

Recommandations ESC sur la prise en charge des valvulopathies: que s'est-il passé?

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DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

Nom de l'orateur : Fabien PRAZ, Berne

Je déclare les liens d'intérêt potentiel suivants :

Travel expenses : Abbott, Edwards, Polares Medical

Recommandations ESC sur la prise en charge des valvulopathies

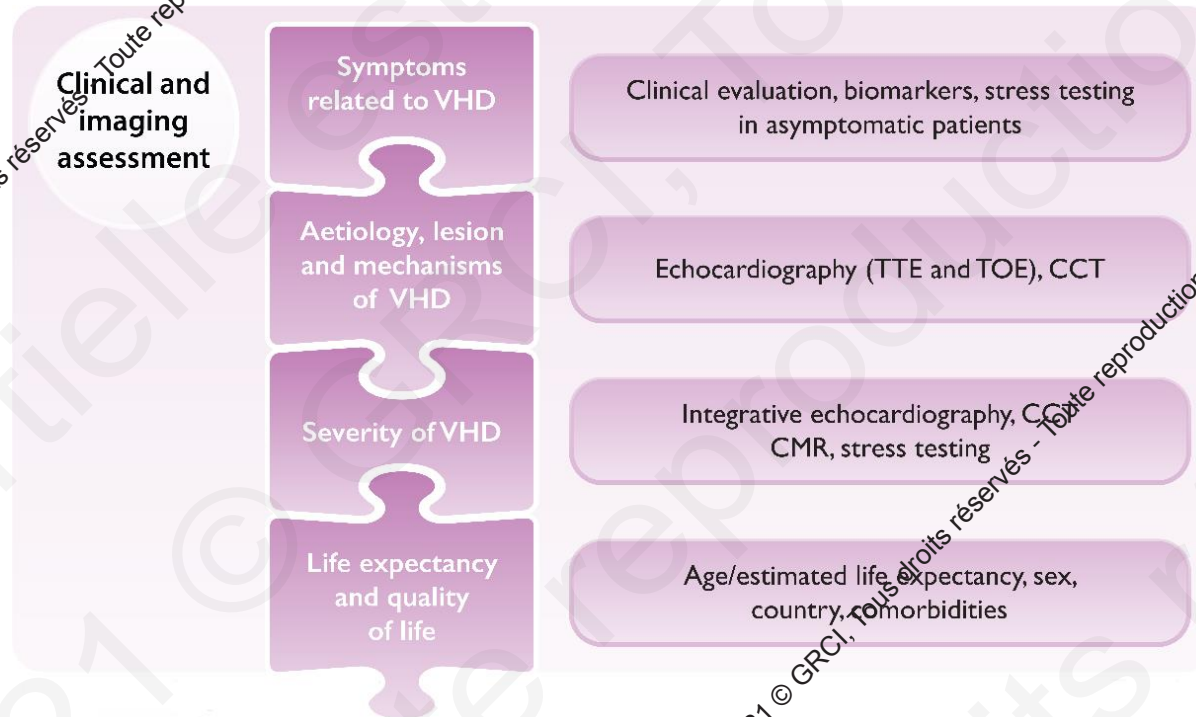
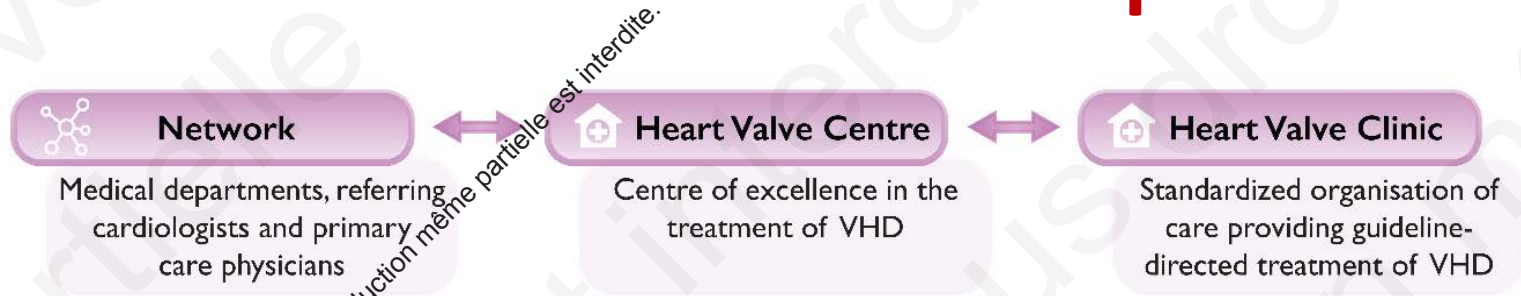
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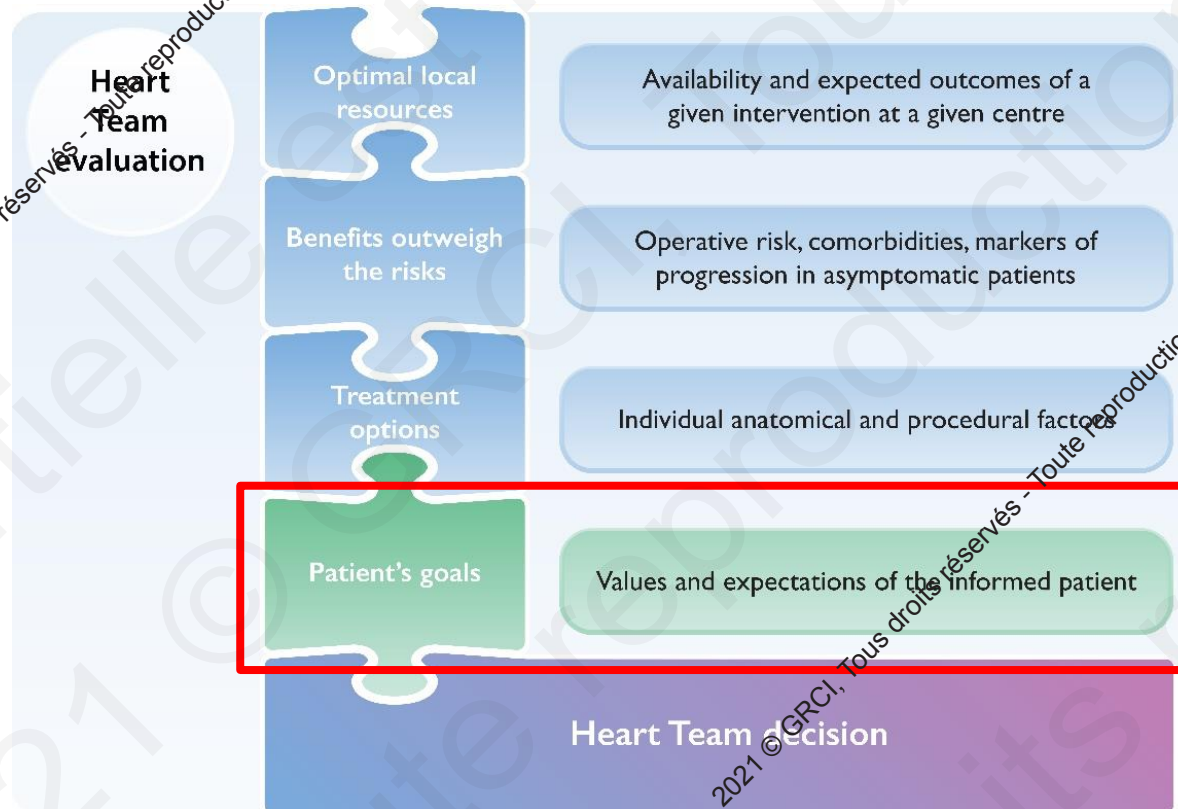
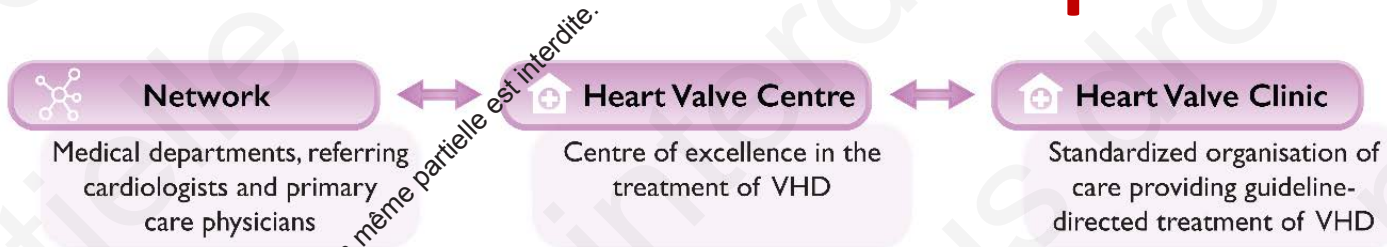
Principales nouveautés des recommandations ESC 2021

