

TAVI EN 1^{ÈRE} INTENTION, DES CRAINTES QUANT À LA DURABILITÉ DES PROTHÈSES?

HÉLÈNE ELTCHANINOFF

La durabilité des bioprothèses

- Comment la définit-on?
- Les mécanismes
- Que montrent les études ?
- Qu'en faire ? : Eric Durand

Comment définir la durabilité d'une bioprothèse ?

- La durabilité est définie par l'absence de dysfonction valvulaire
- Toutes les bioprothèses ont une durabilité limitée
- La durabilité des bioprothèses chirurgicales est connue et définie par l'absence de ré-intervention
- La durabilité des bioprothèses est un « sujet » à l'ère de l'extension des indications à des patients plus jeunes et à un stade plus précoce du RA (ESC 2021)



ACC/AHA CLINICAL PRACTICE GUIDELINE

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by 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: Alec Vahanian¹ (ESC Chairperson) (France), Friedhelm Beyersdorf¹ (EACTS Chairperson) (Germany), Fabien Praz (ESC Task Force Coordinator) (Switzerland), Milan Milojevic¹ (EACTS Task Force Coordinator) (Serbia), Stephan Baldus (Germany), Johann Bauersachs (Germany), Davide Capodanno (Italy), Lenard Conradi¹ (Germany), Michele De Bonis¹ (Italy), Ruggero De Paulis¹ (Italy), Victoria Delgado (Netherlands), Nick Freemantle¹ (United Kingdom), Martine Gilard (France), Kristina H. Haugaa (Norway), Anders Jeppsson¹ (Sweden), Peter Juni (Canada), Luc Pierard (Belgium), Bernard D. Prendergast (United Kingdom), J. Rafael Sádaba¹ (Spain), Christophe Tribouilloy (France), Wojtek Wojakowski (Poland), ESC/EACTS Scientific Document Group



Mécanismes affectant la durabilité

Dysfonction non structurelle

Anomalie non liée à la valve elle-même:

- *Mismatch*
- *IA para-valvulaire*

Présent dès le départ

Thrombose

Modifications « transitoires » des feuillets de la bioprothèse

Endocardite

Détérioration structurelle de la valve

Modifications persistantes des feuillets de la bioprothèse:

- *Calcifications*
- *Déchirure*

Apparaissant durant le suivi

Mécanismes affectant la durabilité

**Dysfonction non
structurelle**

Thrombose

Endocardite

**Détérioration structurelle
de la valve**

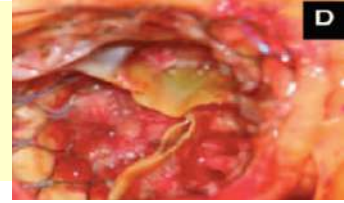
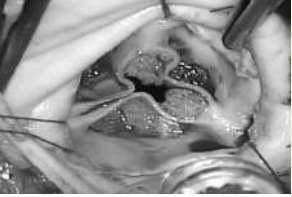
Purement INFRA-clinique

Ou bien

Avec retentissement clinique



Thrombose

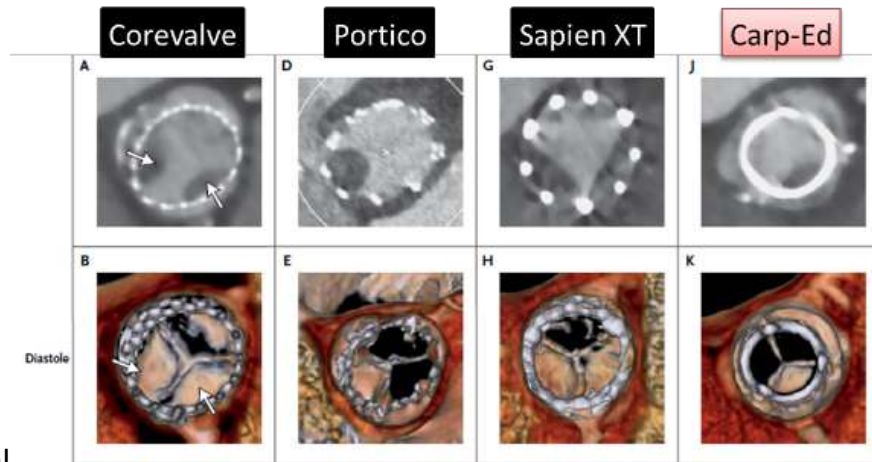
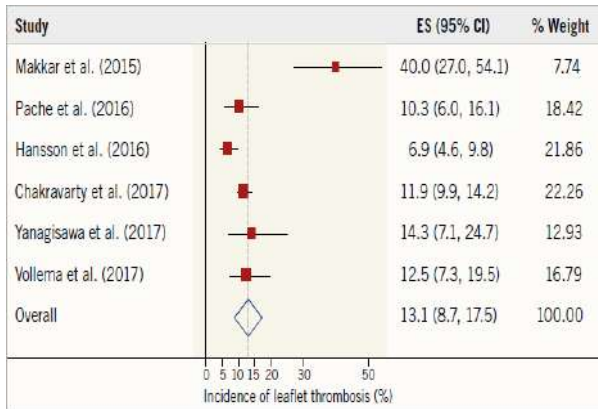


13%

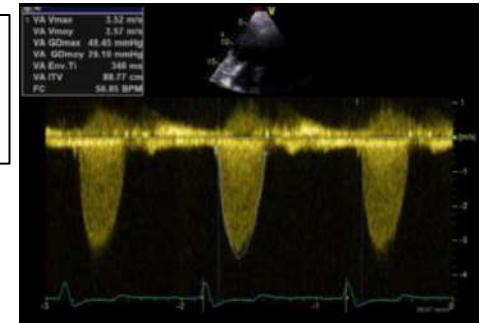
**INFRA-clinique
Découverte au scanner**

