

# Remplacement valvulaire aortique chez le sujet de moins de 75 ans: place du TAVI

Gauthier MOUILLET

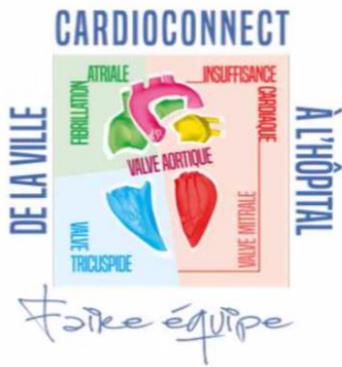
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# Recommandations européennes 2017

SAVR is recommended in patients a not included in these scores, such a	<a href="https://academic.oup.com/DocumentLibrary/EHJ/SupplementaryData/VHDSection.pdf">https://academic.oup.com/DocumentLibrary/EHJ/SupplementaryData/VHDSection.pdf</a>	Favours TAVI	Favours SAVR	Risk factors	I	B
<p>In patients who are at increased sur in these scores such as frailty, porc Heart Team according to the indivi moral access.<sup>91,94-102</sup></p>	<b>Clinical characteristics</b>			included by the r transfe-	I	B
	STS/EuroSCORE II <4% (logistic EuroSCORE I <10%) <sup>a</sup>		+		I	B
	STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%) <sup>a</sup>	+			I	B
	Presence of severe comorbidity (not adequately reflected by scores)	+			I	B
	Age <75 years				I	B
	Age ≥75 years	+			I	B
	Previous cardiac surgery	+			I	B
	Frailty <sup>b</sup>	+			I	B
	Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+			I	B
	Suspicion of endocarditis				I	B



# Recommandations européennes 2017

- <75 ans et STS < 4 % :  
RVAo Niveau IB
- <75 ans et STS >4 % :  
RVAo>TAVI
- > 75 ans et STS>4%:  
TAVI > RVAo
- Fin de la discussion ?



ESC

European Society  
of Cardiology

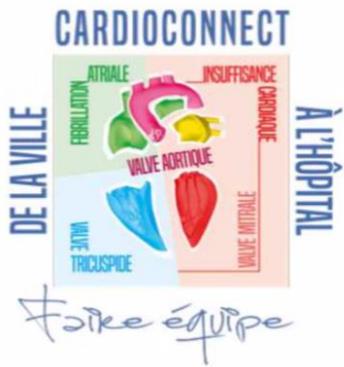
European Heart Journal (2017) 38, 2739–2791  
doi:10.1093/eurheartj/ehx391

ESC/EACTS GUIDELINES

## 2017 ESC/EACTS Guidelines for the management of valvular heart disease

The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Helmut Baumgartner\* (ESC Chairperson) (Germany), Volkmar Falk\*<sup>1</sup> (EACTS Chairperson) (Germany), Jeroen J. Bax (The Netherlands), Michele De Bonis<sup>1</sup> (Italy), Christian Hamm (Germany), Per Johan Holm (Sweden), Bernard Lung (France), Patrizio Lancellotti (Belgium), Emmanuel Lansac<sup>1</sup> (France), Daniel Rodriguez Muñoz (Spain), Raphael Rosenhek (Austria), Johan Sjögren<sup>1</sup> (Sweden), Pilar Tornos Mas (Spain), Alec Vahanian (France), Thomas Walther<sup>1</sup> (Germany), Olaf Wendler<sup>1</sup> (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain)



# Quelques cas particuliers ?

- Patients <75 ans Redux (Valve in valve)



# Cas particulier: Valve in valve

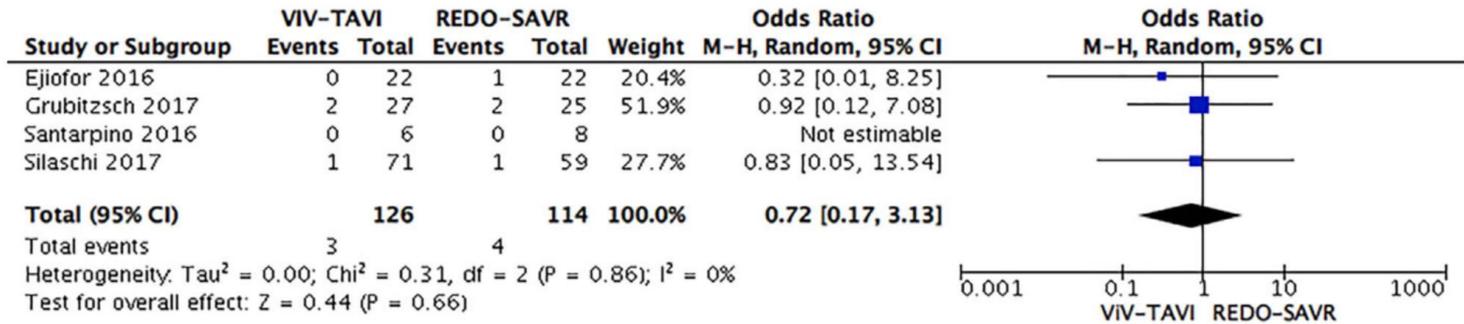


FIGURE 2 Forest plot for procedural mortality

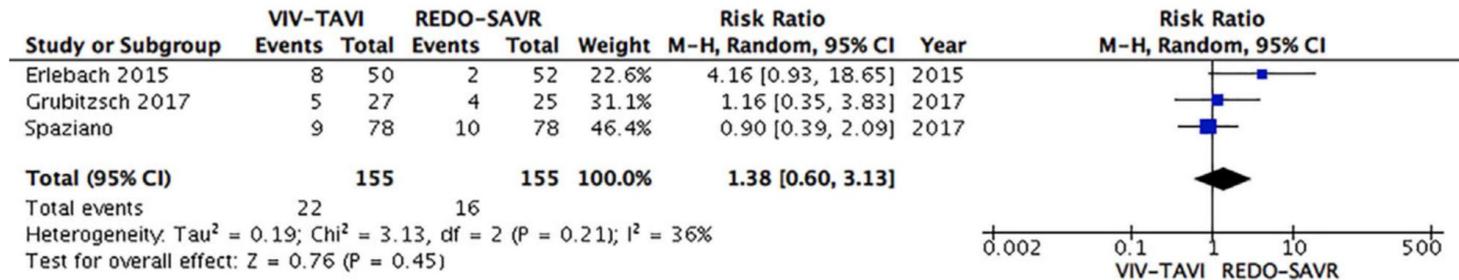
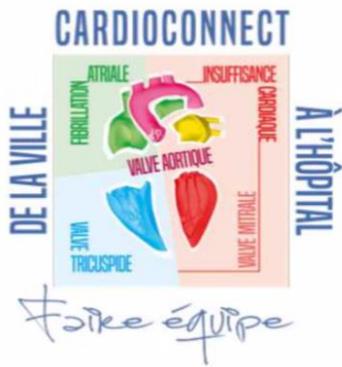


FIGURE 4 Forest plot for 1 year mortality

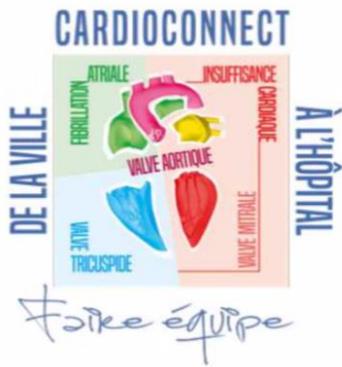


# Quelques cas particuliers ?

- Patients <75 ans Redux (Valve in valve)
- Co-Morbidités non évaluées par scores:
  - Cirrhose
  - Aorte Porcelaine
  - Fragilité
  - Thorax radique



Peut on proposer en 2019 un TAVI à un patient de **<75 ans** et à **faible risque** pour le traitement d'une sténose aortique serrée ?



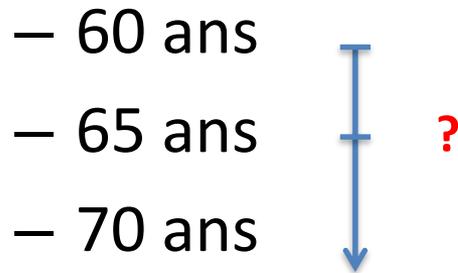
Peut on proposer en 2019 un TAVI à un patient de <75 ans et à faible risque ?

- Question 1: borne de risque opératoire minimal ?

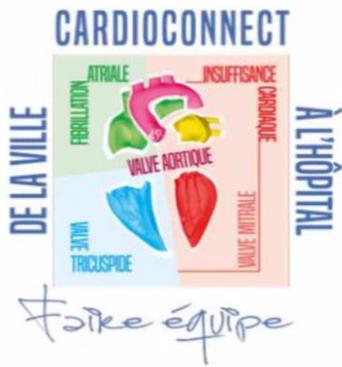


La procédure TAVI (vs RVAo) est elle suffisamment sécurisée pour être proposée à des patients bas risque ?

- Question 2: Borne d'âge minimale ?



La durabilité des dispositifs Percutanés (Vs Bioprothèses chirurgicales) est elle acceptable pour des patients <75 ans.



