

Y a-t-il un age limite
pour le TAVI?
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L'INSTITUT
MUTUALISTE
MONTSOURIS

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Physiopathologie et prévalence

▶ Prévalence :

- 2% >65 ans
- 3% >75 ans
- 4% >85 ans
- Plus fréquente des maladies valvulaires

1.6 Millions personnes aux USA ont >90 ans (500 000 en France)

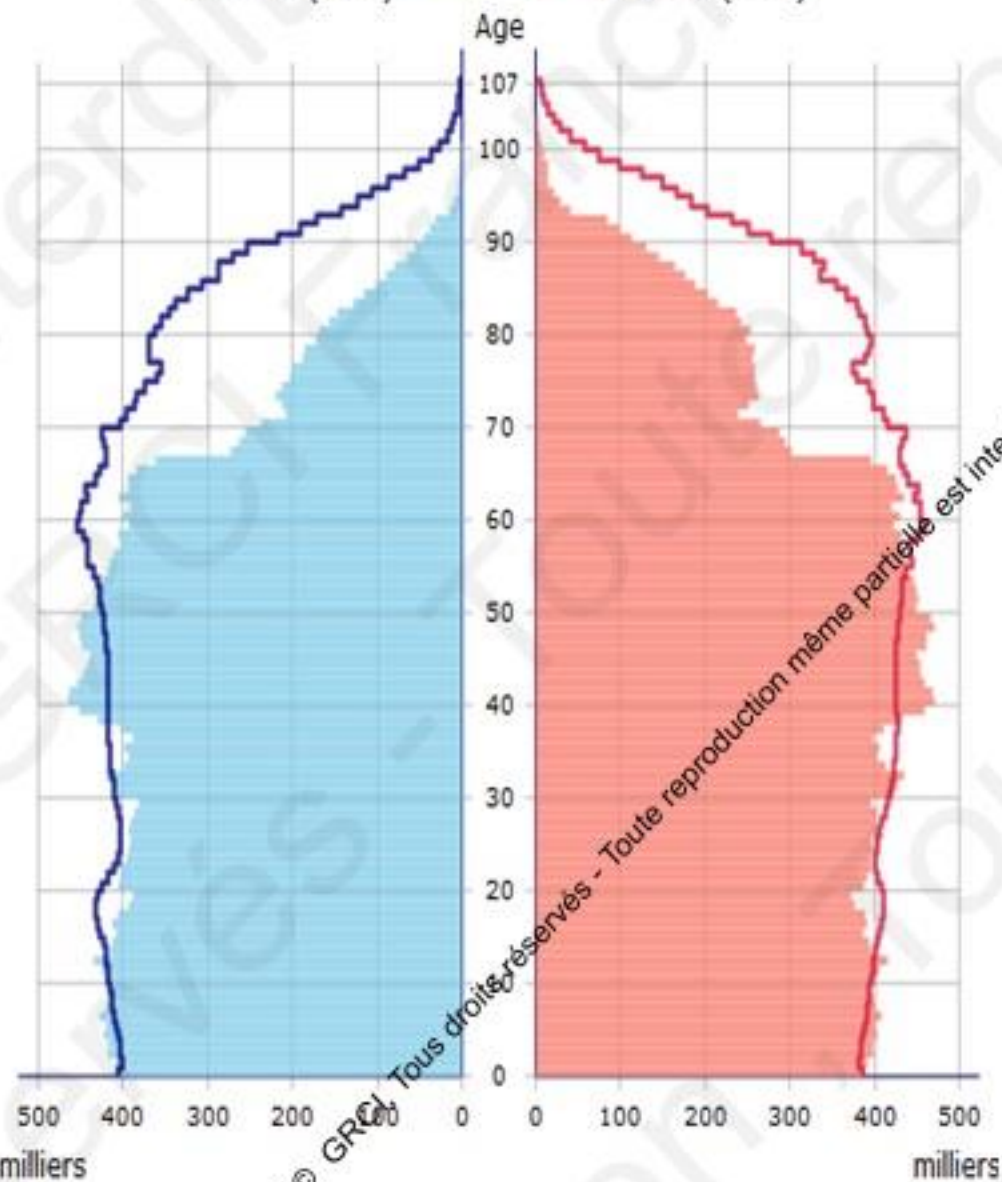
▶ Registre STS 16% des TAVI réalisés >90 ans

Prévisions

Les pyramides des âges de 2013 et 2070

(scénario central)

Hommes (2013) Femmes (2013)
Hommes (2070) Femmes (2070)



Champ : France.

Source : Insee, projections de population 2013-2070.

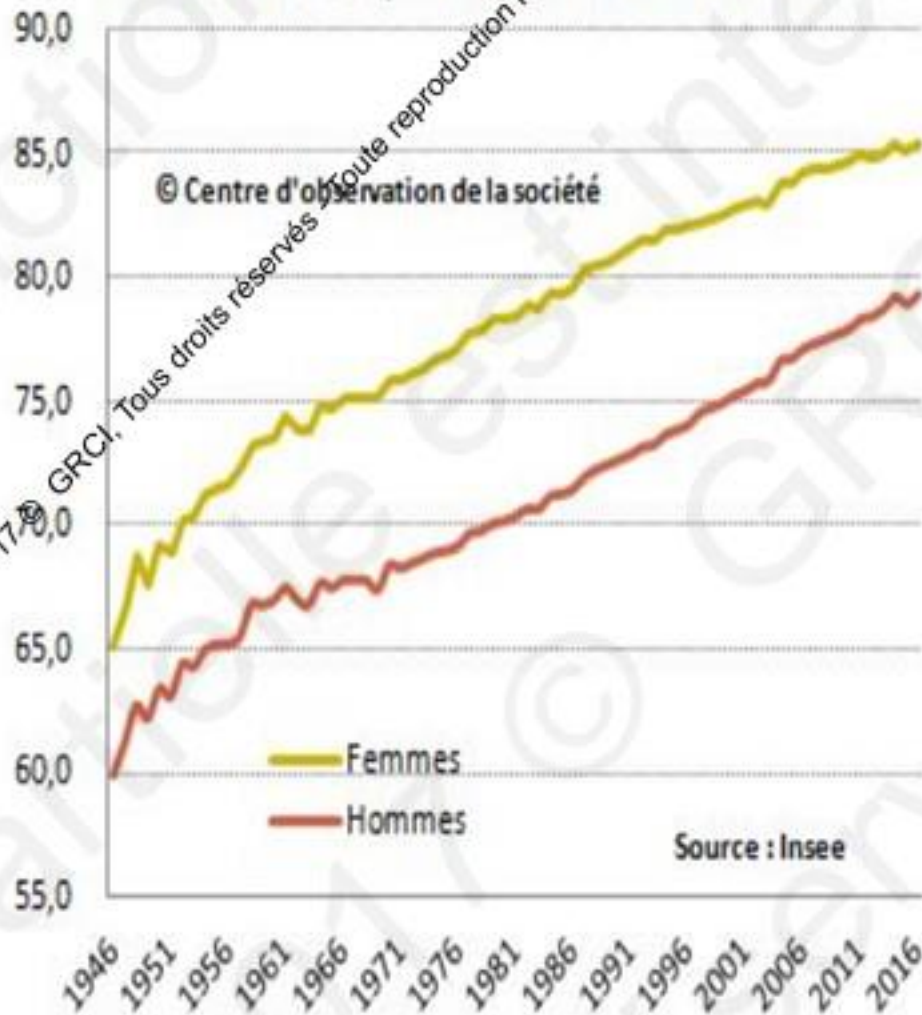
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Espérance de vie d'une femme en 2017