**Expression clinique
Découverte à l'ETT**

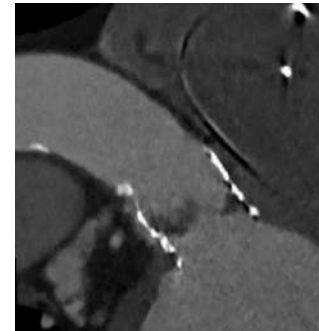
< 1%



Augmentation
du gradient



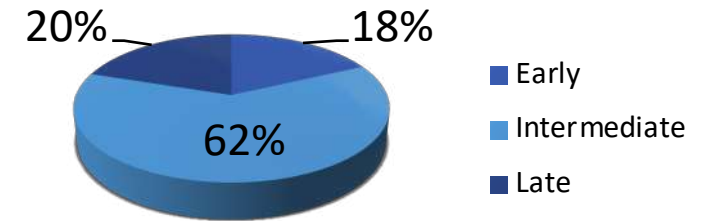
Confirmation au scanner



Anticoagulation prolongée

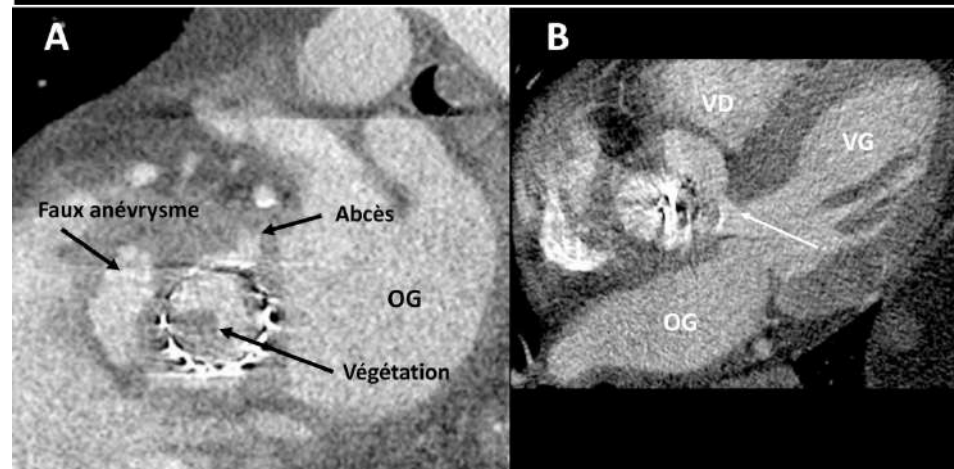
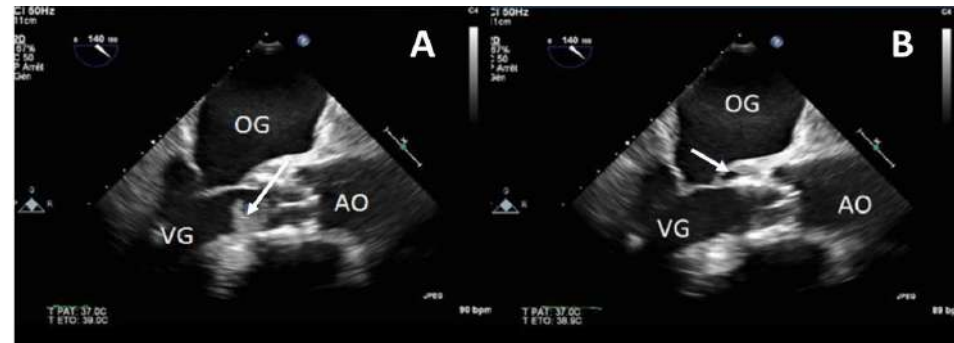
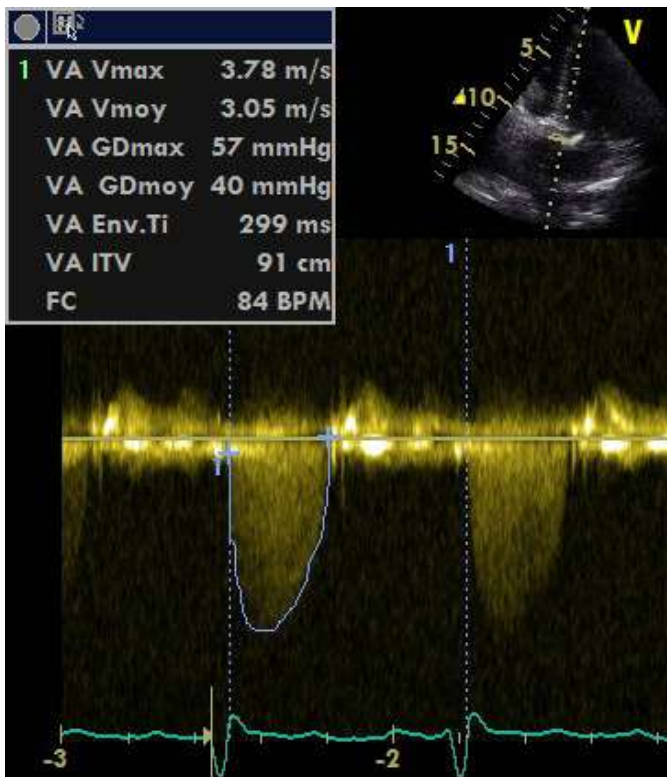
Endocardite

0.3-1.2% / patient / an



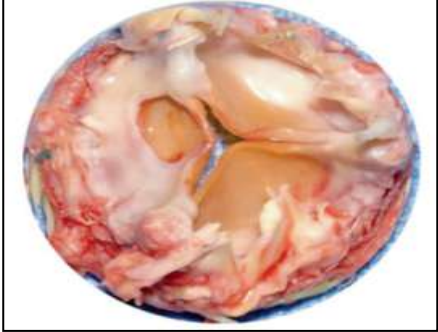
Augmentation du gradient
et/ou IA centrale
à l'échographie

Confirmation par hémocultures; ETO; +/-PET scan



Antibiothérapie
+/-RVA

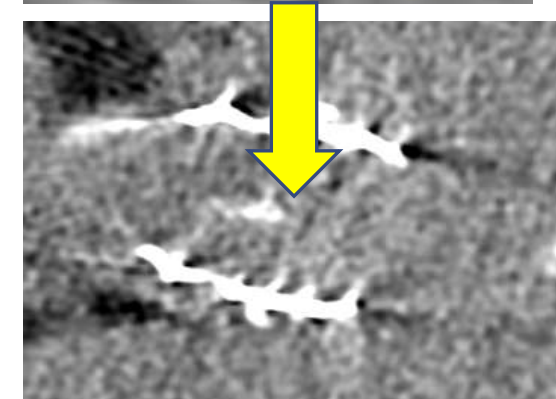
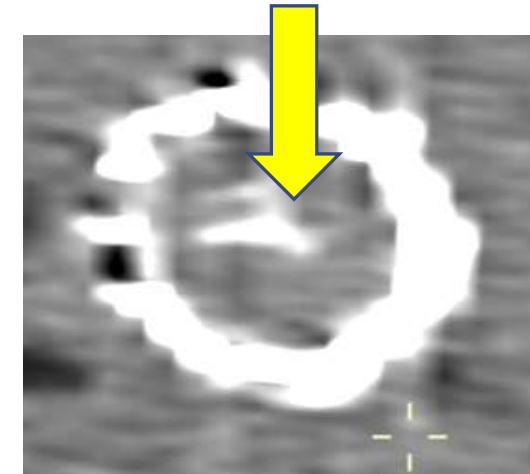
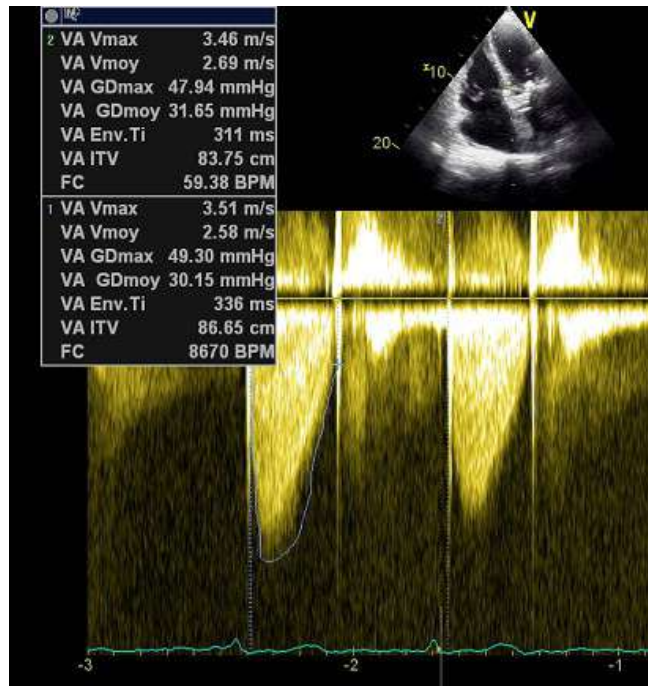
Dégénérescence (Structural Valve Deterioration)



Réapparition des symptômes

Augmentation du gradient
et/ou IA centrale

Diagnostic au scanner



Des définitions standardisées basées sur l'ETT depuis 2017

EAPCI/EACTS 2017

EJ 2017;38:3382-90

Moderate haemodynamic SVD (any of the following)

Mean transprosthetic gradient ≥ 20 mmHg and < 40 mmHg

Mean transprosthetic gradient ≥ 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 transpr

Mean transpr

Severe intra-

($>2+/4+$) fr

Morphological S

Leaflet integr

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

VARC 3 2021

EJ 2021;42:1825-57

Stage 1: Morphological valve deterioration

- Intrinsic permanent changes to the prosthetic valve, including leaflet tear, disruption, flail leaflet, leaflet fibrosis and/or calcification without significant hemodynamic changes.