# Evaluation RVAo sous CEC Vs TAVI chez les patients à bas risque ?

- Essai PARTNER 3
- Critères d'inclusions: STS < 4%
- Evaluation à 1 an sur un critère composite: Mortalité (toute cause), AVC et Hospitalisation
- Design mixte: non-infériorité/Supériorité

**The NEW ENGLAND JOURNAL of MEDICINE**

ESTABLISHED IN 1812      MAY 2, 2019      VOL. 380 NO. 18

**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\*

**ABSTRACT**

**BACKGROUND**  
Among patients with aortic stenosis who are at intermediate or high risk for death with surgery, major outcomes are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. There is insufficient evidence regarding the comparison of the two procedures in patients who are at low risk.

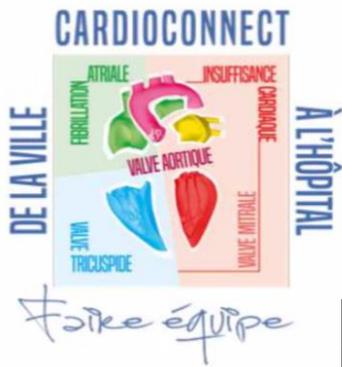
**METHODS**  
We randomly assigned patients with severe aortic stenosis and low surgical risk to undergo either TAVR with transfemoral placement of a balloon-expandable valve or surgery. The primary end point was a composite of death, stroke, or rehospitalization at 1 year. Both noninferiority testing (with a prespecified margin of 6 percentage points) and superiority testing were performed in the as-treated population.

**RESULTS**  
At 71 centers, 1000 patients underwent randomization. The mean age of the patients was 73 years, and the mean Society of Thoracic Surgeons risk score was 1.9% (with scores ranging from 0 to 100% and higher scores indicating a greater risk of death within 30 days after the procedure). The Kaplan-Meier estimate of the rate of the primary composite end point at 1 year was significantly lower in the TAVR group than in the surgery group (8.5% vs. 15.1%; absolute difference, -6.6 percentage points; 95% confidence interval [CI], -10.8 to -2.5; P<0.001 for noninferiority; hazard ratio, 0.54; 95% CI, 0.37 to 0.79; P=0.001 for superiority). At 30 days, TAVR resulted in a lower rate of stroke than surgery (P=0.02) and in lower rates of death or stroke (P=0.01) and new-onset atrial fibrillation (P<0.001). TAVR also resulted in a shorter index hospitalization than surgery (P<0.001) and in a lower risk of a poor treatment outcome (death or a low Kansas City Cardiomyopathy Questionnaire score) at 30 days (P<0.001). There were no significant between-group differences in major vascular complications, new permanent pacemaker insertions, or moderate or severe paravalvular regurgitation.

**CONCLUSIONS**  
Among patients with severe aortic stenosis who were at low surgical risk, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVR than with surgery. (Funded by Edwards Lifesciences; PARTNER 3 ClinicalTrials.gov number, NCT02675114.)

\*A complete list of the PARTNER 3 Investigators is provided in the Supplementary Appendix, available at NEJM.org.  
This article was published on March 16, 2019, at NEJM.org.  
N Engl J Med 2019;380:1695-705.  
DOI: 10.1056/NEJMoa1814052  
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# Mai 2019: PARTNER 3

**Table 1. Characteristics of the Patients at Baseline.\***

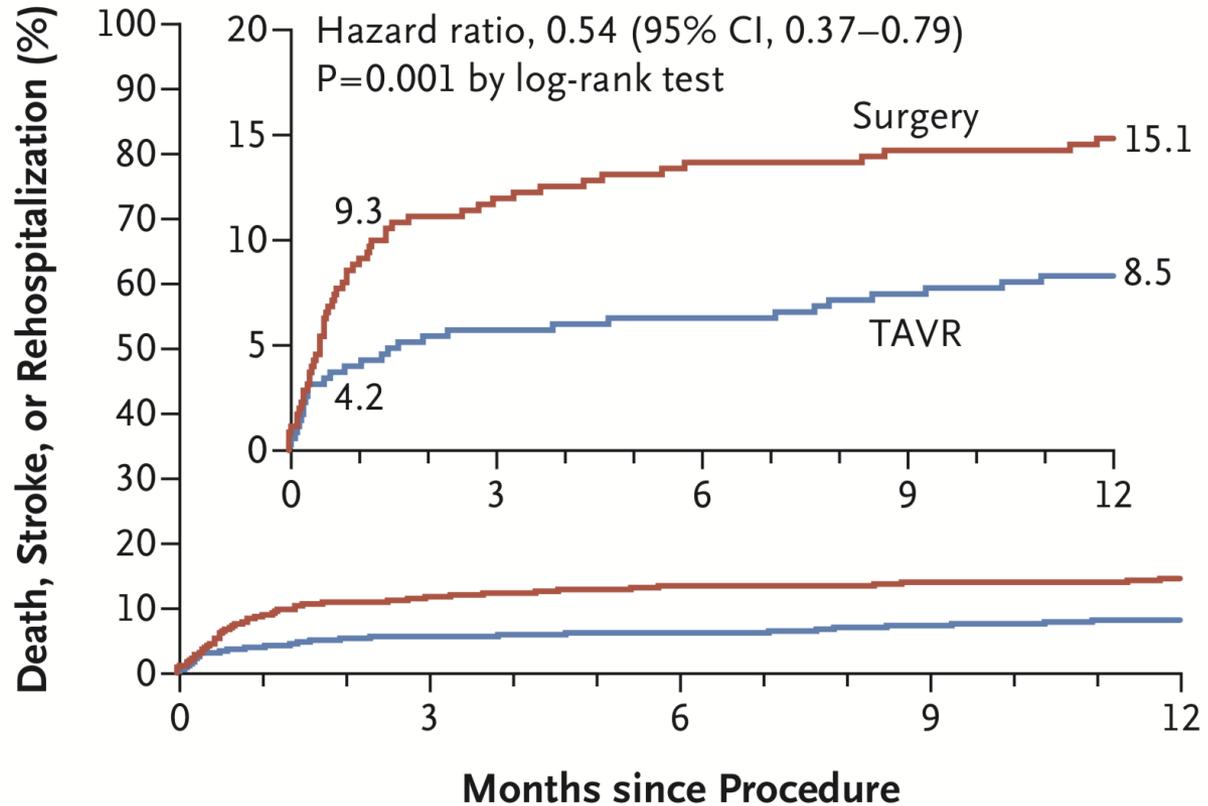
Characteristic	TAVR (N = 496)	Surgery (N = 454)
Age — yr	73.3±5.8	73.6±6.1
Male sex — no. (%)	335 (67.3)	323 (71.1)
Nonwhite race or ethnic group — no. (%)†	38 (7.7)	45 (9.9)
Body-mass index‡	30.7±5.5	30.3±5.1
STS score§	1.9±0.7	1.9±0.6
EuroSCORE II score¶	1.5±1.2	1.5±0.9
NYHA class III or IV — no. (%)	155 (31.2)	108 (23.8)
Coronary artery disease — no./total no. (%)	137/494 (27.7)	127/454 (28.0)
Previous myocardial infarction — no./total no. (%)	28/495 (5.7)	26/452 (5.8)
Previous stroke — no./total no. (%)	17/496 (3.4)	23/453 (5.1)
Carotid disease — no./total no. (%)	61/481 (12.7)	50/442 (11.3)
Peripheral vascular disease — no./total no. (%)	34/494 (6.9)	33/453 (7.3)
COPD — no./total no. (%)	25/495 (5.1)	28/454 (6.2)
Creatinine >2 mg/dl — no. (%)	1 (0.2)	1 (0.2)
Diabetes — no./total no. (%)	155/496 (31.2)	137/453 (30.2)
Atrial fibrillation — no./total no. (%)	78/496 (15.7)	85/453 (18.8)
Permanent pacemaker — no. (%)	12 (2.4)	13 (2.9)
Left bundle-branch block — no./total no. (%)	15/495 (3.0)	15/453 (3.3)
Right bundle-branch block — no./total no. (%)	51/495 (10.3)	62/453 (13.7)
Overall frailty — no./total no. (%)**	0/495	0/453
Pulmonary hypertension — no./total no. (%)	23/495 (4.6)	24/454 (5.3)
Aortic-valve area — cm <sup>2</sup>	0.8±0.2	0.8±0.2
Aortic-valve gradient — mm Hg	49.4±12.8	48.3±11.8
Left ventricular ejection fraction — %	65.7±9.0	66.2±8.6
Moderate or severe regurgitation — no./total no. (%)		
Aortic	19/484 (3.9)	11/446 (2.5)
Mitral	6/477 (1.3)	14/437 (3.2)
Tricuspid	8/473 (1.7)	10/430 (2.3)
Systolic annular perimeter on CT — mm	78.1±6.9	78.6±7.2
Systolic annular area on CT — mm <sup>2</sup>	473.5±83.3	479.6±87.6