Année de naissance	Age	Espérance de vie*	Espérance de vie**
2005	12 ans	98.102 ans	85.31 ans
1995	22 ans	96.846 ans	85.42 ans
1985	32 ans	95.551 ans	85.57 ans
1975	42 ans	94.248 ans	85.85 ans
1965	52 ans	93.181 ans	86.48 ans
1955	62 ans	92.488 ans	87.54 ans
1945	72 ans	92.162 ans	88.98 ans
1935	82 ans	93.109 ans	91.38 ans

Evolution de l'espérance de vie à la naissance



Espérance de vie d'un homme en 2017

Année de naissance	Age	Espérance de vie*	Espérance de vie**
2005	12 ans	94.857 ans	78.96 ans
1995	22 ans	93.478 ans	79.17 ans
1985	32 ans	92.097 ans	79.58 ans
1975	42 ans	90.728 ans	80.11 ans
1965	52 ans	89.57 ans	81.16 ans
1955	62 ans	88.929 ans	83.16 ans
1945	72 ans	89.055 ans	85.81 ans
1935	82 ans	90.901 ans	89.53 ans

De France 2 à FranceTAVI

TABLE 2 Baseline Characteristics per Year of Inclusion Within Centers Involved in Both Registries

	FRANCE 2		FRANCE TAVI			p Value for Trend
	2010 (n = 1,378)	2011/2012 (n = 2,385)	2013 (n = 2,512)	2014 (n = 3,177)	2015 (n = 4,293)	
Clinical characteristics						
Age, yrs	82.4 ± 7.3 1,378	82.9 ± 7.2 2,385	83.1 ± 7.5 2,512	83.2 ± 7.3 3,177	83.0 ± 7.3 4,293	0.01
Median	83.8 (78.6-87.6)	84.4 (79.7-87.8)	84.5 (80.2-87.9)	84.5 (80.1-88.2)	84.3 (80.2-87.8)	
Male	705/1,378 (51.2)	1,207/2,385 (50.6)	1,226/2,512 (48.8)	1,551/3,177 (48.8)	2,122/4,293 (49.4)	0.126
Body mass index, kg/m ²	26.0 ± 5.1 1,372	26.1 ± 5.0 2,382	26.5 ± 5.2 2,483	26.5 ± 5.3 3,151	26.6 ± 5.2 4,151	<0.001
Logistic EuroSCORE, %	23.2 ± 14.7 1,375	20.5 ± 14.0 2,318	18.7 ± 12.5 2,410	17.7 ± 12.1 3,059	16.2 ± 11.6 4,131	<0.001*
Median	20.3 (12.1-30.8)	16.7 (10.4-27.1)	15.3 (10.0-24.0)	15.0 (9.5-23.0)	13.6 (9.0-21.0)	
<10	232 (17.5)	527 (22.7)	564 (23.4)	804 (26.3)	1,234 (29.9)	
10-19	416 (31.4)	862 (37.2)	949 (39.4)	1,221 (39.9)	1,709 (41.4)	
20-39	505 (38.1)	705 (30.4)	718 (29.8)	869 (28.4)	1,005 (24.3)	
≥40	172 (13.0)	224 (9.7)	179 (7.4)	265 (8.4)	183 (4.4)	
NYHA functional class III or IV	1,040/1,378 (75.6)	1,750/2,381 (73.5)	1,706/2,460 (69.4)	2,047/3,074 (66.6)	2,546/4,041 (63.0)	<0.001
≥2 APE within previous year	191/1,374 (13.9)	261/2,367 (11.0)	322/2,424 (13.3)	386/3,025 (12.8)	516/4,066 (12.7)	0.137
Clinical history						
Coronary artery disease†	593/1,375 (43.1)	1,078/2,372 (45.5)	976/2,310 (41.7)	1,281/3,006 (42.6)	1,646/3,858 (42.7)	0.338
Previous myocardial infarction <90 days	17/1,377 (1.2)	32/2,379 (1.4)	54/2,476 (2.2)	46/3,145 (1.5)	62/4,207 (1.5)	0.555
Previous CABG	275/1,375 (20.0)	374/2,372 (15.8)	314/2,499 (12.6)	345/3,164 (10.9)	416/4,211 (9.9)	<0.001

De France 2 à FranceTAVI

TABLE 6 Outcomes per Year of Implantation Within Centers Involved in Both Registries