Stage 2: Moderate hemodynamic valve deterioration[†]

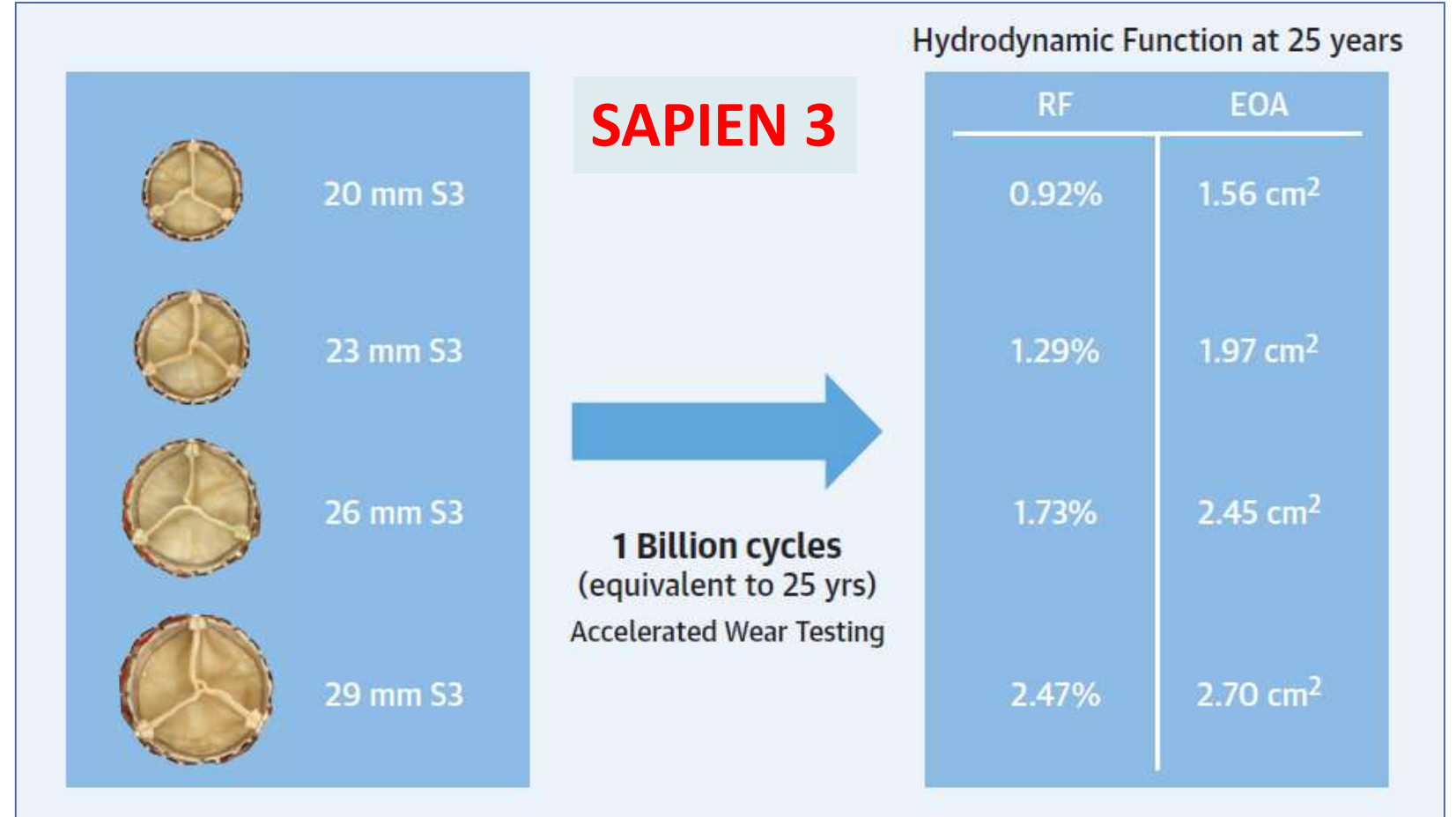
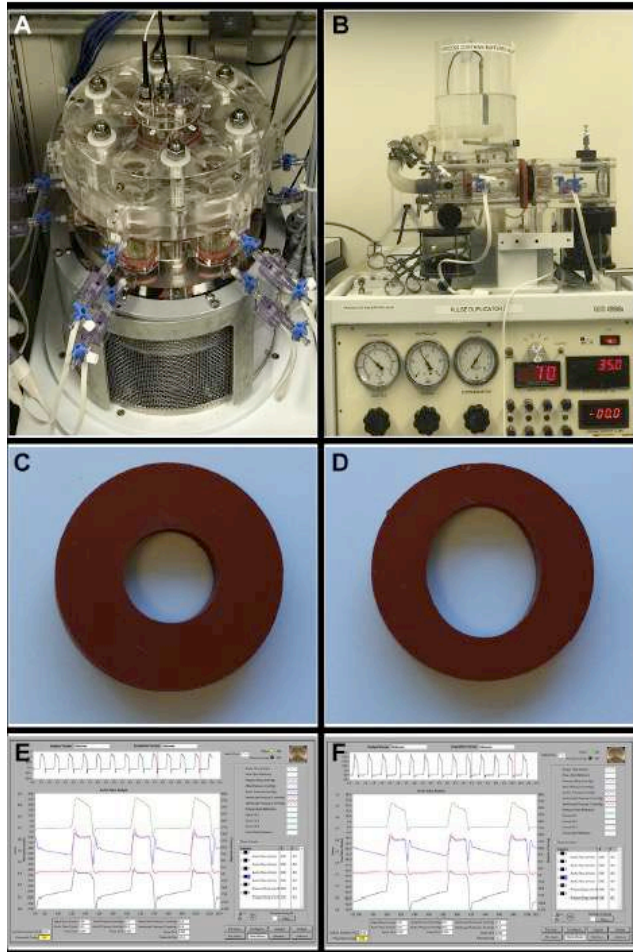
- Morphological valve deterioration (See Stage 1) AND:
- Increase in mean transvalvular gradient ≥ 10 mmHg resulting in mean gradient ≥ 20 mmHg[‡] with concomitant decrease in AVA ≥ 0.3 cm² or $\geq 20\%$ compared with post-procedure (or discharge if not available), OR new occurrence or increase of ≥ 2 grades, of transvalvular AR.

- Valeurs: gradient moyen, Sao, Vmax, IA centrale
- Valeurs seuils

----- → grades de sévérité

- Morphological valve deterioration (See Stage 1) AND:
- Increase in mean transvalvular gradient ≥ 20 mmHg resulting in mean gradient ≥ 30 mmHg[‡] with concomitant decrease in AVA ≥ 0.6 cm² or $\geq 50\%$ and/or decrease in Doppler velocity index ≥ 0.2 or $\geq 40\%$ compared to echocardiographic assessment performed 1 to 3 months post-procedure (or discharge if not available), OR new occurrence, or increase of ≥ 2 grades, of transvalvular AR resulting in severe AR.

