



INSTITUT
CARDIOVASCULAIRE
PARIS
SUD

Le TAVI dans 10 ans ?

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In the last year , I received research grants or speaker fees or I am/was consultant for: Biotronik, Colibri, Cordis, Medtronic, Terumo. I am currently minor shareholder & general director of CERC (CRO)



Les prévisions sont difficiles,
surtout en ce qui concerne l'avenir !

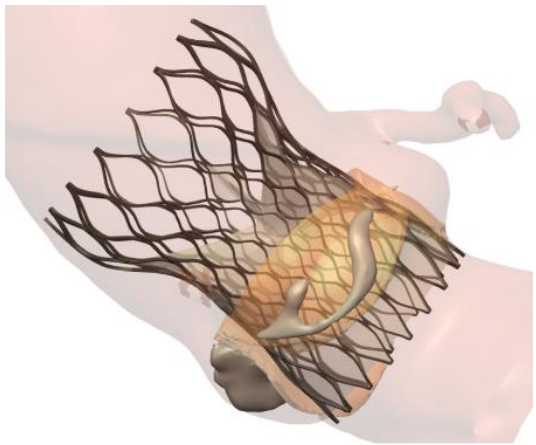


Qu'est ce qui peut changer en 10 ans?

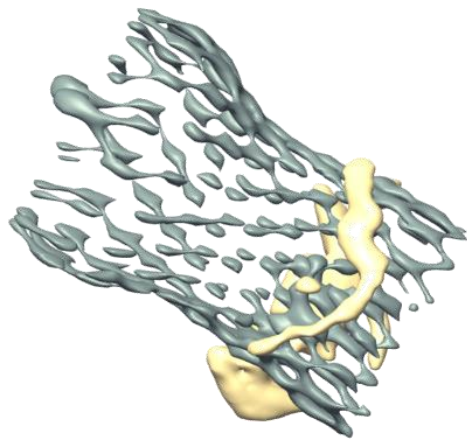
La méthode ?

- IA
- PM
- AVC
- Thrombose +/- asymptomatique

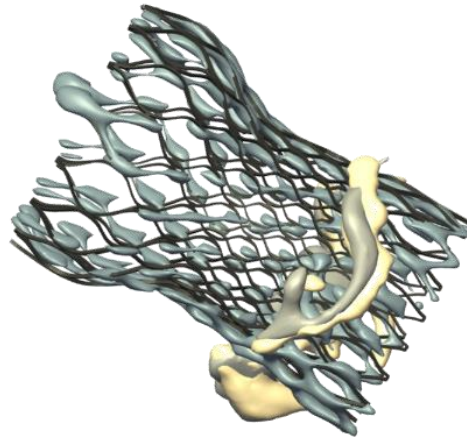
Analyse de simulation



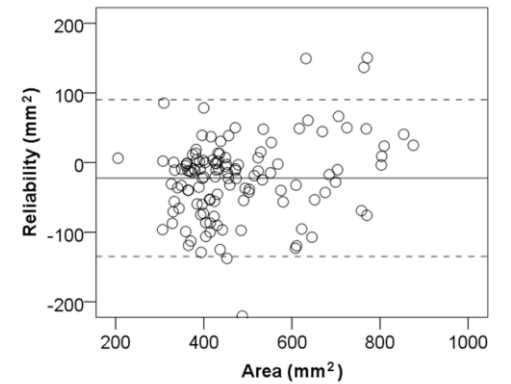
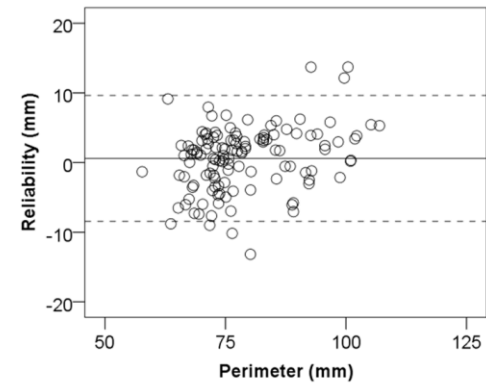
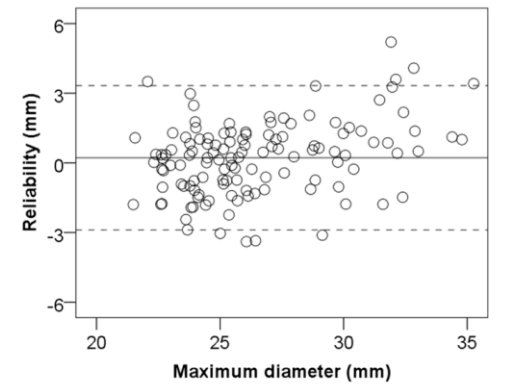
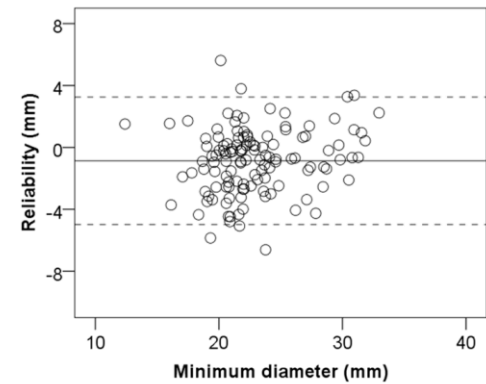
Model



