EARLY TAVR

C Saint Etienne
CHRU Tours
Courtesy of F. Praz

CONFLITS D'INTÉRÊTS

Proctor for Abbott, Edwards, Medtronic, Boston, Biotronik

Consulting Medtronic, Edwards

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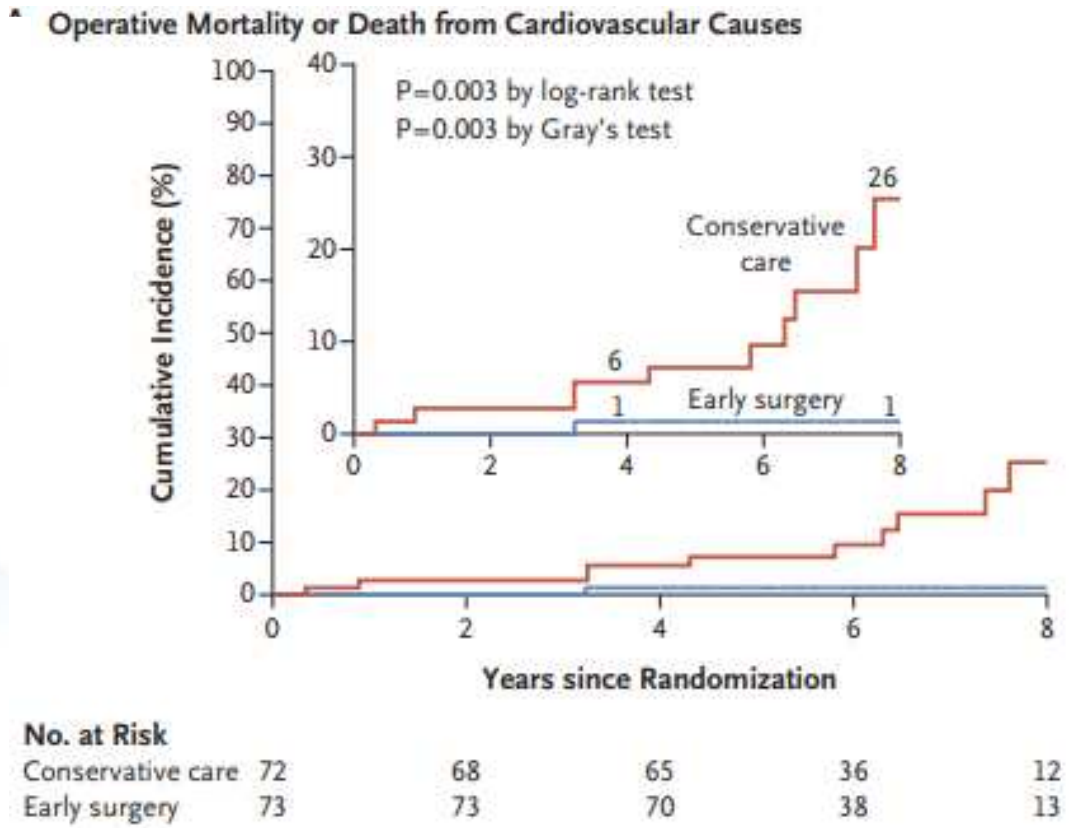
Background

- Reco ESC préconise une surveillance médicale chez le patient asymptomatique avec RAC
- La stratégie de traitement du RAC asymptomatique a fait l'objet de 2 essais randomisés chirurgicaux par le passé chez des patients jeunes.
- La stratégie de traitement: suivi rapproché versus traitement d'emblée reste sujet à spéculations pour la majorité des patients âgés.
- Des données randomisées concernant le TAVI n'existaient pas encore.