1. Traitement plus précoce des patients asymptomatiques
2. Modalités de traitement de la sténose aortique
3. Traitement de l'insuffisance mitrale et tricuspide secondaires
4. Traitement antithrombotique chez les patients avec valves biologiques

Evaluation centrée sur le patient



Evaluation centrée sur le patient



Modalité de traitement de la sténose aortique

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Nouveauté – sténose aortique asymptomatique

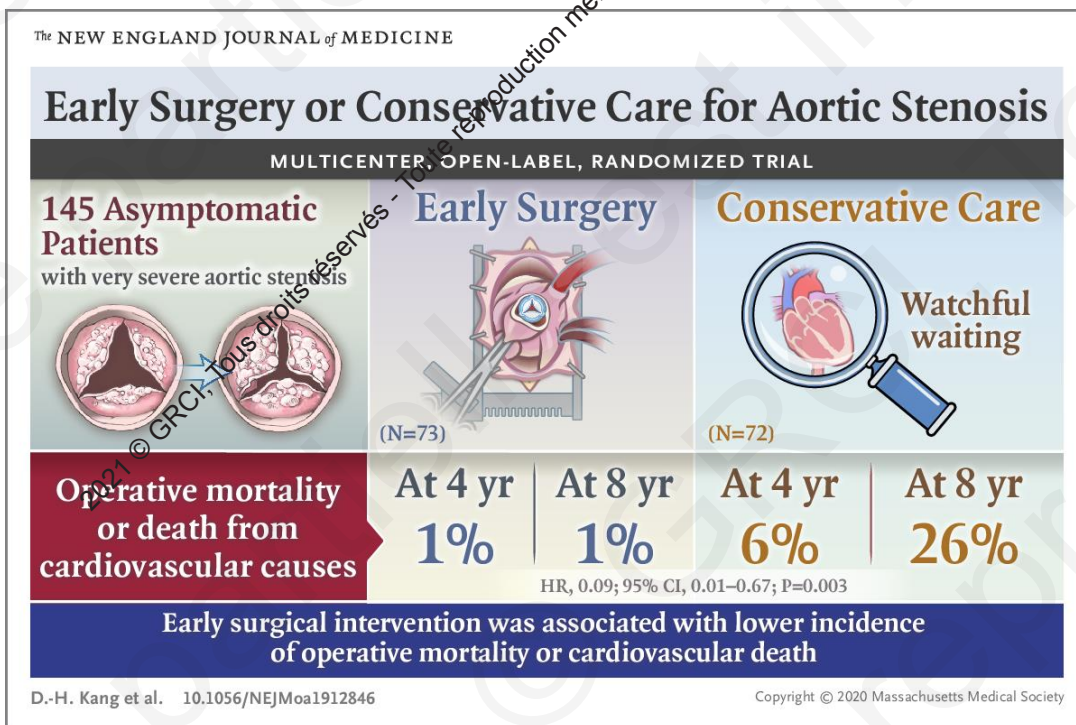
<i>Recommendations on indications for intervention in symptomatic and asymptomatic aortic stenosis</i>			
2017 VHD Guidelines	Class	2021 VHD Guidelines	Class
<i>Asymptomatic patients with severe aortic stenosis</i>			
		Intervention should be considered in asymptomatic patients with severe aortic stenosis and systolic LV dysfunction (LVEF <55%) without another cause.	IIa