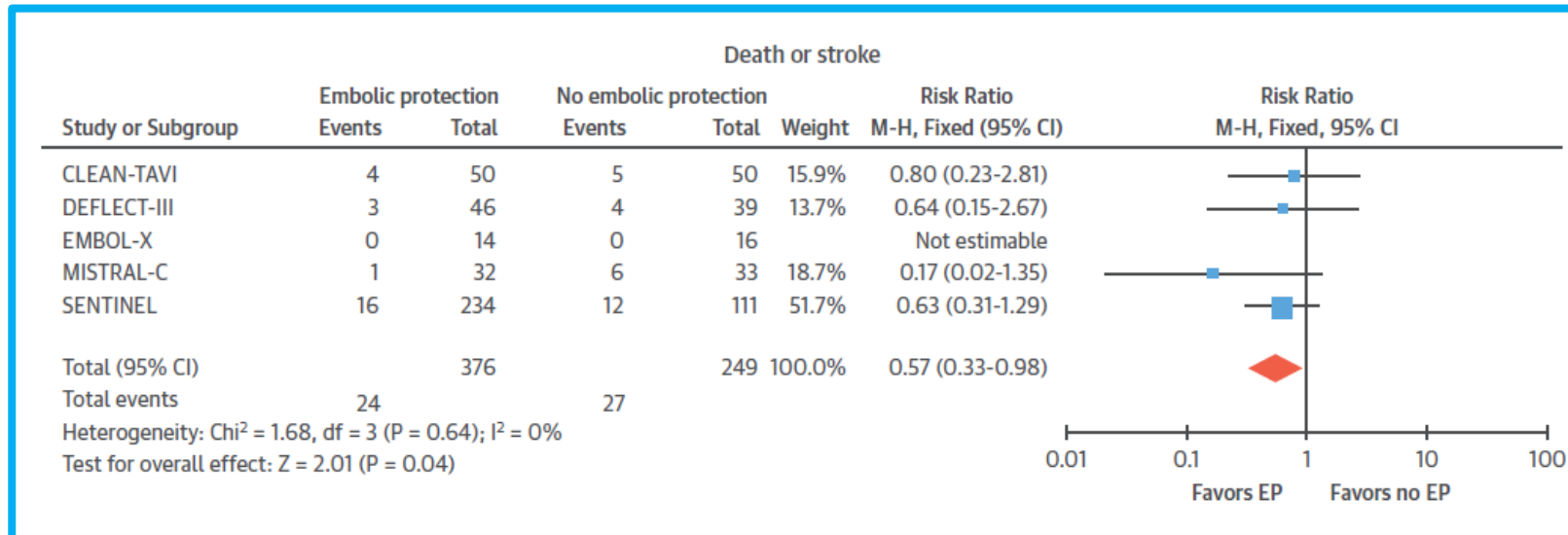
Post-op CT scan



Overlay

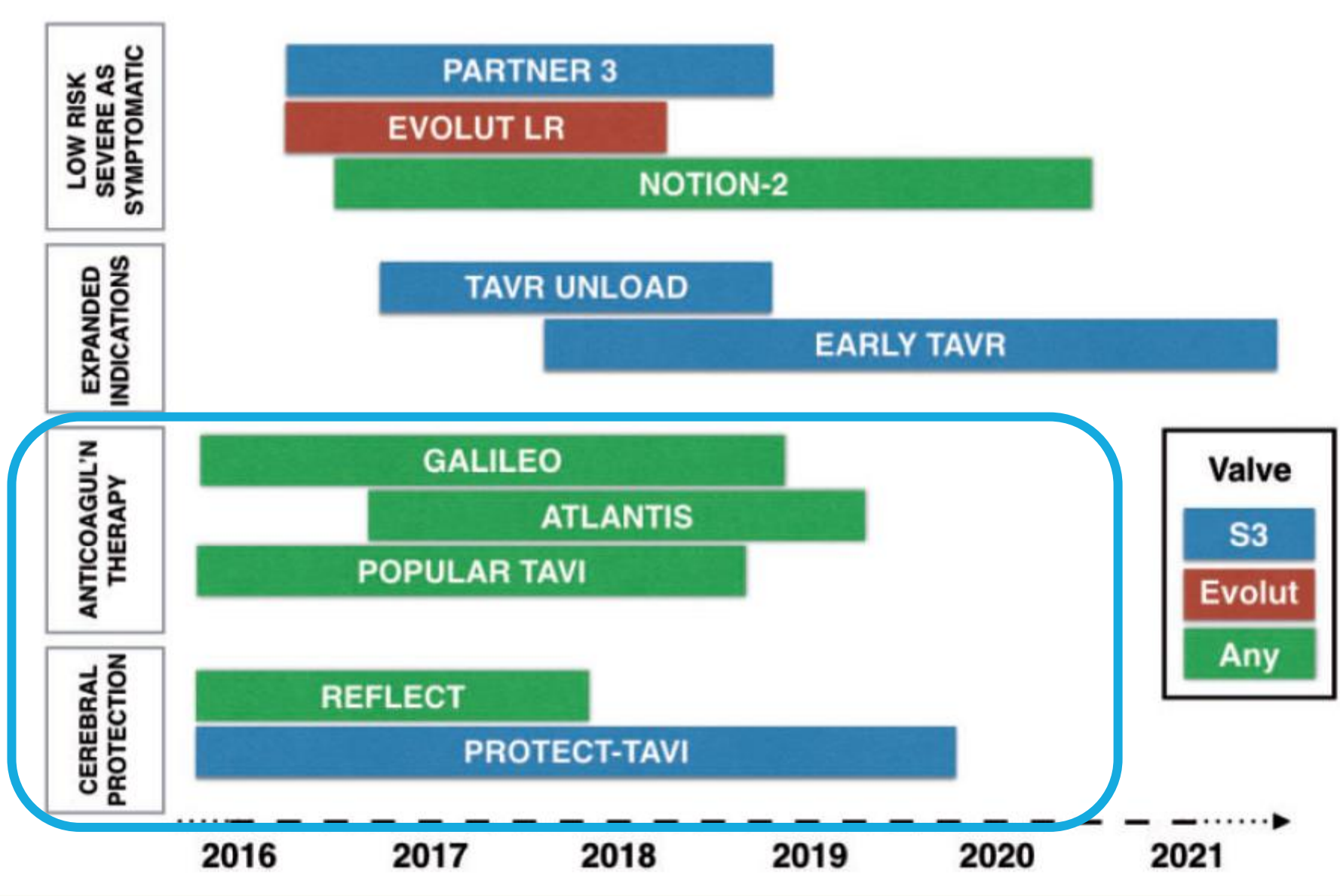


Protection cérébrale



- **Meta-analysis of 5 RCTS of CEP in TAVR (625 pts; 376 with CEP and 249 without CEP)**
- **> 40% reduction in risk of stroke or death (6.4% vs 10.8%; RR: 0.57; 95% CI: 0.33-0.98; p=0.04; I² = 0%)**
- ***NNT = 22 to reduce one stroke or death***

	No protection N=533	With protection N=533	OR (95 %CI)	p-value
Mortality or stroke	6.00 (32/533)	2.06 (11/533)	0.34 (0.17-0.68)	0.0013
All stroke	5.44 (29/533)	1.88 (10/533)	0.35 (0.17-0.72)	0.0028
Disabling stroke	2.44 (13/533)	0.38 (2/533)	0.14 (0.03-0.66)	0.0045
Non-disabling stroke	3.00 (16/533)	1.50 (8/533)	0.53 (0.23-1.24)	0.13