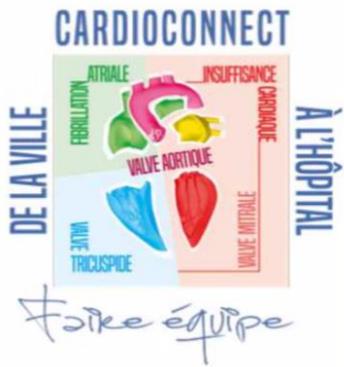
# Mai 2019: PARTNER 3

A



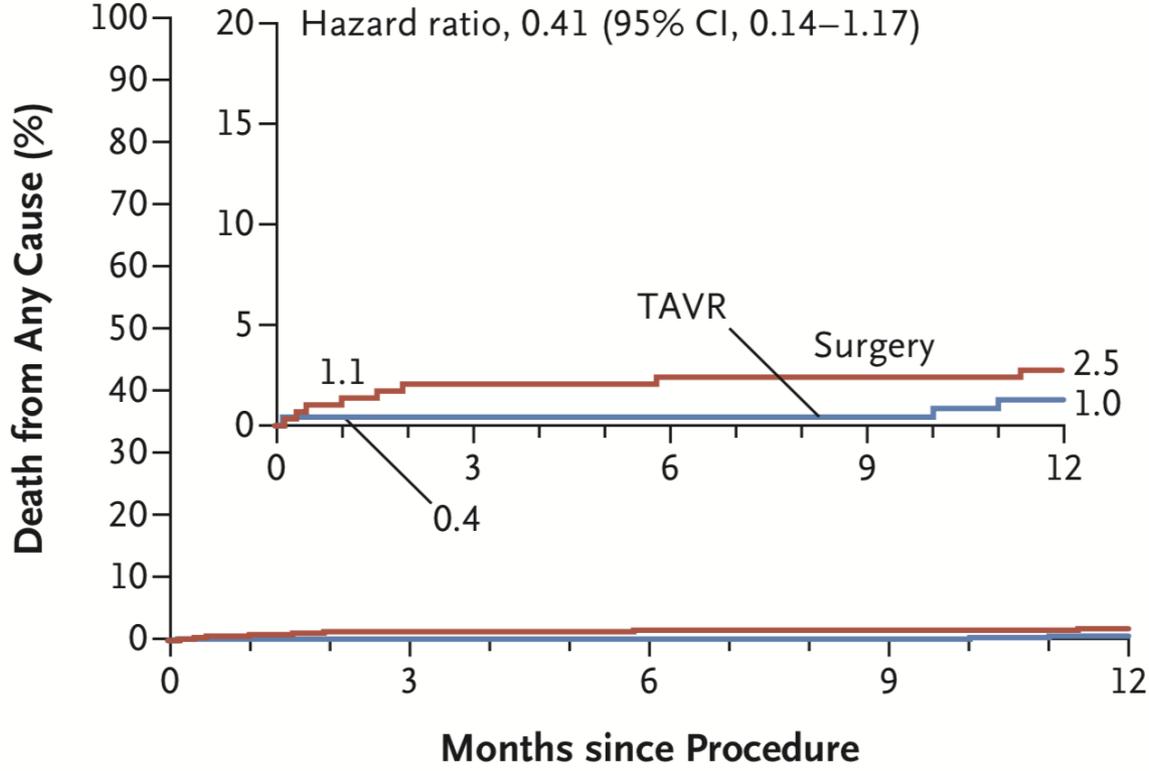
**No. at Risk**

Surgery	454	408	390	381	377	374
TAVR	496	475	467	462	456	451



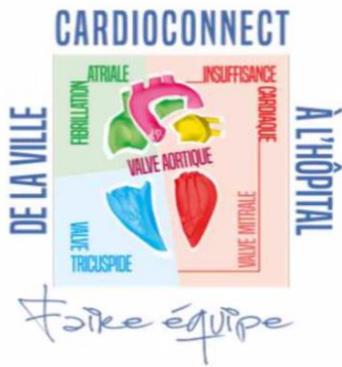
# Mai 2019: PARTNER 3

**B**

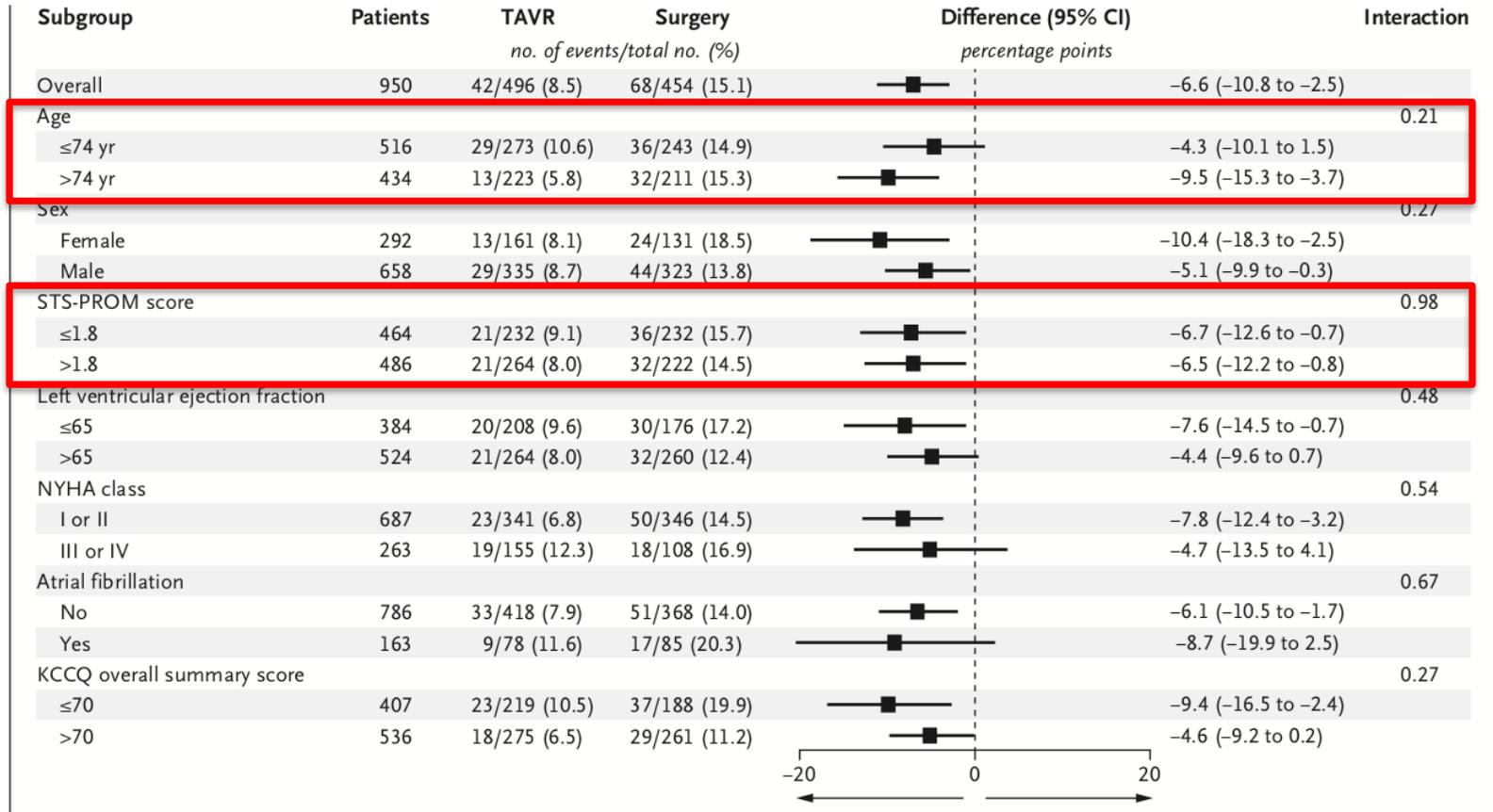


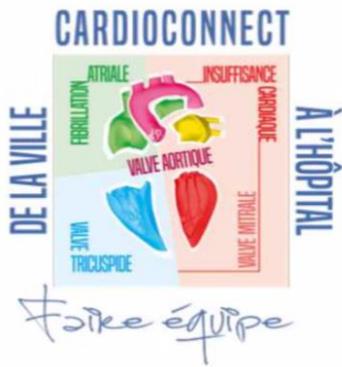
**No. at Risk**

Surgery	454	445	438	433	431	427
TAVR	496	494	494	493	492	488



# Mai 2019: PARTNER 3





# EVOLUT Low Risk

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.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tarvir 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\*

ABSTRACT

BACKGROUND

Transcatheter aortic-valve replacement (TAVR) is an alternative to surgery in patients with severe aortic stenosis who are at increased risk for death from surgery; less is known about TAVR in low-risk patients.

METHODS

We performed a randomized noninferiority trial in which TAVR with a self-expanding supraannular bioprosthesis was compared with surgical aortic-valve replacement in patients who had severe aortic stenosis and were at low surgical risk. When 850 patients had reached 12-month follow-up, we analyzed data regarding the primary end point, a composite of death or disabling stroke at 24 months, using Bayesian methods.

