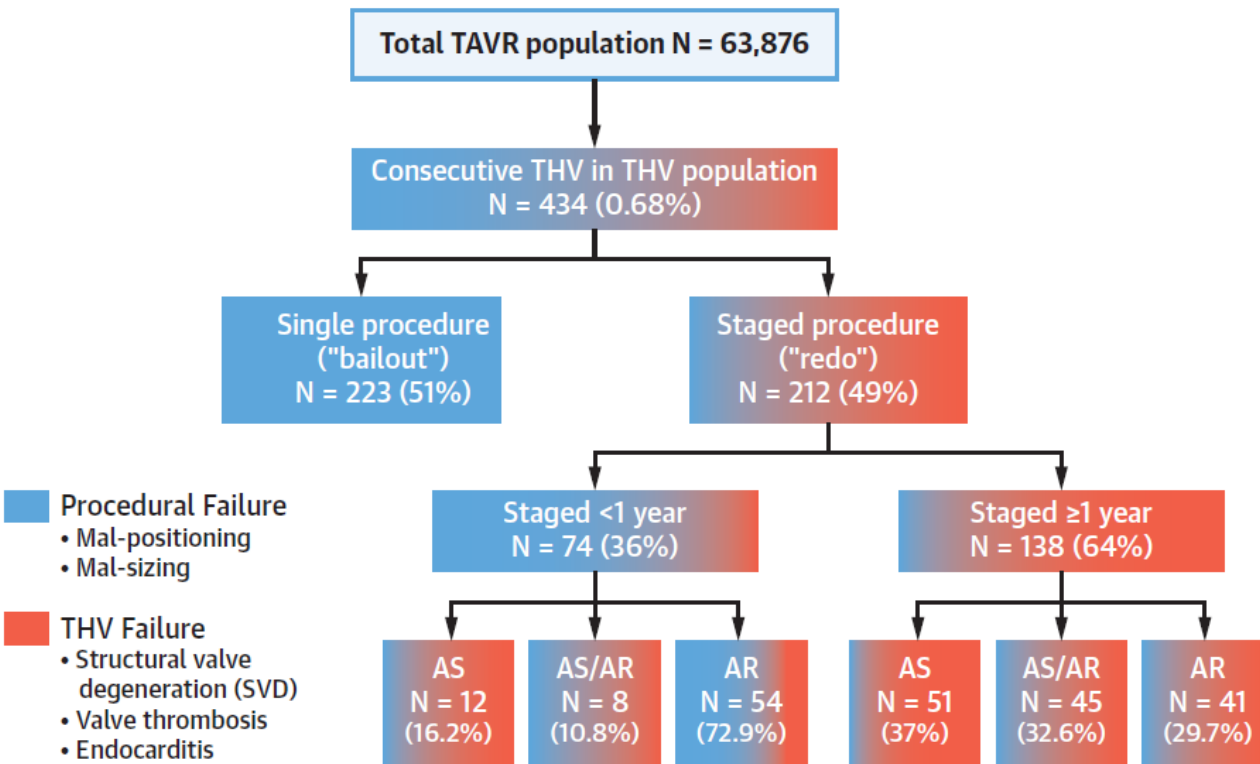
## Mismatch @



# Repeat Transcatheter Aortic Valve Replacement for Transcatheter Prosthesis Dysfunction



**FIGURE 1** Patient Flow Chart



AR = aortic regurgitation; AS = aortic stenosis; TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve.

**CENTRAL ILLUSTRATION** Repeated Transcatheter Aortic Valve Replacement for Transcatheter Heart Valve Dysfunction

	Incidence	Residual Gradient	Coronary Flow Obstruction	Mortality at 30 days
<b>Redo-TAVR For:</b>				
<b>Failed TAVR Valve</b>	0.22%	13 mm Hg	0.7%	1.4%
<b>Failed TAVR Procedure</b>	0.11%	11.5 mm Hg	1.3%	5.4%