	FRANCE 2		FRANCE TAVI			p Value for Trend
	2010 (n = 1,378)	2011/2012 (n = 2,385)	2013 (n = 2,512)	2014 (n = 3,177)	2015 (n = 4,293)	
In-hospital outcomes						
Time from implantation to discharge						<.001*
Median, days	9 (7-13)	9 (7-13)	8 (6-12)	8 (6-11)	7 (5-10)	
n	1,358	2,328	2,502	3,166	4,245	
1-5	135 (9.9)	298 (12.8)	553 (22.1)	684 (21.6)	1,193 (28.1)	
6-9	556 (41.0)	998 (42.9)	1,056 (42.2)	1,416 (44.7)	1,227 (45.4)	
≥10	667 (49.1)	1,032 (44.7)	893 (35.7)	1,066 (33.7)	1,125 (26.5)	
Complications						
Death						<.001
From all-cause	119 (8.6)	186 (7.8)	150 (6.0)	156 (4.9)	115 (2.7)	
Cause of death						
CV death	60/119 (57.1)	119/186 (64.0)	102/150 (68.0)	96/156 (61.5)	71/115 (61.7)	ref
Non-CV death	41/119 (34.5)	61/186 (32.8)	40/150 (26.7)	57/156 (36.5)	28/115 (24.4)	0.413
Unknown	10/119 (8.4)	6/186 (3.2)	8/150 (5.3)	3/156 (1.9)	16/115 (13.9)	n.s.

Mme MOL Jea née le 12/12/1918

- ▶ 98 ans
- ▶ Syncope et dyspnée d'effort stade 3 NYHA
- ▶ 58 kg, 1m54
- ▶ AC/FA permanente non anticoagulée
- ▶ HTA.
- ▶ RAC serré Gm41 mmHg, Vmax4.1, Sao 0.65cm² PAPs80mmHg, IM gr II
- ▶ Coro normale
- ▶ EFR VEMS 0,8l, Tiffeneau 72%

Evaluation gériatrique

- ▶ MMS 22/25
- ▶ Vit à domicile peu d'aides
- ▶ 1 fille
- ▶ NT Pro-BNP: 3461 ng/l
- ▶ Créatinine 73 μmol/l
- ▶ Hb 121 gr/l
- ▶ Albumine 47.2 gr/l
- ▶ Test des 5 mètres: 6s

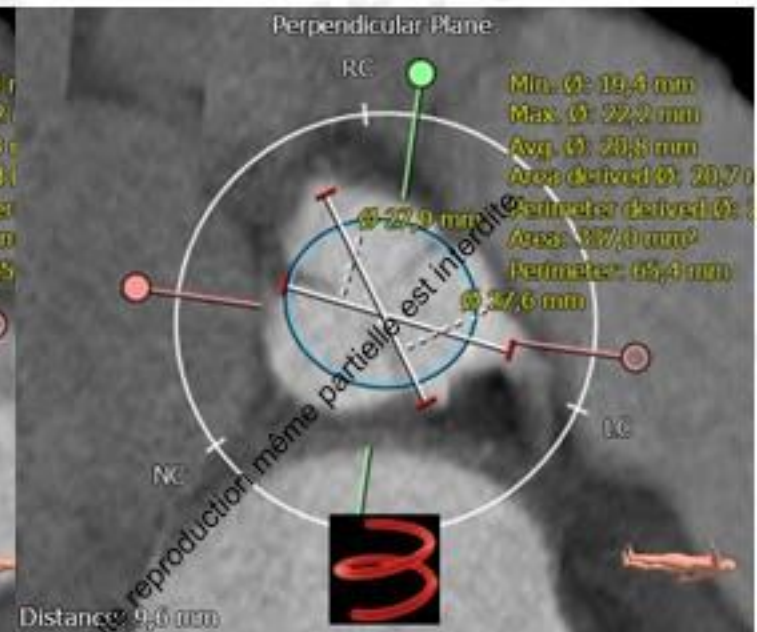
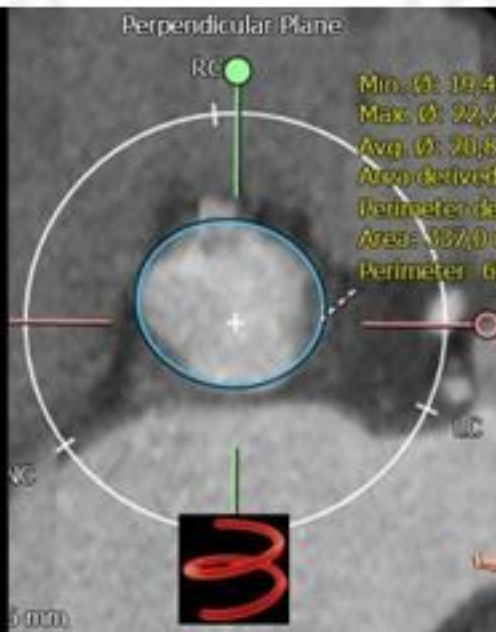
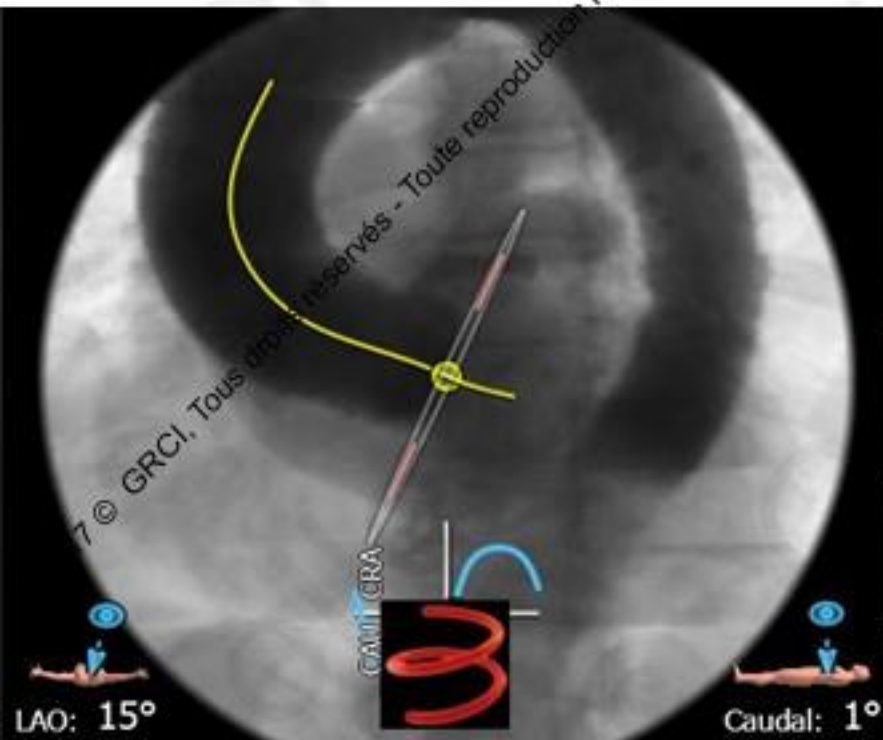
- ▶ Euroscore 1: 40%, Euroscore 2: 7%, STS 19%