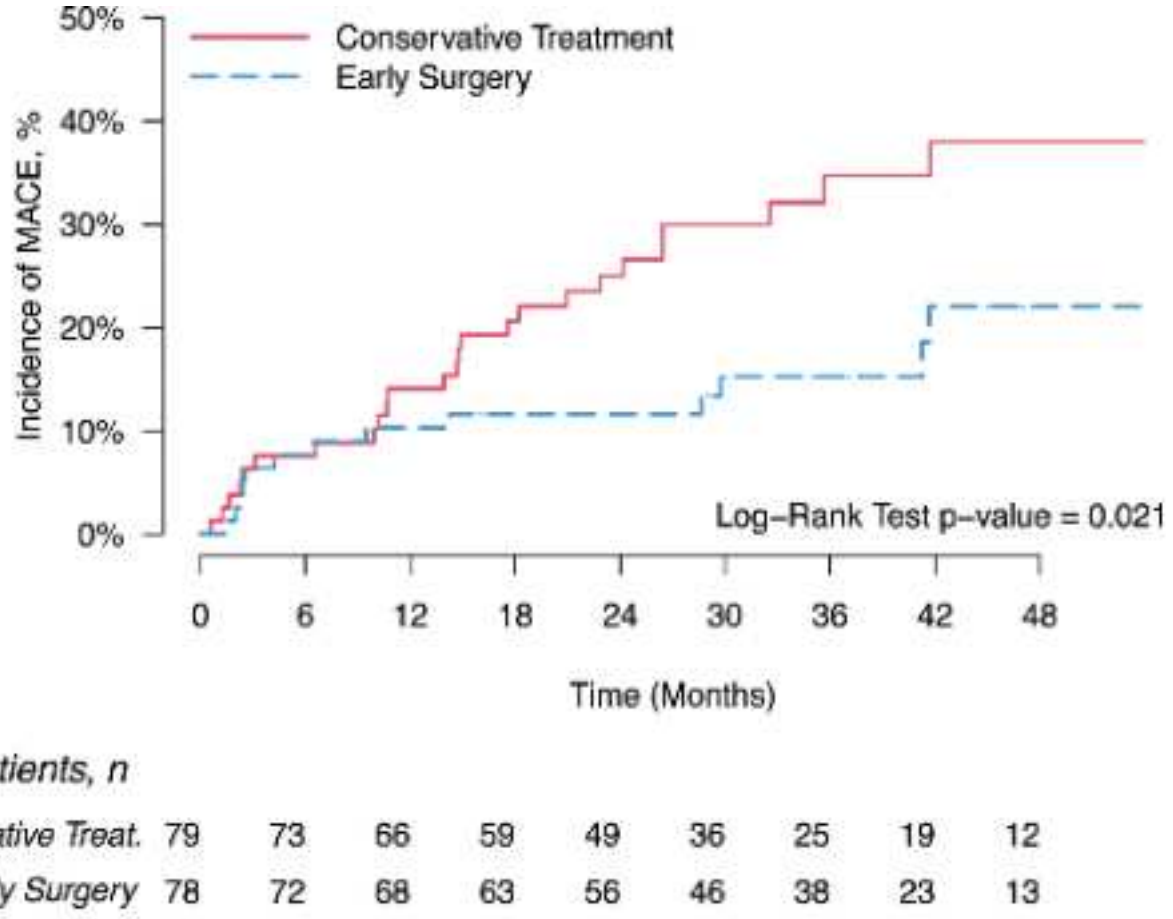
Essais randomisés chirurgicaux chez sujets avec RAC asymptomatique

RECOVERY Trial



Kang et al. N Engl J Med 2020;382:111-9.

AVATAR Trial



Banovic et al. Circulation. 2022;145:648–658..