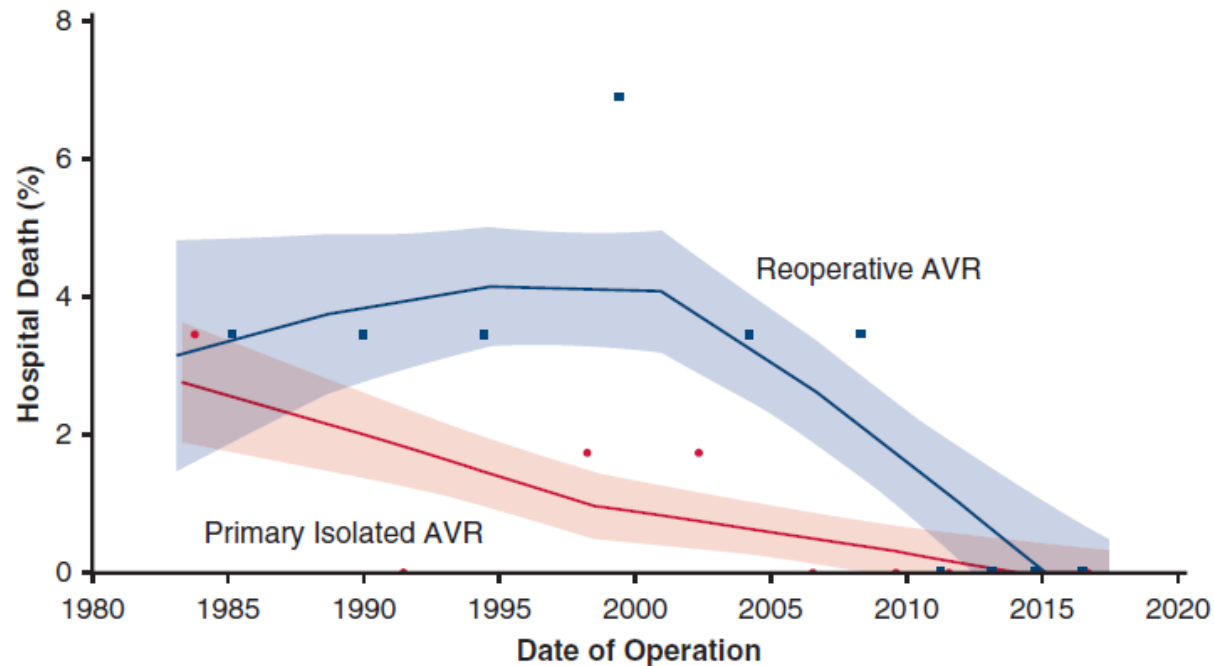
Landes, U. et al. J Am Coll Cardiol. 2020;75(16):1882-93.

Outcomes stratified for patients presented with probable TAVR failure and those with probable THV failure. TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve.

## The decreasing risk of reoperative aortic valve replacement: Implications for valve choice and transcatheter therapy

Rashed Mahboubi, MD,<sup>a</sup> Mona Kakavand, MD,<sup>a</sup> Edward G. Soltesz, MD,<sup>a,b</sup>  
 Jeevanantham Rajeswaran, PhD,<sup>c</sup> Eugene H. Blackstone, MD,<sup>a,c</sup> Lars G. Svensson, MD, PhD,<sup>a,b</sup> and  
 Douglas R. Johnston, MD<sup>a,b</sup>

(J Thorac Cardiovasc Surg 2022; ■ :1-11)