Evaluation scanner



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Evaluation scanner



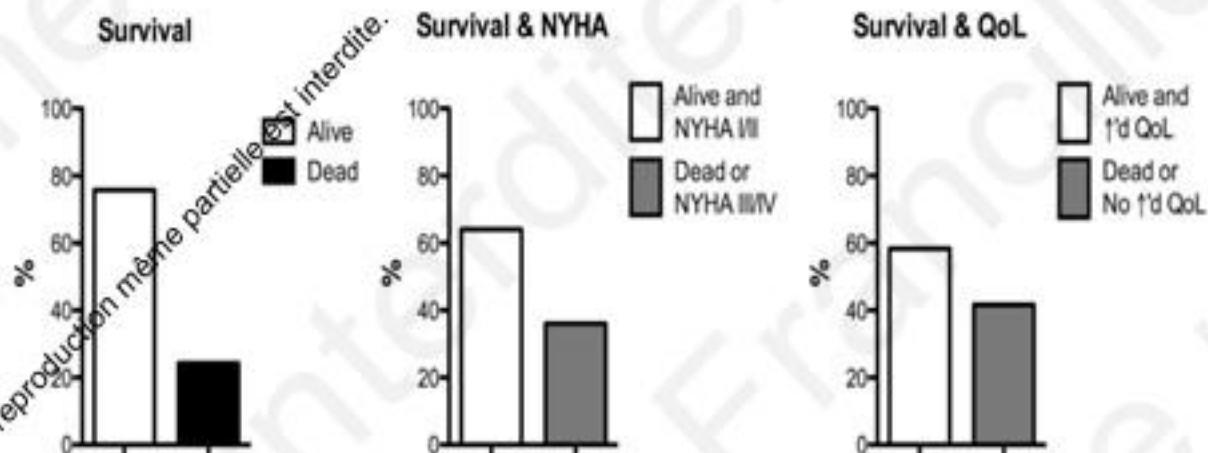
La fragilité

- ▶ Diminution des capacités à récupérer après un stress fatigénique ou opératoire
- ▶ Du à une altération des fonctions en rapport avec l'âge
- ▶ Rôle important dans TAVI ou SAVR
- ▶ Pertinence des scores

...Et Futilité

- ▶ Si espérance de vie < 1 an malgré un succès de procédure
- ▶ Ou une chance de survie avec bénéfice à 2 ans $< 25\%$
 - Gain de classe NYHA ≥ 1 ou CCASS ≥ 1