Nouveauté – sténose aortique asymptomatique

Recommendations on indications for intervention in symptomatic and asymptomatic aortic stenosis

2017 VHD Guidelines	Class	2021 VHD Guidelines	Class
Asymptomatic patients with severe aortic stenosis			
<p>SAVR should be considered in asymptomatic patients with normal ejection fraction and none of the above-mentioned exercise test abnormalities if the surgical risk is low and one of the following findings is present:</p> <ul style="list-style-type: none"> • Very severe aortic stenosis defined by a $V_{max} > 5.5$ m/s. • Severe valve calcification and a rate of V_{max} progression ≥ 0.3 m/s/year. 	IIa	<p>Intervention should be considered in asymptomatic patients with LVEF $> 55\%$ and a normal exercise test if the procedural risk is low and one of the following parameters is present:</p> <ul style="list-style-type: none"> • Very severe aortic stenosis (mean gradient ≥ 60 mmHg or $V_{max} \geq 5$ m/s). • Severe valve calcification (ideally assessed by CCT) and V_{max} progression ≥ 0.3 m/s/year. 	IIa

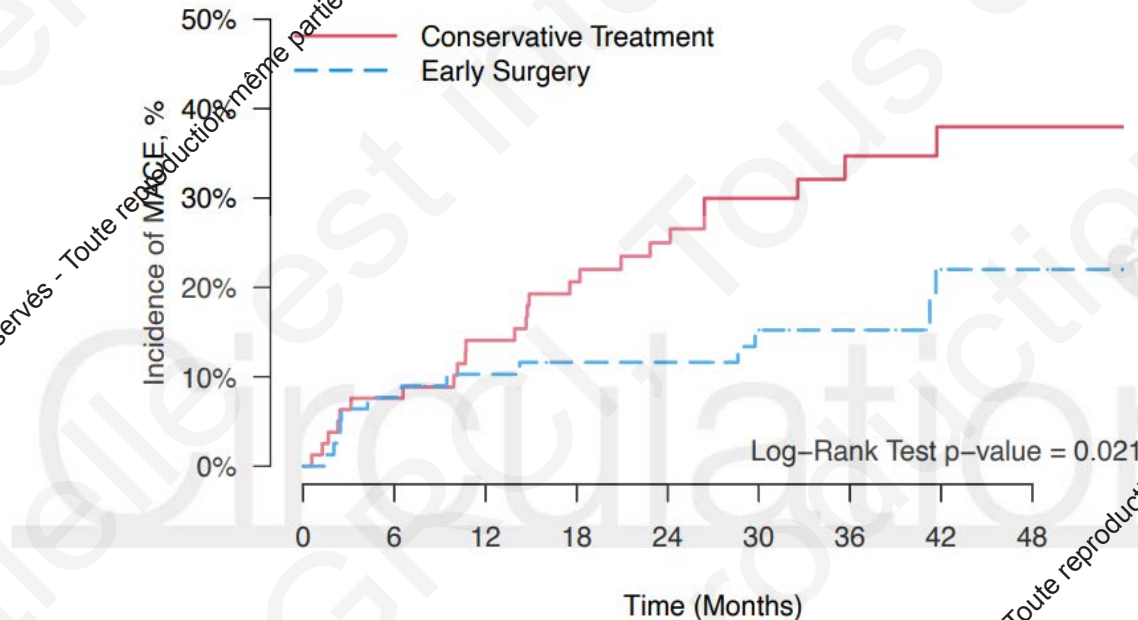
Nouveauté – sténose aortique asymptomatique



