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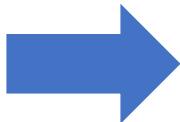
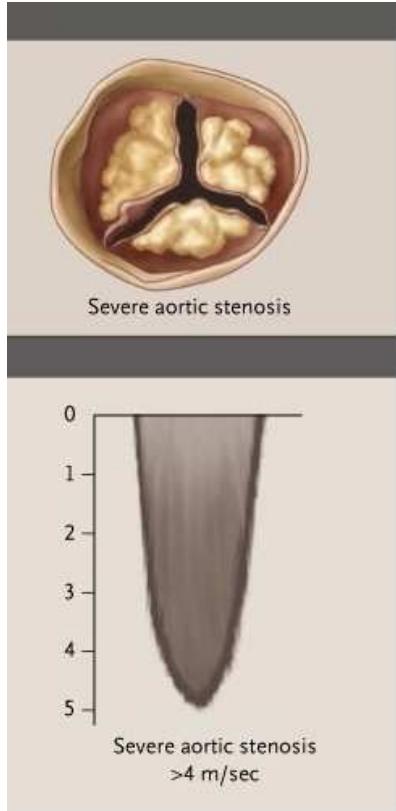
Le TAVI au-delà du RA serré symptomatique

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Indications actuelles d'une intervention pour un RA serré

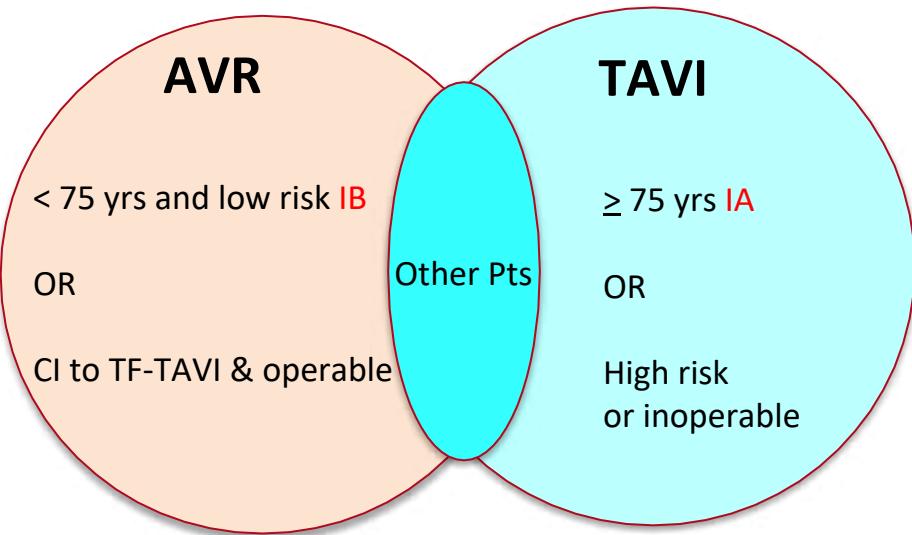


- **SYMPTOMATIC severe AS**

- **ASYMPTOMATIC severe AS with:**
 - EF < 50-55%
 - Symptoms or sustained fall in BP > 20 mm on stress test
 - Vmax > 5 m/sec
 - Mean gradient > 60 mm Hg
 - V max progression > 0.3 m/sec/year
 - Elevated BNP X3

Indications actuelles du type d'intervention en cas de RA serré

Heart team
Surgery on site
Patient decision



RA serré asymptomatique sans critères d'intervention ?

MD: You have Severe AS

Patient: What Should we do?

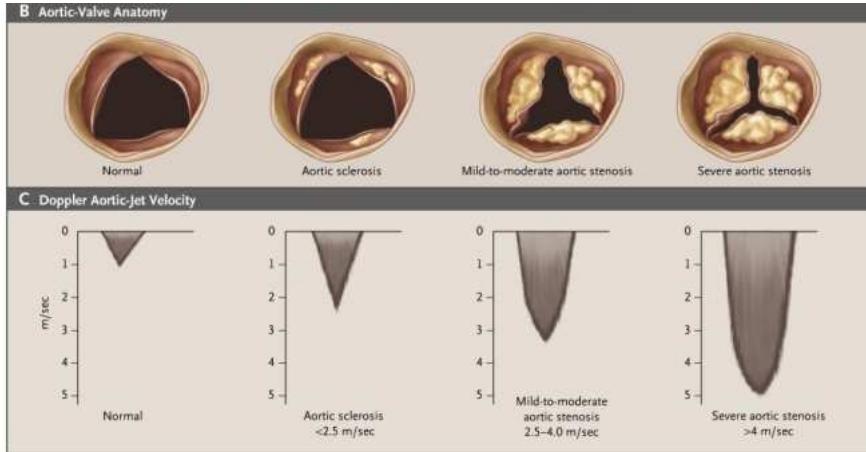
MD: You tell me when you don't feel well...