High Risk Patients in the PARTNER Trial - 1 Year Outcomes



Prohibitive Risk Patients in the PARTNER Trial - 1 Year Outcomes

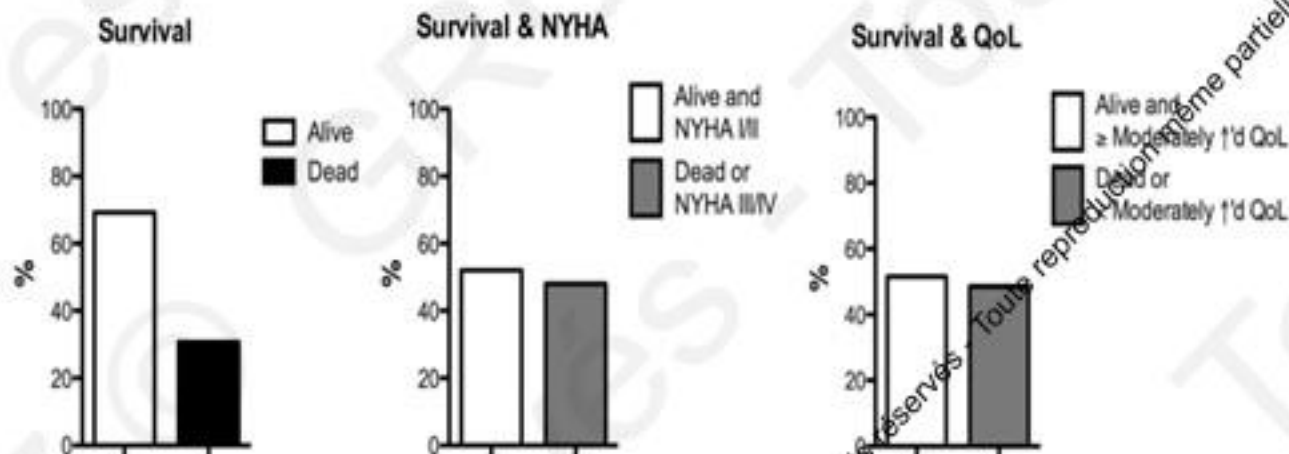
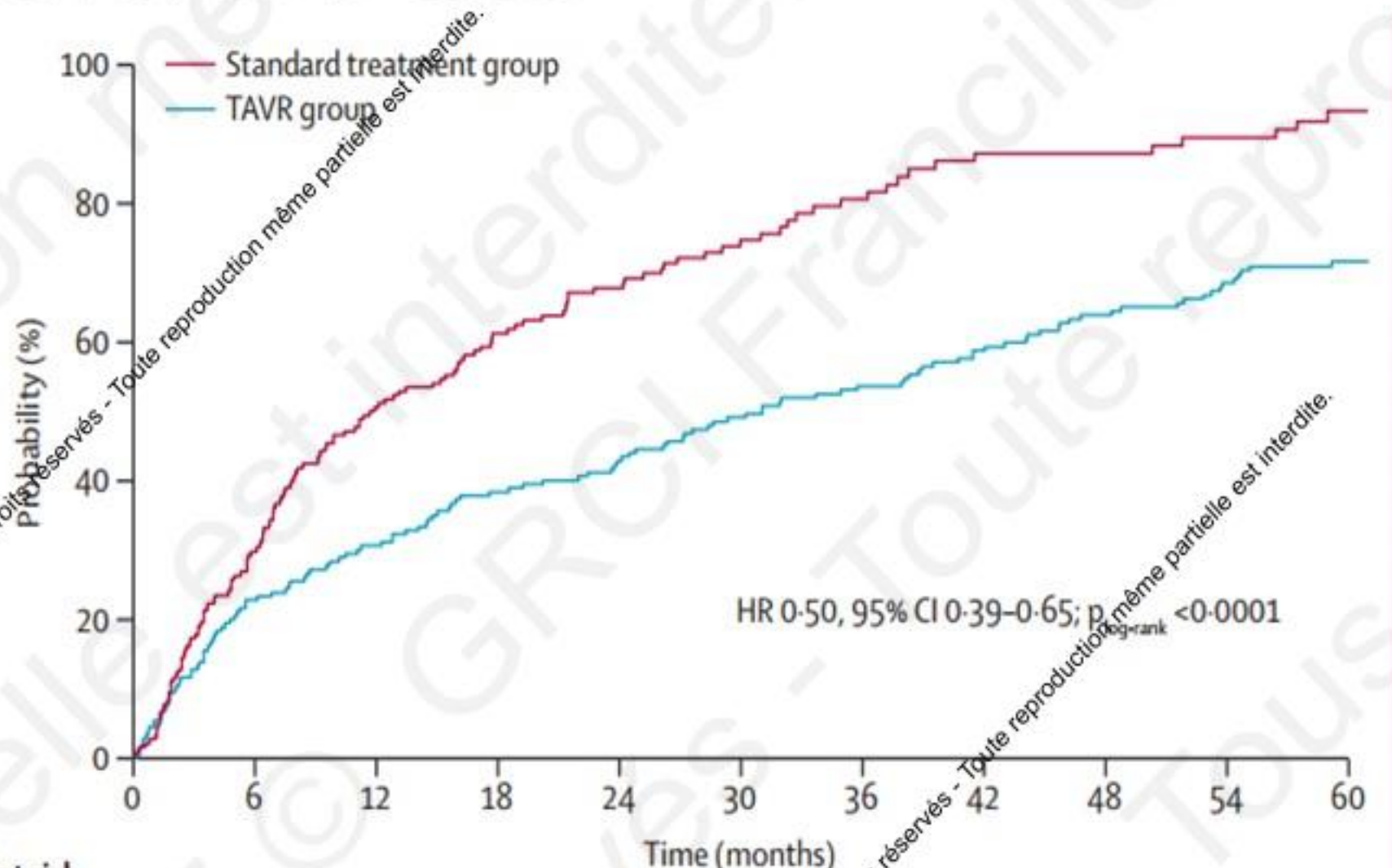


Figure 1. Survival, Heart Failure Symptoms, and QoL at 1 Year in Patients Treated With TAVR in the PARTNER Trial

Data shown is from the PARTNER Trial (8-11). NYHA = New York Heart Association; PARTNER = Placement of Aortic Transcatheter Valve trial; QoL = quality of life; TAVR = transcatheter aortic valve replacement; ↑'d = increased.

Patner B 5 ans



Number at risk		0	6	12	18	24	30	36	42	48	54	60
Standard treatment group	179	121	85	62	46	27	19	11	11	9	3	
TAVR group	179	138	124	110	101	89	81	72	63	53	35	