RESULTS

Of the 1468 patients who underwent randomization, an attempted TAVR or surgical procedure was performed in 1403. The patients' mean age was 74 years. The 24-month estimated incidence of the primary end point was 5.3% in the TAVR group and 6.7% in the surgery group (difference, -1.4 percentage points; 95% Bayesian credible interval for difference, -4.9 to 2.1; posterior probability of noninferiority >0.999). At 30 days, patients who had undergone TAVR, as compared with surgery, had a lower incidence of disabling stroke (0.5% vs. 1.7%), bleeding complications (2.4% vs. 7.5%), acute kidney injury (0.9% vs. 2.8%), and atrial fibrillation (7.7% vs. 35.4%) and a higher incidence of moderate or severe aortic regurgitation (3.5% vs. 0.5%) and pacemaker implantation (17.4% vs. 6.1%). At 12 months, patients in the TAVR group had lower aortic-valve gradients than those in the surgery group (8.6 mm Hg vs. 11.2 mm Hg) and larger effective orifice areas (2.3 cm<sup>2</sup> vs. 2.0 cm<sup>2</sup>).

CONCLUSIONS

In patients with severe aortic stenosis who were at low surgical risk, TAVR with a self-expanding supraannular bioprosthesis was noninferior to surgery with respect to the composite end point of death or disabling stroke at 24 months. (Funded by Medtronic; ClinicalTrials.gov number, NCT02701283.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Popma at Interventional Cardiology, Beth Israel Deaconess Medical Center, 185 Pilgrim Rd., Boston, MA 02215, or at jpopma@bidmc.harvard.edu.

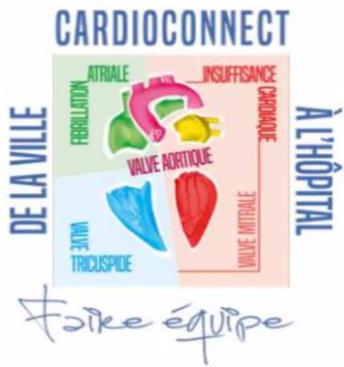
\*A complete list of investigators, institutions, and research personnel participating in the Evolut Low Risk Trial is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on March 16, 2019, at NEJM.org.

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DOI: 10.1056/NEJMoa1816885  
Copyright © 2019 Massachusetts Medical Society.

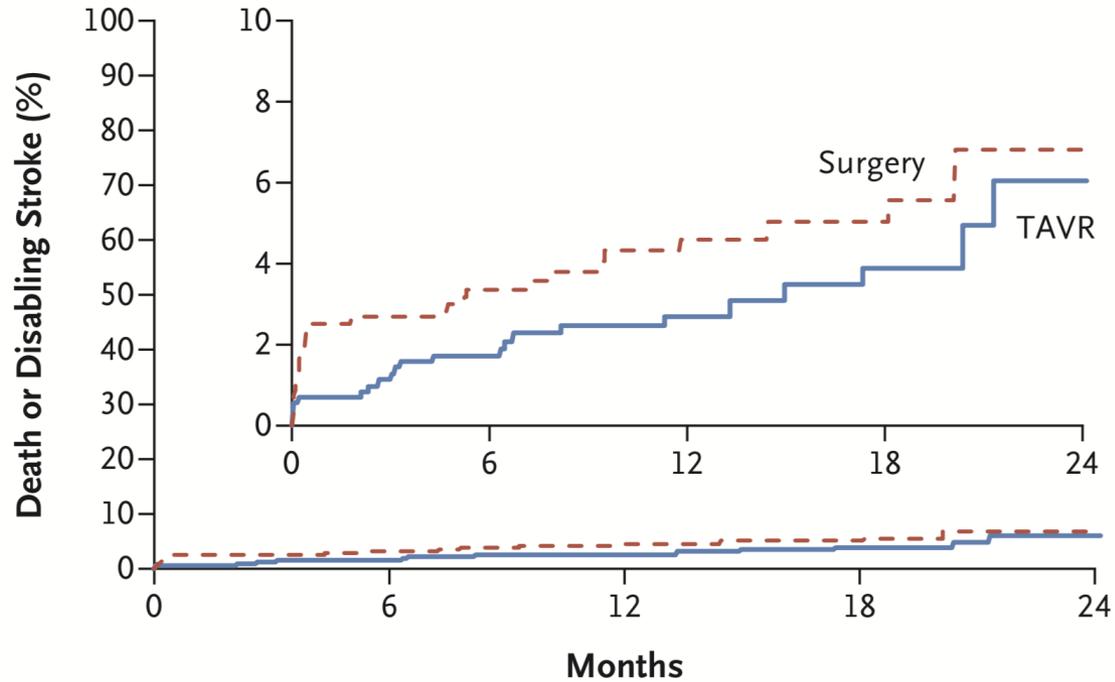
- Critères d'inclusions: Mortalité opératoire prédite <3%
- Evaluation à 1 an sur un critère composite: Mortalité (toute cause).
- Design: non-infériorité
- STS: 1,9%
- Age moyen 73 ans





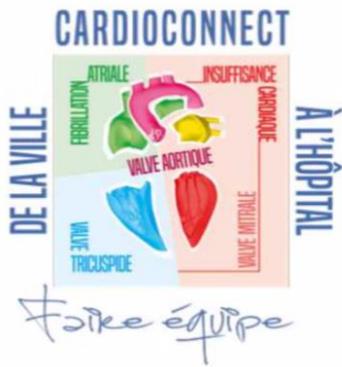
# EVOLUT Low Risk

## B Incidence of Primary End Point



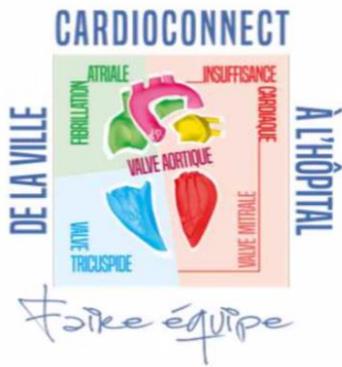
### No. at Risk

Surgery	678	576	366	195	69
TAVR	725	648	435	233	80



## Question 1: Risque Procédure TAVI versus Chirurgie sous CEC

- Pas de sur-risque péri-opératoire TAVI Vs RVAo pour:
- Une population à faible risque.
- des patients jeune < 75 ans.
- Tendance confirmée à 1 an (2 ans.. ).
- Pas de borne basse du risque opératoire identifiée



## Existe t il un âge minimal pour proposer un TAVI ?

- Préoccupation durabilité des prothèses percutanées +++
- Quels sont les résultats des Bioprothèses chirurgicales « Gold standard » ?
- Résultats des études comparants SAVR Vs TAVR ?

# Recommandations Européennes 2017

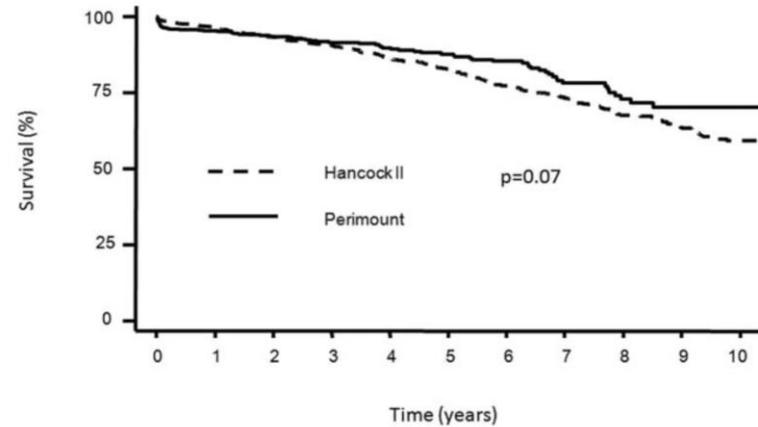
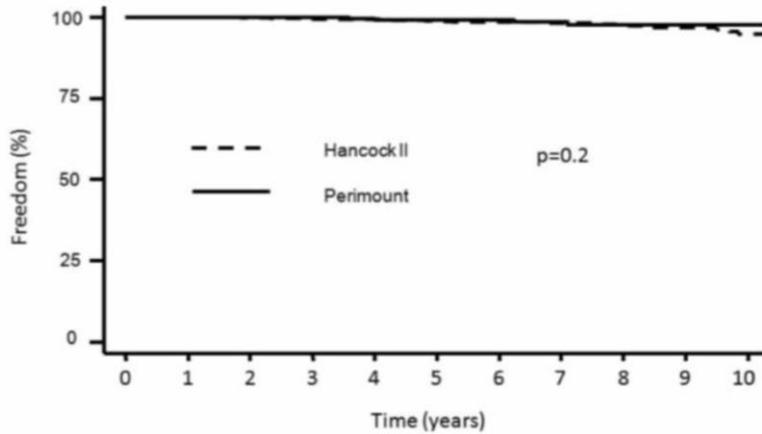
## Valvulopathies: choix du dispositif en fonction de l'âge et du type de valvulopathie.

