

# TAVI pour tous

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# TAVI pour tous, ou presque ...

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# Conflits d'intérêts



# Commemorating the 15-year anniversary of TAVI: insights into the early stages of development, from concept to human application, and perspectives



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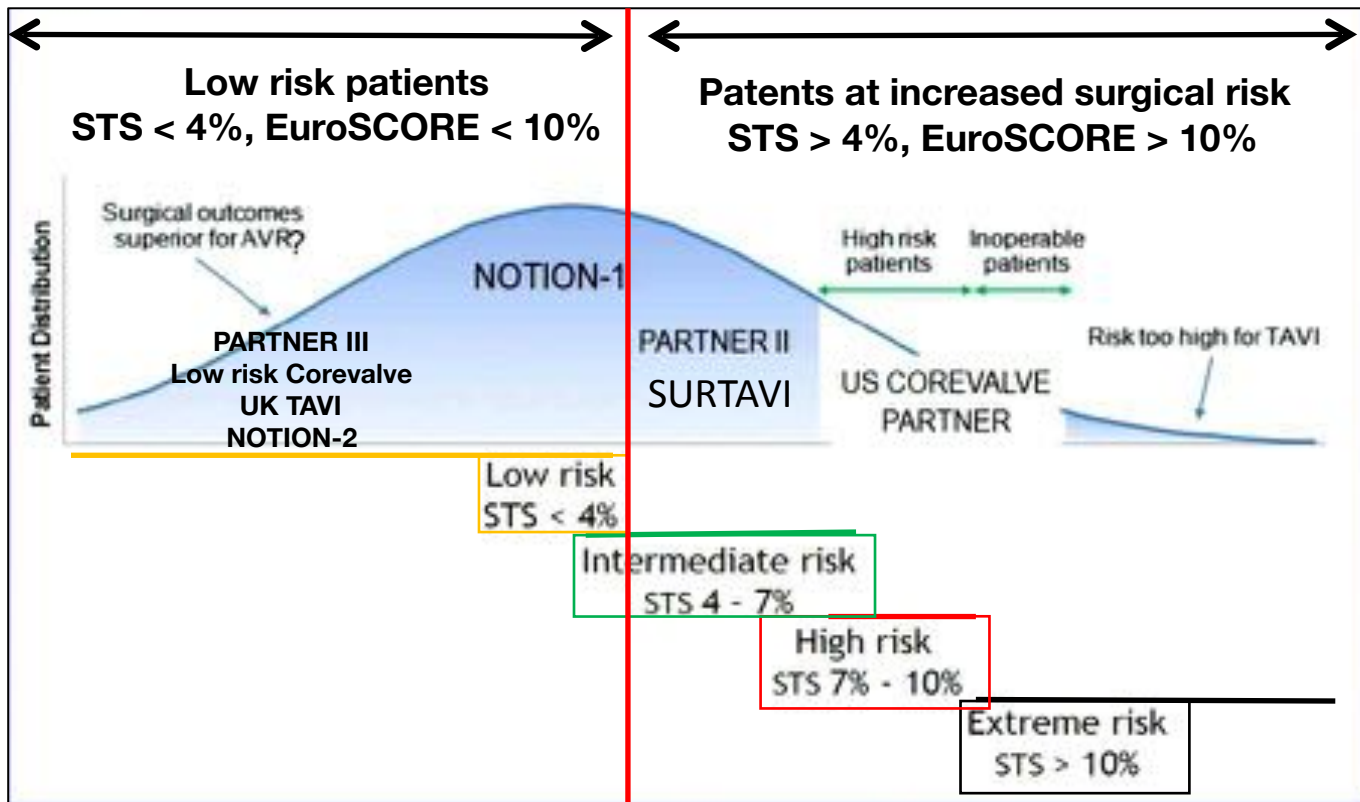
It can be predicted that within five years the indication for SAVR will be limited to patients who are not optimal candidates for TAVI.

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**Merci pour votre attention**



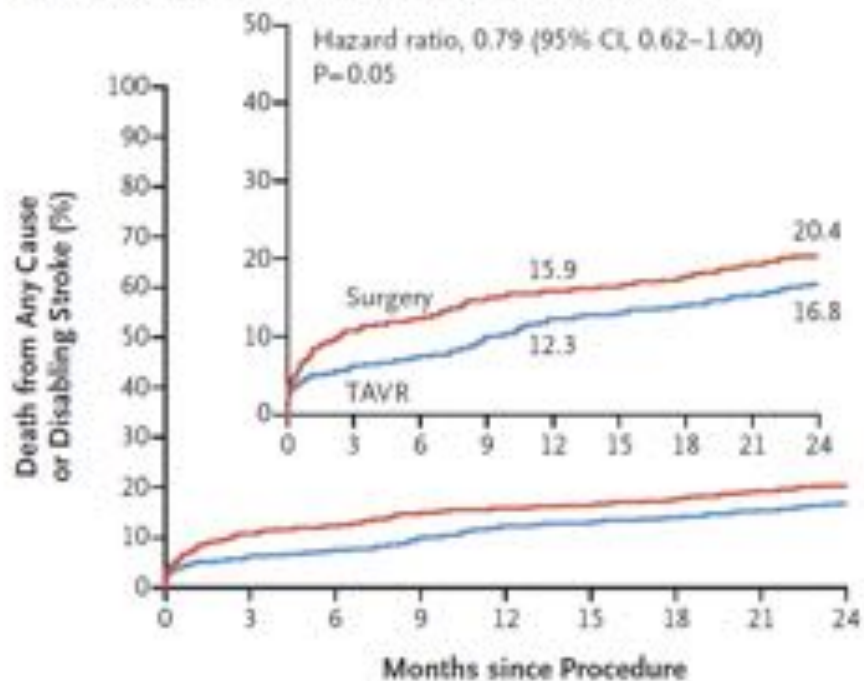
# Risque opératoire et RA





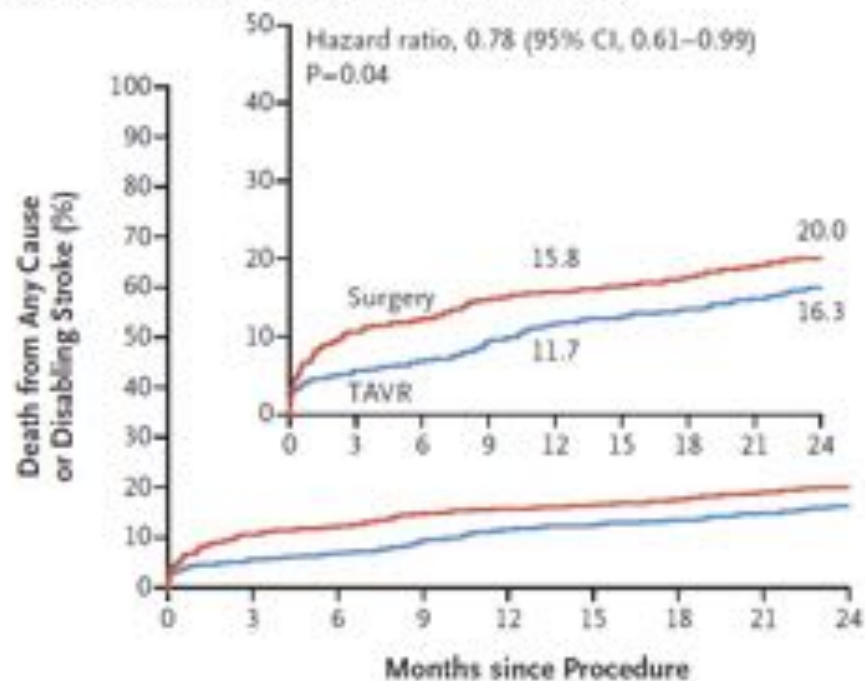
# TAVI et patients à risque intermédiaire