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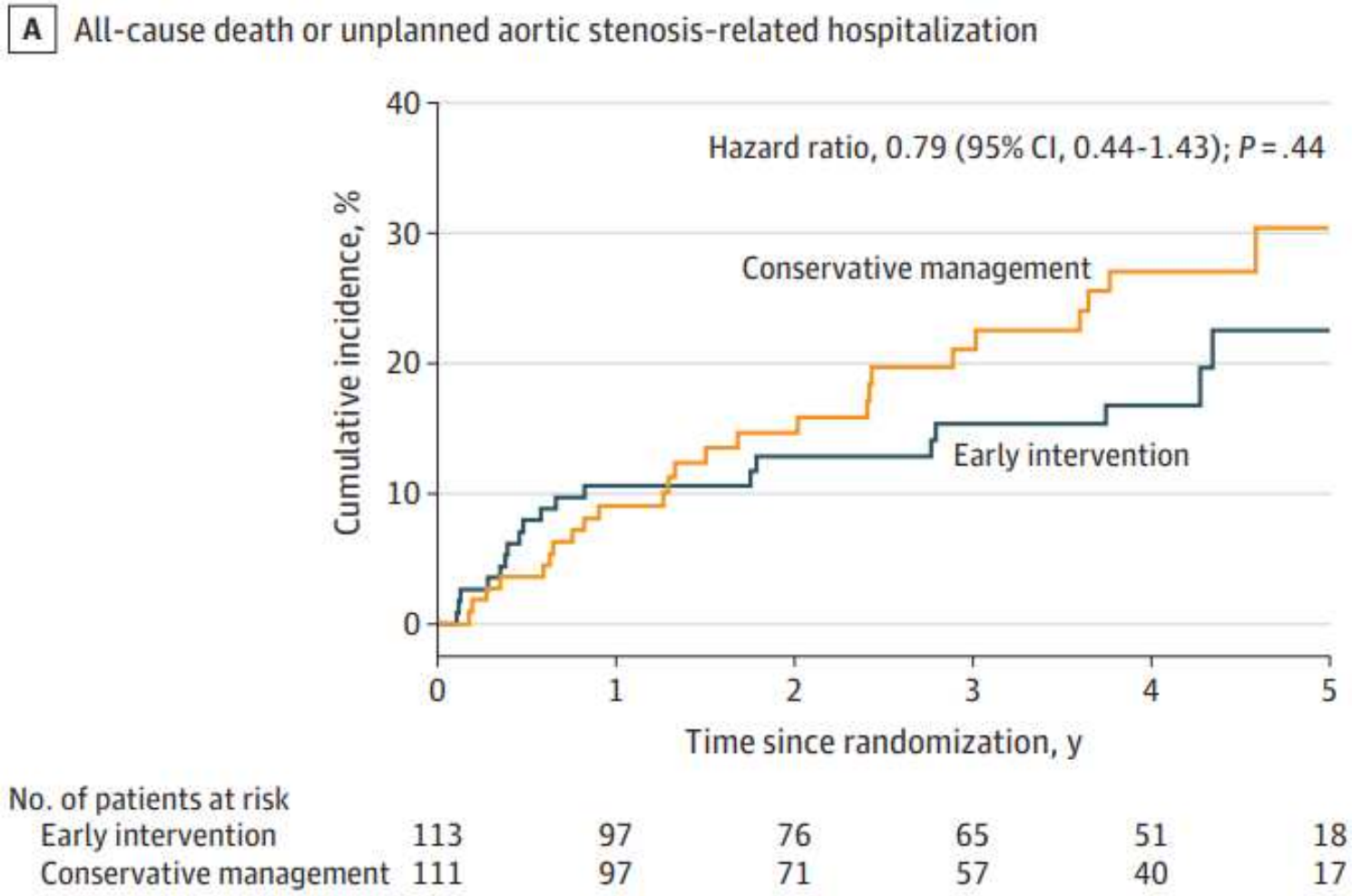
Limitations des essais chirurgicaux

- Etudes de petite taille
- Population de patients très sélectionnés (jeunes, très haut gradient)
- Utilisation inconstante du test d'effort (seulement 16% dans RECOVERY)

Essai randomisé EVOLVED



Outcome[a]	No. (%) Early intervention (n = 113)	No. (%) Conservative management (n = 111)	Absolute difference (95% CI), %
Primary end point			
All-cause death or unplanned aortic stenosis-related hospitalization	20 (18)	25 (23)	−4.82 (−15.31 to 5.66) [*P* = .37]
Secondary end points			
All-cause death	16 (14)	14 (13)	1.55 (−7.37 to 10.46)
Cardiovascular death	10 (9)	8 (7)	1.64 (−5.47 to 8.75)
Aortic stenosis-related death	6 (5)	5 (5)	0.81 (−4.85 to 6.46)
Unplanned aortic stenosis-related hospitalization	7 (6)	19 (17)	−10.92 (−19.22 to 2.62)

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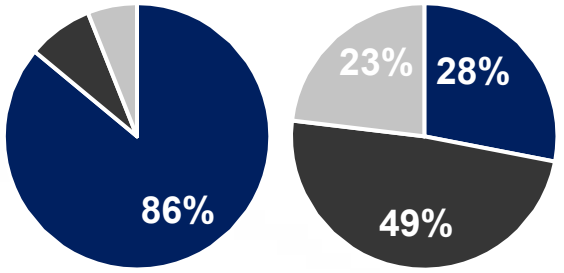
Résultats de l'étude EVOLVED