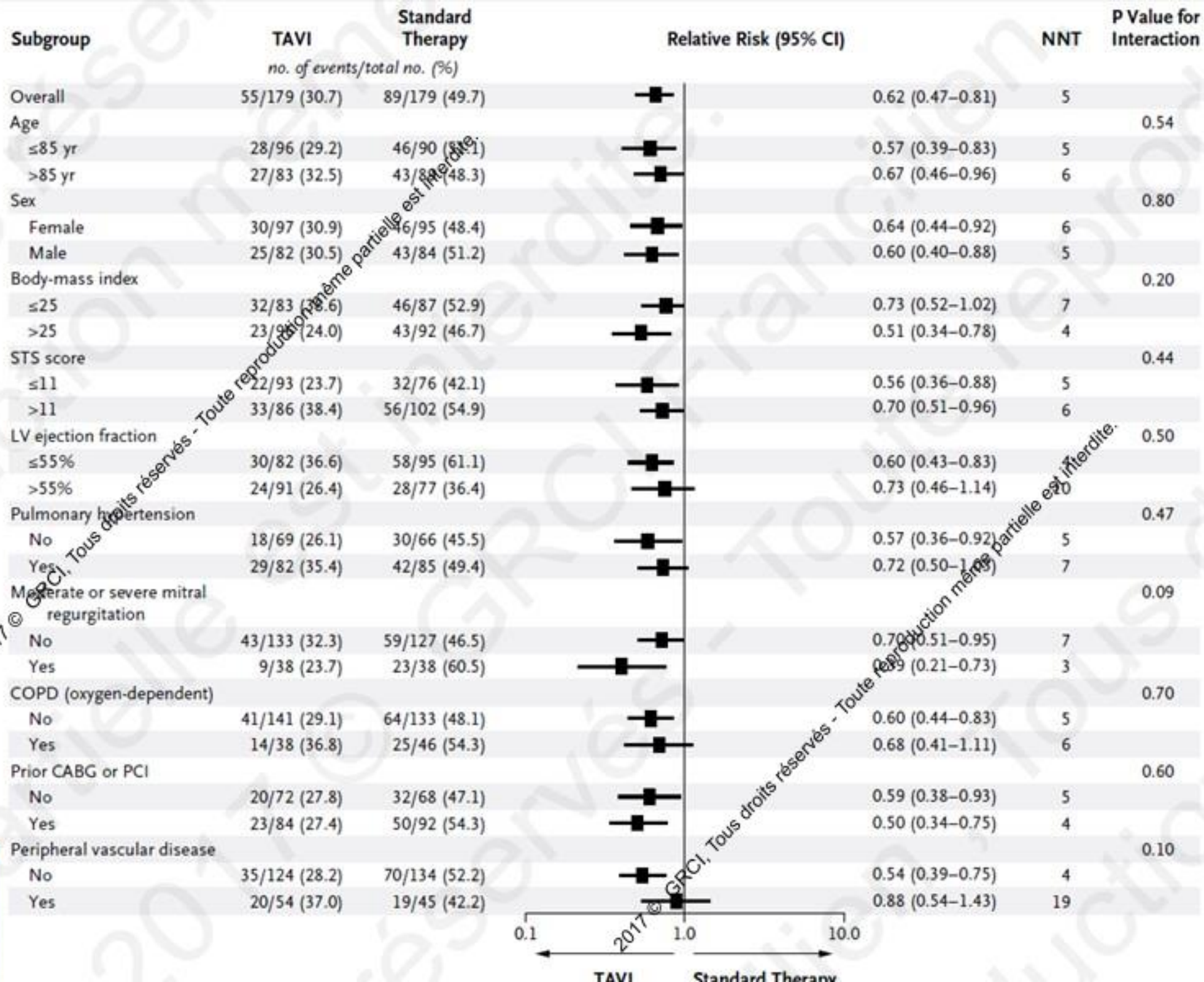


TABLE 1 Continued**5.1.4 Overall Procedural Risk**

Risk categories	<input type="checkbox"/> Low risk	<input type="checkbox"/> STS-PROM <4% and <input type="checkbox"/> No frailty and <input type="checkbox"/> No comorbidity and <input type="checkbox"/> No procedure specific impediments
	<input type="checkbox"/> Intermediate risk	<input type="checkbox"/> STS-PROM 4%–8% or <input type="checkbox"/> Mild frailty or <input type="checkbox"/> 1 major organ system compromise not to be improved postoperatively or <input type="checkbox"/> A possible procedure-specific impediment
	<input type="checkbox"/> High risk	<input type="checkbox"/> STS-PROM >8% or <input type="checkbox"/> Moderate-severe frailty or <input type="checkbox"/> >2 major organ system compromises not to be improved postoperatively or <input type="checkbox"/> A possible procedure-specific impediment
	<input type="checkbox"/> Prohibitive risk	<input type="checkbox"/> PROMM >50% at 1 year or <input type="checkbox"/> ≥3 major organ system compromises not to be improved postoperatively or <input type="checkbox"/> Severe frailty <input type="checkbox"/> Severe procedure-specific impediments

5.1.5 Integrated Benefit-Risk of TAVR and Shared Decision-Making

No current indication for AVR	<input type="checkbox"/> AS not severe or <input type="checkbox"/> No AS symptoms or other indication for AVR	<input type="checkbox"/> Periodic monitoring of AS severity and symptoms <input type="checkbox"/> Re-evaluate when AS severe or symptoms occur
AVR indicated but SAVR preferred over TAVR	<input type="checkbox"/> Lower risk for surgical AVR <input type="checkbox"/> Mechanical valve preferred <input type="checkbox"/> Other surgical considerations	<input type="checkbox"/> SAVR recommended in lower-risk patients <input type="checkbox"/> Valve durability considerations in younger patients <input type="checkbox"/> Concurrent surgical procedure needed (e.g., aortic root replacement)
TAVR candidate with expected benefit > risk	<input type="checkbox"/> Symptom relief or improved survival <input type="checkbox"/> Possible complications and expected recovery <input type="checkbox"/> Review of goals and expectations	<input type="checkbox"/> Discussion with patient and family <input type="checkbox"/> Proceed with TAVR imaging evaluation and procedure
Severe symptomatic AS but benefit < risk (futility)	<input type="checkbox"/> Life expectancy <1 year <input type="checkbox"/> Chance of survival with benefit at 2 years <25%	<input type="checkbox"/> Discussion with patient and family <input type="checkbox"/> Palliative care inputs <input type="checkbox"/> Palliative balloon aortic valvuloplasty in selected patients





AS = aortic stenosis; AVR = aortic valve replacement; BMI = body mass index; CT = computed tomography; CV = cardiovascular; DLCO = diffusing capacity of the lung for carbon monoxide; eGFR = estimated glomerular filtration rate; FEV1 = forced expiratory volume in 1 s; GIB = gastrointestinal bleeding; IBD = inflammatory bowel disease; LV = left ventricular; MMSE = mini mental state examination; MNA = mini nutritional assessment; MR = mitral regurgitation; MS = mitral stenosis; PFT = pulmonary function test; PROMM = predicted risk of mortality or major morbidity; PVD = peripheral vascular disease; SAVR = surgical aortic valve replacement; STS-PROM = predicted risk of mortality; TAVR = transcatheter aortic valve replacement.