**C** Transfemoral-Access Cohort, Intention-to-Treat Analysis



775	718	709	685	663	652	644	634	612
775	643	628	604	595	577	569	557	538

**D** Transfemoral-Access Cohort, As-Treated Analysis

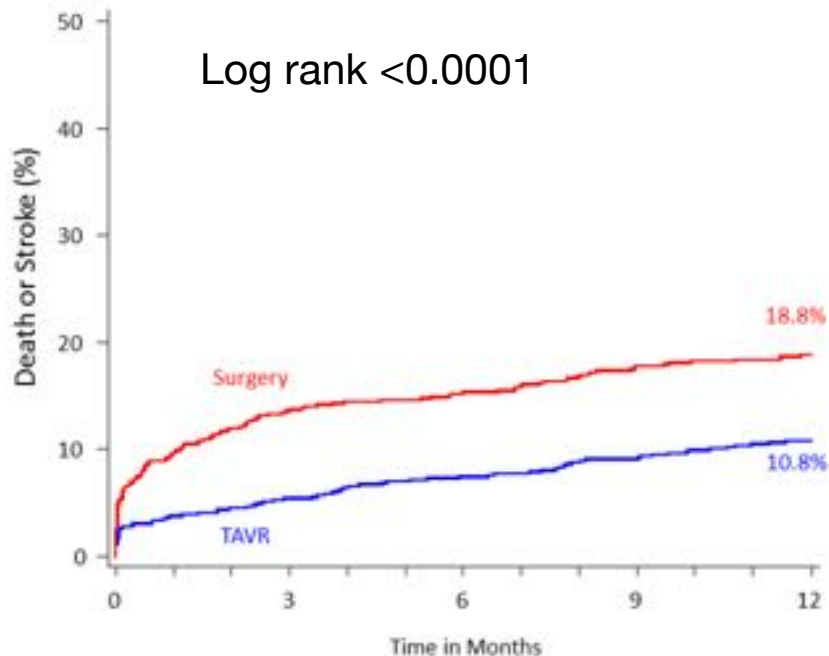


No. at Risk	
TAVR	762 717 708 685 663 652 644 634 612
Surgery	722 636 624 600 591 573 565 555 537



# TAVI et patients à risque intermédiaire

- Age (years)
- Men
- Body-mass ind
- Society of Thor



value

0-23
0-002
0-32
0-0002

Number at risk:

TAVR	1077	1012	987	962	930
Surgery	944	805	786	757	743



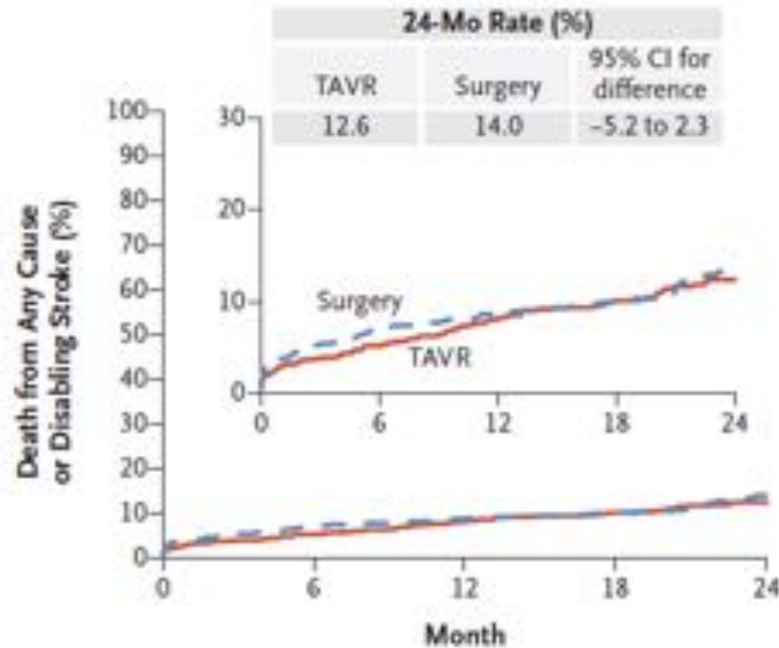


# TAVI et patients à risque intermédiaire

Table 1. Characteristic

Characteristic
Age — yr
Age group — no. (%)
<75 yr
75 to 85 yr
>85 yr
Male sex — no. (%)
Body-surface area —
New York Heart Assn
II
III
IV
Society of Thoracic S
Mortality s
Mean — %
Category — no. (%)
<3%
3 to <5%
5 to <8%
≥8%
Logistic EuroSCORE

## B Primary Outcome



### No. at Risk

	0	6	12	18	24
TAVR	864	755	612	456	272
Surgery	796	674	555	407	241

### Analysis

Surgery (N= 867)	79.8±6.0
<75 yr	167 (19.3)
75 to 85 yr	553 (63.8)
>85 yr	147 (17.0)
Male sex	484 (55.8)
Body-surface area	1.9±0.2
New York Heart Assn	367 (42.3)
II	448 (51.7)
III	52 (6.0)
IV	4.5±1.6
Society of Thoracic S	135 (15.6)
Mortality s	447 (51.6)
Mean — %	250 (28.8)
Category — no. (%)	35 (4.0)
<3%	11.6±8.0
3 to <5%	
5 to <8%	
≥8%	
Logistic EuroSCORE	



# Indications du TAVI en 2018

Severe AS  
 Symptomatic  
 (Class I)

Class I

## Recommendations

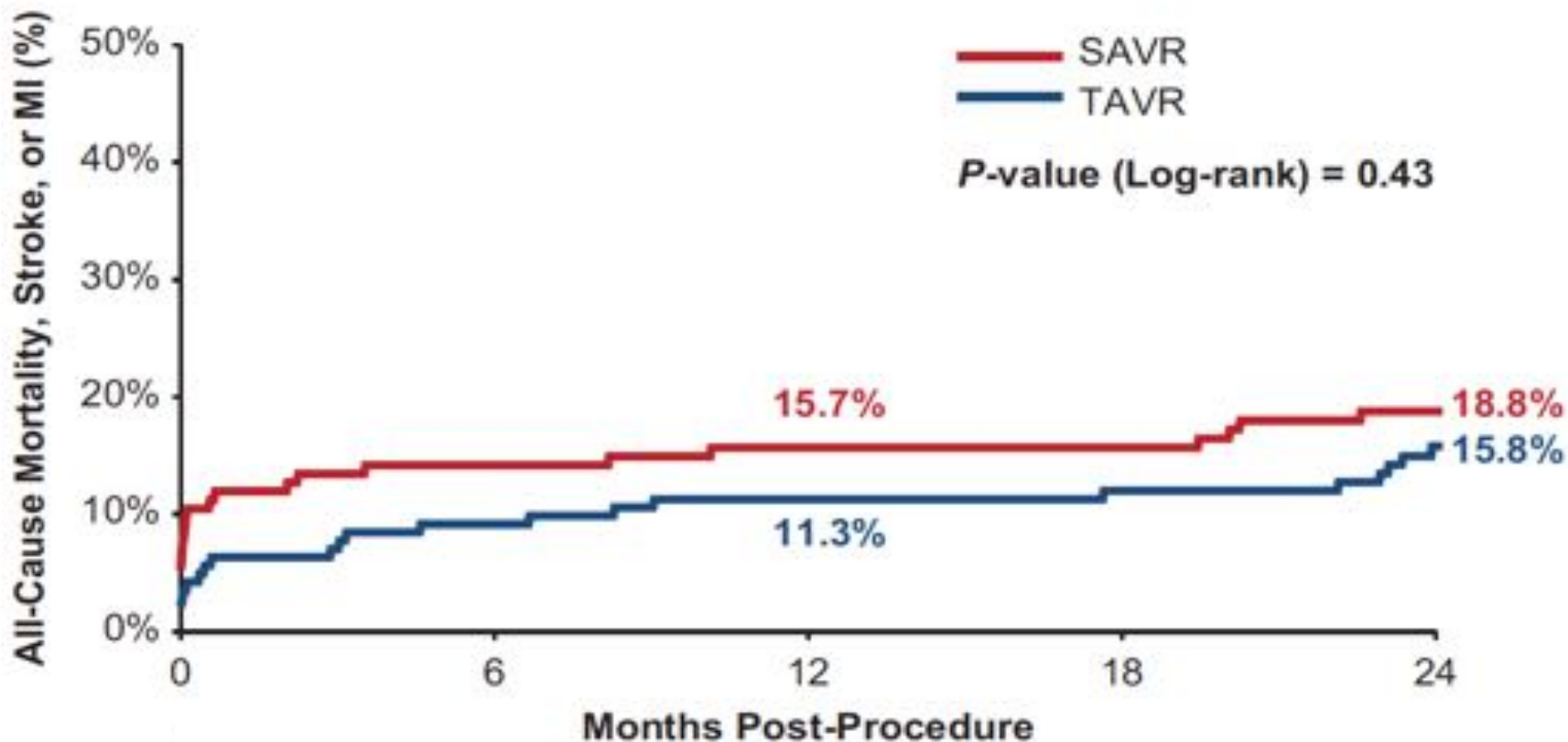
In patients who are at increased surgical risk (STS or EuroSCORE II  $\geq 4\%$  or logistic EuroSCORE I  $\geq 10\%$  or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see according table), with TAVI being favoured in elderly patients suitable for transfemoral access.