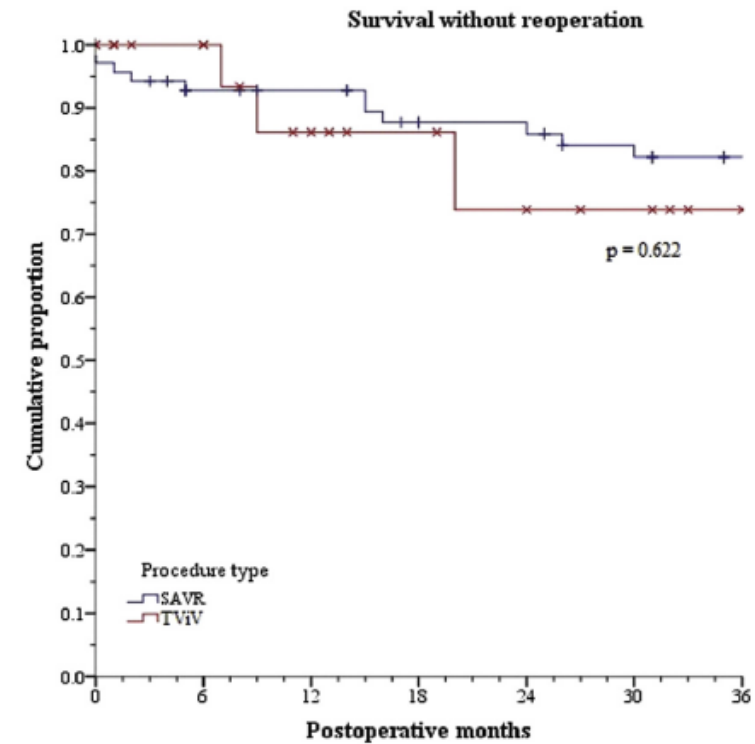


**FIGURE 2.** Association of date of operation and risk of hospital death stratified according to reoperative versus primary isolated surgical aortic valve replacement (AVR) in the matched cohorts. Each *symbol* represents the probability of death over different time frames. Hospital mortality after reoperative AVR decreased from 3.4% in 1985 to 1.3% in 2011, when confidence intervals begin to overlap. This is indicative of absence of a statistically significant difference in hospital death for reoperative and primary isolated surgical AVR. *Solid lines* are nonparametric Loess estimates enclosed within a 68% confidence band. *Red lines and squares* indicate reoperative AVR, and *blue lines and circles* indicate primary isolated AVR.

# Reoperative Surgical Aortic Valve Replacement Versus Transcatheter Valve-in-Valve Replacement for Degenerated Bioprosthetic Aortic Valves

Julius I. Ejiofor, MD, Maroun Yammine, MD, Morgan T. Harloff, MD, Siobhan McGurk, BS, Jochen D. Muehlschlegel, MD, MMS, Prem S. Shekar, MD, Lawrence H. Cohn, MD, Pinak Shah, MD, and Tsuyoshi Kaneko, MD

Division of Cardiac Surgery, Department of Anesthesiology, Perioperative and Pain Medicine, and Division of Cardiology, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts



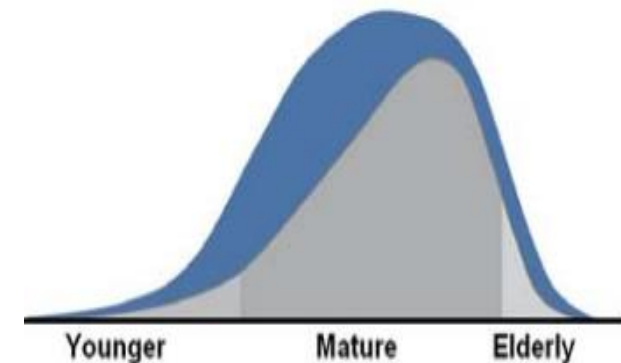
N at risk

Starting period (month)	0	6	12	18	24	30
SAVR	22	17	16	14	14	14
TViV	20	15	10	8	5	3

Fig 2. Kaplan-Meier survival curve for the 22 matched pairs by procedure type—surgical aortic valve replacement (SAVR [blue line]) and transcatheter valve in valve replacement (TViV [red line]) out to 3 years.

# Expanding heart valve opportunity

- Aging global populations in developed markets
- Expanding tissue valve segment:
  - Addressing younger patients with innovative tissue valve solutions
  - Growing incomes drive adoption of tissue valves in emerging markets



Emerging  
Markets



# The Dilemma

## Valve Selection: Open Surgical

### Mechanical Valves



### Tissue Valves



**Table 10** Target international normalized ratio for mechanical prostheses

Prosthesis thrombogenicity	Patient-related risk factors <sup>a</sup>	
	None	≥ 1 risk factor
Low <sup>b</sup>	2.5	3.0
Medium <sup>c</sup>	3.0	3.5
High <sup>d</sup>	3.5	4.0

© ESC/EACTS 2021

- **Pros:**  
Likely 1
- **Cons:**  
Anticoag  
elevated

AF = atrial fibrillation; LVEF = left ventricular ejection fraction.

<sup>a</sup>Mitral or tricuspid valve replacement; previous thromboembolism; AF; mitral stenosis of any degree; LVEF <35%.