Le lieu

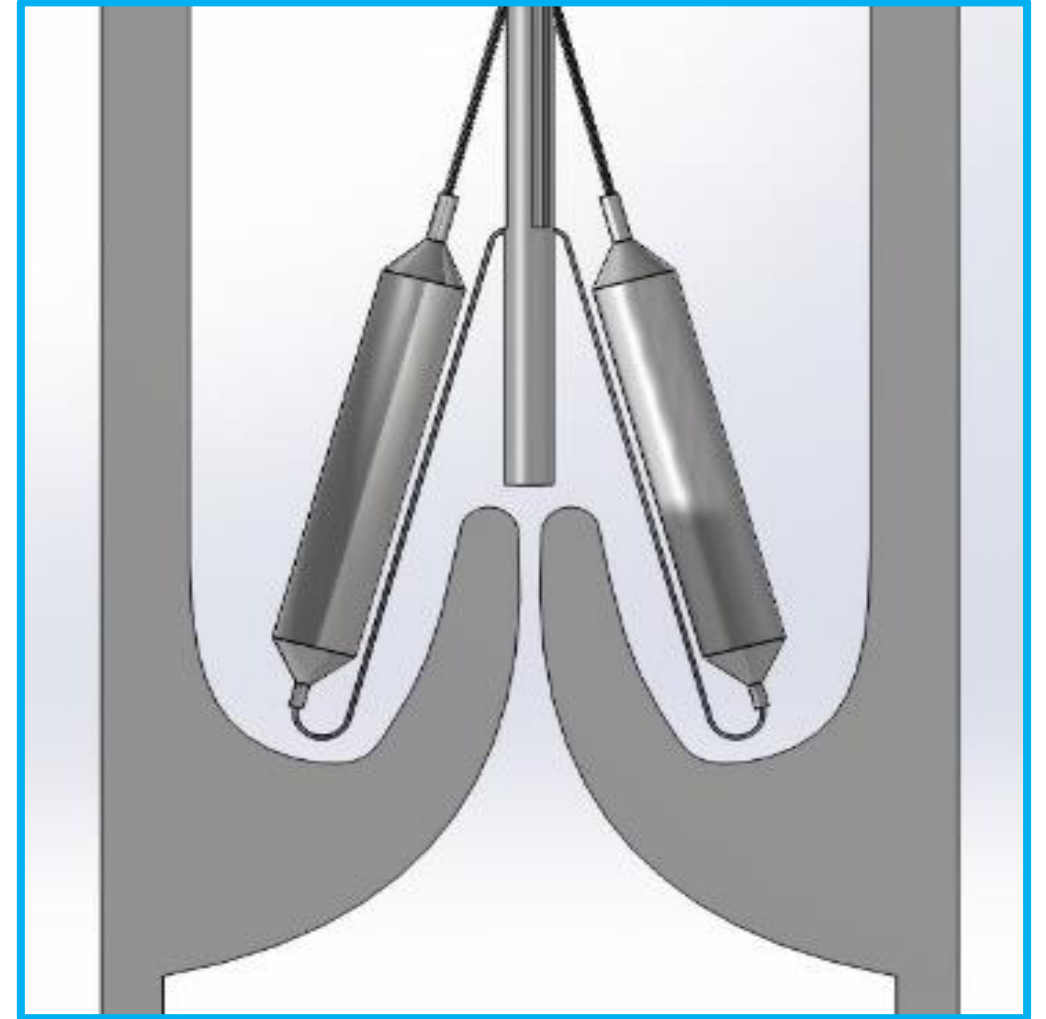
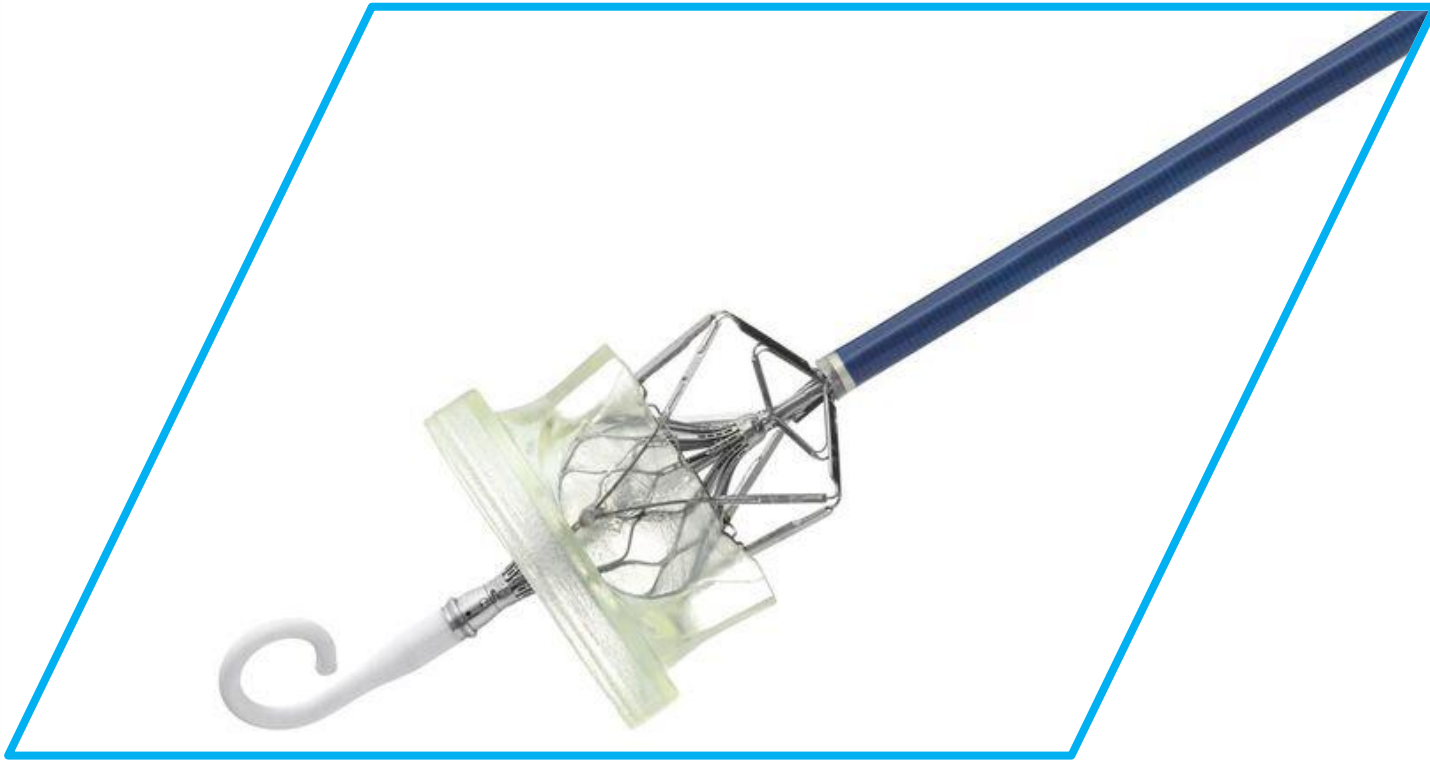
Table 5 Recommended requirements of a heart valve centre (modified from Chambers *et al.*³²)

Requirements	Discover news
<p>Multidisciplinary teams with competencies in valve replacement, aortic root surgery, mitral, tricuspid and aortic valve repair, as well as transcatheter aortic and mitral valve techniques including reoperations and reinterventions. The Heart Teams must meet on a regular basis and work with standard operating procedures.</p>	
<p>Imaging, including 3D and stress echocardiographic techniques, perioperative TOE, cardiac CT, MRI, and positron emission tomography-CT.</p>	
<p>Regular consultation with community, other hospitals, and extracardiac departments, and between non-invasive cardiologists and surgeons and interventional cardiologists.</p>	
<p>Back-up services including other cardiologists, cardiac surgeons, intensive care and other medical specialties.</p>	
<p>Data review:</p> <ul style="list-style-type: none"> • Robust internal audit processes including mortality and complications, repair rates, durability of repair, and reoperation rate with a minimum of 1-year follow-up. • Results available for review internally and externally. • Participation in national or European quality databases. 	