Que savons-nous des tests de durabilité ?



Durabilité similaire au comparateur chirurgical testé

Long-Term Durability of Transcatheter Heart Valves

Insights From Bench Testing to 25 Years

Janarthanan Sathananthan, MChB, MPH,¹ Mark Hensey, MB BCh BAO,² Uri Landes, MD,³ Abdullah Alkhodair, MD,⁴ Adeb Saiduddin, BSc,⁵ Stephanie Sellers, PhD,⁶ Anson Cheung, MD,⁷ Sandra Lauck, PhD,⁸ Philipp Blanke, MD,⁹ Jonathon Leipsic, MD,¹⁰ Jian Ye, MD,¹¹ David A. Wood, MD,¹² John G. Webb, MD¹³

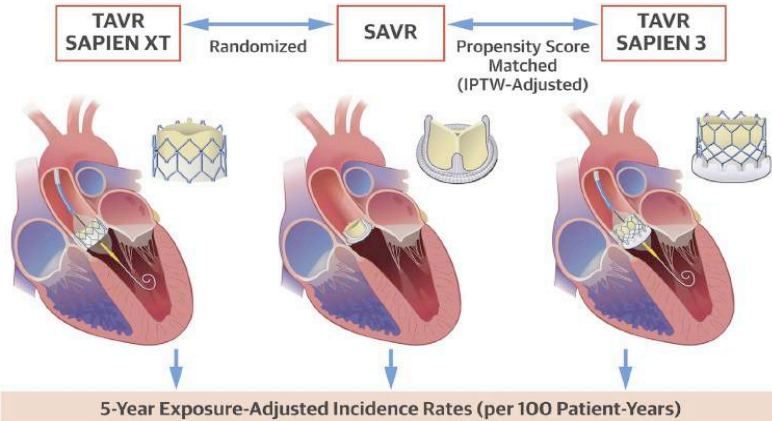
Les données des registres à 7-8 ans

| Author | N | Period | Valve | 7-y Survival | 7/8-y Severe SVD | 7-8 yr Re-intervention |
|--------------|------|-----------|----------------------|--------------|------------------|------------------------|
| Eltchaninoff | 378 | 2002-2012 | BE (100%) | 18% | 1% | 0.6% |
| Deutch | 300 | 2007-2009 | SE (71%) BE (29%) | 23.2% | 0.6% | 1.3% |
| Holy | 152 | 2007-2011 | SE (100%) | - | - | 3.3% (not for SVD) |
| Barbanti | 288 | 2007-2009 | SE (100%) | - | - | 0.7% |
| Durand | 1403 | 2007-2011 | SE (100%) | - | 4.2% | 1% |
| Blackman | 241 | 2007-2011 | SE (100%) | ? | 0.4% | 0% |
| Orwin | 184 | 2008-2011 | SE (69%) BE (31%) | - | 3.3% (BVF) | 1.6% |
| Panico | 278 | 2007-2013 | SE (100%) | 20% | 1.8% | 1.1% |

Pas de signal d'alarme
 SVD sévère: 0 - 4.2%
 Re-intervention: 0 - 1.3%

Les données dans les études randomisées (vs RVA)

Structural Deterioration of Transcatheter Versus Surgical Aortic Valve Bioprostheses in the PARTNER-2 Trial



A 5 ans

PARTNER 2 J Am Coll Cardiol. 2020;76(16):1830-43.

5-Year Clinical and Echocardiographic Outcomes from the Randomized SURTAVI Trial

Nicolas M. Van Mieghem, MD, PhD
For the SURTAVI Trial Investigators

CRF
TCT

SURTAVI (risque intermédiaire non publié)

A 8 ans

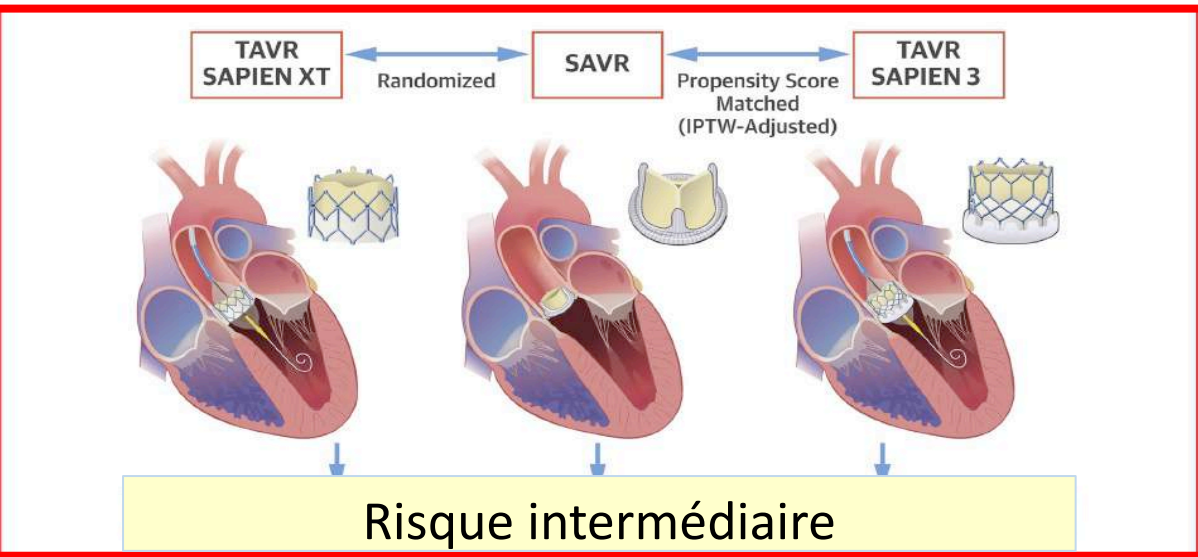
Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement

Eur Heart J, 2021

Troels Højsgaard Jørgensen^{1*†}, Hans Gustav Hørsted Thyregod^{2†},
Nikolaj Ihlemann³, Henrik Nissen³, Petur Petursson⁴, Bo Juel Kjeldsen⁵,
Daniel Andreas Steinbrüchel⁶, Peter Skov Olsen², and Lars Søndergaard¹