<sup>b</sup>Carbomedics, Medtronic Hall, ATS, Medtronic Open-Pivot, St Jude Medical, Sorin Bicarbon.

<sup>c</sup>Other bileaflet valves with insufficient data.

<sup>d</sup>Lillehei-Kaster, Omniscience, Starr-Edwards (ball-cage), Bjork-Shiley and other tilting-disc valves.

or most

rioration,  
intervention

d in young pts.

# 2017 AHA/ACC Guidelines

## Valve selection: Patient age considerations

### Mechanical

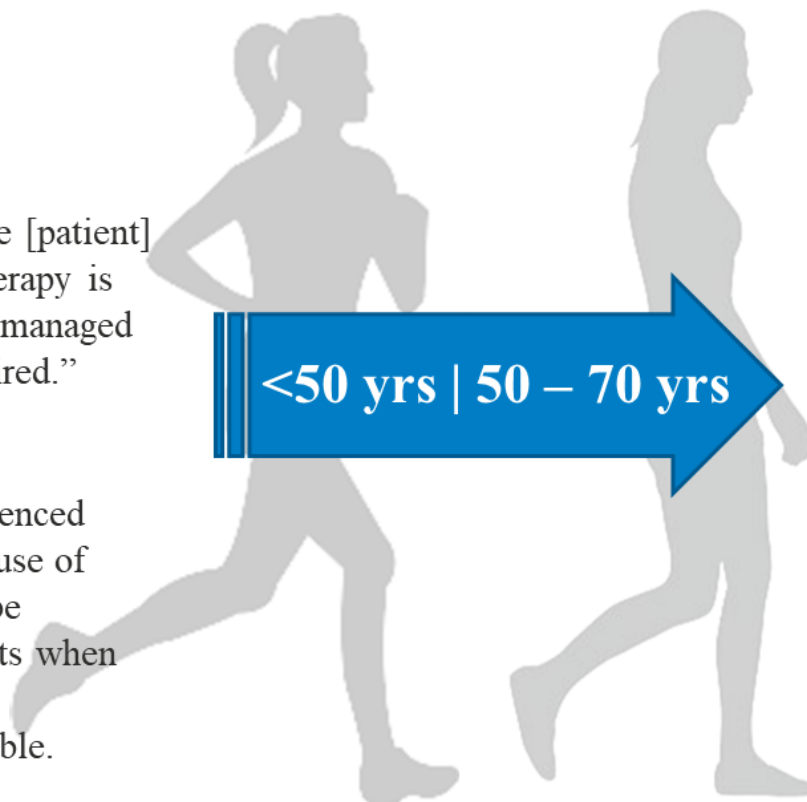
- Favored Choice

### Bioprosthetic

- Recommended for “any age [patient] for whom anticoagulant therapy is contraindicated, cannot be managed appropriately, or is not desired.”

### Ross Procedure

- When performed by experienced surgeon, the less common use of pulmonary autograft may be considered in young patients when VKA anticoagulation is contraindicated or undesirable.

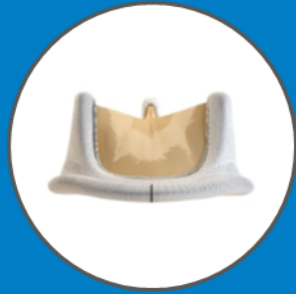


### Mechanical or Bioprosthetic

- “...it is reasonable to individualize the choice of either a mechanical or bioprosthetic valve prosthesis on the basis of individual patient factors and preferences, after full discussion of the trade-offs involved.”<sup>1</sup>

Nishimura R et al., 2017 AHA/ACC Guidelines. Circulation. 2017;135:e1159–e1195.