Class	Level
I	B

I

B

# TAVI et patients à bas risque



# Etudes en cours chez les bas risques

## The PARTNER 3 Trial Study Design



Symptomatic Severe Calcific Aortic Stenosis

Low Risk ASSESSMENT by Heart Team  
(STS < 4%, TF only)

1:1 Randomization  
(n=1228)

TF - TAVR  
(SAPIEN 3)

Surgery  
(Bioprosthetic Valve)

CT Imaging Sub-Study (n=200)    CT Imaging Sub-Study (n=200)

Actigraphy/QoL Sub-Study (n=200)    Actigraphy/QoL Sub-Study (n=200)

**PRIMARY ENDPOINT:**

Composite of all-cause mortality, all strokes, or re-hospitalization at 1 year post-procedure

Follow-up: 30 days, 6 mos, 1 year and annually through 10 years

## Low Risk: Study Overview

Primary Objective	To demonstrate that the safety and effectiveness of the Medtronic TAVR system is non-inferior to SAVR in patients with severe AS at low risk for SAVR
Patients	Subjects with severe AS with indication for SAVR with a bioprosthesis and predicted risk of mortality at 30 days < 3%
Study Design	<ul style="list-style-type: none"> <li>Multi-center, prospective, randomized</li> <li>1:1 randomization to either TAVR or SAVR</li> </ul>
Devices	<p>Investigational TAVR Arm</p> <ul style="list-style-type: none"> <li>Evolut R 23, 26, and 29 TAV with Edwards SAPIEN 3</li> <li>CoreValve 31 mm TAV with AccuTrans catheter</li> </ul> <p>Control Arm</p> <ul style="list-style-type: none"> <li>Any commercially available bioprosthesis</li> </ul>
Number of Subjects	1256 subjects, inclusive of 400 subjects in the LTI sub-study and 200 SAVR in LTI sub-study
Scope	Up to 80 sites

The NOTION 2: Low-risk Trial in Younger Patients

## The UK All-comer TAVI Study

The UK TAVI Trial



Lars Sondergaard, MD, D  
Professor of Cardiology  
The Heart Center, Rigshospitalet  
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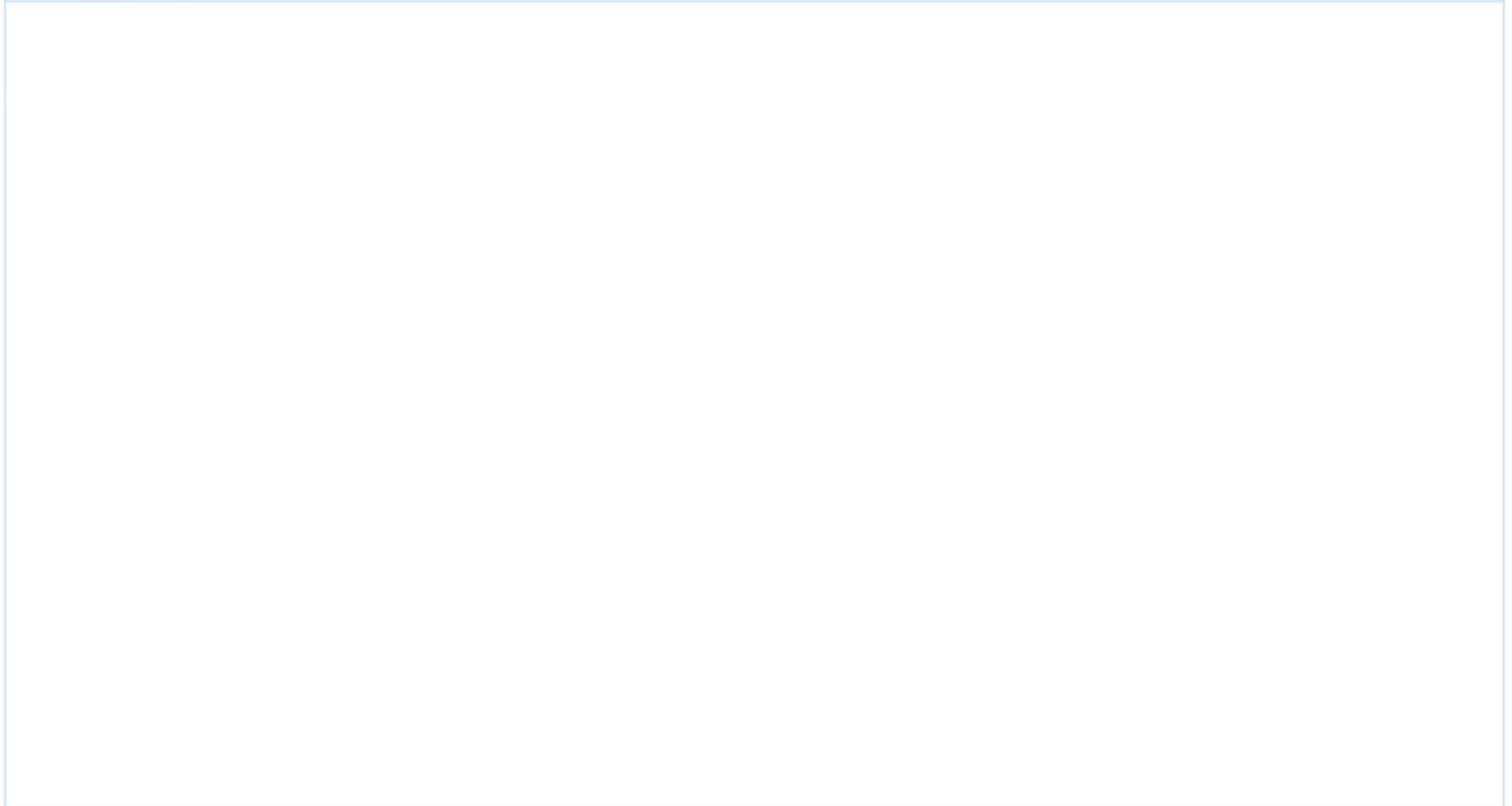
Neil E Moat MS FRCS

Senior Consultant Cardiac Surgeon  
Director Trans-Catheter Valve Programme  
Royal Brompton & Harefield NHS Trust London, UK