- Single RCT
- Normal LVEF
- Young patients (median age 64 years)
- Minimal comorbidities
- Low operative risk (EuroScore II 0.9%)
- Stress testing performed in a low number of patients (24 patients; 17%)
- Study possibly underpowered

Nouveauté – sténose aortique asymptomatique

The AVATAR Trial



	Patients, n								
Conservative Treat.	79	73	66	59	49	36	25	19	12
Early Surgery	78	72	68	63	56	46	38	23	13

MACE = acute myocardial infarction (AMI), stroke and unplanned heart failure (HF) hospitalization needing intravenous treatment with diuretics or inotropes.

Banovic M et al., Circulation. 2021 Nov 13

Essais randomisés comparant TAVI au remplacement chirurgical (bas risque)

Pts 280 patients / STS: 3% / Age 79 ans

NOTION

Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis

1-Year Results From the All-Comers NOTION Randomized Clinical Trial

Hans Gustav Hørsted Thyregod, MD,* Daniel Andreas Steinbrüchel, MD, PhD,† Nikolaj Ihlemann, MD, PhD,‡ Henrik Nissen, MD, PhD,§ Bo Juel Kjeldsen, MD, PhD,¶ Petur Petursson, MD,|| Yanping Chang, MS,¶ Olaf Walter Franzen, MD,† Thomas Engström, MD, DMSc,‡ Peter Christensen, MD, DMSc,‡ Peter Bo Hansen, MD,‡ Lars Willy Andersen, MD, DMSc,¶ Peter Skov Olsen, MD, DMSc,¶ Lars Søndergaard, MD, DMSc,¶

Thyregod et al J Am Coll Cardiol 2015;65:2184-94

Pts 1000 / STS 1,9% / Age 73 ans

PARTNER 3

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators*

Mack et al N Engl J Med 2019;380:1695-705.

Pts 1468 / STS 1,9% / Age 74 ans

Evolut Low risk

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hernal Gada, M.D., Daniel O'Hara, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Moore, M.D., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Soriano, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David J. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn III, M.D., John K. Forrest, M.D., Didier Tchétché, M.D., Jon Resar, M.D., Anthony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Maxwell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, M.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators*

Popma et al N Engl J Med 2019;380:1706-15.