## What does the 55 year old patient hear??

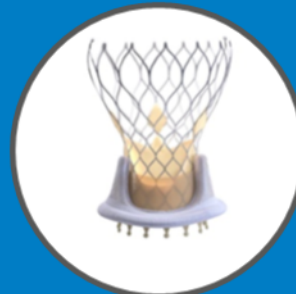


55 years

**Older therapy**

**More invasive w/ Long recovery**

**Valve durability 15-20 years**



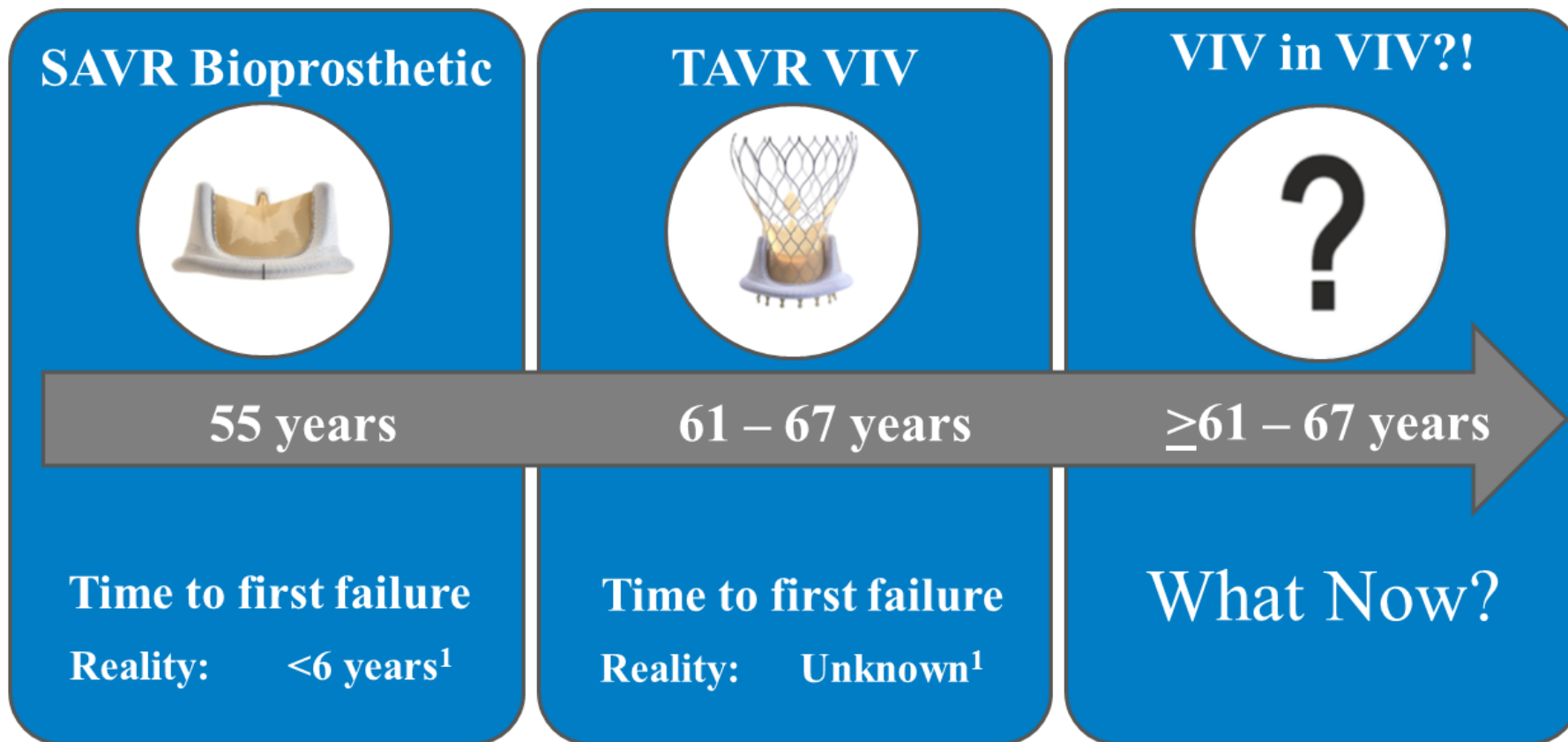
70 – 75 years

**Newer more exciting therapy**

**Less invasive w/ short recovery**

**Valve durability reminder of life**

## What the 55 year old patient should know:

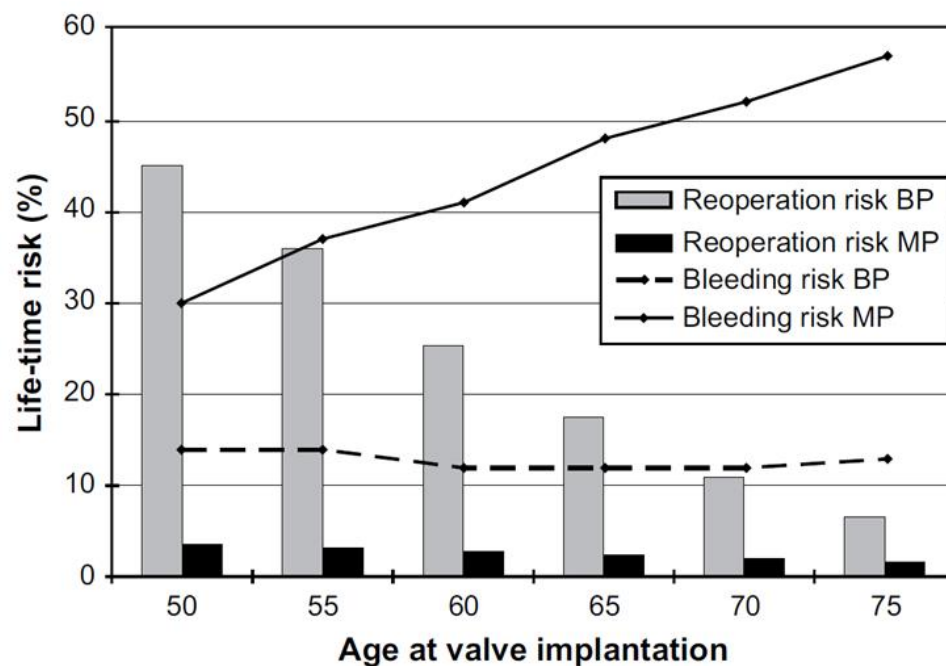


Time since last SAVR for VIV, median (IQR), yrs.: 9 (6-12)

## Risk of Reoperation

### Bioprosthetic vs. Mechanical Aortic Valves

For 55 year old patients, risk of needing reoperation is ~10x higher than mechanical valves.