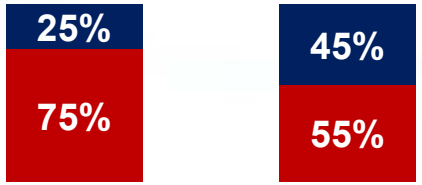
AVR rate

Early intervention
N = 113

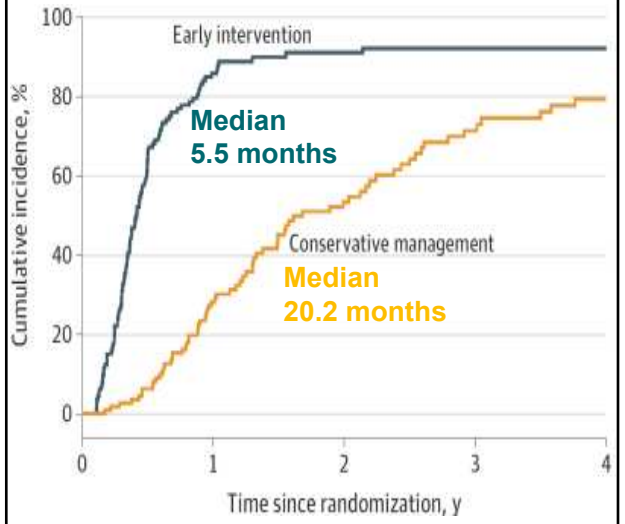
Conservative management
N = 111



AVR within 12 mo
AVR after 12 mo
No AVR or died before AVR



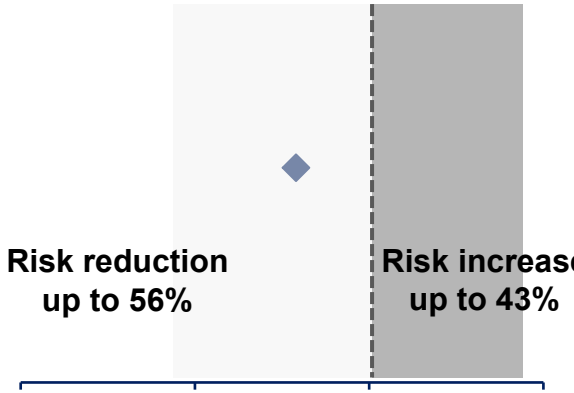
Time to intervention



✓ 6 Pts in the early intervention group died before AVR.

Primary EP

Early intervention vs. Conservative:
HR 0.79 (0.44-1.43)



✓ Very wide 95% CI resulting in imprecise estimates of potential benefit or harm of early intervention.

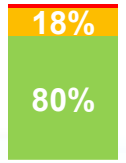
Hypothesis

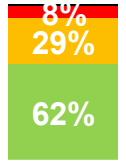
Unplanned AS-hosp

HR 0.37 (0.16-0.88)

NYHA at 1 year

OR 0.37 (0.20-0.70)





Loganath et al. JAMA 2024

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THE EARLY TAVR TRIAL

Study Design

Prospective, multicenter RCT evaluating patients with asymptomatic, severe AS aged ≥ 65 years w/ an STS score ≤ 10% and LVEF ≥ 50%

Asymptomatic Assessment
Confirmed by negative treadmill stress test*

Randomization 1:1

Transfemoral-TAVR
(SAPIEN 3 or SAPIEN 3 Ultra THV)

Clinical Surveillance

PRIMARY ENDPOINT (Superiority)
Non-hierarchical composite of all-cause death, any stroke, or unplanned CV hospitalization at a minimum follow-up of 2 years