**Quels sont les possibles  
obstacles à une extension des  
indications ?**



# Avantages/inconvénients TAVI

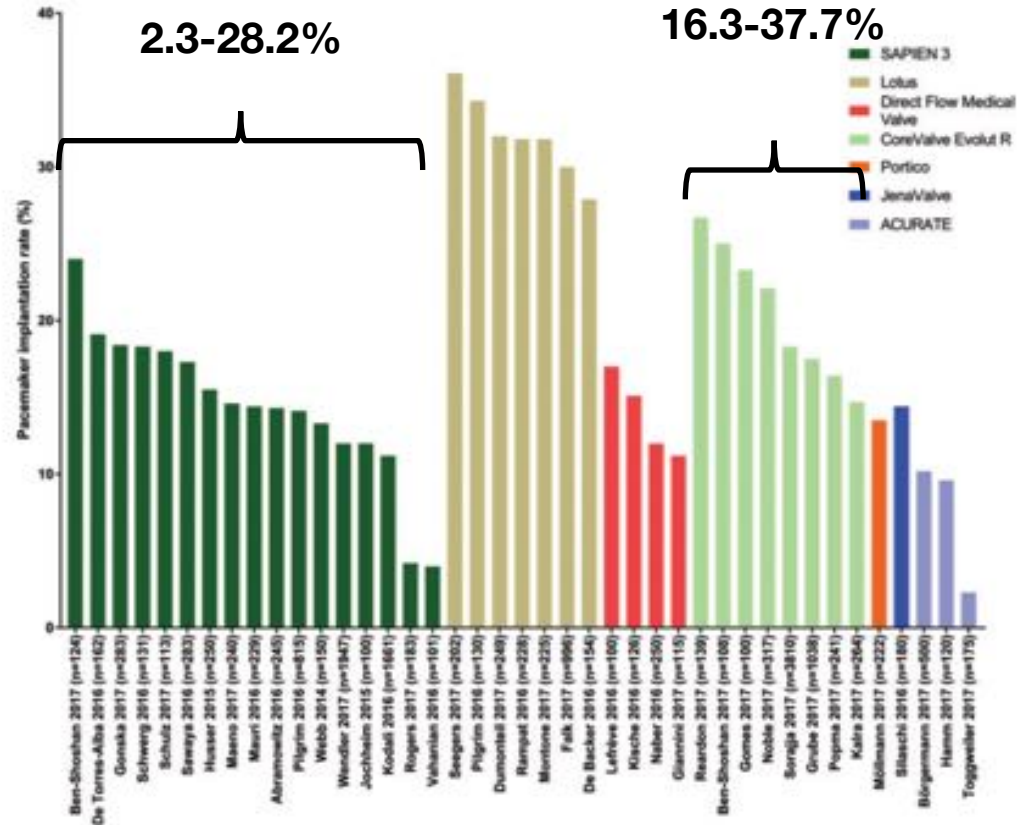




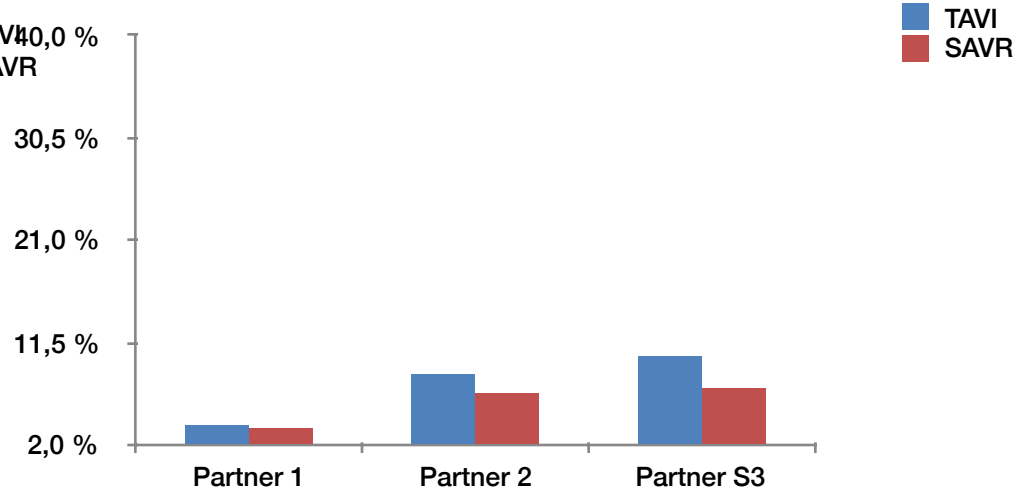
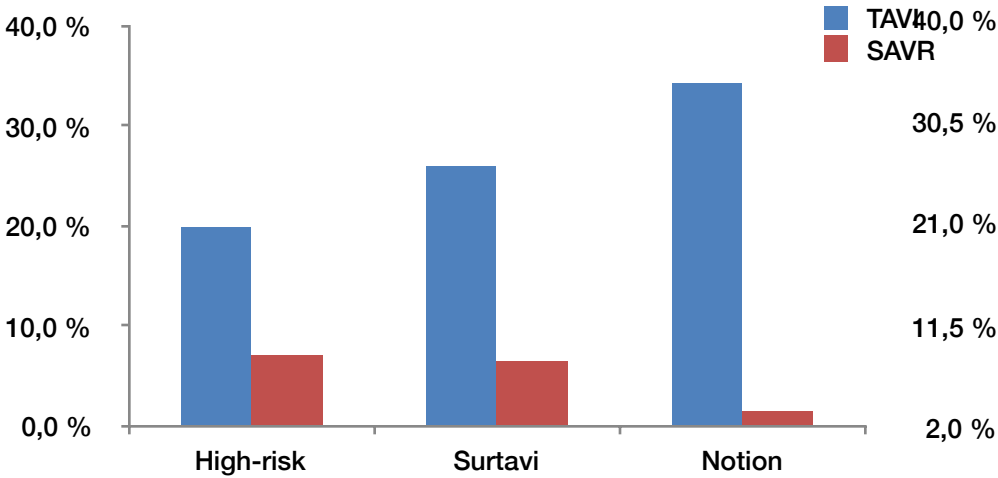
# Pacemaker après TAVI

## Predicting factors:

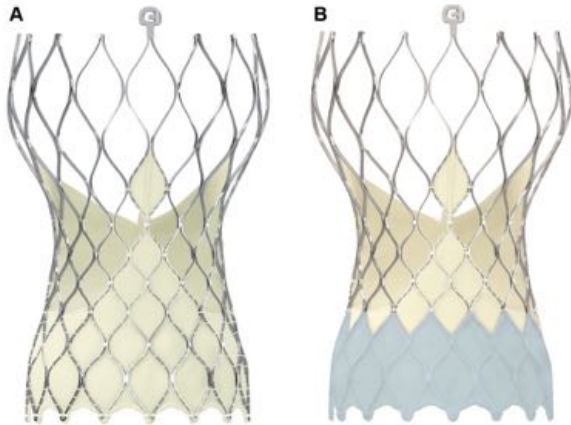
- Age
- Pre-existent conduction abnormalities
- Calcification of LVOT
- Balloon valvuloplasty
- Depth of implantation