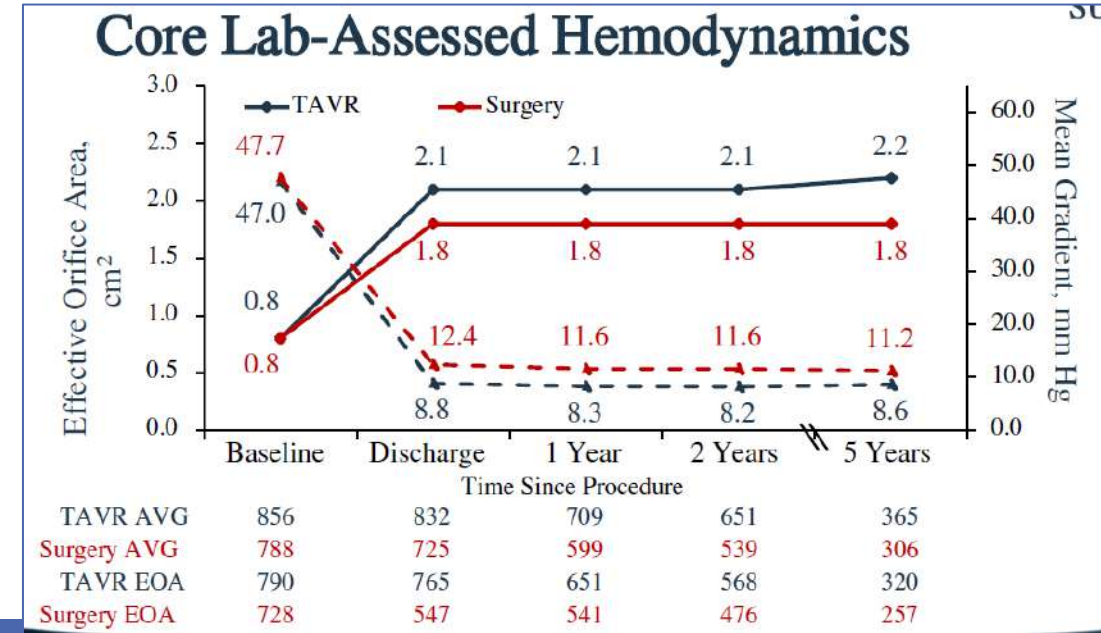
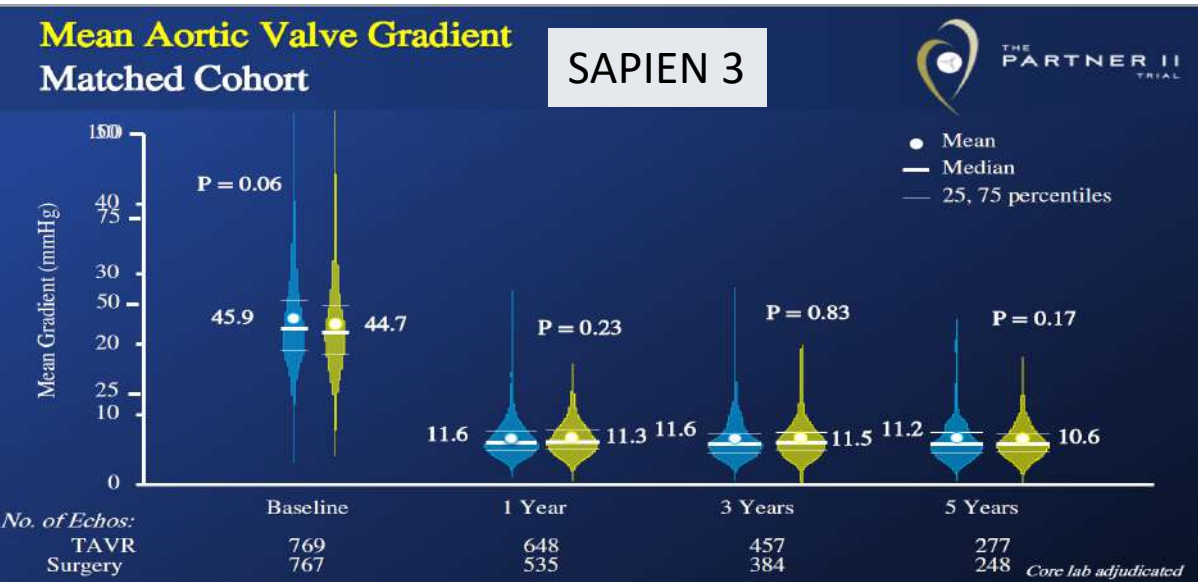
NOTION 3

Durabilité à 5 ans dans PARTNER 2



5-Year Clinical and Echocardiographic Outcomes from the Randomized SURTAVI Trial

Nicolas M. Van Mieghem, MD, PhD
For the SURTAVI Trial Investigators

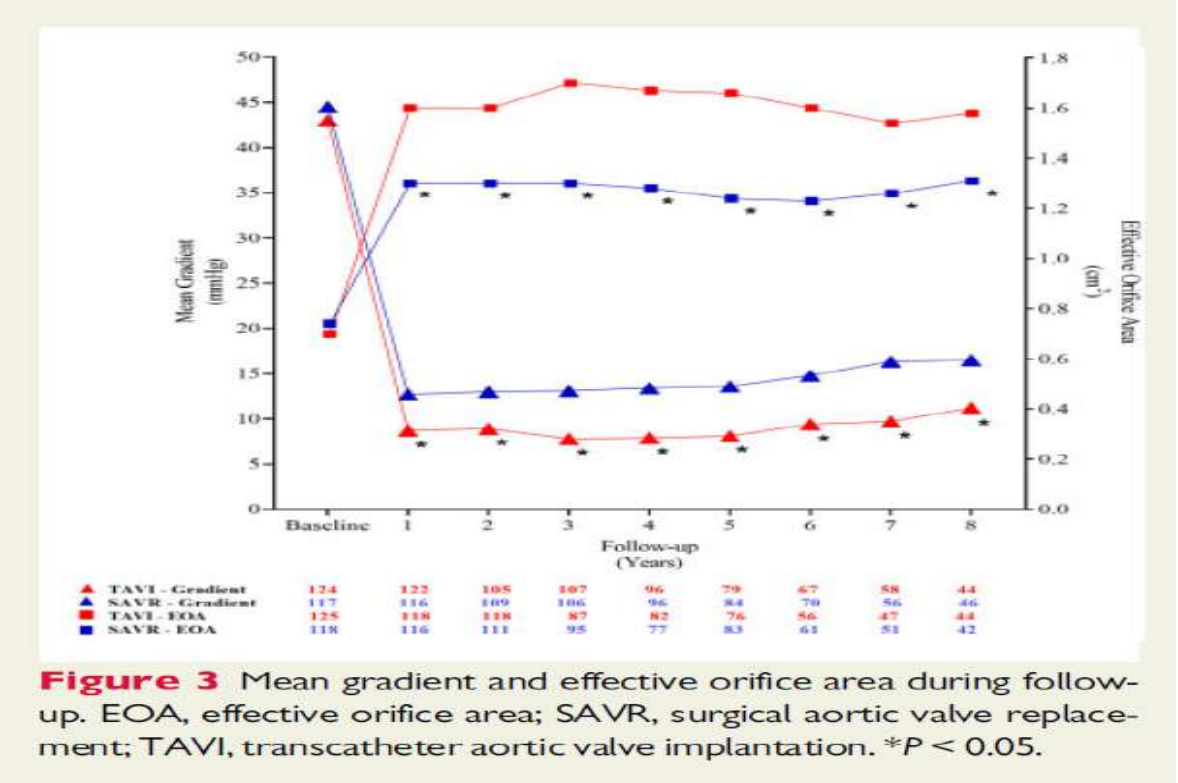
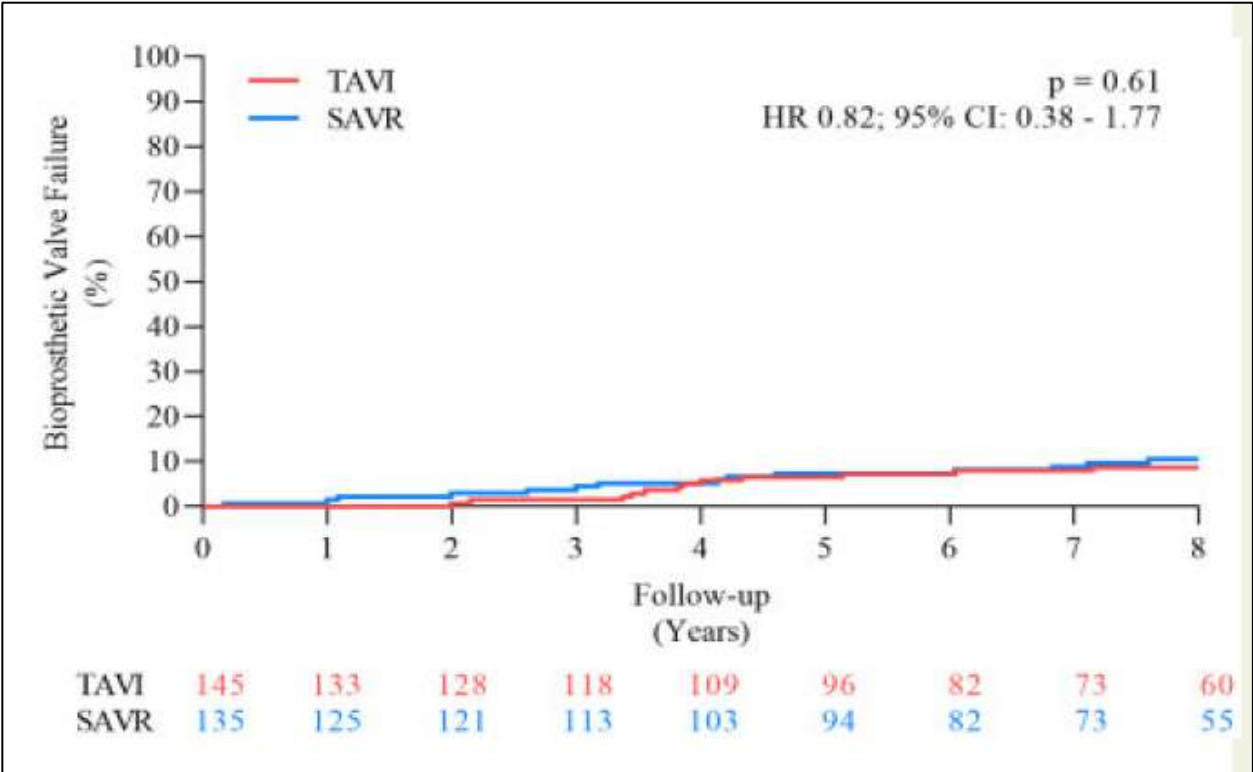