van Geldorp M et al., J Thorac Cardiovasc Surg. 2009;137:881-6.

# Longevity of Bioprosthetic Valves

Patients 50-65 years

Perception: 20 year valve durability

Reality:

- Mean time to SVD was  $13 \pm 5$  years
- Risk of Reoperation due to SVD
  - ~10% at 10 years
  - ~25% at 15 years
  - ~50% by 20 years
- Only 3% of population reach 20 years

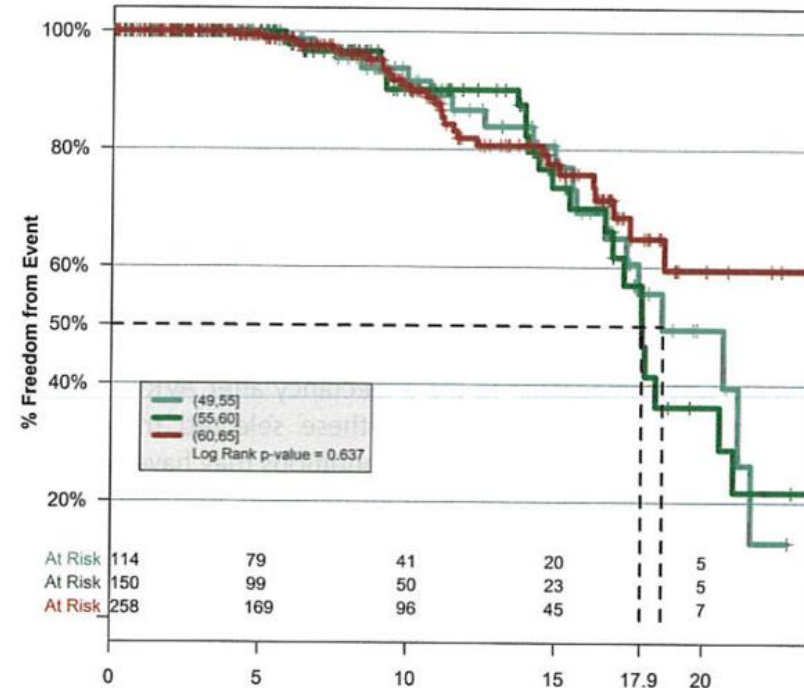


Figure 4: Kaplan-Meier estimates of freedom from reoperation due to structural valve deterioration (SVD) by age group. Age was not a significant risk factor among this age subgroup. SVD: structural valve deterioration.