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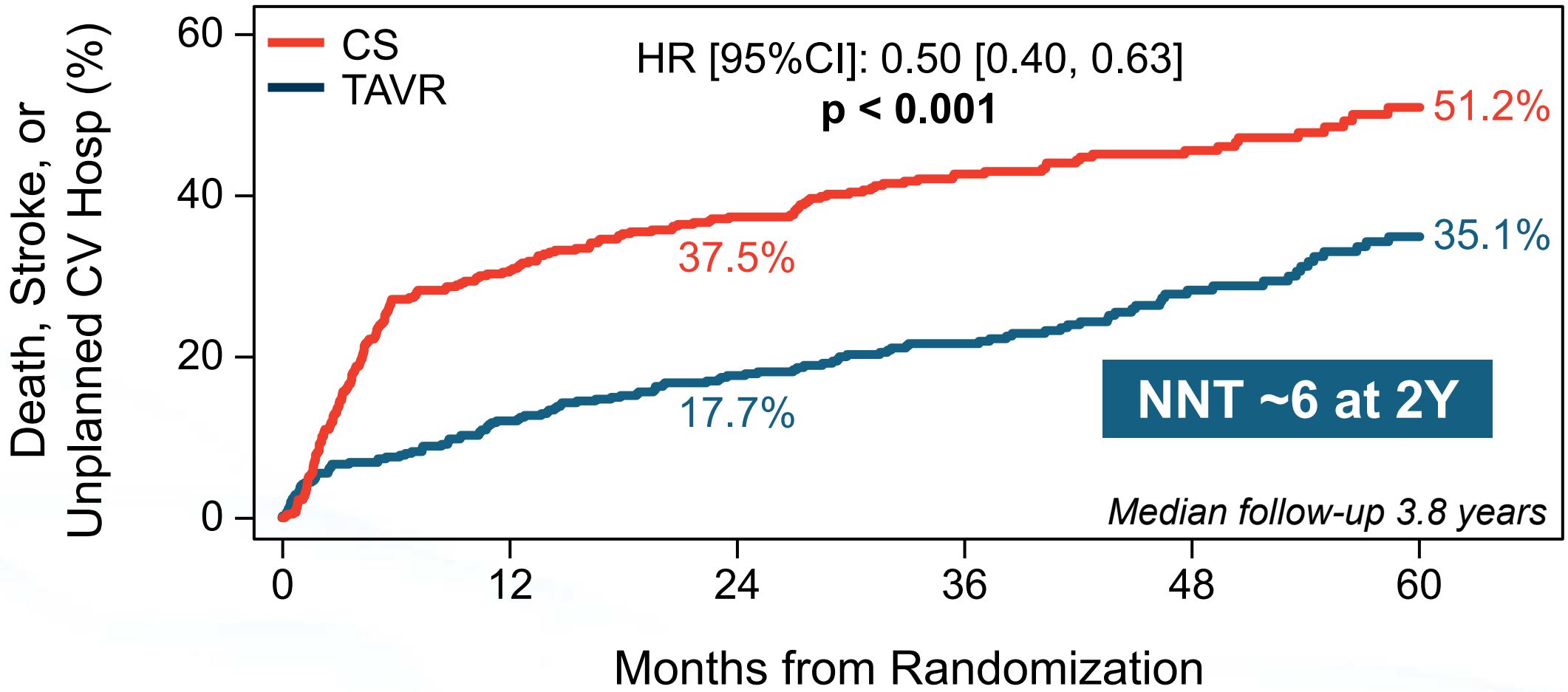
**Confirmed by detailed clinical history alone if patient was unable to perform stress test*

THE EARLY TAVR TRIAL

Primary Endpoint



No. at risk:

TAVR	455	390	363	285	142	103
CS	446	305	266	187	117	46

Event rates are Kaplan-Meier estimates

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Patients had a minimum follow-up of 2 years

THE EARLY TAVR TRIAL

Primary Endpoint Components

Endpoint – % (no. of pts w/ an event)	TAVR (N=455)	CS (N=446)	P-value
Primary Endpoint	**26.8% (122)**	**45.3% (202)**	**<0.001**
All-cause Death	8.4% (38)	9.2% (41)	---
Any Stroke	4.2% (19)	6.7% (30)	---
Unplanned CV Hospitalization	20.9% (95)	41.7% (186)	---