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>
A mechanical prosthesis is recommended according to the desire of the informed patient and if there are no contraindications to long-term anticoagulation. <sup>c</sup>	I	C
A mechanical prosthesis is recommended in patients at risk of accelerated structural valve deterioration. <sup>d</sup>	I	C
A mechanical prosthesis should be considered in patients already on anticoagulation because of a mechanical prosthesis in another valve position.	IIa	C
A mechanical prosthesis should be considered in patients <60 years of age for prostheses in the aortic position and <65 years of age for prostheses in the mitral position. <sup>e</sup>	IIa	C
A mechanical prosthesis should be considered in patients with a reasonable life expectancy <sup>f</sup> for whom future redo valve surgery would be at high risk.	IIa	C
A mechanical prosthesis may be considered in patients already on long-term anticoagulation due to the high risk for thromboembolism. <sup>g</sup>	IIb	C





# Durabilité des bioprothèses chirurgicales ?



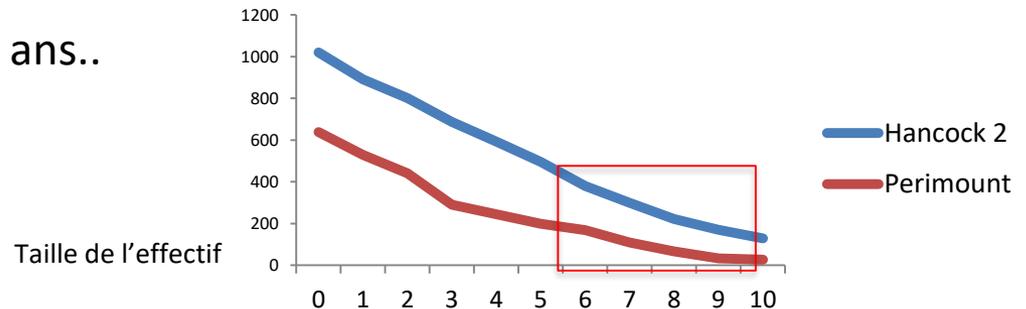
Number of patients at risk

Hancock II	1021	891	800	685	590	491	375	295	217	165	122
Perimount	638	528	440	290	243	198	167	107	65	33	27

Number of patients at risk

Hancock II	1021	891	801	687	593	495	380	299	221	169	128
Perimount	638	528	440	290	244	199	168	108	66	33	27

- 1659 Patients
- Période d'inclusion longue > 15 ans
- Taille de l'effectif très réduit après 5 ans..



# Durabilité des bioprothèses chirurgicales?

## Bioprosthetic Valve Durability metrics in studies of SAVR

● Survival

● Freedom from reoperation

● Valve-related

reoperation for SVD

● Freedom from

presence of explant due to SVD

### SAVR series

David et al (2010)

Mohammadi et al (2012)

Forcillo et al (2013)

Senage et al (2014)

Bourguignon et al (2015)

Johnstone et al (2015)



Mitroflow

Carpentier-Edwards

Carpentier-Edwards

### Bioprosthetic Valve Durability metrics

● ●

Undefined

● ●

Echocardiographic (1)

●

-

● ●

Echocardiographic (2)

● ● ●

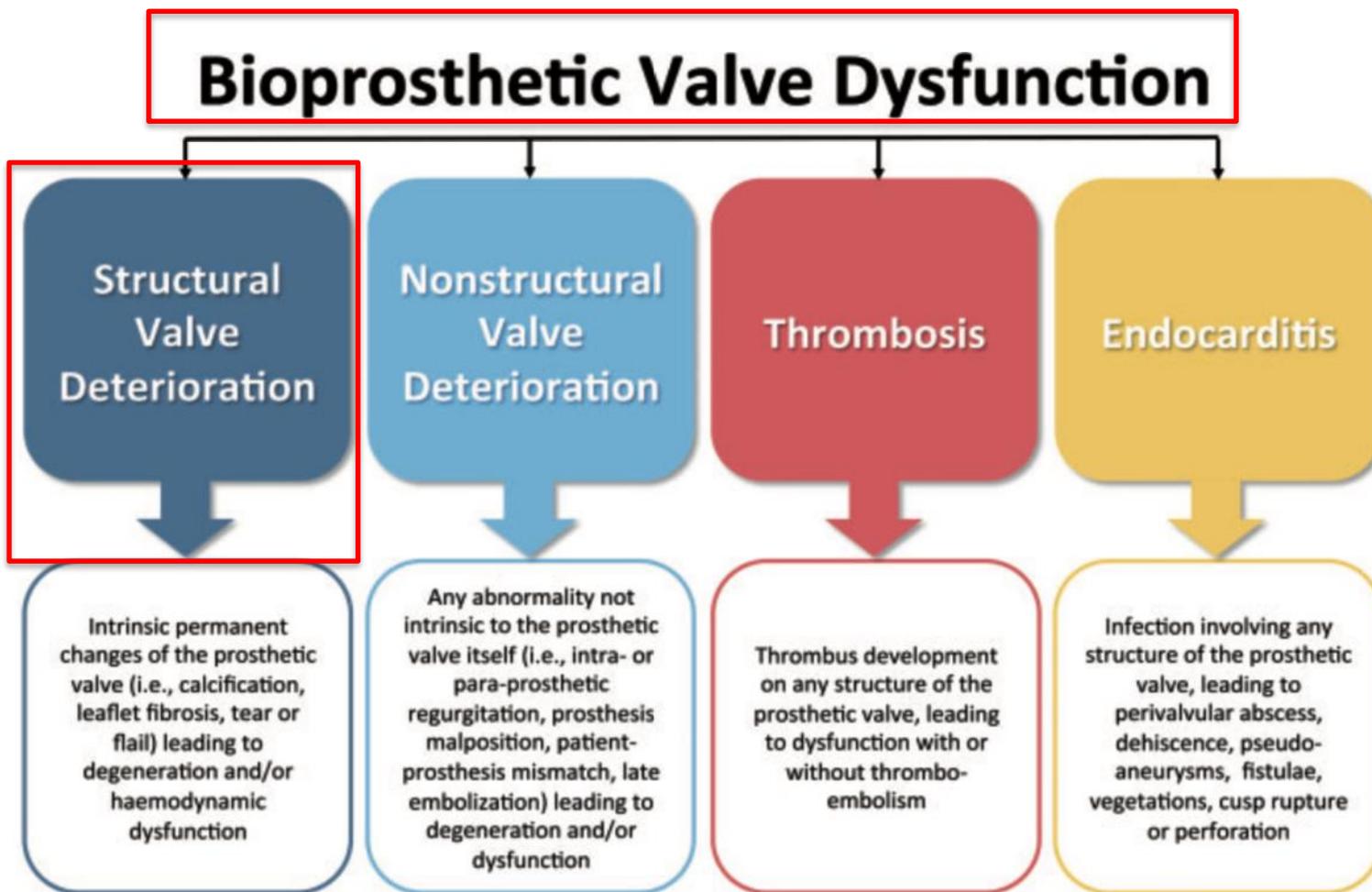
Echocardiographic (3)

●

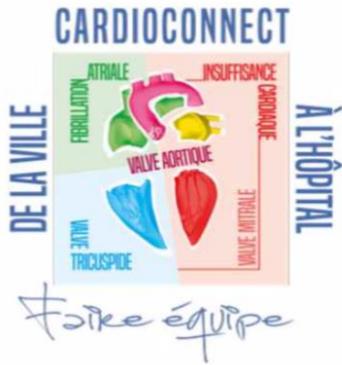
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# Nécessité d'harmoniser les définitions

!







# Structural Valve Deterioration (SVD)= Dégénérescence structurelle de bioprothèse

ESC European Heart Journal (2017) 38, 3392–3396 SPECIAL ARTICLE Valvular heart disease

**Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)**

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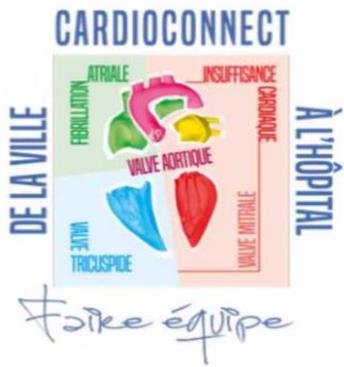
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Moderate haemodynamic SVD (any of the following)

- Mean transprosthetic gradient  $\geq 20$  mmHg and  $< 40$  mmHg
- Mean transprosthetic gradient  $\geq 10$  and  $< 20$  mmHg change from baseline
- Moderate intra-prosthetic aortic regurgitation, new or worsening ( $> 1+/4+$ ) from baseline