1. RA serré asymptomatique sans critères d'intervention?

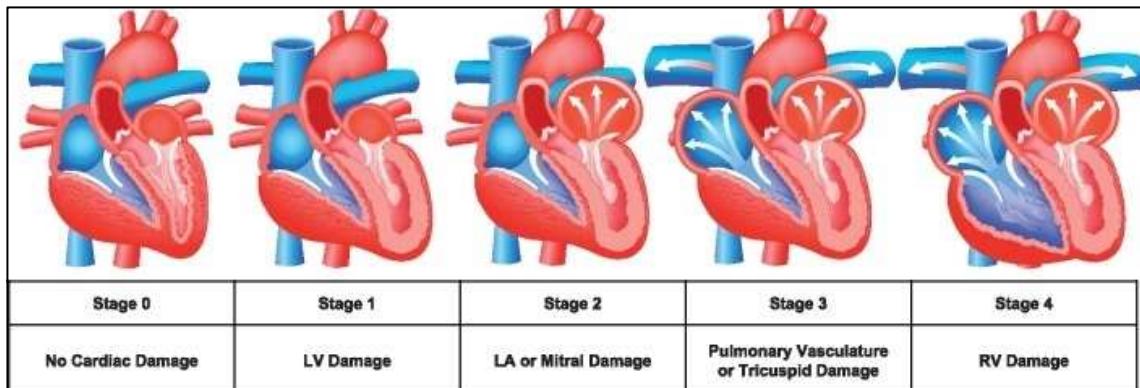
- Prévalence du RA serré asymptomatique: 25-50% des RA serrés
- Epreuve d'effort rarement pratiquée (<10%)
- Risque de mort subite 1-2%/an
- Difficulté de prévoir l'évolution
- Absence de prise en compte du retentissement cardiaque du RA (staging)
- Intérêt de l'IRM (Etendue de la fibrose myocardique) ?

1. RA serré asymptomatique sans critères d'intervention



Aortic stenosis progresses slowly due to accumulation of calcifications on valve leaflets

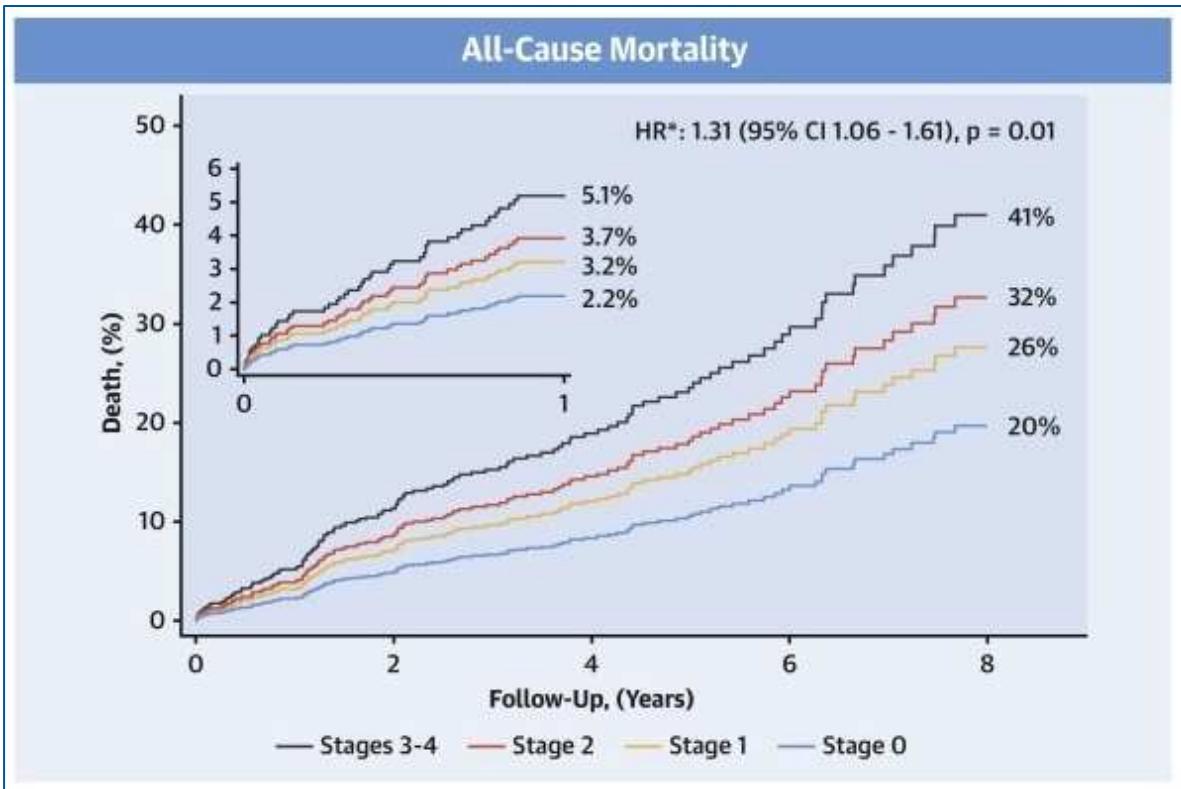
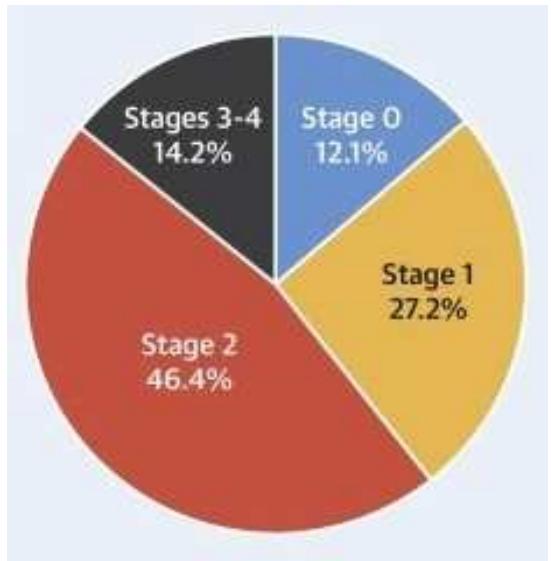
In parallel, without intervention, cardiac remodeling with develop: from LV hypertrophy, LA enlargement to LV dysfunction and finally RV dysfunction