# Pacemaker vs. chirurgie



# Pacemaker après TAVI

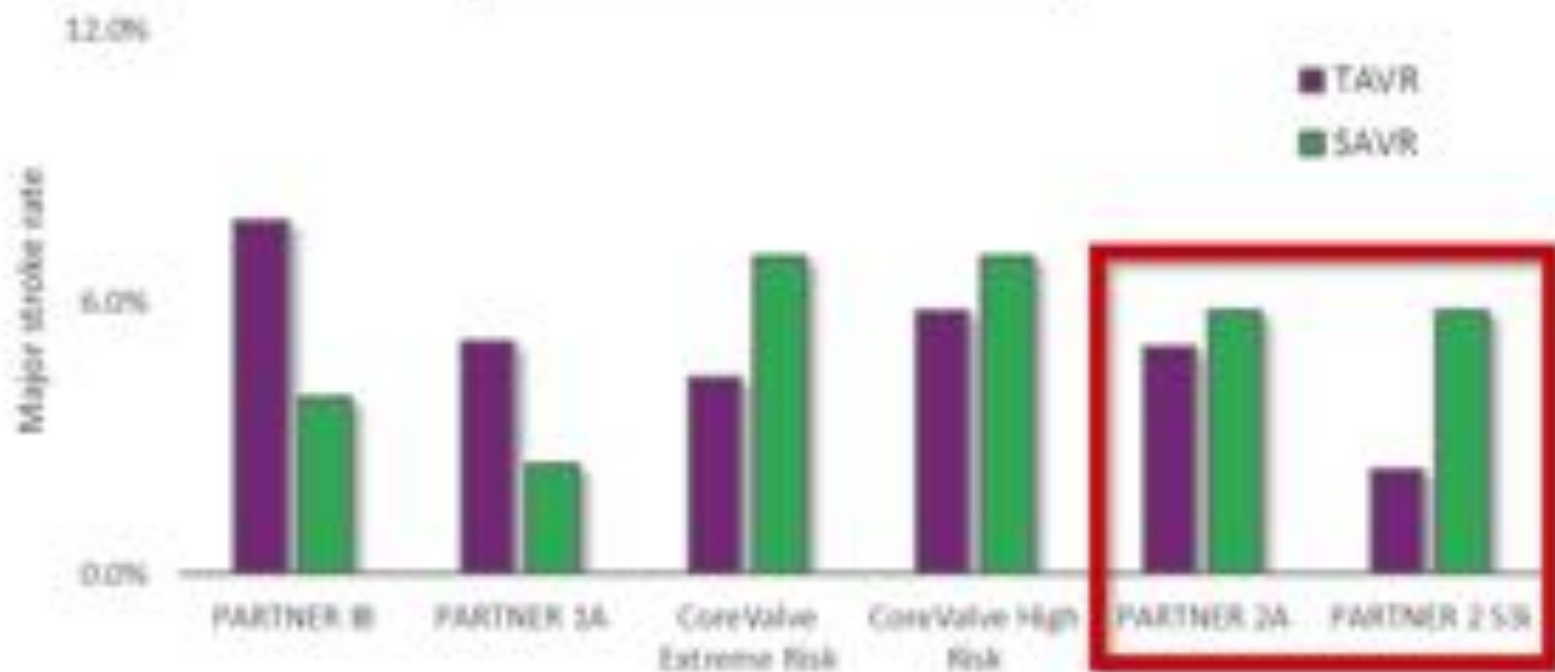


**Corevalve Evolut Pro**

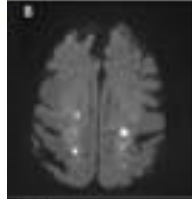
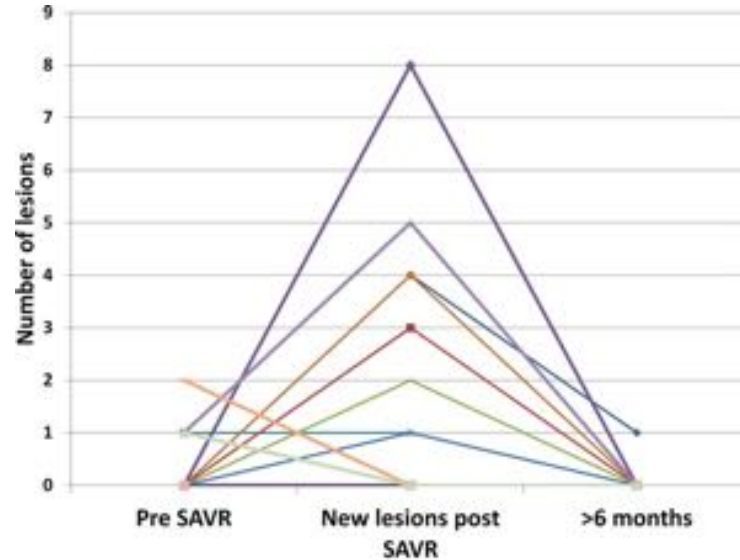
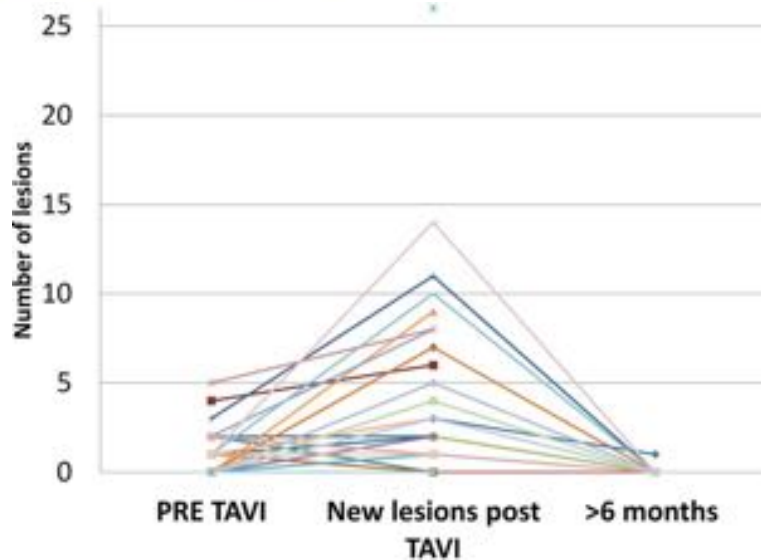
**TABLE 4 Safety Endpoint Outcomes at 30 Days (N = 60)**

All-cause mortality	1 (1.7)
Any stroke	1 (1.7)
Disabling stroke	1 (1.7)
Nondisabling stroke	0 (0.0)
Myocardial infarction	0 (0.0)
Life-threatening or disabling bleeding	7 (11.7)
Acute kidney injury: stage 2 or 3	1 (1.7)
Coronary artery obstruction	0 (0.0)
Vascular complications	7 (11.7)
Major vascular complication	6 (10.0)
Minor vascular complication	1 (1.7)
Valve-related dysfunction requiring repeat procedure	0 (0.0)
VARC-2 composite endpoint	9 (15.0)
Valve embolization or migration	1 (1.7)
<b>New permanent pacemaker*</b>	<b>6 (11.8)</b>

## Stroke in major TAVR trials



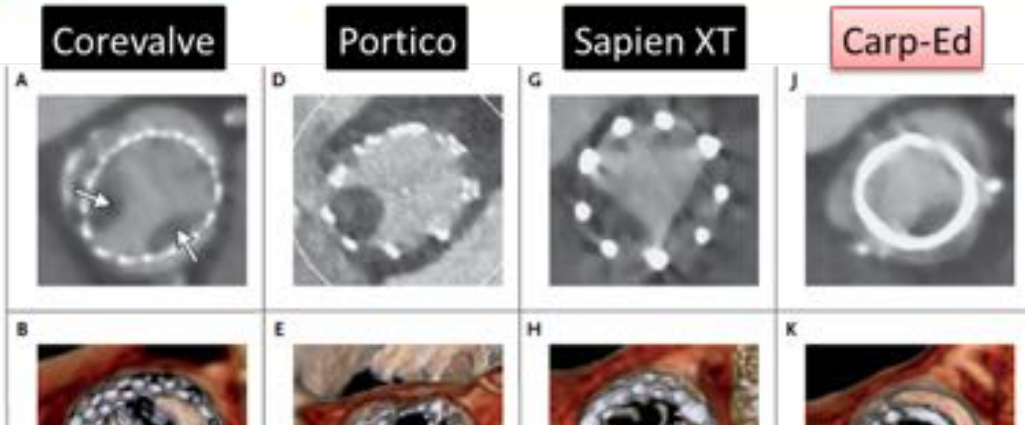
# AVC infra clinique et troubles cognitifs



## Plus d'AVC infra-clinique MAIS

- Très peu d'études comparatives
- Lésions « fugaces »
- Pas d'impact cognitif démontré

# Thrombose de prothèse

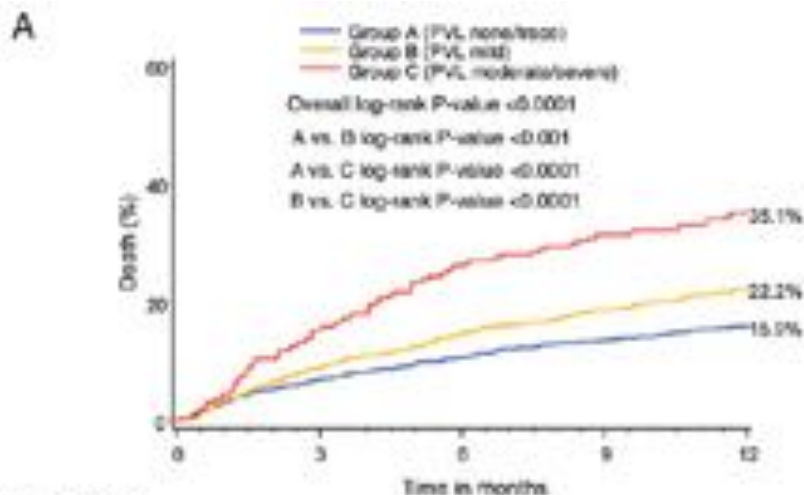


Frequency of reduced leaflet motion (n=106)	
Transcatheter valves	101/752 (13%)
Edwards	63/453 (14%)
Edwards-Sapien	1/22 (5%)
Sapien XT	12/122 (10%)
Sapien 3	50/309 (16%)
Evolut or CoreValve	9/145 (6%)
CoreValve	3/70 (4%)
Evolut	6/75 (8%)

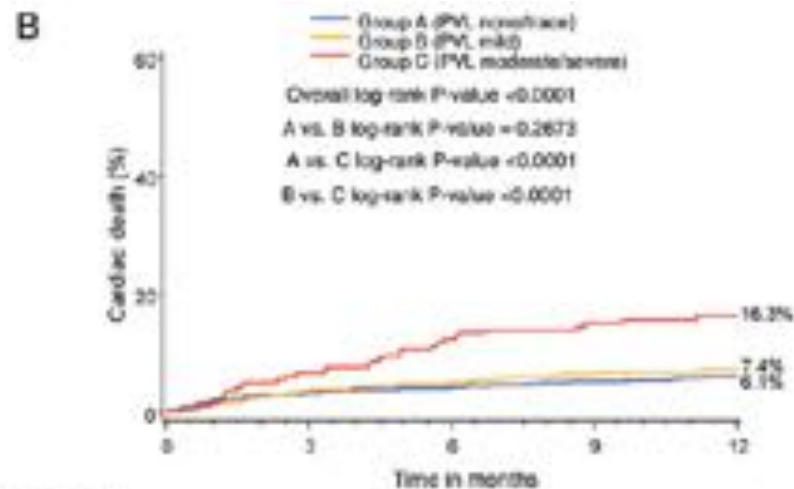
- Impact à long terme ?
- Peu de données avec les bioprothèses chirurgicales
- Doit faire reconsidérer le traitement anti-thrombotique post TAVI/RVA ?



# IA paravalvulaires



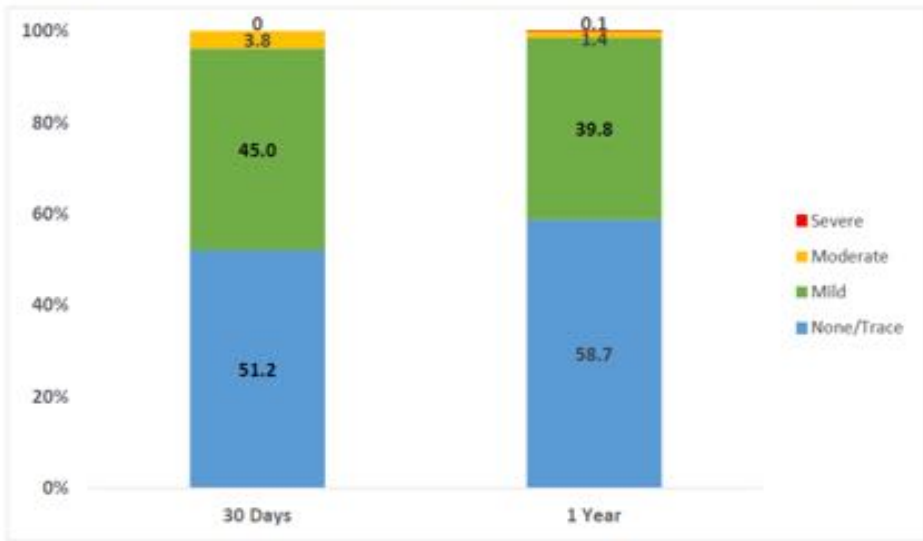
Number at risk	0	3	6	9	12
Group A	1268	1189	1126	1077	953
Group B	525	439	378	335	242
Group C	221	187	150	148	134