Bourguignon T et al., Eur J Cardiothorac Surg. 2016;1462-8.

# Longevity of Bioprosthetic Valves

## Patients <65 years

### Perception:

“Excellent long-term durability has previously been reported when using the CE pericardial valve at select institutions, and our experience reaffirms these findings.”

### Reality:

- Patients <65 years start to receive explants at 7 years
- Limited long-term data on <65 years patients (6 patients at 12.5 years)
- Freedom from reoperation for SVD at 12.5 years was:
  - 34.7% for patients <65 years
  - 89.4% for patients 65 to 75 years
  - 99.5% for patients >75 years

### Freedom from SVD

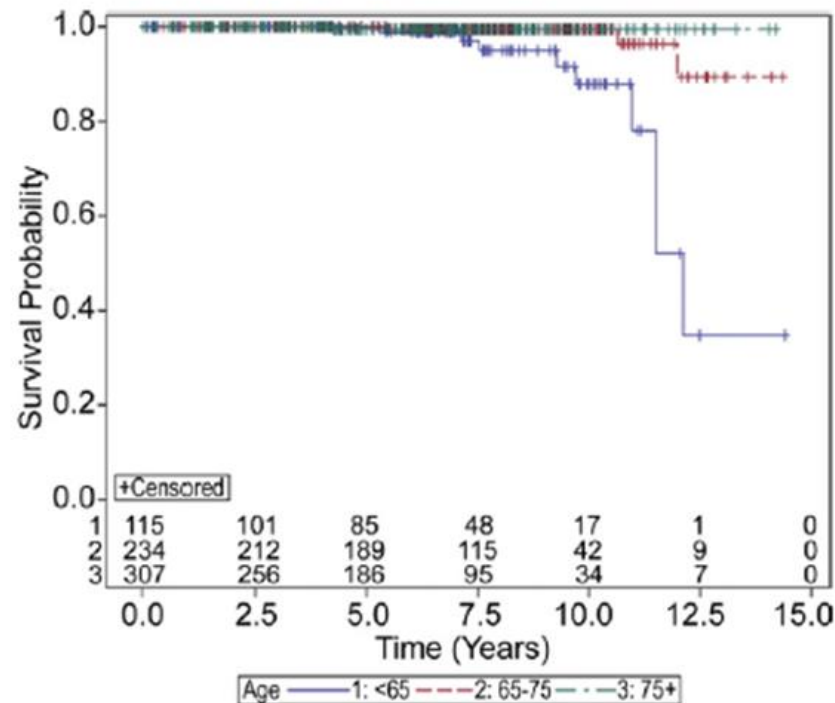


Fig 2. Age-stratified freedom from structural valve deterioration necessitating reoperation using the Carpentier-Edwards pericardial aortic bioprosthesis. (Blue line = age less than 65 years; red line = age 65 to 75 years; green line = age 75 years or more.)

McClure R et al., Ann Thorac Surg. 2010;89:1410–6.

# Bioprosthetic Valves in Patients $\leq 60$ years

## Perception:

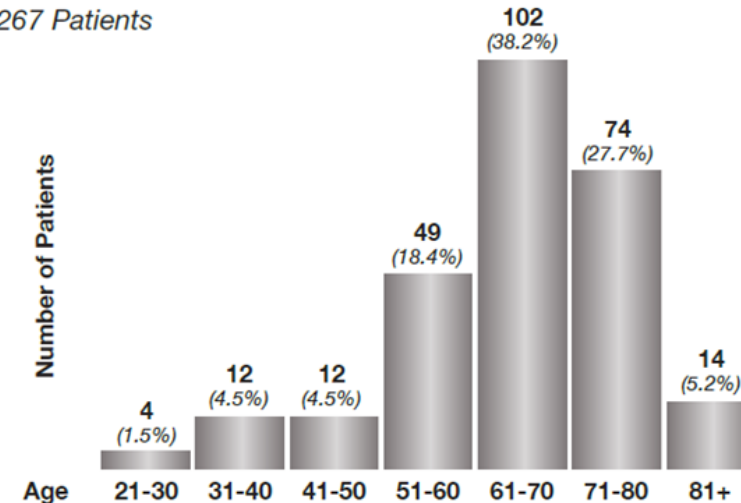
- 20 year valve durability for all ages

## Reality:

- Durability data for patients  $\leq 60$  years is omitted
- All explanted valves due to SVD were adjudicated prior to being included/excluded from data