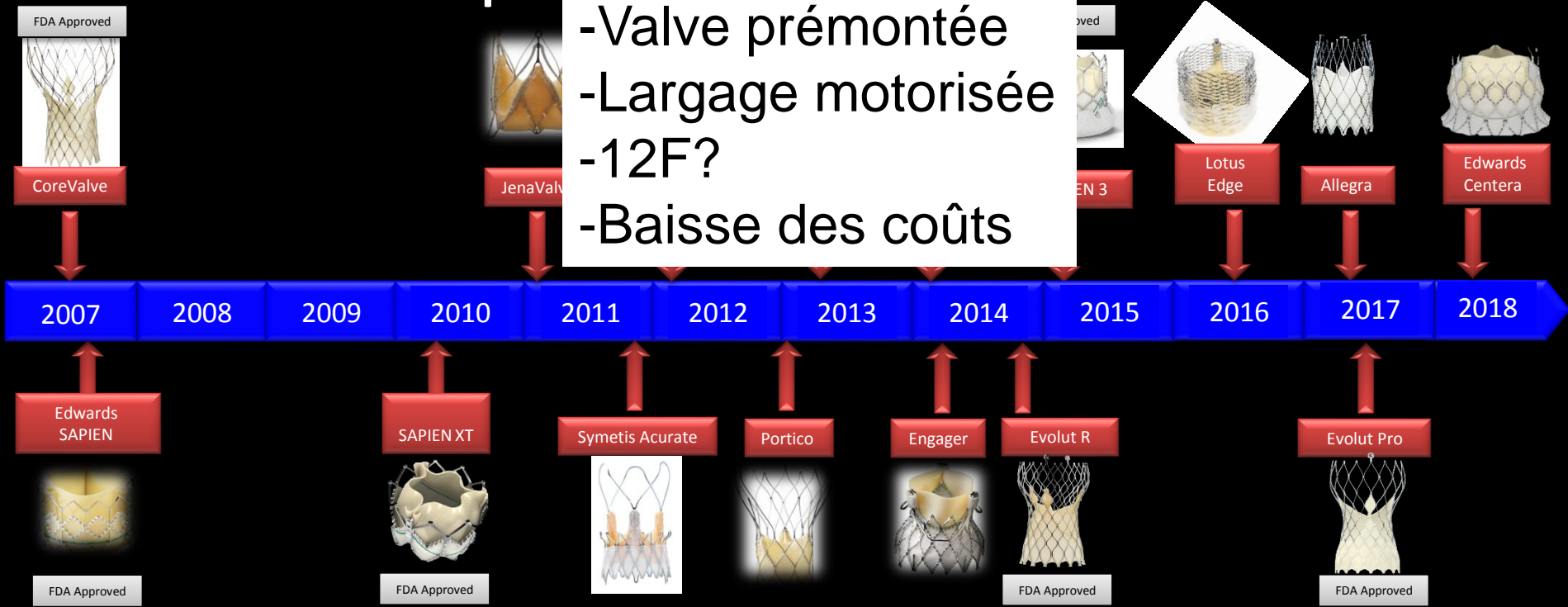
©ESC 2017

L'outil ?

Valvuloplastie



Conformité Européenne (CE) Mark TAVR Systems



- Valve prémontée
 - Largage motorisée
 - 12F?
 - Baisse des coûts

Non-Approved TAVR Systems

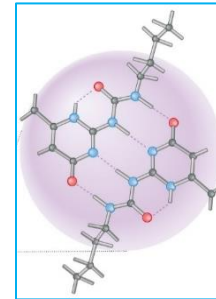


Supramolecular
Chemistry

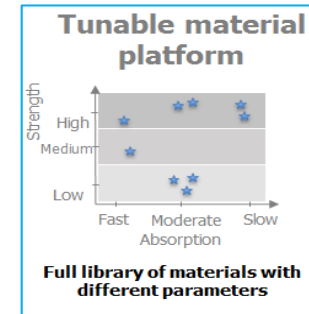


Jean Marie Lehn

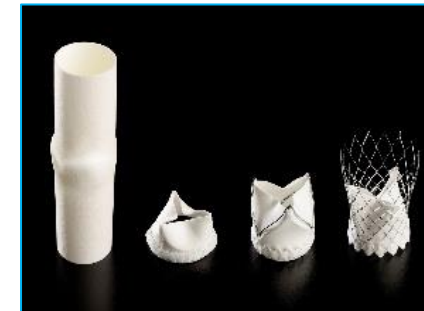
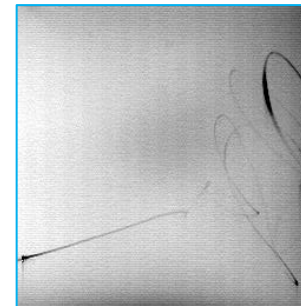
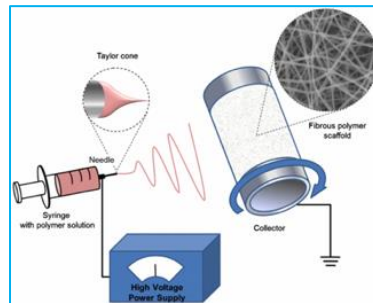
Nobel prize for
Supramolecular
Chemistry , 1987



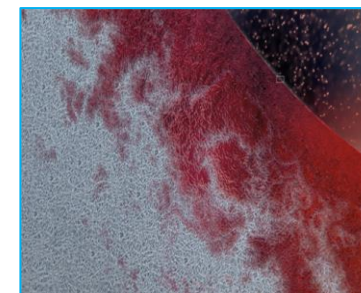
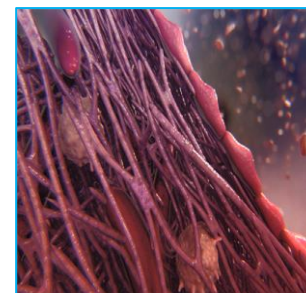
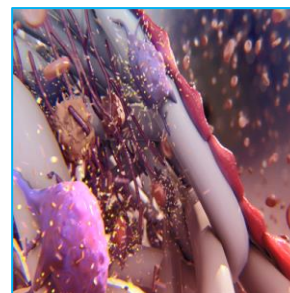
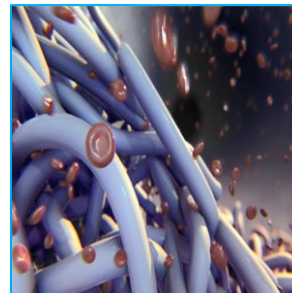
Sijbesma,
Science, 1997



Electrospinning



Regenerative
Medicine



Endogenous Tissue Restoration (ETR)