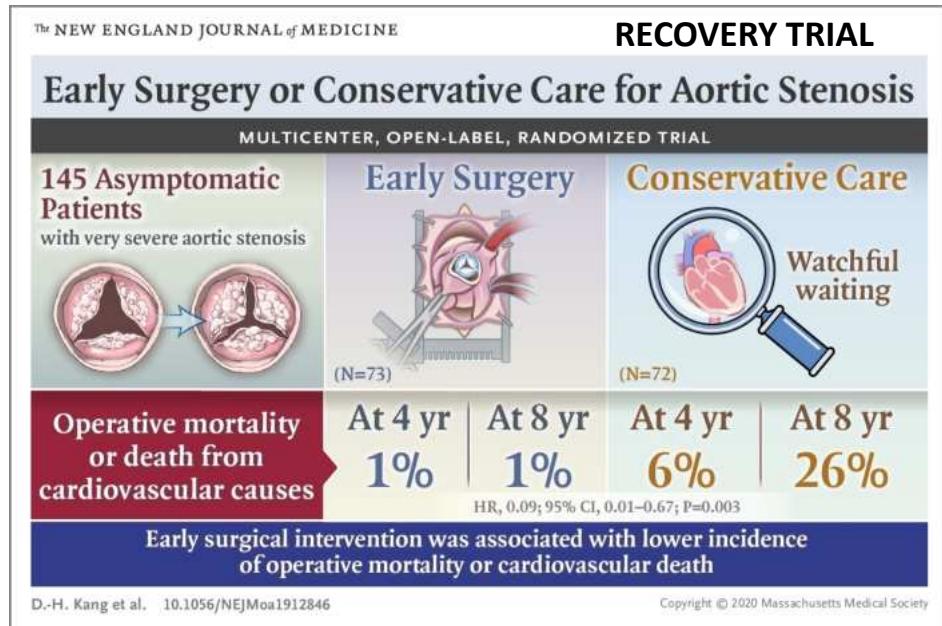
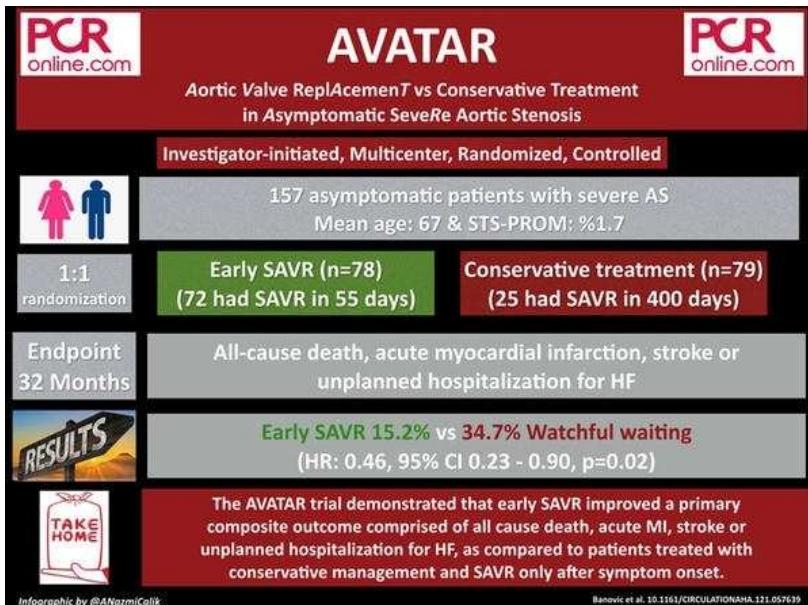
1. RA asymptomatique sans critères d'intervention