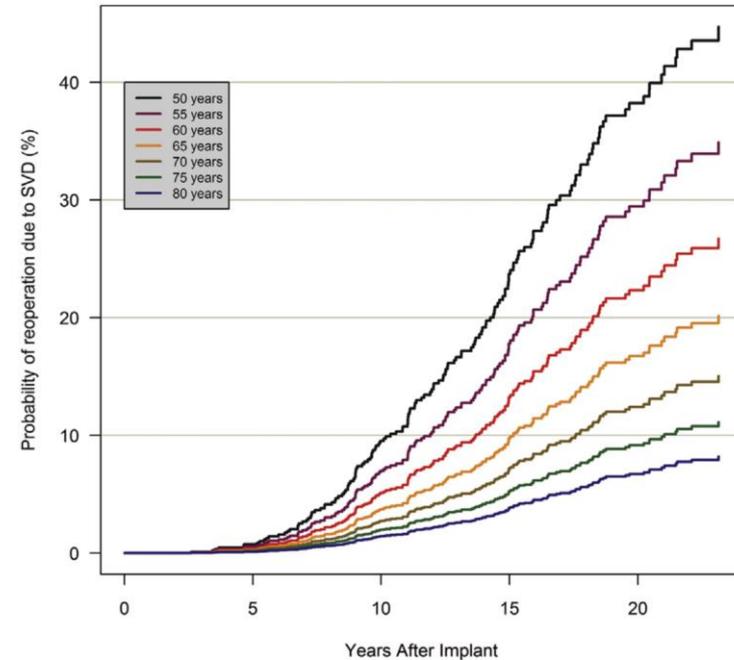
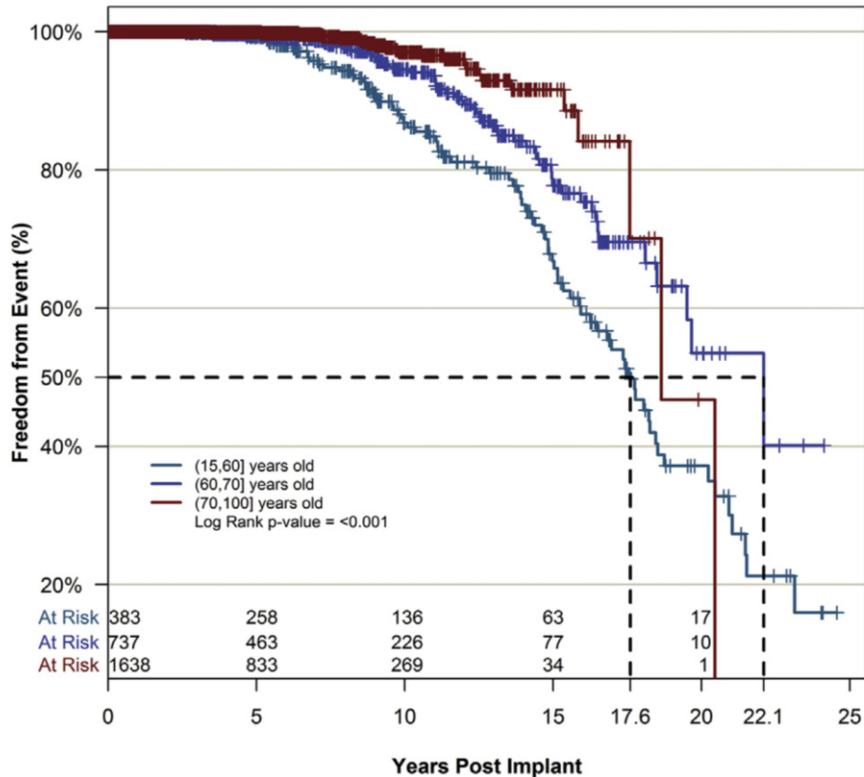
Severe haemodynamic SVD (any of the following)

- Mean transprosthetic gradient  $\geq 40$  mmHg
- Mean transprosthetic gradient  $\geq 20$  mmHg change from baseline
- Severe intra-prosthetic aortic regurgitation, new or worsening ( $> 2+/4+$ ) from baseline

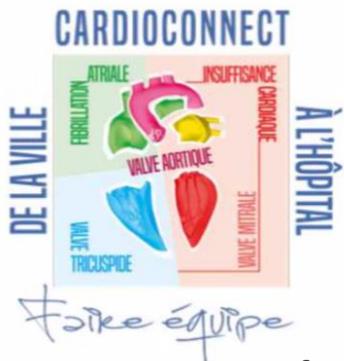


# Durabilité des dispositifs chirurgicaux: 20 d'expérience avec la Perimount

Analyse rétrospective basée sur la nouvelle définition

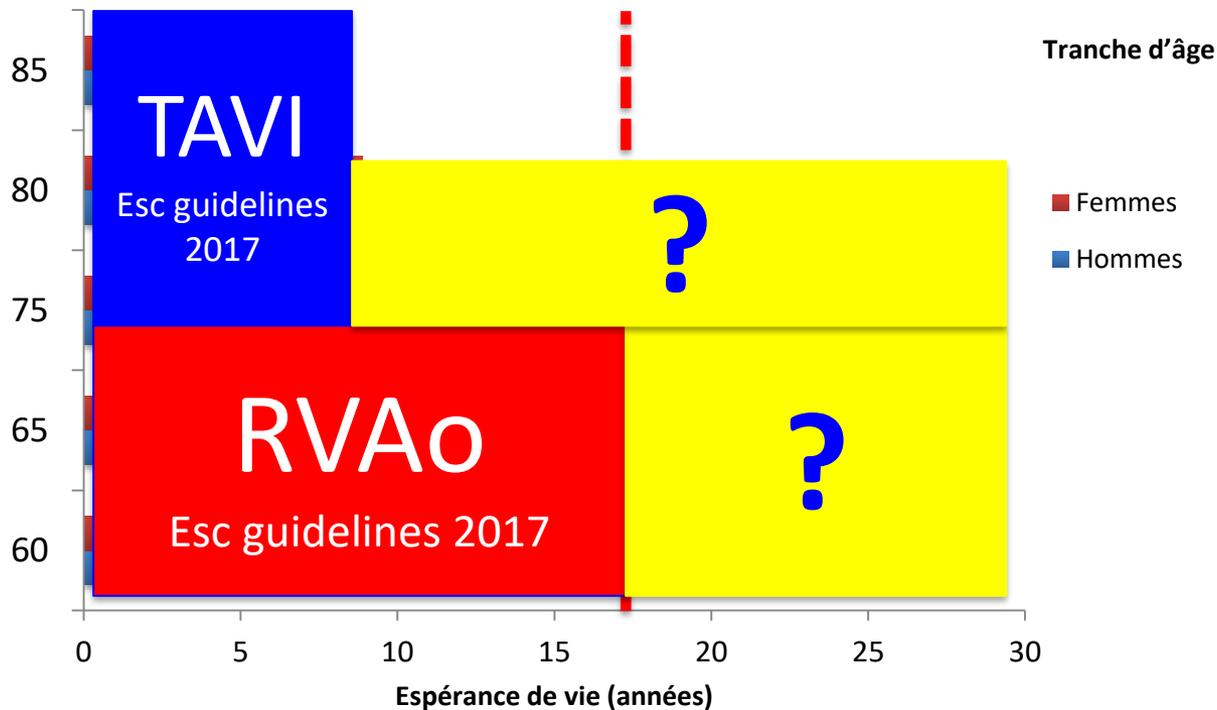


Survie médiane sans SVD  
 17,6 ans pour <60 ans  
 22,1 ans pour 60-70 ans

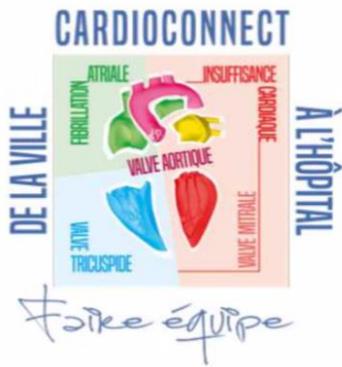


## Durabilité des dispositifs chirurgicaux

- Espérance de vie par tranche d'âge (source Insee)

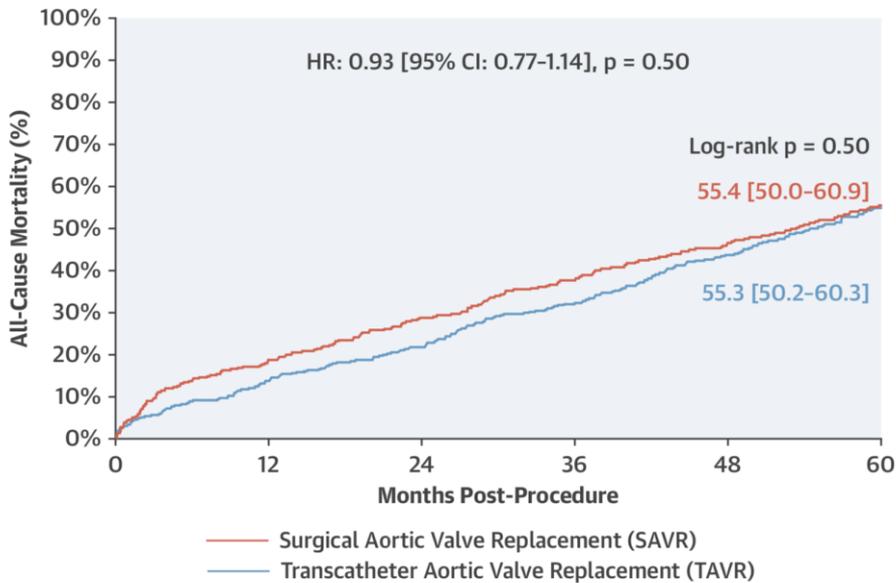






# Durabilité des dispositifs Percutanés ?

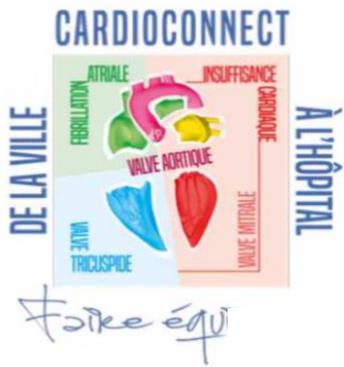
- Résultats de Pivotal US-Corevalve à 5 ans.
- Cohorte haut risque opératoire