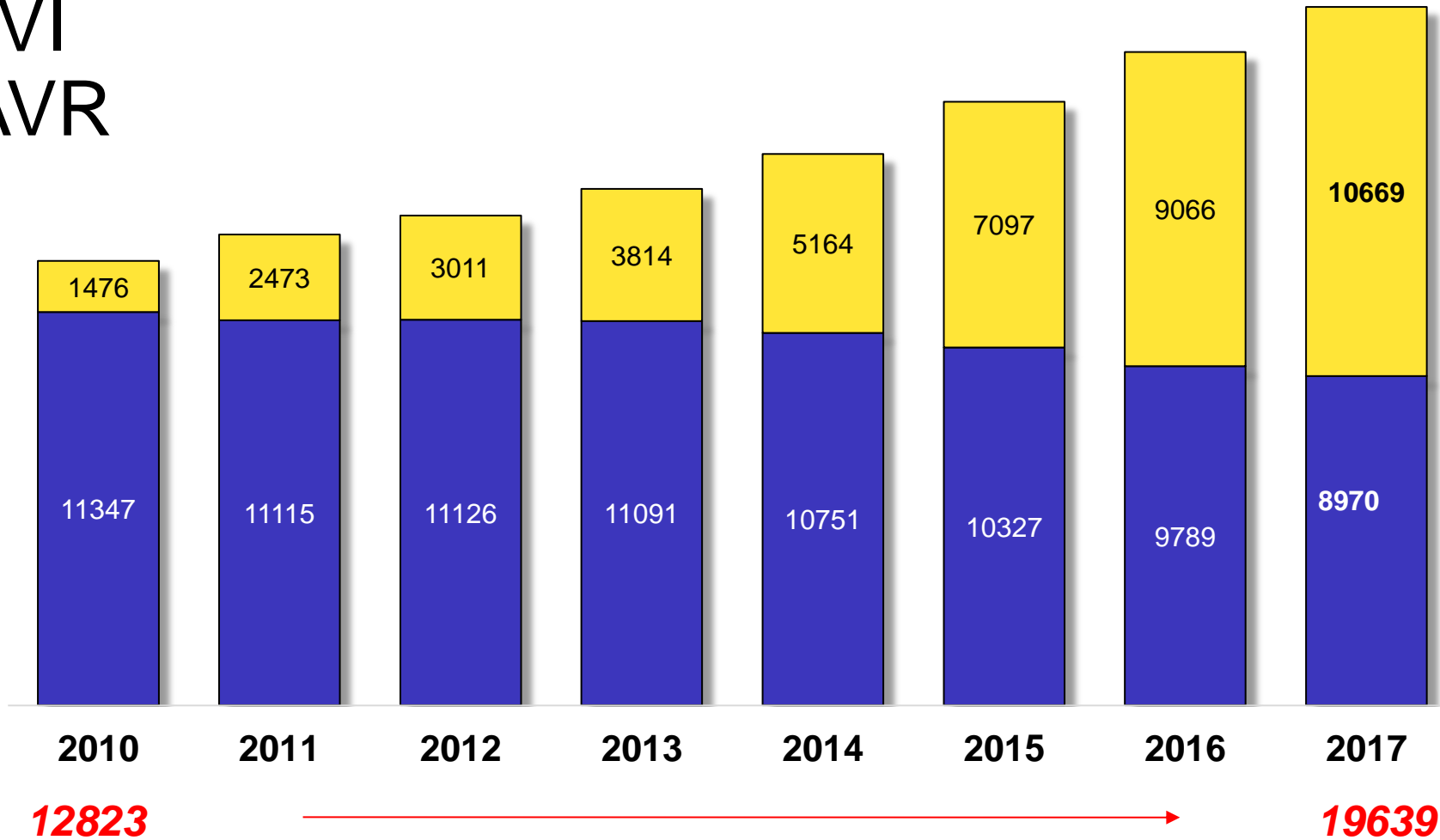
*Valve after
bioabsorption*

- Synthetic matrix made of novel bioabsorbable supramolecular polymers using electrospinning techniques
- Polymer leaflets mounted on nitinol self-expanding frame
- Regrowth of endogenous tissue coincident with bioabsorption of polymer implant
- Natural self-healing anti-inflammatory leaflets

L'indication ?

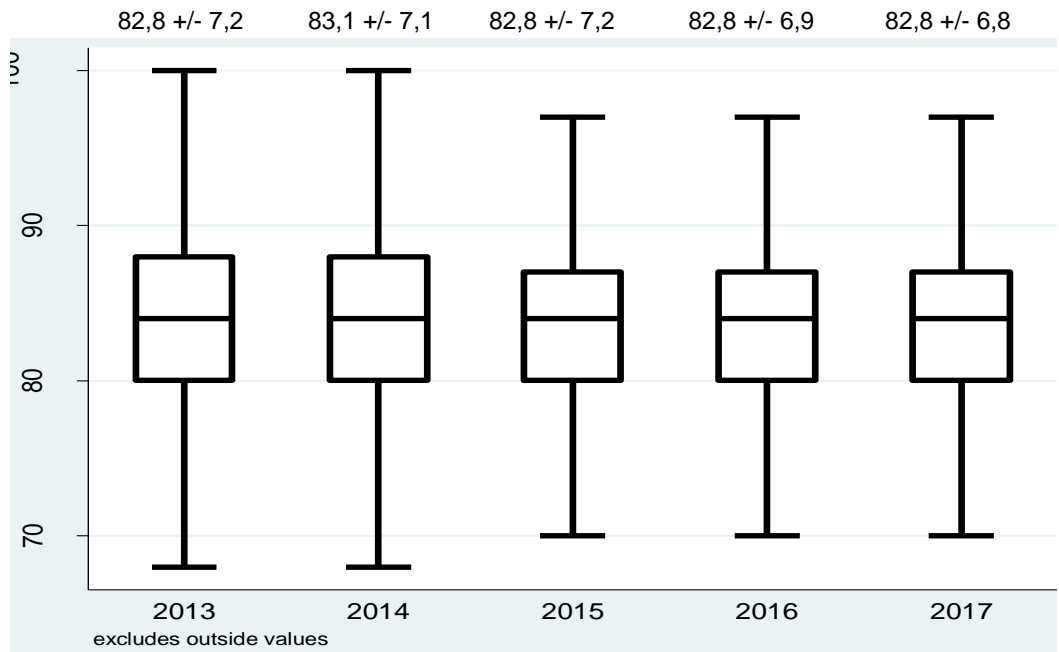
TAVI in France (2017)