Domain	Tool(s)	Operational Definition	Common Cutoffs for Frailty
Slowness	5-m gait speed test	Patient is positioned behind start line and asked to walk at a comfortable pace past 5-m finish line; cue to trigger stopwatch is first footfall after start line and first footfall after finish line; repeated 3 times and averaged	Slow: <0.83 m/s (>6s) Very slow: <0.69 m/s (>7.7 s) Extremely slow: <0.50 m/s (>10 s)
Weakness	Handgrip strength test	Patient is asked to squeeze a handgrip dynamometer as hard as possible; repeated 3 times (once with each hand and then with strongest hand); maximum value is recorded	Men: <30 kg Women: <20 kg
	Knee extensor strength test	Patient is seated on the dynamometer machine and asked to extend his/her knee against resistance; maximum isotonic force is recorded	Frailty cutoffs not yet established
Low physical activity	Physical activity questionnaire	Many questionnaires have been validated. Those that provide a measure of activity in kcal/week are recommended (e.g., Minnesota Leisure Time Activity, PASE, Paffenbarger Physical Activity Questionnaire)	Men: <383 kcal/week Women: <270 kcal/week
	Portable accelerometer	Patient is asked to wear a portable accelerometer for a period of 1 to 7 days; total kcal expenditure is recorded	Frailty cutoffs not yet established
Exhaustion	CES-D questionnaire	Patient is asked 7 questions: How often in the past week did you feel like everything you did was an effort?/like you could not get going? (often [i.e., >3 days] or not often [i.e., 0-2 days])	Positive if often is the answer to either question
	Anergia questionnaire	Patient is asked 7 questions pertaining to lack of energy over the past month	Positive if major criterion "sits around a lot for lack of energy" + any 2 of 6 minor criteria
Shrinking	Weight loss	Self-reported or measured unintentional weight change not due to dieting or exercise	>10 lbs in past year
	Appendicular muscle mass	Measured muscle mass in arms and legs using a dual-energy x-ray absorptiometry scan	Frailty cutoffs not yet established; general cutoffs >2 SD from controls Men: <7.23 kg/height in m ² Women: <5.67 kg/height in m ²
	Serum albumin	Measured serum albumin	<3.3 g/dl

Table 2. Continued

Scale	Components	Operational Definition	Scoring
Short Physical Performance Battery	Balance test	Patient is asked to stand in semitandem position for 10 s; if patient is able, then he/she is asked to stand in full tandem position for 10 s; if patient is not able, then he/she is asked to stand in side-by-side position for 10 s	0 = side by side 0-8 s or unable 1 = side by side 10 s 2 = full tandem 0-2 s 3 = full tandem 3-8 s 4 = full tandem 10 s
	Chair rise test	Patient is seated on a straight-backed chair and asked to stand up 5 times as quickly as possible with arms folded across his/her chest; time to complete 5 chair rises is recorded (cue to stop stopwatch is when patient is standing after 5th chair rise)	0 = unable 1 = ≥16.7 s 2 = 13.7-16.6 s 3 = 11.2-13.6 s 4 = ≤11.1 s
	5-m gait speed test	As described above	0 = unable to walk 5 m 1 = ≥11.6 s (0.43 m/s) 2 = 8.3-11.5 s (0.44-0.60 m/s) 3 = 5.9-8.2 s (0.61-0.77 m/s) 4 = ≤5.4 s (≥0.78 m/s)
			Each item is scored 0-4 Total if Composite score ≤8/12
Final score	5-m gait speed test Handgrip strength test Physical activity questionnaire CES-D questionnaire Weight loss	As described above	Each item is scored 0-1 Total if Composite score ≥3/5

CENTRAL ILLUSTRATION Essential Frailty Toolset in Older Adults Undergoing Aortic Valve Replacement

	Five chair rises <15 seconds	0 Points
	Five chair rises ≥15 seconds	1 Point
	Unable to complete	2 Points
	No cognitive impairment	0 Points
	Cognitive impairment	1 Point
	Hemoglobin ≥13.0 g/dL ♂ ≥12.0 g/dL ♀	0 Points
	Hemoglobin <13.0 g/dL ♂ <12.0 g/dL ♀	1 Point
	Serum albumin ≥3.5 g/dL	0 Points
	Serum albumin <3.5 g/dL	1 Point

EFT Score	1-Year Mortality	
	TAVR	SAVR
0-1	6%	3%
2	15%	7%
3	28%	16%
4	30%	38%
5	65%	50%

EFT Points:

Alkalo, J. et al. J Am Coll Cardiol. 2007;70(5):689-700.

TABLE 4 Multivariable Model to Predict 1-Yr Mortality

	Adjusted OR (95% CI)
Age, per yr	1.03 (0.99-1.08)
Female	1.07 (0.70-1.62)
BMI, per kg/m ²	0.95 (0.91-0.98)
Atrial fibrillation	1.59 (1.06-2.41)
Home oxygen	3.33 (1.06-10.47)
Cancer	1.31 (0.79-2.19)
Prior stroke	0.93 (0.48-1.81)
Prior gastrointestinal bleed	1.47 (0.72-3.00)
GFR, per 10 ml/min/1.73 m ²	0.88 (0.78-0.99)
Mean aortic gradient, per 10 mm Hg	0.87 (0.75-1.01)
LVEF, per %	1.01 (0.99-1.02)
PASP ≥60 mm Hg	2.08 (1.19-3.63)
Procedure type	
TAVR transfemoral	1 (Referent)
TAVR nonfemoral	1.82 (1.09-3.05)
SAVR isolated	0.40 (0.16-1.01)
SAVR with bypass	1.39 (0.75-2.59)
Frailty*, ordinal (per EFT point)	1.87 (1.57-2.24)
dichotomous (EFT ≥3 of 5)	3.42 (2.29-5.12)

*The Essential Frailty Toolset (EFT) encompasses lower-extremity weakness, cognitive impairment, anemia, and hypoalbuminemia, for a composite score of 0 to 5.

GFR = Glomerular filtration rate; LVEF = left ventricular ejection fraction; other abbreviations as in Tables 1 and 3.

TAVI

- ▶ Nouvelles recommandations européennes

2017 ESC/EACTS Guidelines for the management of valvular heart disease

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: Helmut Baumgartner* (ESC Chairperson) (Germany), Volkmar Falk*¹ (EACTS Chairperson) (Germany), Jeroen J. Bax (The Netherlands), Michele De Bonis¹ (Italy), Christian Hamm (Germany), Per Johan Holm (Sweden), Bernard Iung (France), Patrizio Lancellotti (Belgium), Emmanuel Lansac¹ (France), Daniel Rodriguez Muñoz (Spain), Raphael Rosenhek (Austria), Johan Sjögren¹ (Sweden), Pilar Tornos Mas (Spain), Alec Vahanian (France), Thomas Walther¹ (Germany), Olaf Wendler¹ (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain)

RAC serré symptomatique

B) Choice of intervention in symptomatic aortic stenosis

Aortic valve interventions should only be performed in centres with both departments of cardiology and cardiac surgery on site and with structured collaboration between the two, including a Heart Team (heart valve centres).