735 asymptomatic patients

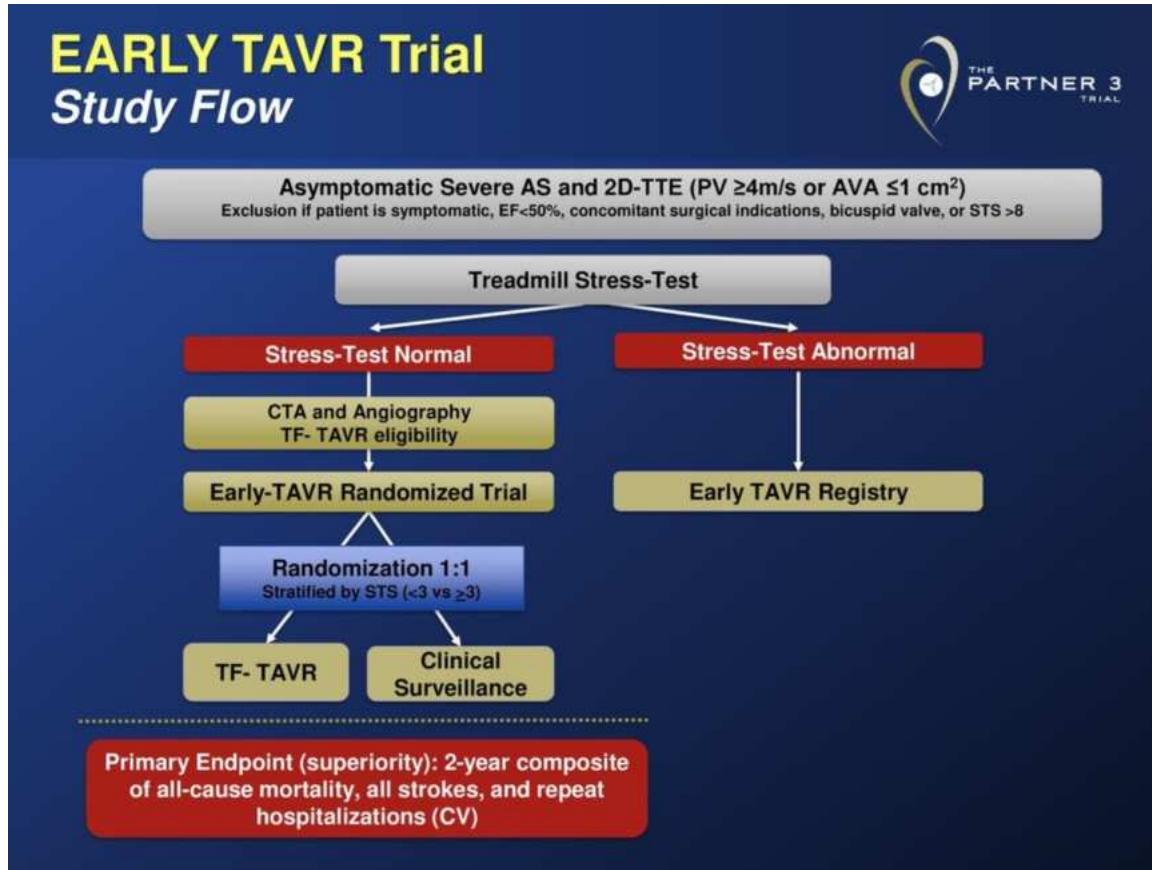
- with at least moderate AS
- preserved LVEF