TAVI
SAVR



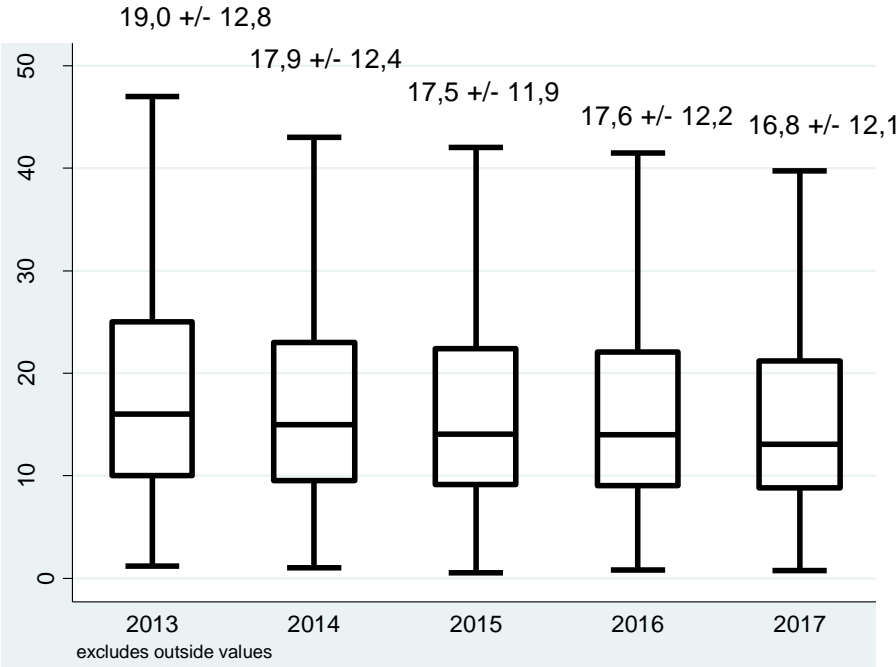
82,9 ans +/- 7,0

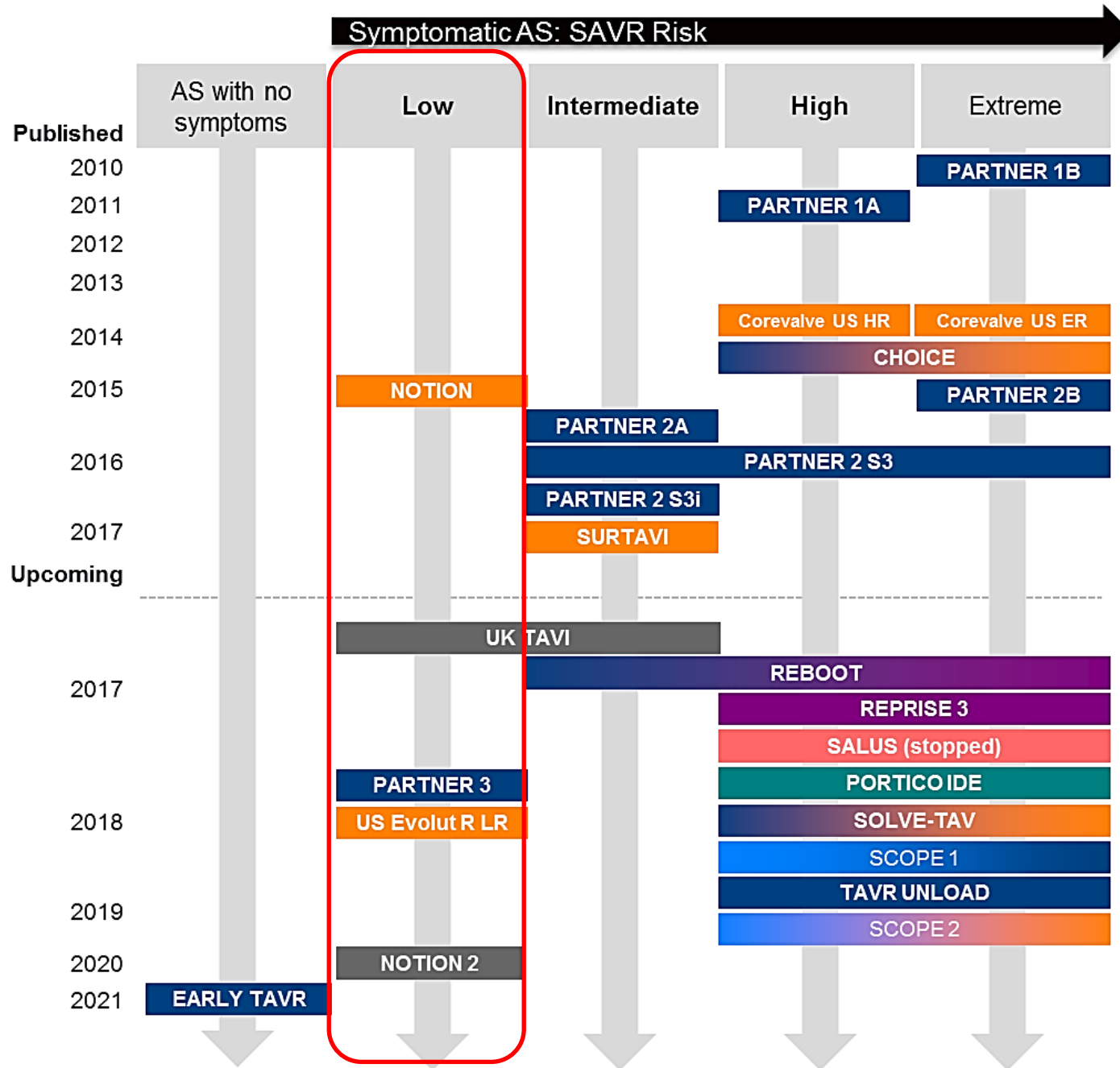
p = 0,423



Logistic EUROSCORE

p < 0,001





Pipeline of TAVR Trials across the spectrum of aortic stenosis

Investigational devices

- Edwards Sapien/Sapien XT/S3
- Medtronic CoreValve/Evolut R
- Boston Lotus
- Direct Flow Medical Direct Flow
- Abbott Vascular Portico
- Symetis Acurate Neo
- Any available TAVR system

24 TAVR RCTs

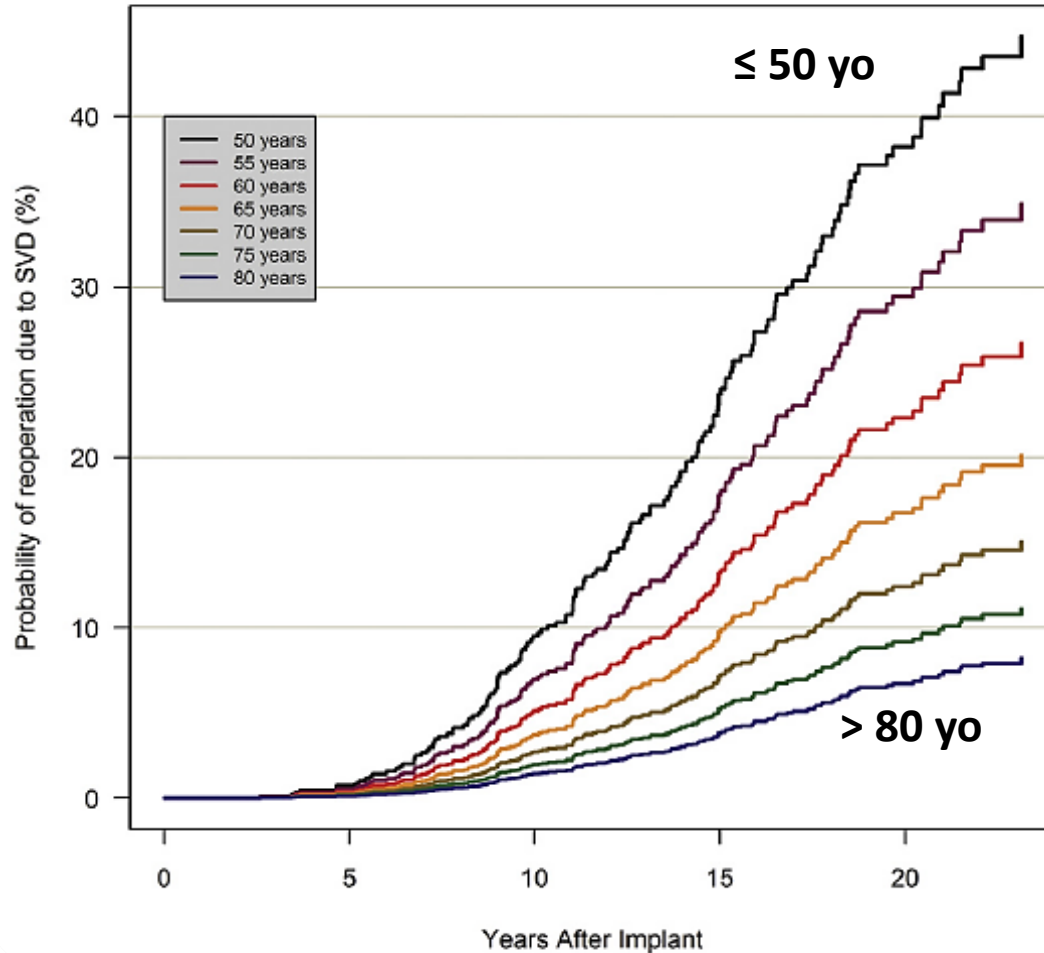
L'âge?

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.^e

IIa

C

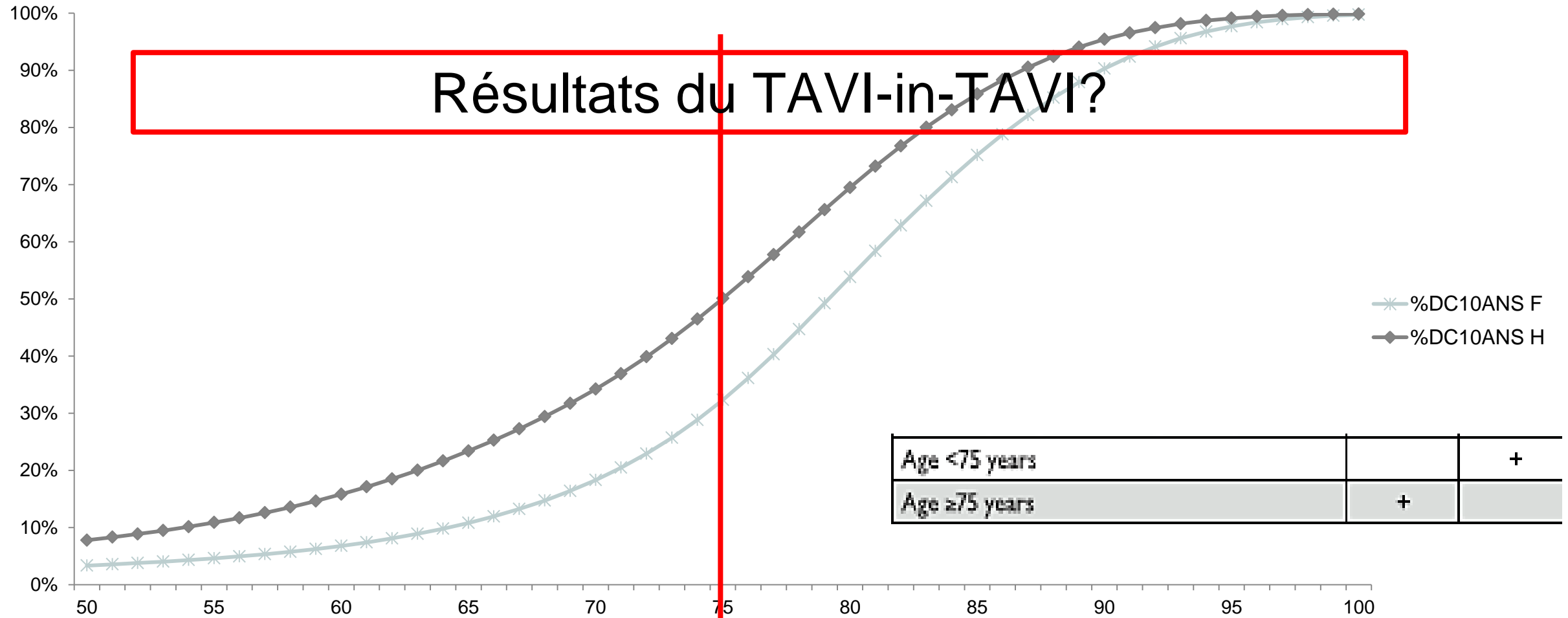
Durabilité des bioprothèses depend de l'âge