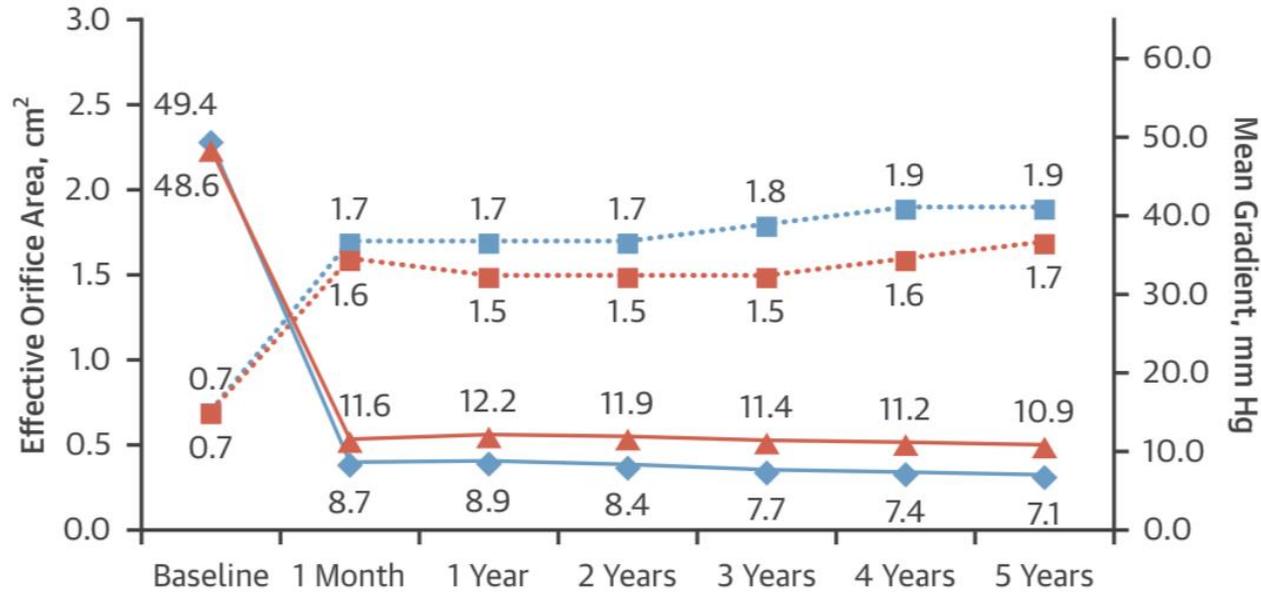
No. at Risk						
SAVR	359	284	241	199	162	101
TAVR	391	336	301	253	205	135



Gleason, T.G. et al. J Am Coll Cardiol. 2018;72(22):2687-96.



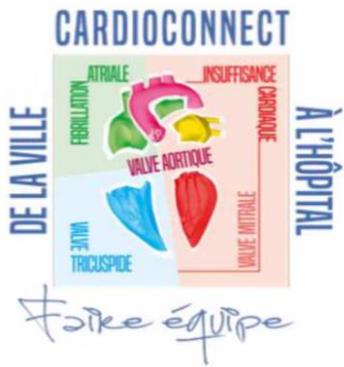
# Durabilité des dispositifs Percutanés: Pivotal US Corevalve 5 ans



No. of patients with echo data

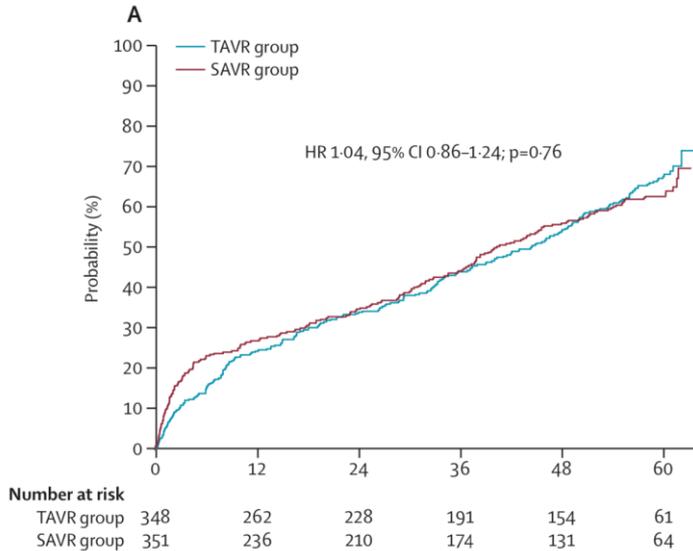
TAVR AVG	391	363	303	250	193	152	112
SAVR AVG	359	317	230	188	141	114	88
TAVR EOA	384	343	284	238	182	144	99
SAVR EOA	353	289	210	174	134	106	84

---■--- TAVR    ---■--- SAVR

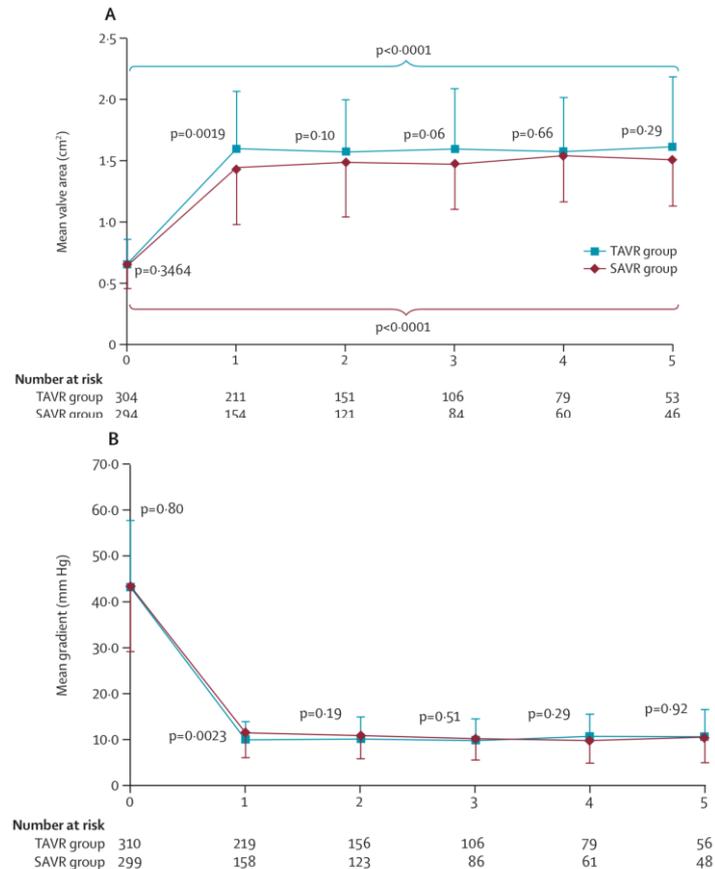


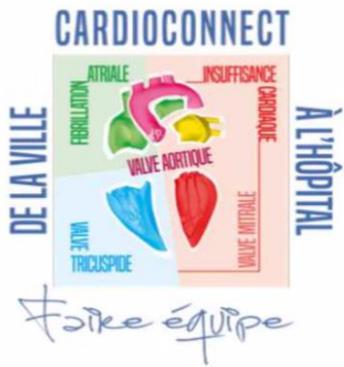
# Durabilité des dispositifs Percutanés: PARTNER à 5 ans