Figure 1: Age Distribution at Implant

267 Patients



Durability data omitted for these patients  $< 60$  years (28%)



## Full Disclosure

### Young Patients Who Choose a Tissue Valve

“Some otherwise healthy young patients may choose a bioprosthesis to avoid anticoagulation with warfarin, but this decision should be made with the full understanding that:

- **the choice may increase late mortality,**
- oral anticoagulation may be necessary in the future,
- subsequent management of prosthesis failure with transcatheter valve-in-valve insertion is an attractive but unproven long-term strategy.”



Anticoagulation



VIV Unproven

Suri R and SchaffH. Circulation. 2013;128:1372-80.

# Advancement of Anticalcification Treatment

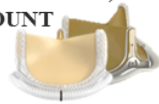
## Bioprosthetic Valves



**Perception:** New additions of various chemical treatments for bioprosthetic valves have significantly improve their longevity.

**Reality:** ‘No long-term clinical data is available’

Edwards® RESILIA,  
PERIMOUNT



“*No long-term clinical data* are available that evaluate the impact of RESILIA or PERIMOUNT tissue valves in patients.”<sup>1,2</sup>

Medtronic®  
Mosaic®



“*No clinical data* are available which evaluate the long-term impact of AOA® tissue treatment and the Physiologic Fixation process in patients.”<sup>3</sup>

St. Jude Medical®  
Trifecta™



“There is *no clinical data* currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.”<sup>4</sup>

1. Edwards Lifesciences, Resilia Tissue. [http://www.edwards.com/\\_layouts/Edwards.moss.web.webapp/resilia-eu/](http://www.edwards.com/_layouts/Edwards.moss.web.webapp/resilia-eu/), downloaded on 12/08/2017.
2. Edwards Lifesciences website. <http://www.edwards.com/devices/heart-valves/aortic>, downloaded on 07/19/2016.
3. Medtronic website. <http://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/heart-valves-surgical/mosaic-mosaic-ultra-bioprostheses.html>, downloaded on 07/26/16.
4. St. Jude Medical website. <https://www.sjm.com/en/professionals/feature-d-products/structural-heart/tissue-heart-valves/aortic-and-mitral-valves/trifecta-valve>, downloaded on 07/26/16.

# Edwards' INSPIRIS RESILIA – VFit Technology

## Perception:

- The need for future surgical reoperations due to SVD of bioprosthesis can be avoided with TAVR Valve-In-Valve (VIV).
- The INSPIRIS RESILIA VFit\* SAVR allows the valve to be enlarged due to an expandable frame.

**Reality:** Safety, effectiveness, and long-term durability of expanding the frame of the INSPIRIS RESILIA for valve-in-valve procedures have not been established.

From Edward's website: \***“These features have not been observed in clinical studies to establish the safety and effectiveness ... for use in valve-in-valve.”**

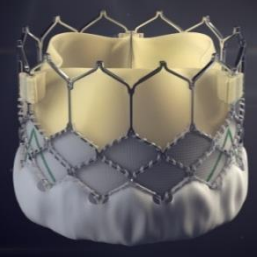


25 mm  
Inspiris  
Resilia

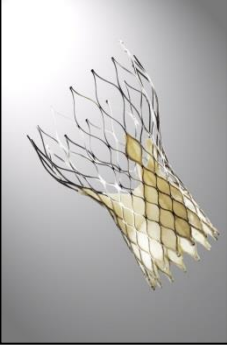


23 mm  
Sapien XT

Edwards Lifesciences, Resilia Tissue. <http://www.edwards.com/layouts/Edwards.moss.web.webapp/resilia-eu/>, downloaded on 12/08/2017.



## Take Home Message



VIV donne de bons résultats immédiat  
Attention au Mismatch

Choix de la taille de la valve chirurgicale est primordial  
Toujours choisir la valve la plus grande  
Position supra annulaire  
Elargissement de l'anneau aortique

En cas de petit anneau discuter une prothèse mécanique