1. RA asymptomatique: études randomisées (RVA)

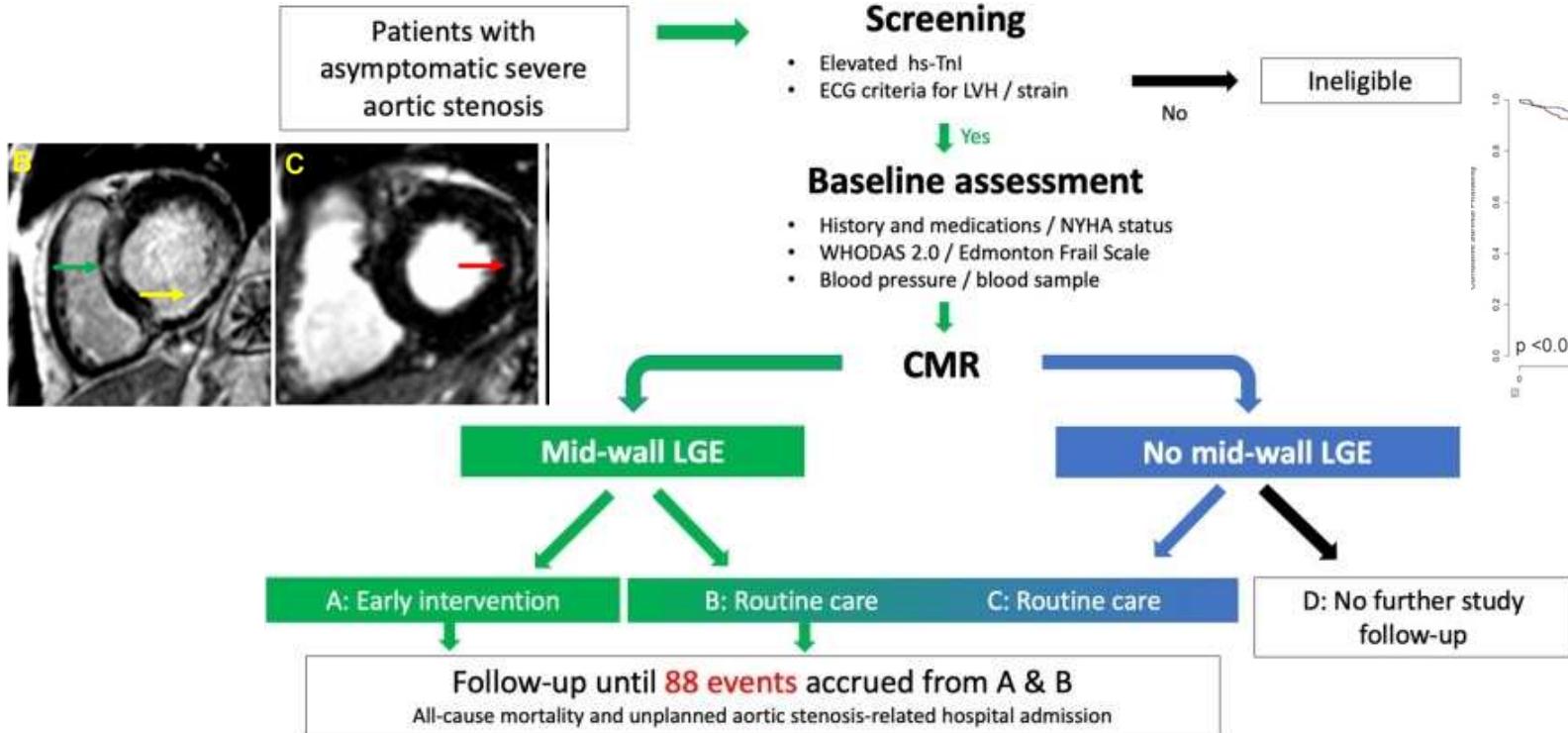


1. RA serré asymptomatique sans critères d'intervention

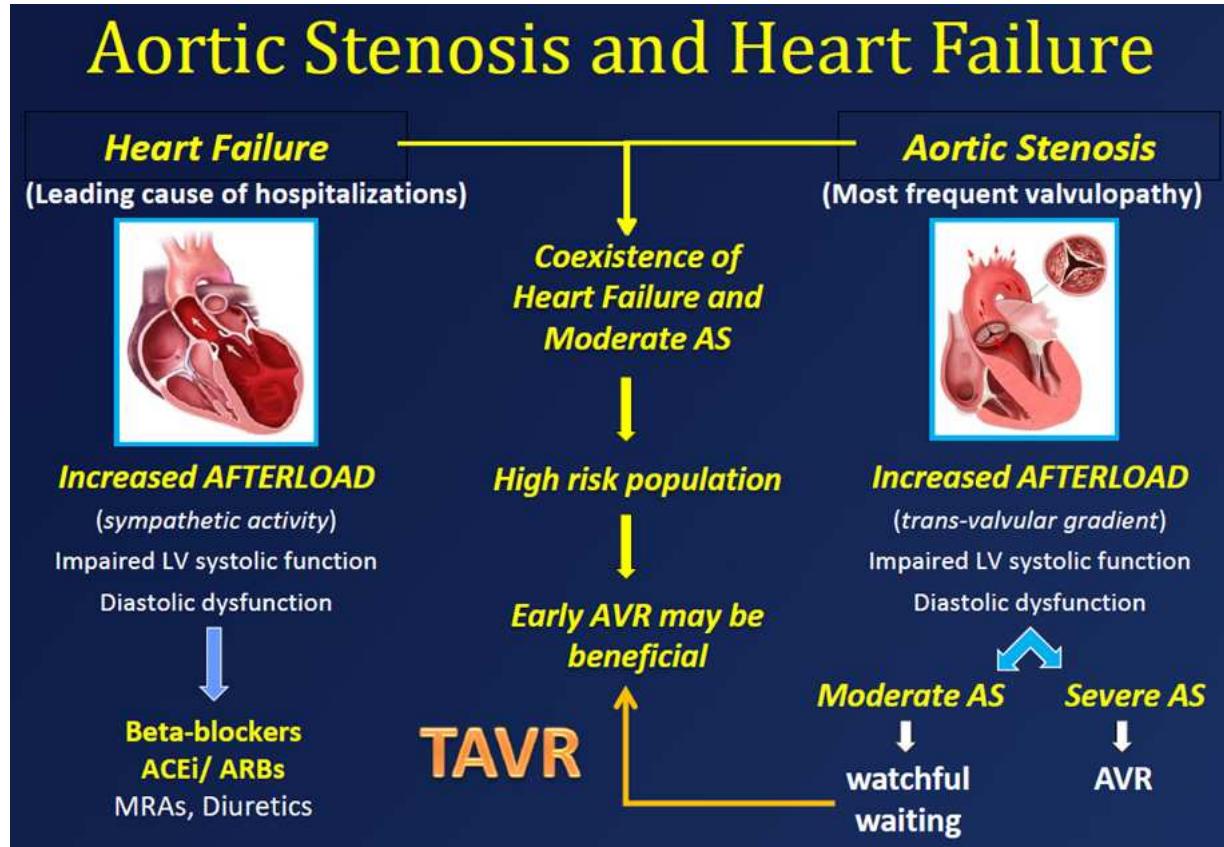


1. RA asymptomatique sans critères d'intervention

EVOLVED Trial

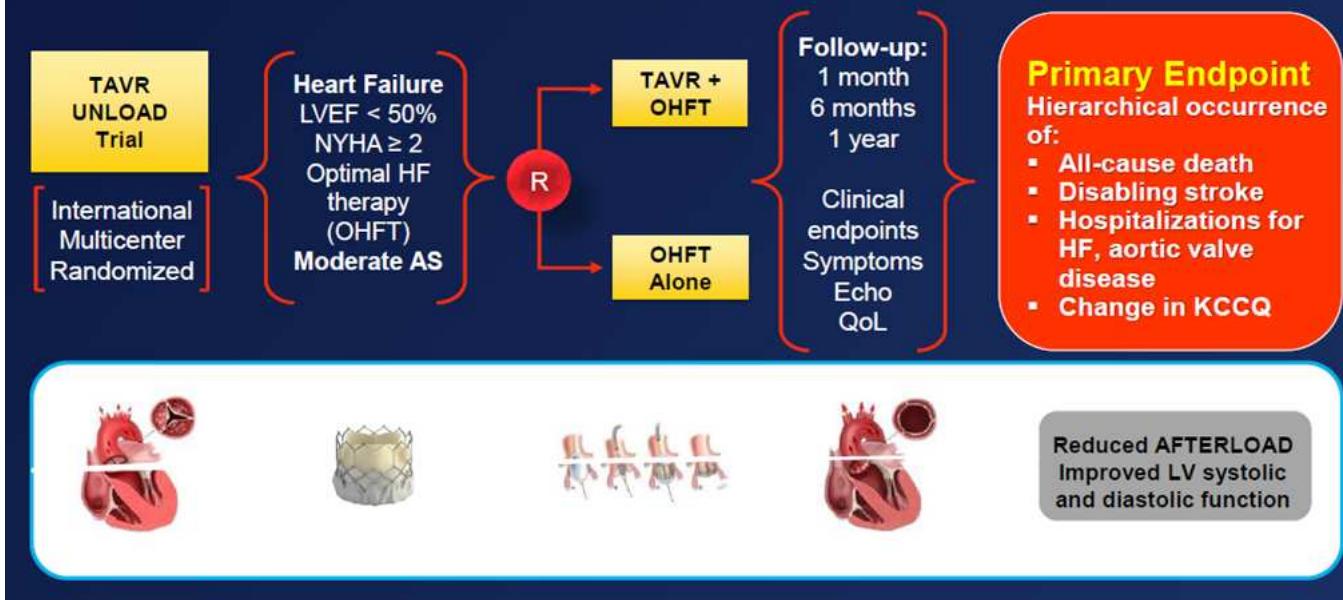


2. RA modéré avec dysfonction VG



2. RA modéré avec dysfonction VG

TAVR UNLOAD Trial Study Design (600 patients, 1:1 Randomized)



2. RA modéré avec dysfonction VG/IC

- International, randomized open-label in 750 patients
- **TAVR (Sapien 3) vs. Medical treatment alone**



- **Inclusion criteria:**
 - Patients with moderate AS and
 - Symptoms or heart failure or LV dysfunction
- **Endpoint at 2 years:** All cause death, Disabling stroke, Re-hospitalization, Improved QOL
- Follow-up = 10 years