La durabilité à 8 ans dans l'étude randomisée NOTION 3

Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement

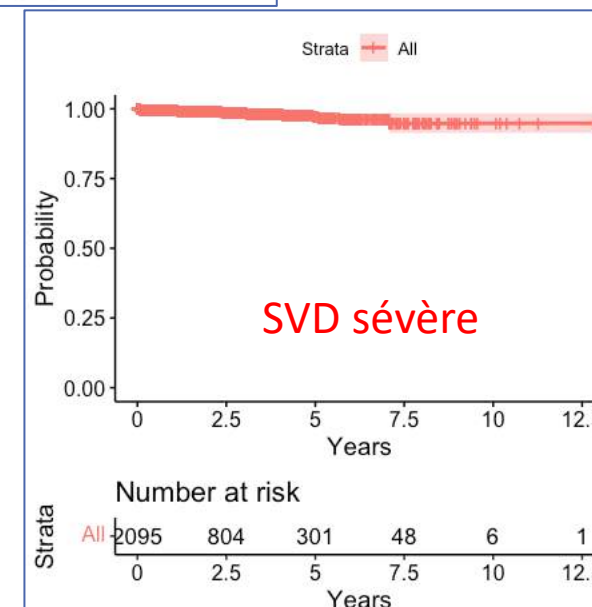
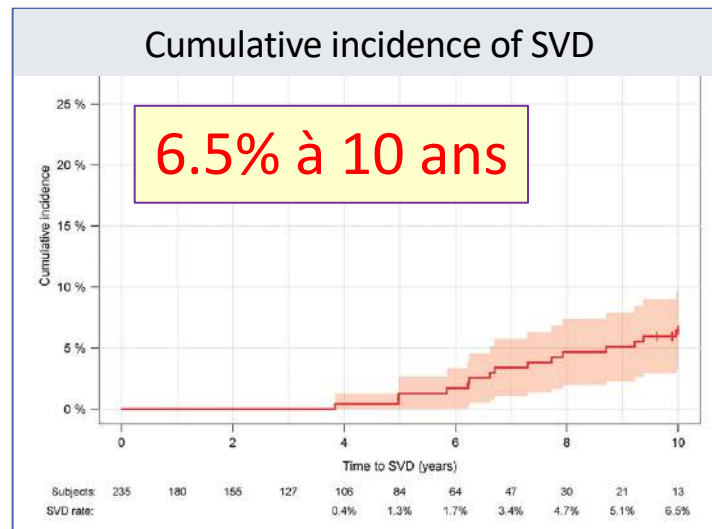
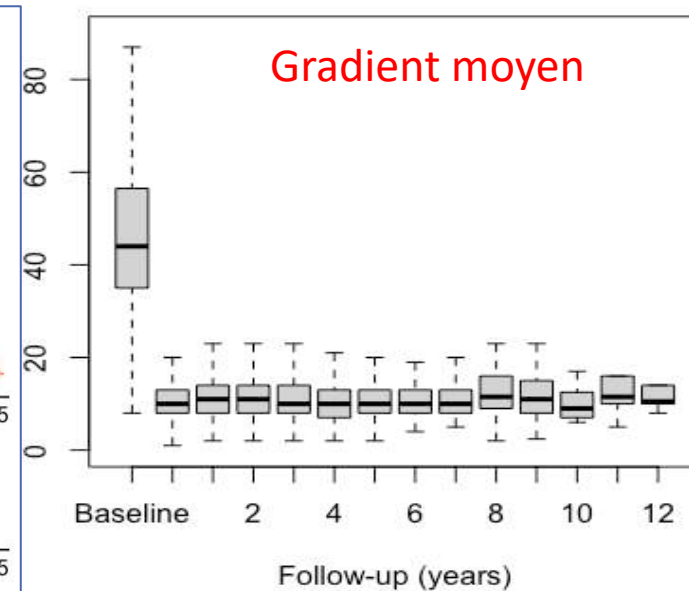
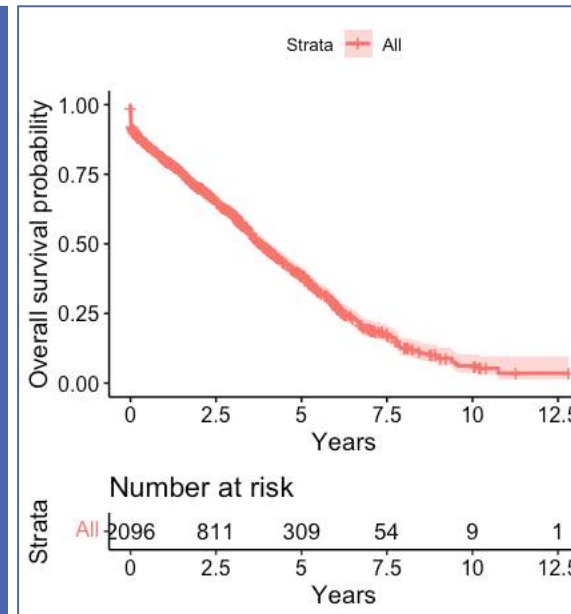
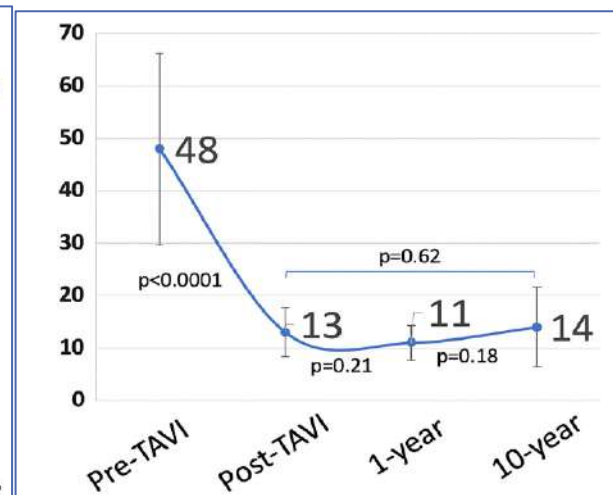
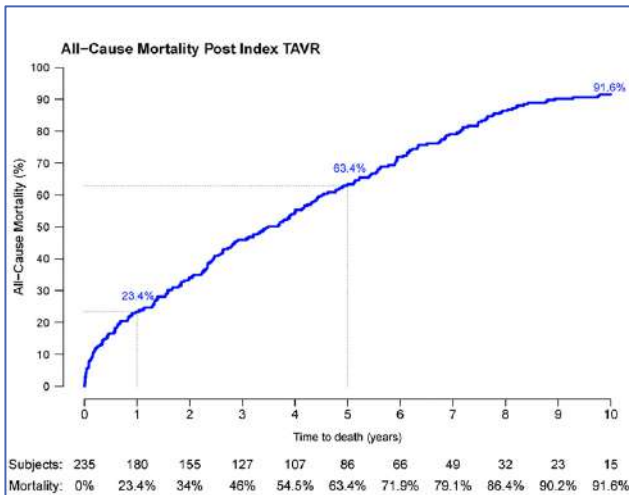
Troels Højsgaard Jørgensen^{1*†}, Hans Gustav Hørsted Thyregod^{2†}, Nikolaj Ihlemann³, Henrik Nissen³, Petur Petursson⁴, Bo Juel Kjeldsen⁵, Daniel Andreas Steinbrüchel⁶, Peter Skov Olsen², and Lars Søndergaard¹