Median follow-up of 3.8 years

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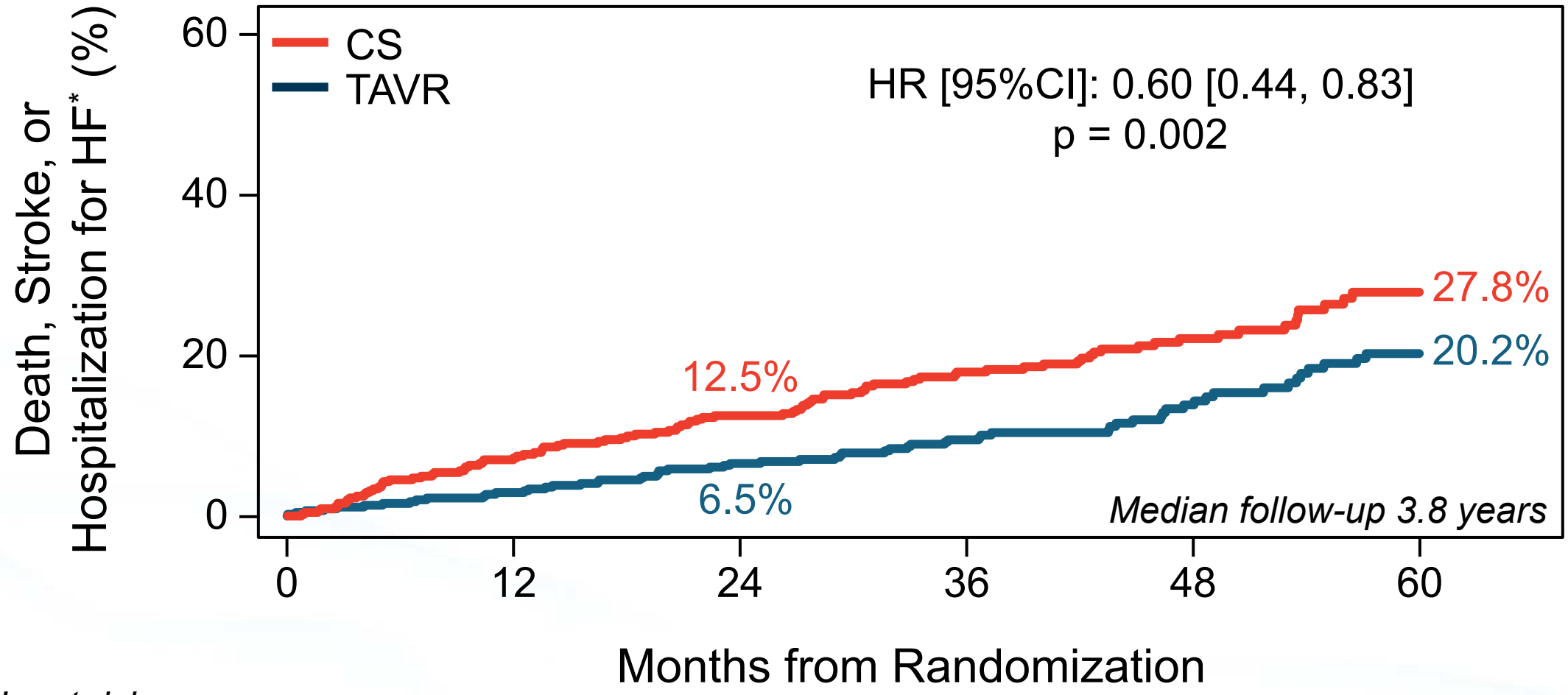
Death, Stroke, or Hosp. for HF*



No. at risk:

TAVR	455	431	412	331	175	128
CS	446	410	376	268	163	77

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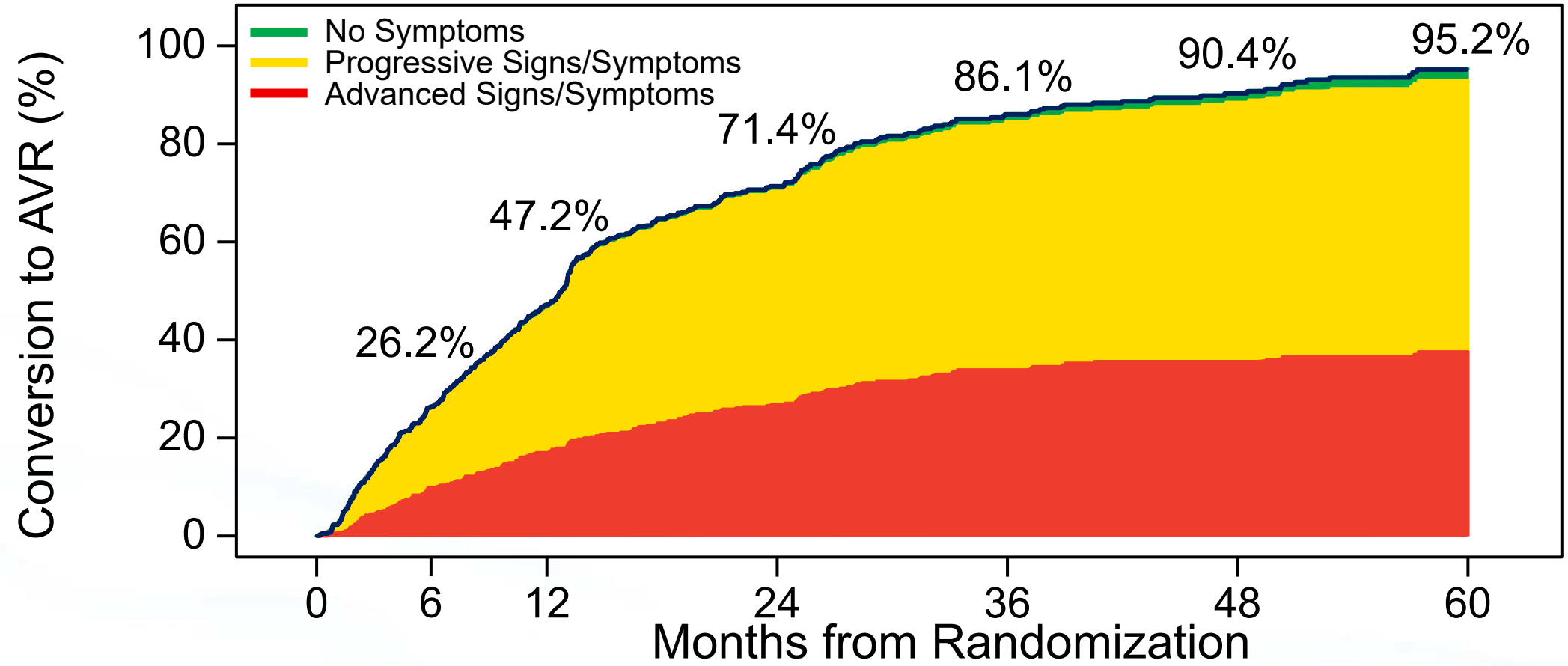
*Hosp for symptomatic CHF treated with IV diuresis, inotropic therapy, IABP, ventilation for pulmonary edema, or hemodialysis for vol. overload

Signs & Symptoms at Time of Conversion to AVR



No. at risk:

CS	446	326	231	119	45	22	9

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Median follow-up 3.8 years; At the time of analysis, 30 patients were still on study but hadn't converted to AVR

Limitations de EARLY TAVR

Le remplacement aortique est compté comme une hospitalisation non planifiée et contribue au plus grand nombre d'événement.

Laps de temps entre l'inclusion et l'apparition de symptômes beaucoup plus court que dans les autre études.

Pas de différence en terme de mortalité cardiovasculaire et all-cause

Positionnement de l'étude EARLY TAVR

	RECOVERY		AVATAR		EARLY-TAVR		EVOLVED	
Total number of patients	145		157		901		224	
Key patient demographics (mean)*	age 64 yrs, Female 51%, EuroScore II 0.9%		age 67 yrs, Female 43%, STS-PROM 1.7%		age 76 yrs, Female 31%, STS-PROM 1.8%		age 75 yrs, Female 27%, unknown	
Stress test performed	16.6%		100%		90.6%		Not mandatory	
Key baseline echo results (mean)*	V_{max} 5.1 m/sec; Mean PG 62.7 mmHg;		V_{max} 4.3 m/sec; Mean PG 50.7 mmHg;		V_{max} 4.3 m/sec; Mean PG 46.5 mmHg;		V_{max} 4.3 m/sec; Mean PG 45.2 mmHg;	
Bicuspid etiology	61%		14%		8.4%		29%	
AVR (actual rate)	Intervention (100%)	CS (74%)	Intervention (92.3%)	CS (44.3%)	Intervention (97.6%)	CS (87.0%)	Intervention (94%)	CS (77%)
Time to intervention (median)	23 days	700 days	55 days	476 days	14 days	11.1 months (≈333 days)	5.5 months (≈165 days)	20.2 months (≈606 days)
AVR modality	SAVR 100%	SAVR 98.1%; TAVI 1.9%	SAVR 100%	SAVR 88.6%; TAVI 11.4%	TAVI 100%	SAVR 1.8%; TAVI 98.2%	SAVR 75%; TAVI 25%	SAVR 45%; TAVI 55%