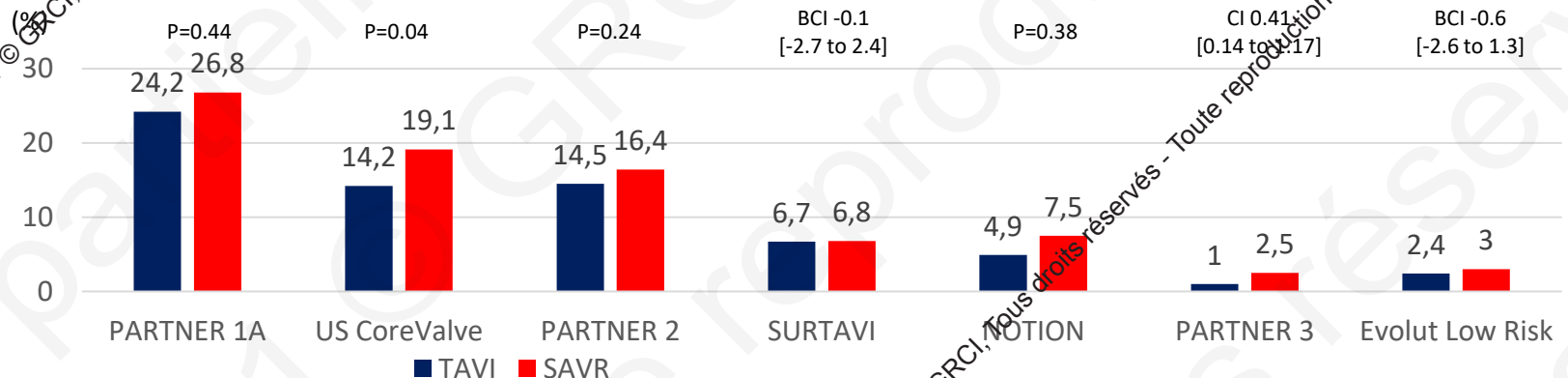
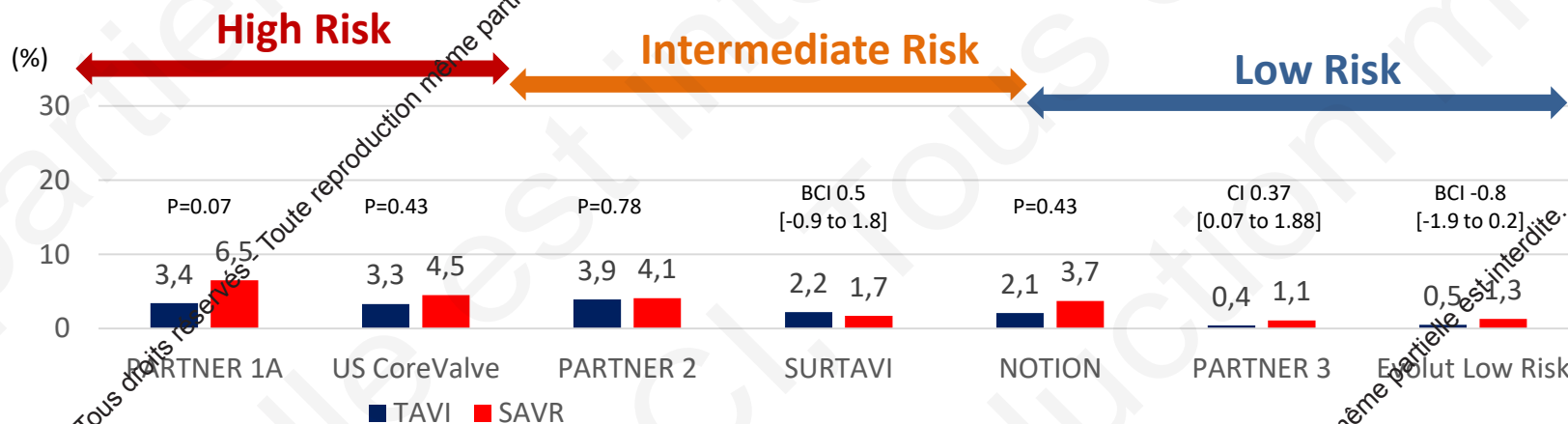
Critères d'exclusion

- CAD sévère
- Autres valvulopathies
- ATCD de chirurgie cardiaque
- Urgence
- AVC ou IDM récent
- IR sévère