280 PTS
Corevalve vs RVA
STS=3.0+1.7%



Le mismatch après RVA explique la différence de gradient (dès JO) entre TAVI et RVA

La durabilité à 10 ans et au-delà !



Ten year follow-up of high-risk patients treated during the early experience with transcatheter aortic valve replacement

Janarthanan Sathananthan MBChB, MPH | Sandra Lauck PhD | Jopie Polderman BSN | Maggie Yu BSc | Anna Stephenson | Gnalini Sathananthan MD | Robert Moss MD | Anson Cheung MD | Jian Ye MD | Philipp Blanke MD | Jonathon Leipsic MD | David A. Wood MD | John G. Webb MD

Modéré: 9 Pts
Sévère: 6 Pts

Catheter Cardiovasc Interv. 2020;1-7.

Conclusions

- Toutes les biorothèses ont une durée de vie limitée
- La durabilité peut être réduite par plusieurs mécanismes: dégénérescence, thrombose, endocardite, dysfonction initiale (mismatch, IA para-valvulaire)
- Les données sur la durabilité des valves percutanées s'accumulent et aucune alerte n'est à signaler à ce jour chez les patients à haut risque traités il y a plusieurs années
- Chez les patients plus jeunes avec espérance de vie plus longue, la question d'une ré-intervention se posera à un moment donné et soulève encore de nombreuses questions



Une différence entre les valves ?

| | Balloon-Expandable Valve (n = 121) | Self-Expanding Valve (n = 120) | p Value |
|---------------------------------|---------------------------------------|-----------------------------------|---------|
| Bioprosthetic valve dysfunction | 28 (22.5) | 26 (20.9) | 0.91 |
| Components | | | |
| SVD | 6 (6.6) | 0 (0.0) | 0.018 |
| Moderate SVD | 4 (5.6) | 0 (0.0) | 0.047 |
| Severe SVD | 2 (0.9) | 0 (0.0) | 0.20 |
| NSVD | 17 (17.8) | 23 (26.7) | 0.20 |
| Moderate/severe PPM | 14 (15.9) | 13 (16.0) | 1.0 |
| Moderate/severe PVL | 3 (2.5) | 10 (8.5) | 0.08 |
| Valve thrombosis | 6 (7.3) | 1 (0.8) | 0.06 |
| Endocarditis | 2 (1.6) | 4 (3.4) | 0.39 |

Values are n (%). NSVD was diagnosed from post-procedural echocardiography, and p values were calculated from Fischer's exact test. All other percentages are Kaplan-Meier estimates, and p values were calculated from Gray's test.

BVD = bioprosthetic valve dysfunction; NSVD = nonstructural valve deterioration; PPM = patient-prosthesis mismatch; PVL = paravalvular leak; SVD = structural valve deterioration.

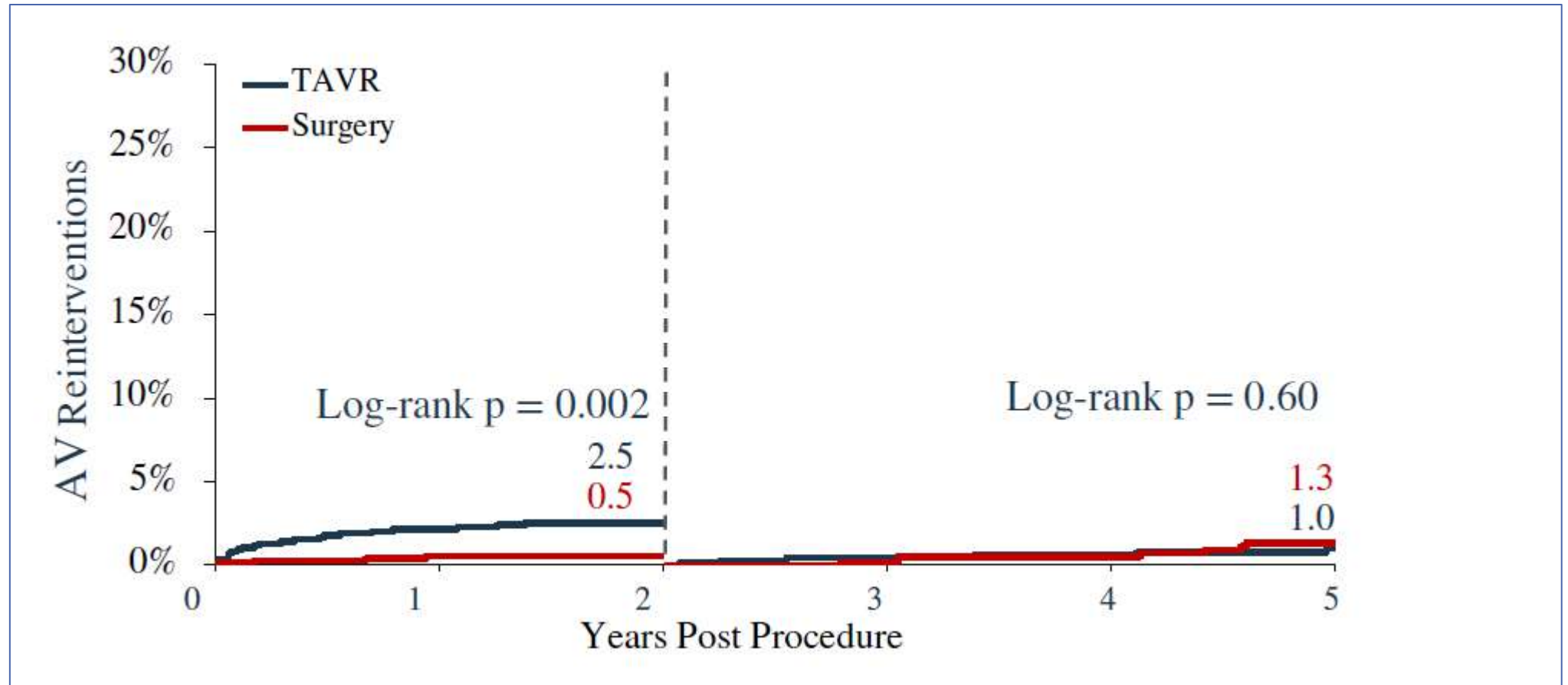
5-Year Outcomes After TAVR With Balloon-Expandable Versus Self-Expanding Valves