3. Place du TAVI dans l'insuffisance aortique

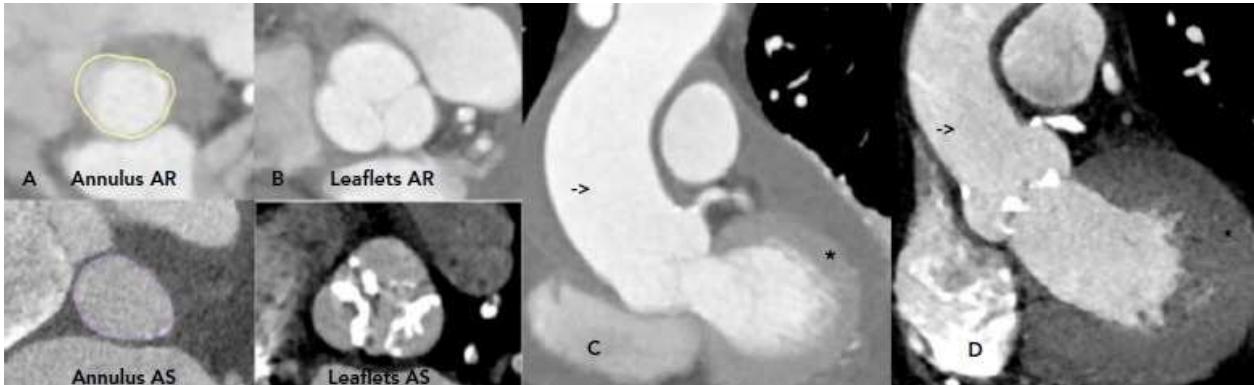


Table 2: Main Results of Recent Retrospective Studies Evaluating Early Generation Devices Versus New Generation Devices

Author, year	Patients (n)	EGD	NGD	Device Success (EGD/NGD)	CV Mortality (EGD/NGD)	Second Valve (EGD/NGD)	AR >Moderate (EGD/NGD)
Roy et al. 2013 ⁴¹	43	100%	NA	74.4%/NA	10.7%*/NA	18.6%/NA	4.7%/NA
Yoon et al. 2017 ⁴⁹	331	36%	64%	61.3%/81.1%	23.6%/9.6%*	24.4%/12.7%	18.8%/4.2%
De Backer et al. 2018 ⁴⁸	254	43%	57%	47%/82%	12%/7% ¹	40.4%/9.4%	31%/4%
Sawaya et al. 2017 ⁵⁰	78	47.4%	52.6%	54%/85%	11%/5% ¹	24%/10%	29%/2%
Silaschi et al. 2018 ³⁹	30	NA	100%	NA/96.7%	NA/10%	NA/0%	NA/0%

* 1-year mortality; ¹30-day mortality. AR = aortic regurgitation; CV = cardiovascular; EGD = early generation device; NGD = new generation device.

3. Place du TAVI dans l'insuffisance aortique

Trilogy THV in AR Anatomy



Alignment

- Aligns THV with native cusps



Positioning/Anchoring

- Locators “clip” onto native leaflets forming a natural seal and stable securement

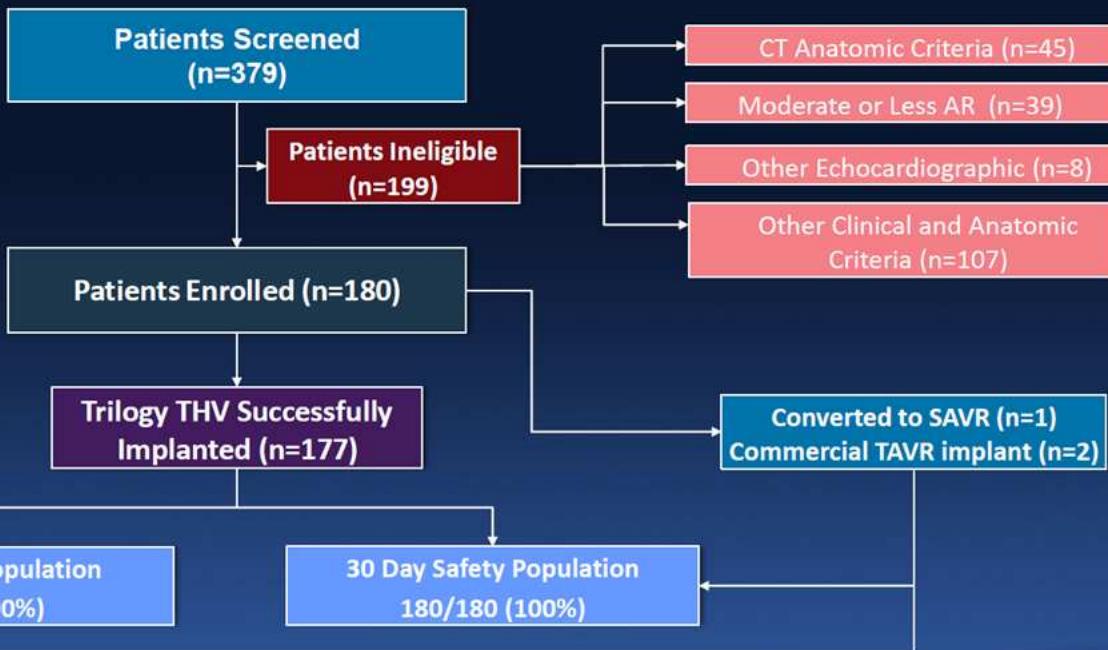


Deployment

- Large open cells provide access to low coronaries
- Flared sealing ring conforms to annulus