Number at risk	0	3	6	9	12
Group A	1268	1182	1126	1077	953
Group B	525	439	378	335	242
Group C	221	187	159	147	134

# IA paravalvulaires

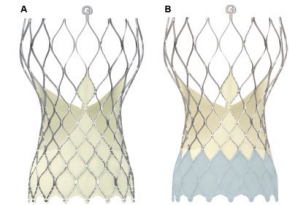
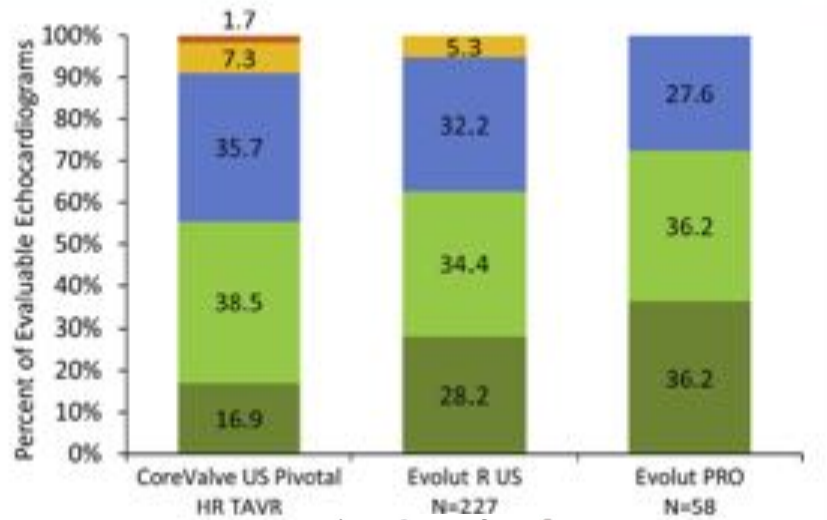
Appendix Figure 3. Paravalvular aortic regurgitation at 30 days and one year following TAVR



Number of evaluable echos 992



FIGURE 2 Paravalvular Leak at 30 Days



**Ce n'est plus un problème ...**

# Accès aux coronaires après TAVI

## Factors Impacting Coronary Access

## Imaging Evaluation

Zivelonghi et al.  
(19), 2017

66  
41 (Sapien 3 [Edwards  
Lifesciences, Irvine,  
California])  
25 (Evolut R [Medtronic])

### Fluoroscopy

Angiogram and FFR assessed pre- and post-TAVR

Successful coronary angiography:

- 98.0% (65 of 66) successful diagnostic angiogram performed (6 semiselective angiograms requiring wiring [2 cases with Sapien 3 and 4 cases with Evolut R])
- 1 nondiagnostic angiogram with Evolut R (presumed due to high valve implantation)

Successful PCI:

- 100% (17 of 17 [5 Evolut R, 12 Sapien 3]) with 5 cases requiring rotational atherectomy (3 Evolut R, 2 Sapien 3)

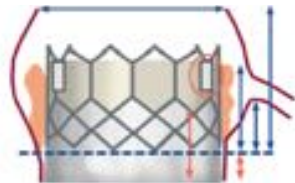
- Initial strategy was to use EBU and JR catheters

Sapien 3:

- standard catheters used

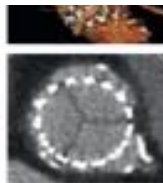
Evolut R:

- 6 of 25 cases needed a change of catheter (from EBU to JL)
- Generally, a smaller catheter was used (JL3.5 instead of JL4 and EBU3.0 instead of EBU3.5)
- For horizontal aorta: JL3.5 and 3DRC



### Device and Procedural

1. Commissural tab orientation
2. Sealing skirt height
3. Valve implant depth



# Durabilité: nouvelles définitions

**Table 3 Structural valve deterioration**

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

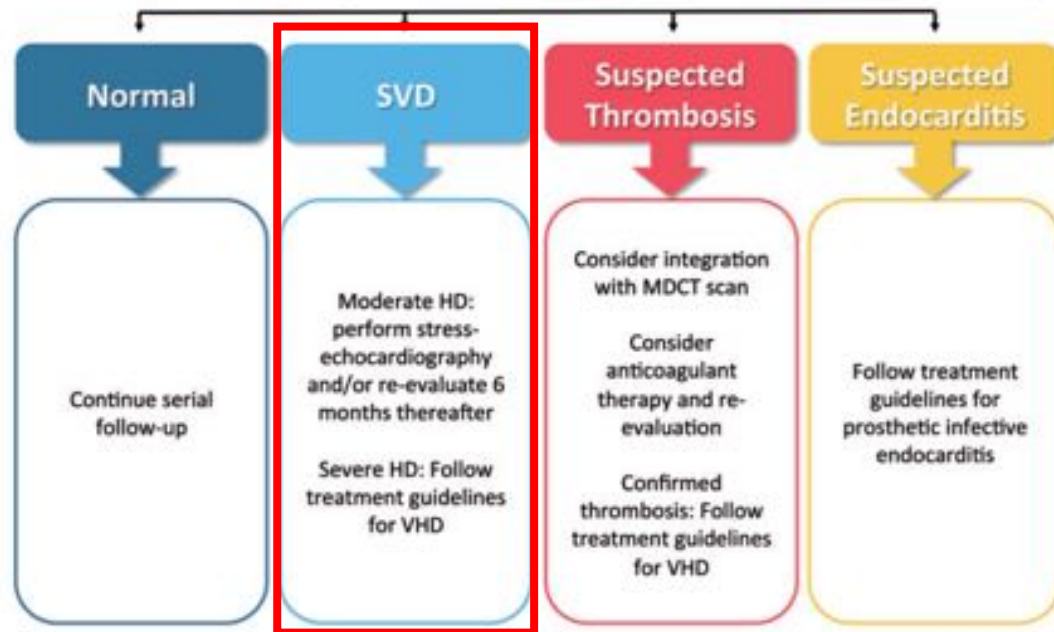
Morphological SVD (any of the following)

- Leaflet integrity abnormality (i.e. torn or flail causing intra-frame regurgitation)
- Leaflet structure abnormality (i.e. pathological thickening and/or calcification causing valvular stenosis or central regurgitation)
- Leaflet function abnormality (i.e. impaired mobility resulting in stenosis and/or central regurgitation)
- Strut/frame abnormality (i.e. fracture)