Results From the CHOICE Randomized Clinical Trial

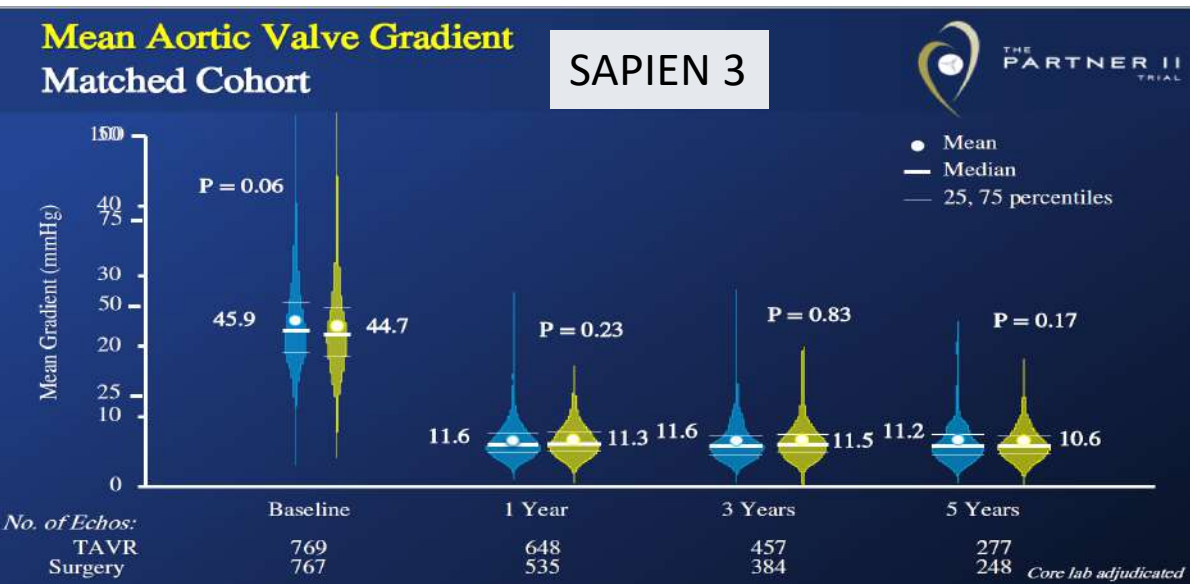
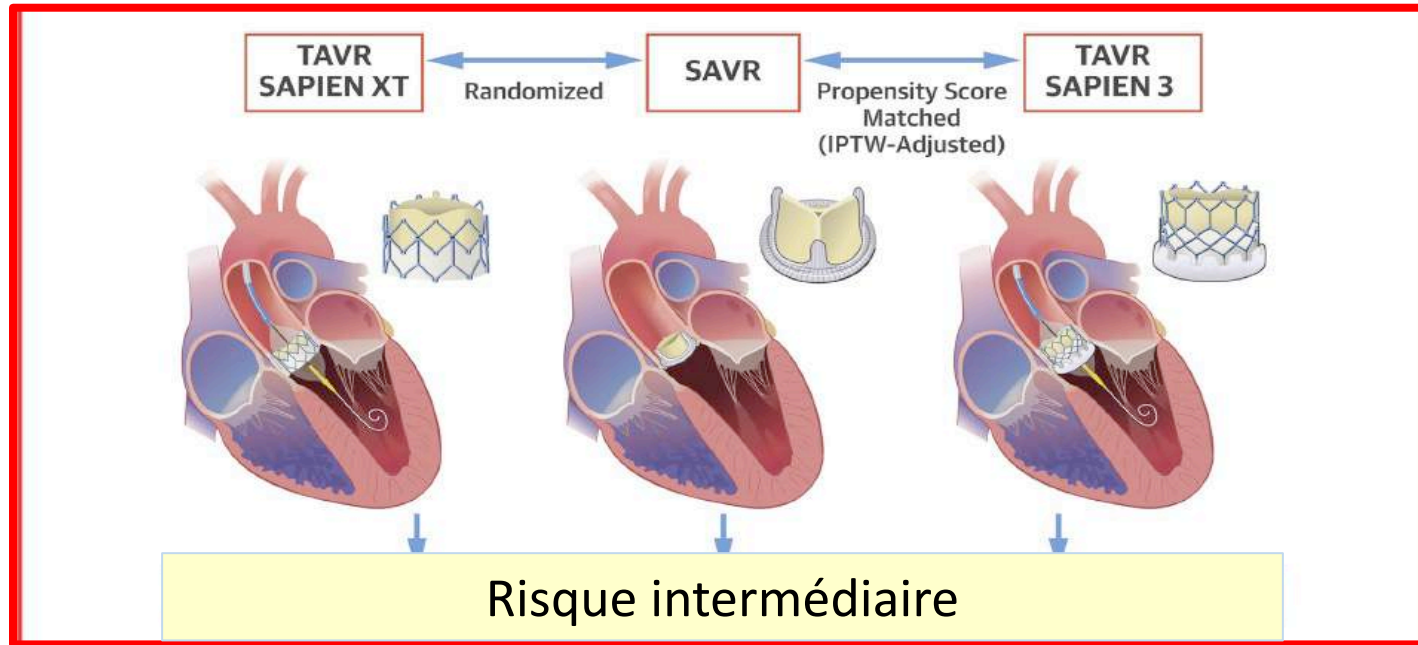


Mohamed Abdel-Wahab, MD,¹ Martin Landt, MD,² Franz-Josef Neumann, MD,³ Steffen Massberg, MD,⁴ Christian Frerker, MD,⁵ Thomas Kurz, MD,⁶ Jatinderjit Kaur, MD,⁷ Ralph Toolg, MD,⁸ Susanne Sachse, MTA,⁹ David Jochheim, MD,¹⁰ Ulrich Schäfer, MD,¹¹ Mohamed El-Mawardi, MD,¹² Derek R. Robinson, DPM,¹³ Gert Richardt, MD,¹⁴ for the CHOICE Investigators

SURTAVI à 5 ans



Durabilité à 5 ans dans PARTNER 2



| | TAVR (n=783) | Surgery (n=783) | OR (95%CI) | P-value |
|-----------------|--------------|-----------------|-------------------|---------|
| Endocardite | 2.2 (17/783) | 2.4 (19/783) | 1.12 (0.58, 2.17) | 0.74 |
| Re-intervention | 1.3 (10/783) | 0.8 (6/783) | 0.60 (0.22; 1.65) | 0.31 |
| Thrombose | 0.8 (6/783) | 0.1 (1/783) | 0.17 (0.02, 1.38) | 0.12 |