3. Place du TAVI dans l'insuffisance aortique

Screening and Patient Disposition (As Treated)



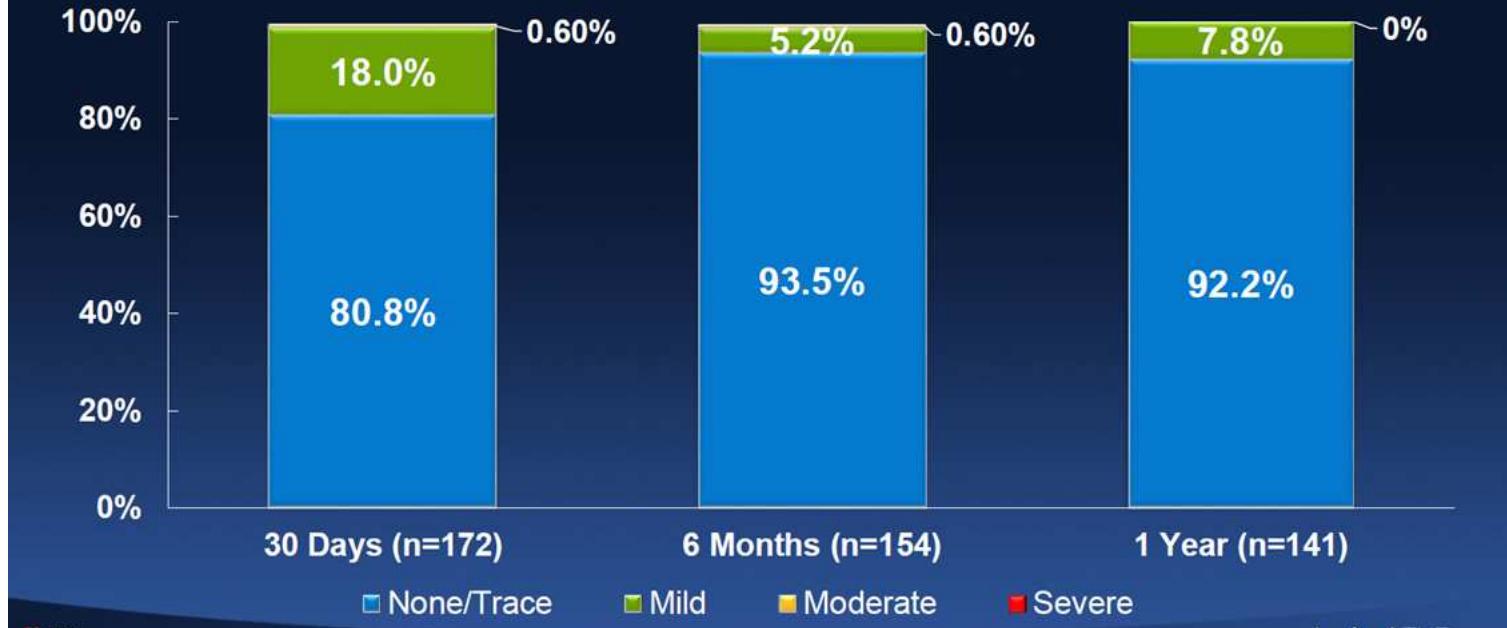
3. Place du TAVI dans l'insuffisance aortique

Procedural Outcomes

Outcome	% (n)
In-procedural Death	0
Annular Rupture	0
Ventricular Perforation	0
Coronary Obstruction	0
Valve Embolization	2.2% (4)
Aortic Dissection	0.6% (1)
Femoral Access Site Intervention	2.2% (4)
Success	
Technical Success	95.0% (171)
Device Success	96.7% (174)
Procedure Success	92.8% (167)

3. Place du TAVI dans l'insuffisance aortique

Paravalvular Regurgitation



Conclusions

- RA serré asymptomatique :
 - TAVI indiqué quand EE d'effort anormale et/ou FEVG <50(55)%
 - Dans les autres cas, les études Early-TAVR (TAVI vs surveillance) et EVOLVED (TAVI/RVA selon biomarqueurs/IRM) préciseront la place du TAVI dans cette population
- RA modéré et dysfonction VG :
 - Etude TAVR unload (recrutement depuis 2016) et PROGRESS (recrutement terminé)
- Insuffisance aortique pure :
 - Résultats prometteurs du registre ALIGN AR avec la valve Trilogy (Jenavalve)

Place du TAVI dans l'insuffisance aortique

ALIGN AR Study Design

Multicenter, Non-blinded, Single Arm Evaluation of Patients with Symptomatic $\geq 3+$ Aortic Regurgitation at High Risk for SAVR

Trilogy THV Implantation

Clinical Evaluation, Echocardiography, Functional and QoL Assessment at 30 Days, 6 Months, 1 Year and Annually up to 5 Years

30 Day Primary Safety Endpoint

1 Year Primary Efficacy Endpoint

Comparison with Prespecified Performance Goal