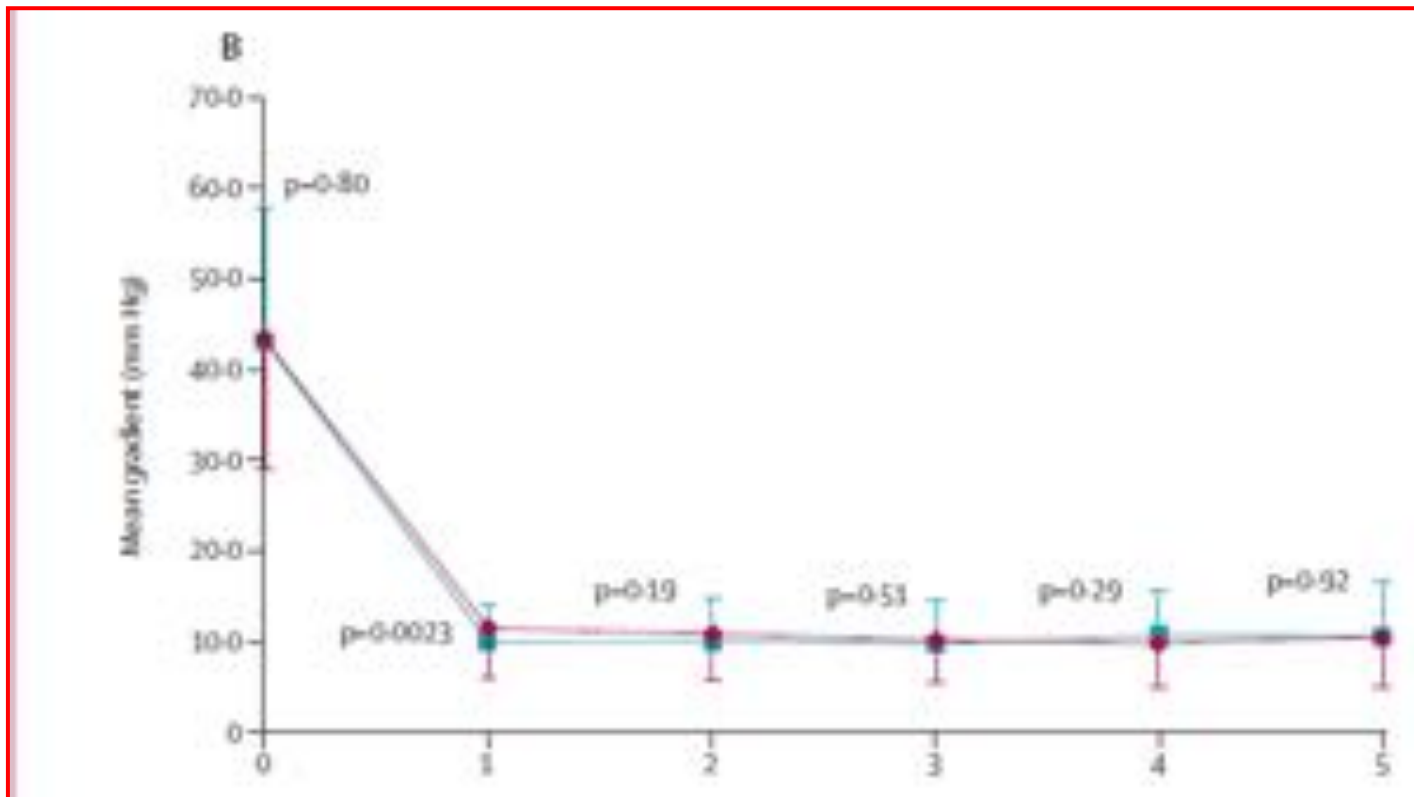
Haemodynamic and morphological SVD

SVD, structural valve deterioration.

## Echocardiographic follow-up (TTE and/or TOE)



# Durabilité: étude Partner 1 à 5 ans

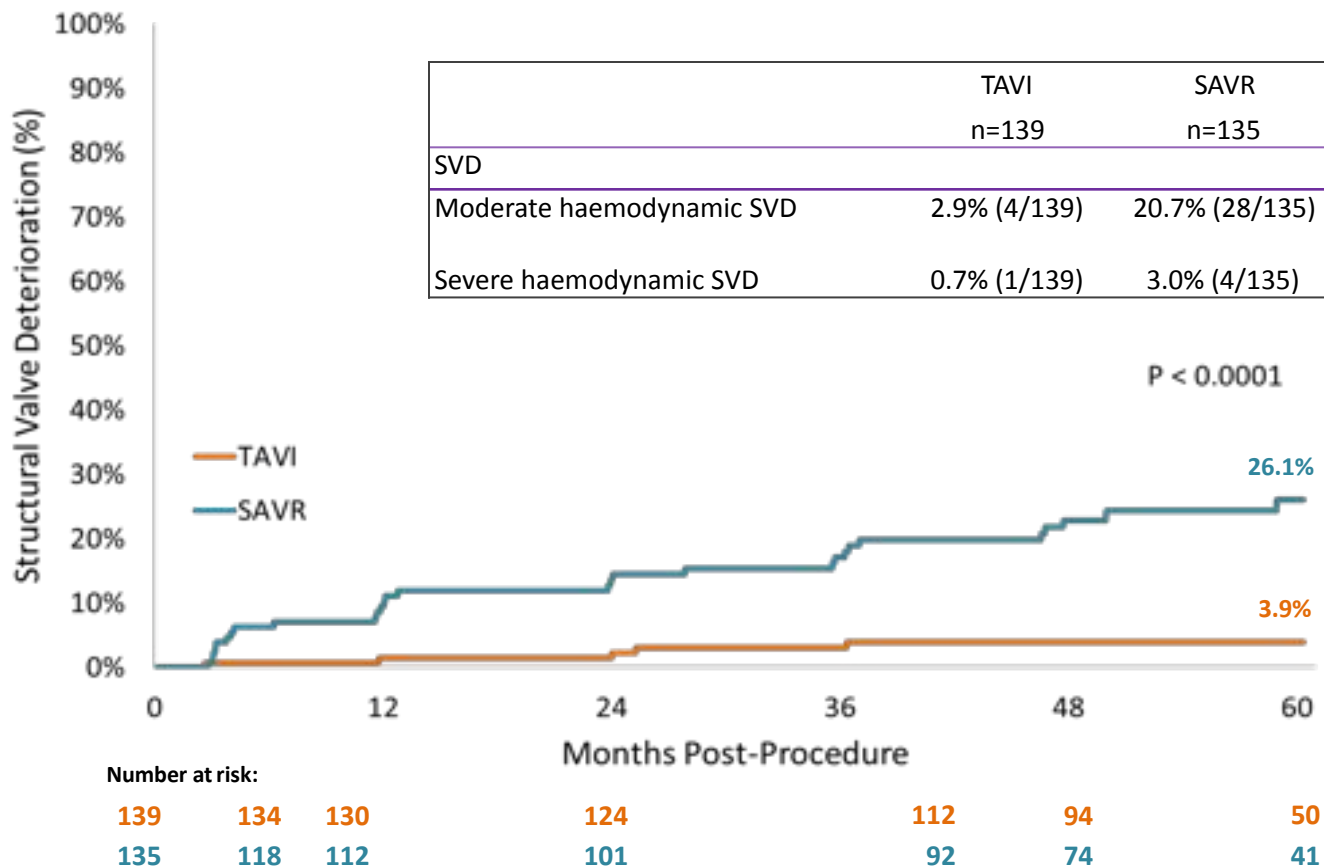


**Aucun cas de ré-intervention dans les 2 groupes**

Mack MJ et al. Lancet 2015; 385:2477-2484.

# The NOTION Trial

## Structural Valve Deterioration



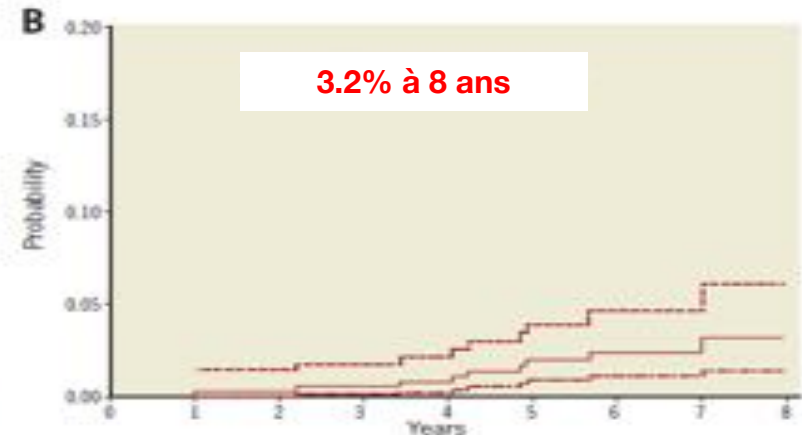
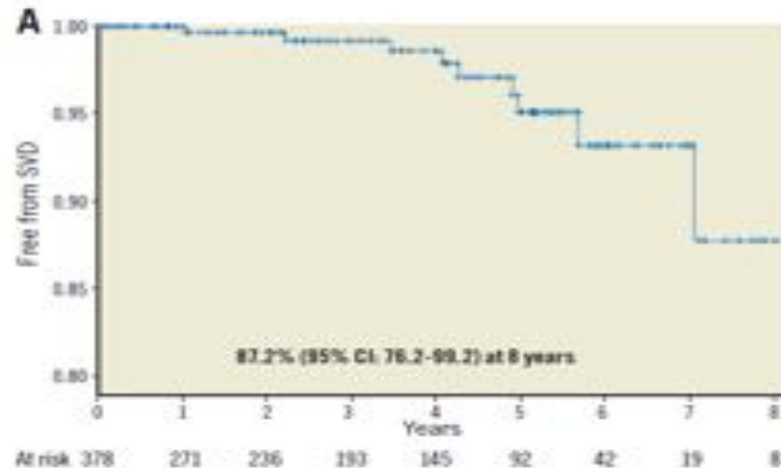


## Assessment of structural valve deterioration of transcatheter aortic bioprosthetic balloon-expandable valves using the new European consensus definition