- 2,659 patients with AVR using CE pericardial Perimount bioprosthesis followed for 20 years
- Competing risk regression evaluating the cumulative risk of reoperation due to SVD with age at surgery

**Bourguignon T et al.
Ann Thorac Surg 2015;
99:831-7.**

Mortalité à 10 ans de la population française

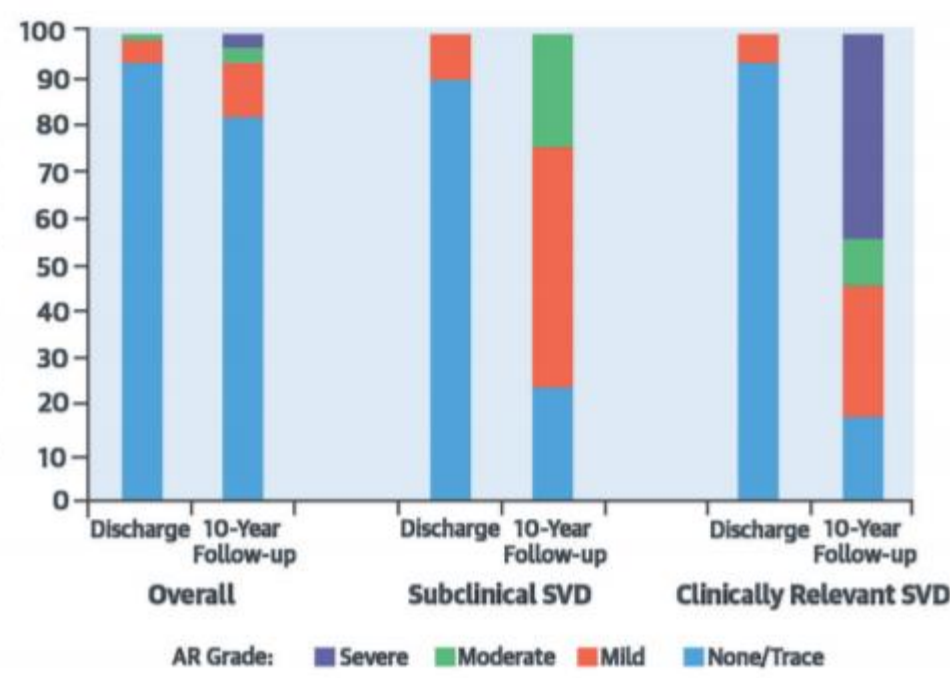
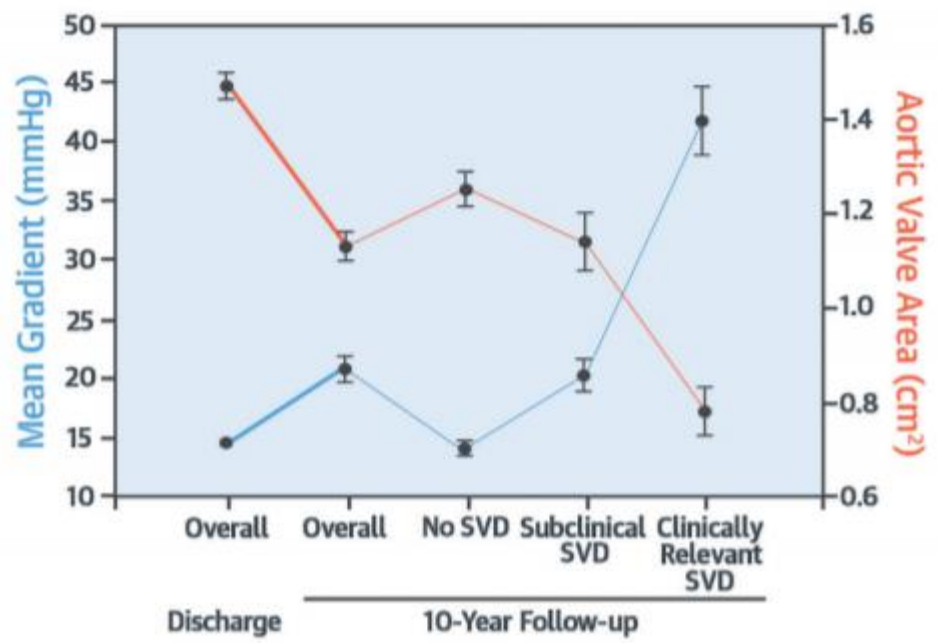


Source INED - Courtesy of D. Blanchard

Structural Valve Degeneration (10-Year Follow-up)