I

C

The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in Table 7). In addition, the local expertise and outcomes data for the given intervention must be taken into account.

I

C

SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II < 4% or logistic EuroSCORE I < 10%^d and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).⁹³

I

B

TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.^{91,94}

I

B

In patients who are at increased surgical risk (STS or EuroSCORE II > 4% or logistic EuroSCORE I > 10%^d 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 Table 7), with TAVI being favoured in elderly patients suitable for transfemoral access.^{91,94-102}

I

B

Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients or in patients with symptomatic severe aortic stenosis who require urgent major non-cardiac surgery.

IIb

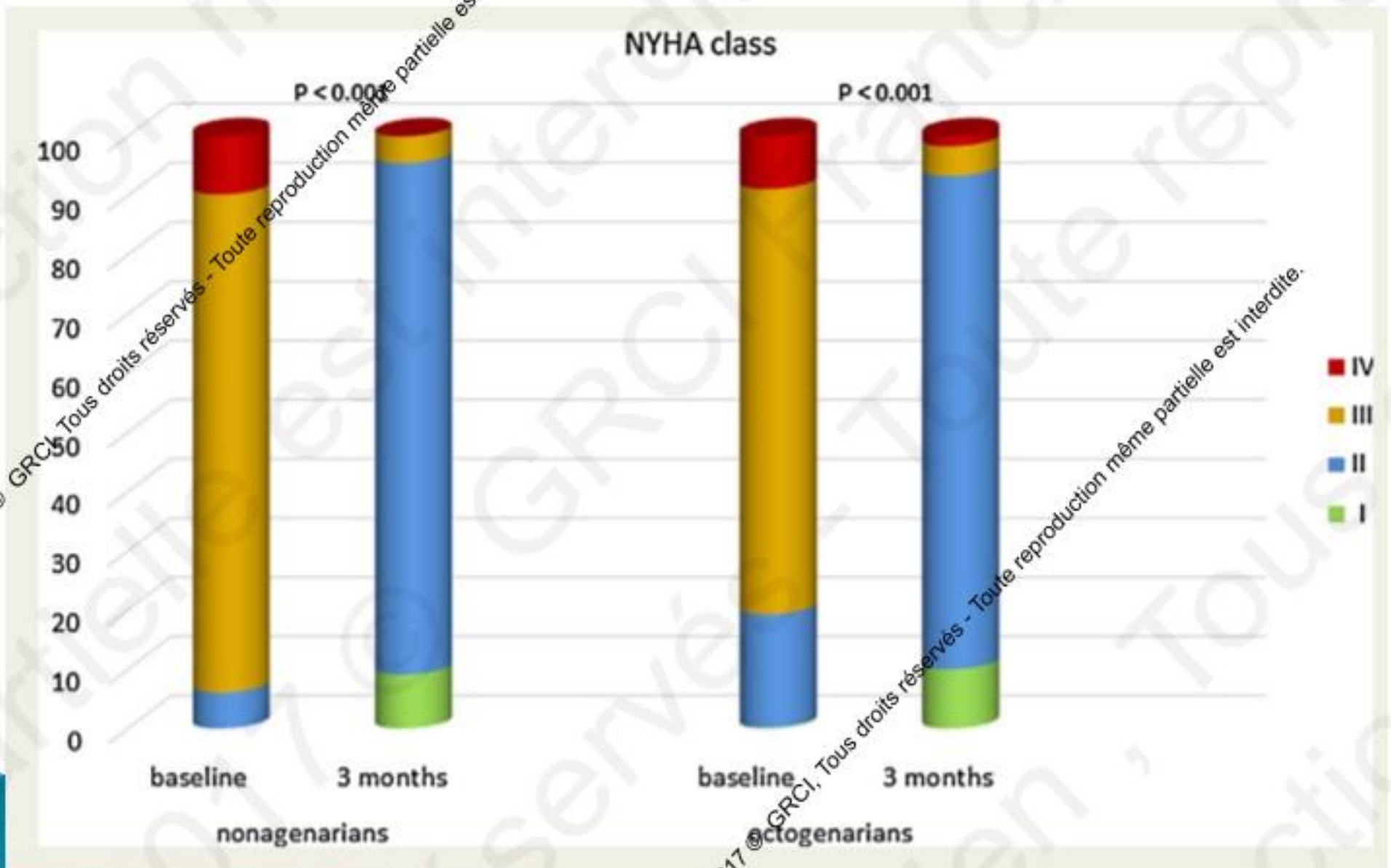
C

Balloon aortic valvotomy may be considered as a diagnostic means in patients with severe aortic stenosis or other potential causes for symptoms (i.e. lung disease) and in patients with severe myocardial dysfunction, pre-renal insufficiency or other organ dysfunction that may be reversible with balloon aortic valvotomy when performed in centres that can escalate to TAVI.

IIb

C

Amélioration fonctionnelle



Score de fragilité

Table 3 Independent predictors of one-year mortality.

	Hazard ratio (95% confidence interval)	p
Charlson Index	1.18 (1.01–1.39)	0.006
Creatinine clearance	0.98 (0.97–0.99)	0.035
Mean aortic gradient	1.02 (1.01–1.03)	0.012
LVEF	0.98 (0.96–0.99)	0.004
Mitral regurgitation	2.19 (1.32–3.62)	0.002
TAVI	0.49 (0.26–0.94)	0.032

Abbreviations: *LVEF: Left ventricular ejection fraction; TAVI: percutaneous aortic valve replacement.

Mme MOL TAVI



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3mensio

Evolution

- ▶ Sortie dans son hôpital référent à J3
- ▶ Sortie à domicile à J7
- ▶ Institutionnalisation après 3 mois. Toujours autonome
- ▶ Décès (mort subite nocturne) au 11^{ème} mois à quelques semaines de sa 100^{ème} année



CONCLUSION

- ▶ Age n'apparaît pas comme un prédicteur de risque
- ▶ Scores de fragilité et de comorbidités sont plus pertinents que l'âge
- ▶ Intérêt de la valvuloplastie au ballon
- ▶ Le TAVI ne rend pas immortel
- ▶ La limite c'est le ciel

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