■ EuroIntervention 2018;13-online publish-ahead-of-print March 2018

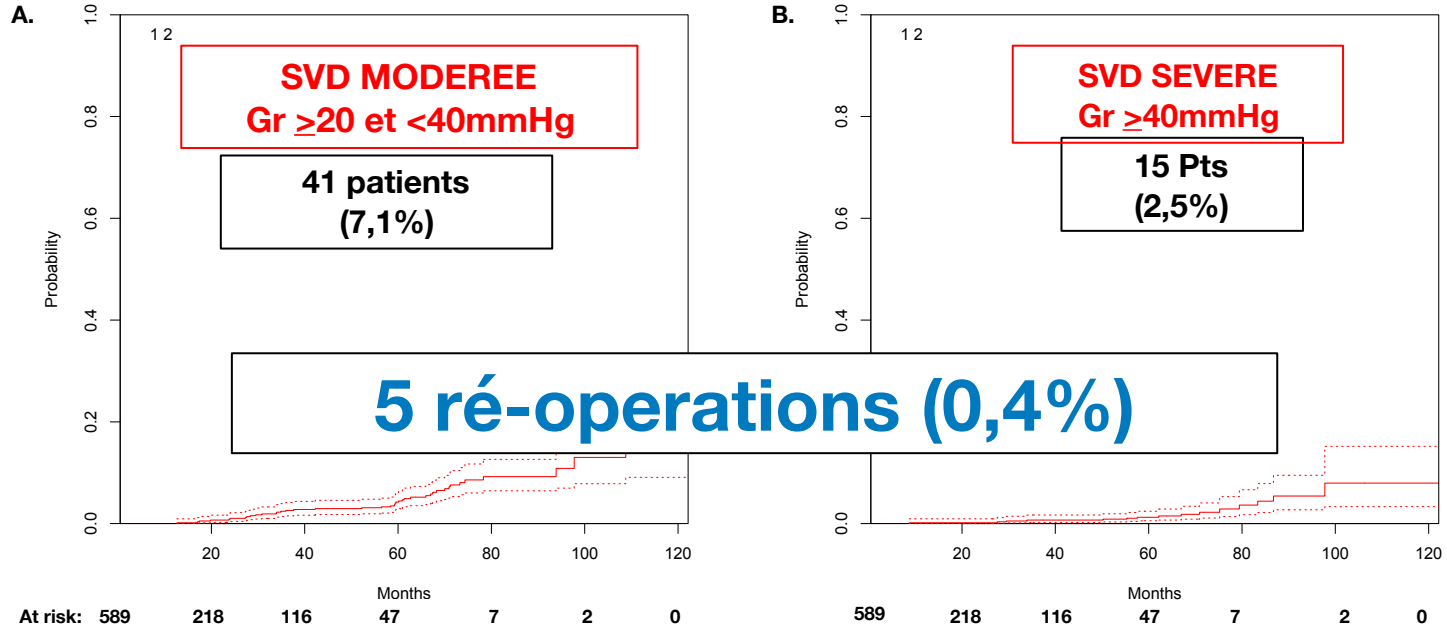
Hélène Eltchaninoff<sup>1,2\*</sup>, MD; Eric Durand<sup>1,2</sup>, MD, PhD; Guillaume Avinée<sup>1,2</sup>, MD; Christophe Tron<sup>1</sup>, MD; Pierre-Yves Litzler<sup>2,3</sup>, MD; Fabrice Bauer<sup>1,2</sup>, MD; Jean-Nicolas Dacher<sup>2,4</sup>, MD; Camille Werhlin<sup>1</sup>, MD; Najime Bouhzam<sup>1</sup>, MD; Nicolas Bettinger<sup>1</sup>, MD; Pascal Candolfi<sup>5</sup>, PhD; Alain Cribier<sup>1</sup>, MD

CLINICAL RESEARCH  
INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE



**Figure 3.** Freedom from structural valve deterioration (SVD) and incidence of SVD. *A)* Freedom from SVD (Kaplan-Meier analysis). *B)* Incidence of SVD (death-competing risk analysis).

# Durabilité du TAVI > 5 ans



7 ans 9.2% (95%CI: 6.5-12.6)

10 ans 16.6% (95%CI: 9.1-26.0)

7 ans 4.4% (95%CI: 2.2-7.9)

10 ans 8.0% (95%CI: 3.3-15.2)



# Indications « résiduelles » de la chirurgie

- **Anévrisme de l'aorte ascendante** > 55 mm
- **Valvulopathie mitrale et/ou tricuspide** associée nécessitant une prise en charge chirurgicale
- **Indication associée de revascularisation coronaire par pontage aortocoronaire**
- **Certaines bicuspidies, notamment très calcifiées**
- **Age < 65 ans**: « on ne pourra pas mettre plus de 2 stents dans l'anneau aortique ! »
- **Mauvais candidats au TAVI**, notamment chez des patients à faible risque chirurgical :
  - Anneau trop petit ou trop large
  - Distance réduite entre l'anneau et les ostia coronaires
  - Accès fémoral impossible ou dangereux (calibres et/ou tortuosités et/ou calcifications)

# Conclusions

- Le TAVI occupe une place croissante dans la prise en charge du RA serré symptomatique mais les indications **sont actuellement limitées aux patients à risque chirurgical** (STS score  $>4\%$ , EuroSCORE log,  $>10\%$ ), fragiles ou ayant des co-morbidités non prises en compte par les scores de risque
- **Nous aurons prochainement les résultats des 4 études évaluant la non-infériorité du TAVI chez les patients  $> 65$  ans à faible risque**
- **Il reste cependant à démontrer**, même en l'absence de signe d'alarme actuel, que la **durabilité des bioprothèses (TAVI et RVA) est similaire**

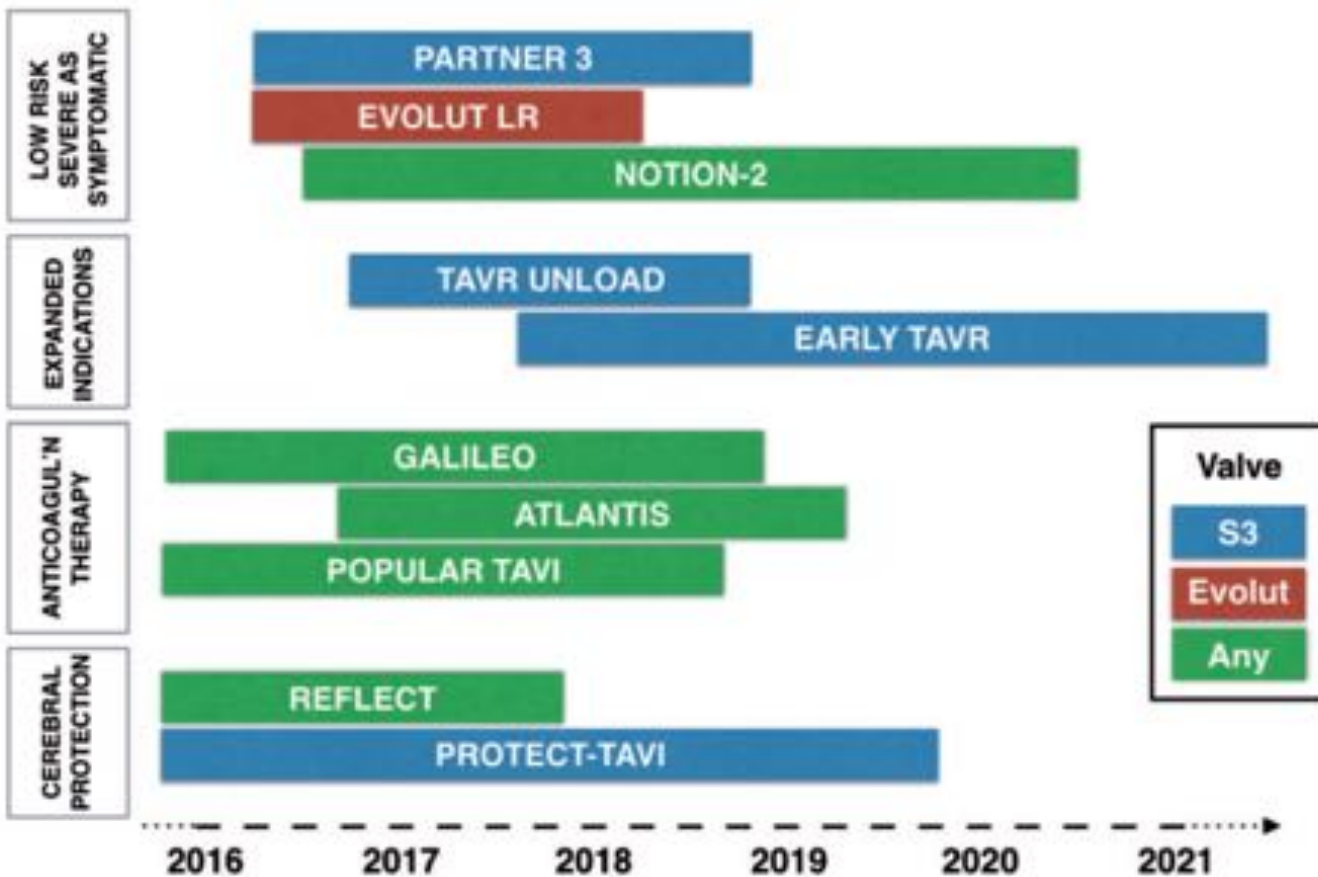
# Conclusions

- Un bon candidat à la chirurgie n'est pas forcément un bon candidat à un TAVI, notamment quand on s'adresse à une population à bas risque chirurgical !

**Merci pour votre attention**







# Durabilit  (NOTION) 5 ans

## Aortic Valve Performance