Subclinical 30.1%

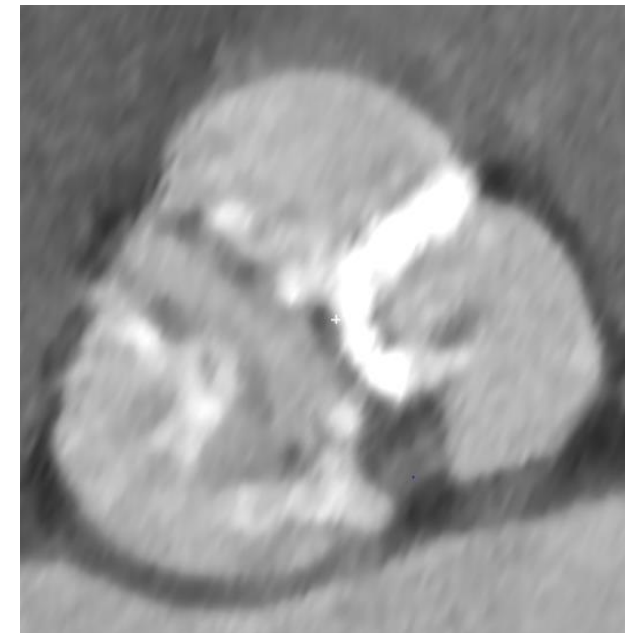
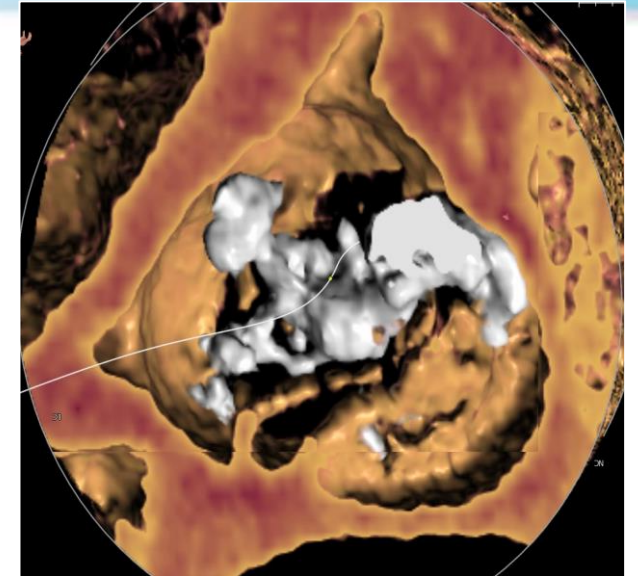
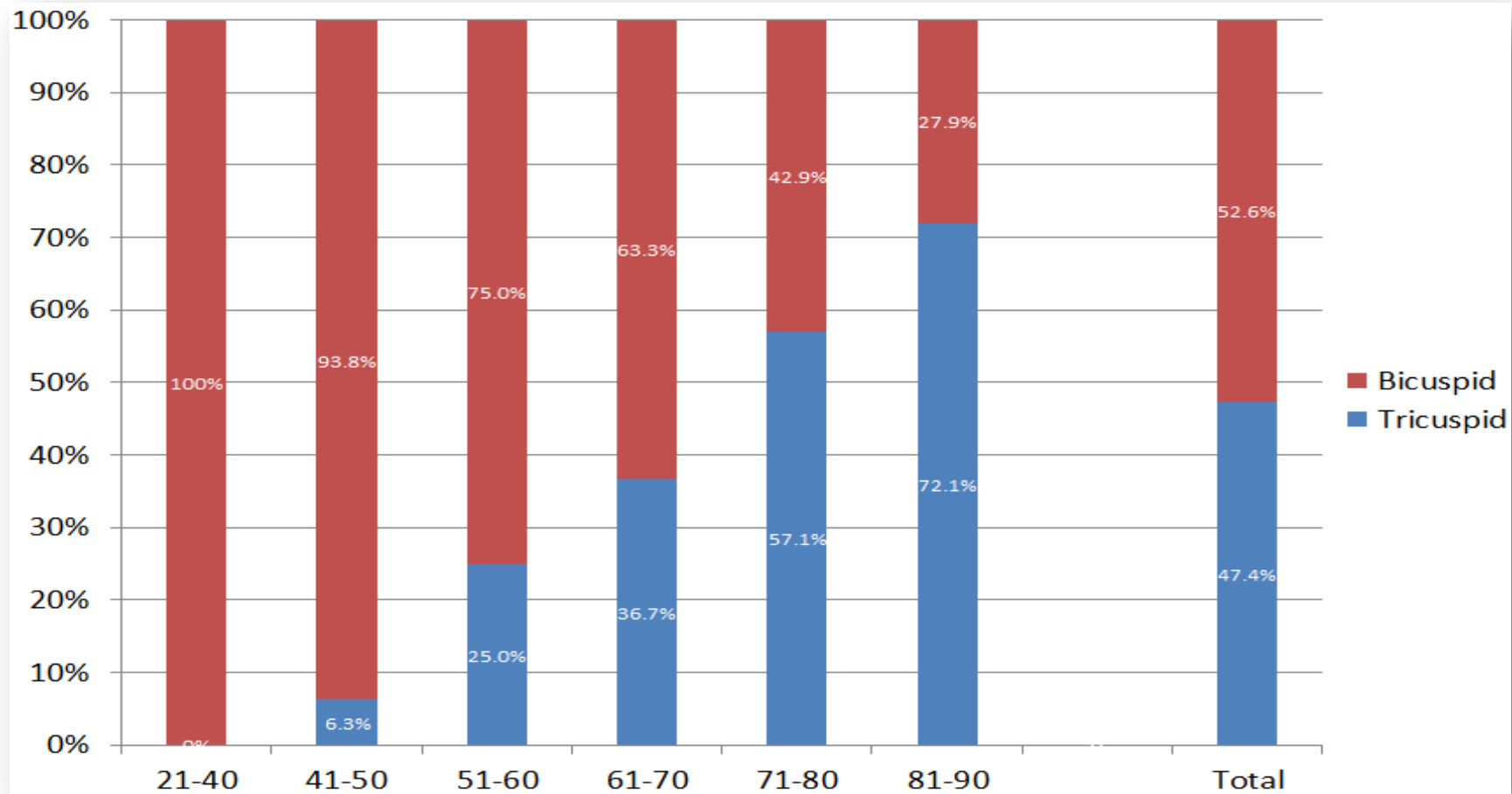
Clinically Relevant 6.6%



Rodriguez-Gabella, T. et al. J Am Coll Cardiol. 2018;71(13):1401-12.

E. Salaün Circulation 2018 / Rodriguez-Gabella JACC 2018

Bicuspidie



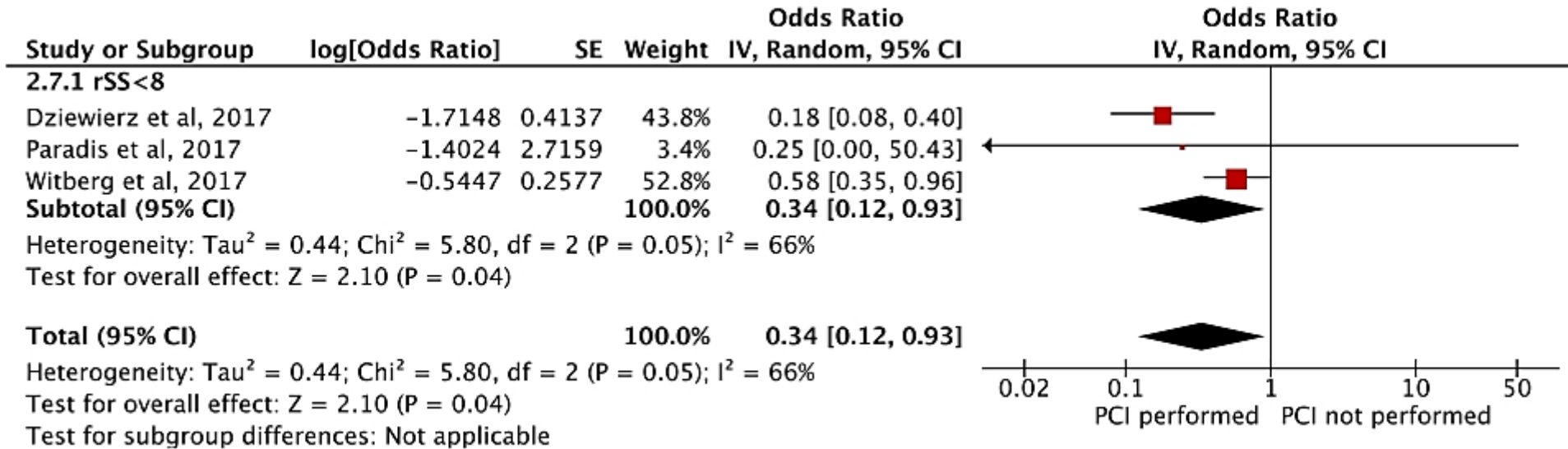
TAVR vs SAVR in BAV

Proposed Trial with NHLBI/FDA Support

- Randomized (1:1)
- Registry-based Trial
 - Include baseline and selected follow-up data from the STS and TVT registries
 - Long-term follow-up will be by:
 - Centralized Follow-up
 - Medicare Claims Data
 - Truven Marketscan Database
- Trial duration: up to 10 years



Maladie coronaire



En 2028 ?

- Des réponses sur la méthode et les indications grâce à une recherche hyperactive
- De nouvelles valves
- Des limites plus claires
 - Bioprothèse
 - Chirurgie associée