- Résultats de PARTNER à 5 ans.
- Cohorte haut risque opératoire



Mac et al Lancet 2015

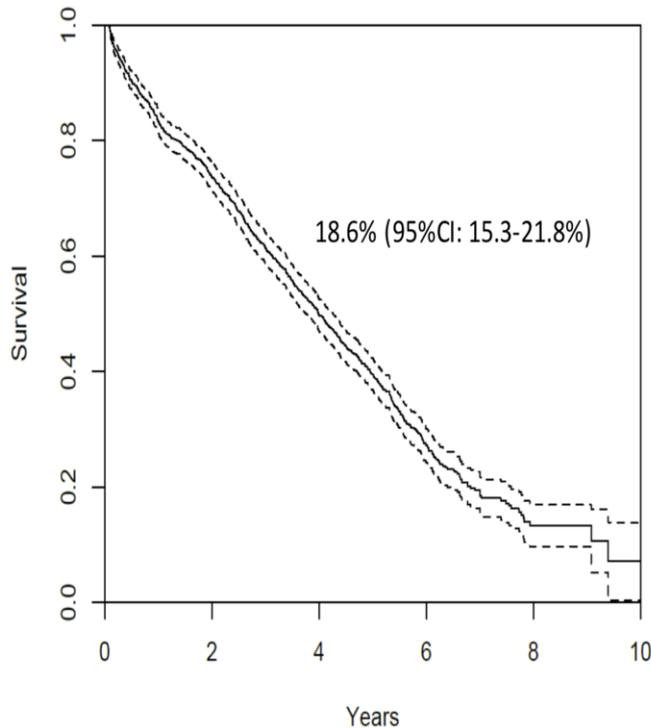




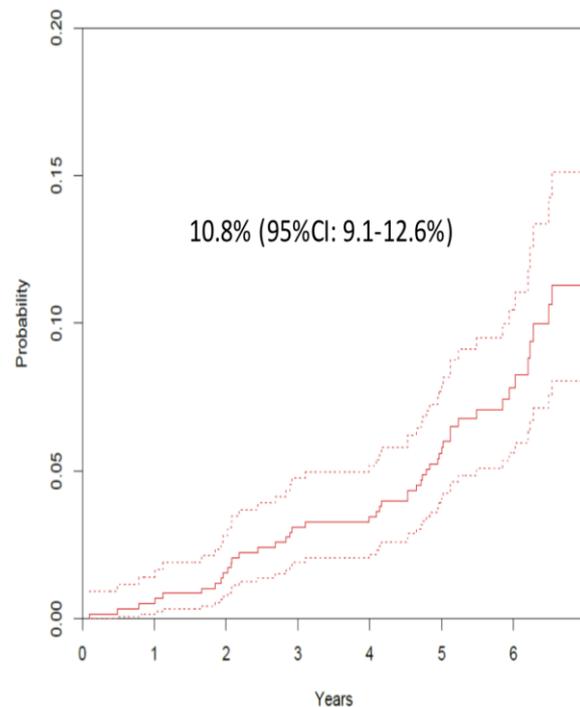
# Et au delà de 5 ans ?

1403 pts (2002-2011) 589 patients had echocardiography complete FU

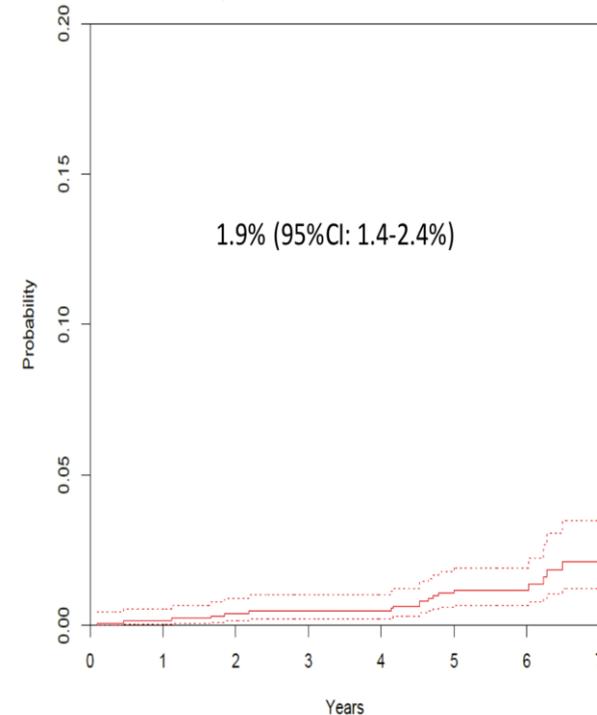
Survival



Structural valve deterioration

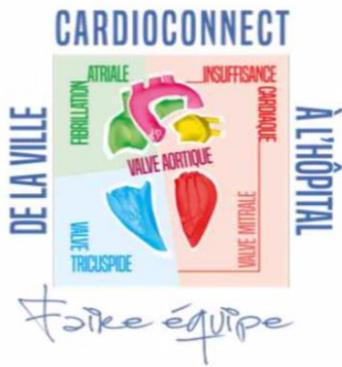


Bioprosthetic valve failure



**Severe SVD: 4.2% (95% CI, 2.9%–5.5%) at 7 years**

**Re-intervention: 1.0% (95% CI, 0.4%–1.6%) at 7 years**



# Durabilité des dispositifs Percutanés: synthèse

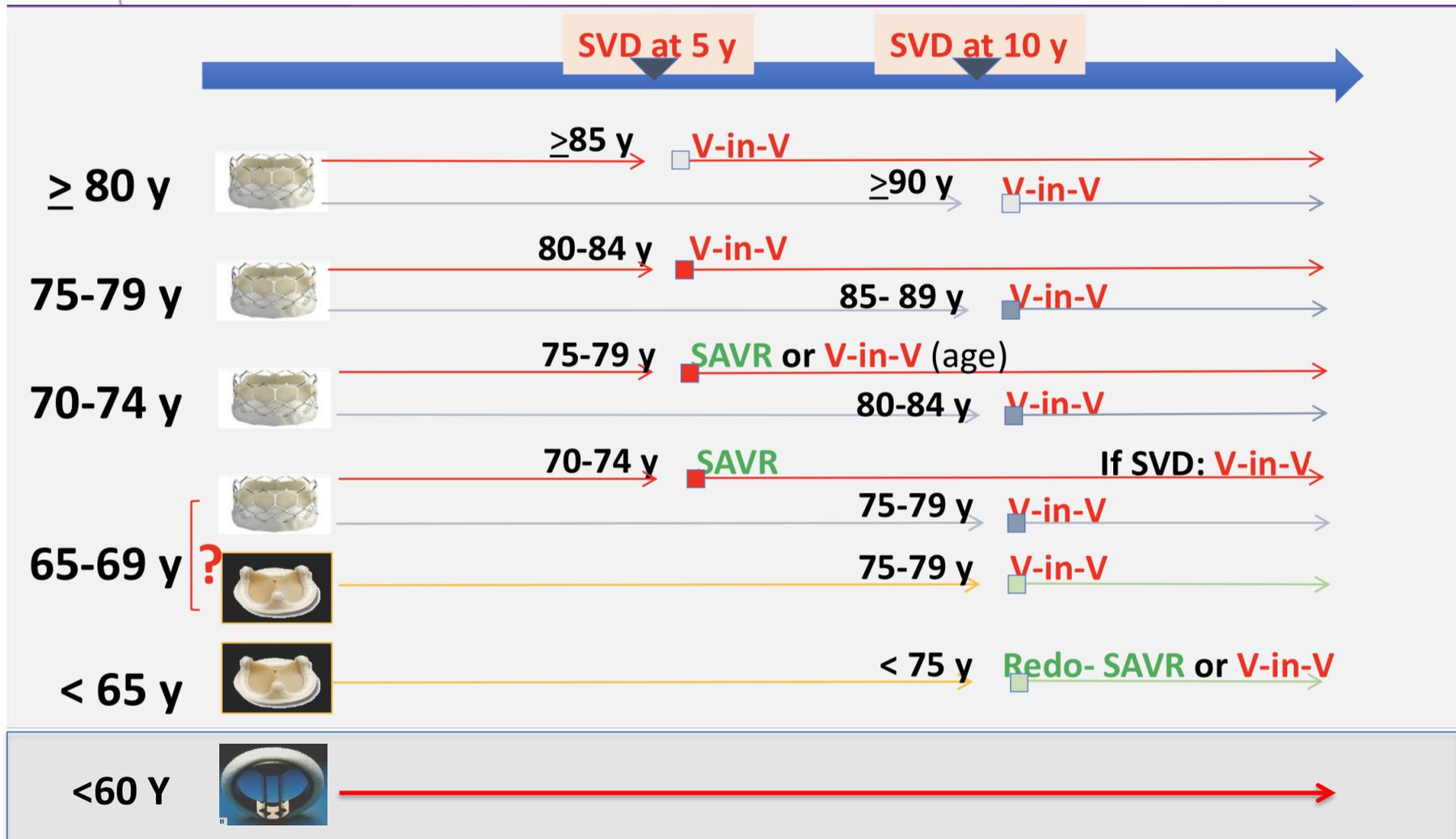
- Bon résultats cliniques
- Bon résultats hémodynamiques
- A 5 ans et au delà
- Ré-intervention à 7 ans sur 3 séries publiées <1%.
- Accessibilité coronaire ultérieure (Medtronic).
- **Données encore limitées pour définir une borne basse de l'âge.**



Faire équipe

# Perspectives

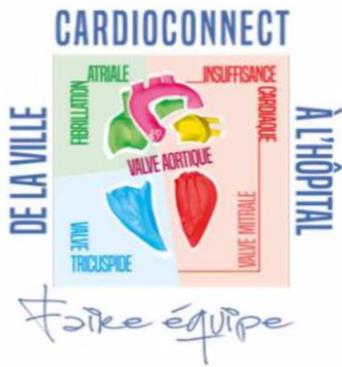
Courtesy of Hélène Eltchaninoff





# Conclusions

- TAVI est maintenant la technique de choix pour la prise en charge du RAC serré à haut risque/risque intermédiaire.
- Au vu des résultats récents, le TAVI devrait s'imposer comme TTT de choix pour les patients à bas risque
- L'âge du patient sera le facteur déterminant



# Conclusions

- Le RVAo par voie chirurgicale reste le TTT de choix pour les patients <70 (65?) ans et les mauvais candidats au TAVI.
- Pour les plus jeunes/plus faibles risques: le choix éclairé du patient s'invitera à la décision de la heart team.