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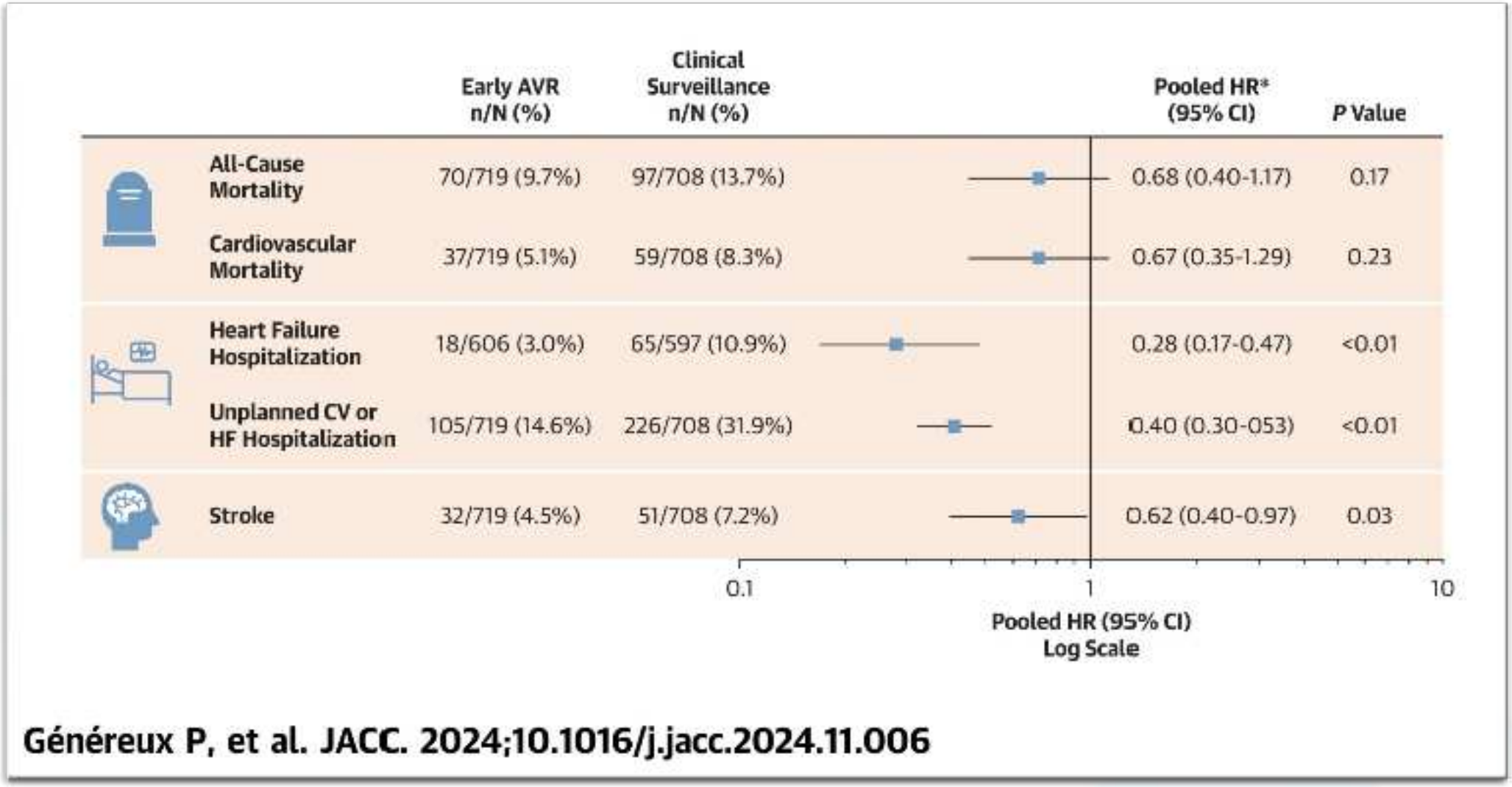
Study-level Meta-analysis of RCTs



Généreux P, et al. JACC. 2024;10.1016/j.jacc.2024.11.006

Mon algorithme