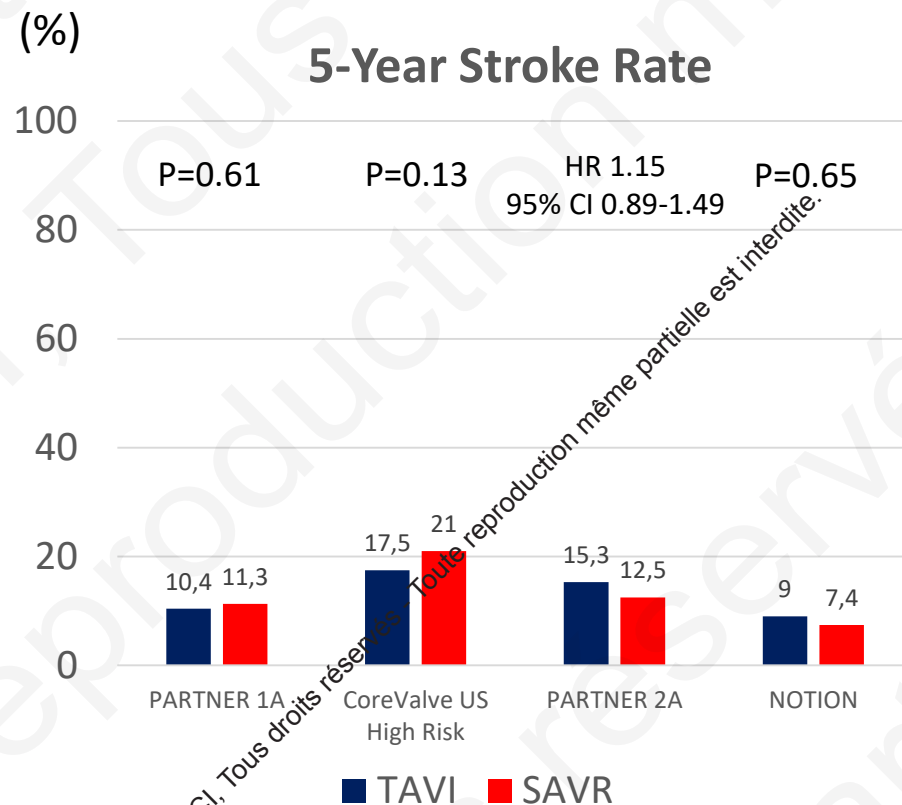
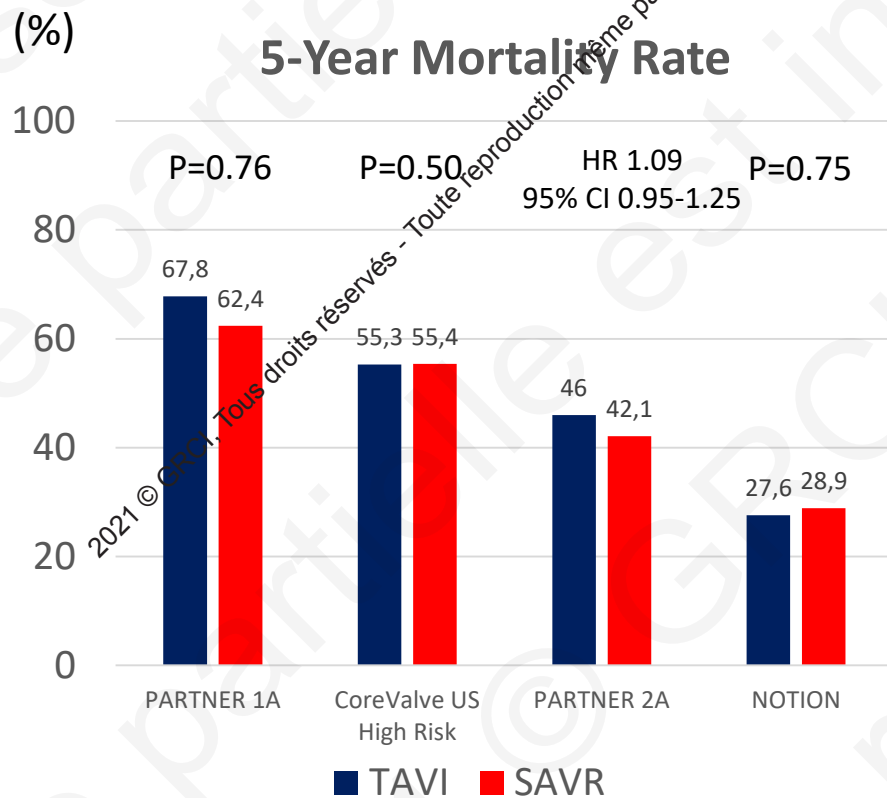
Critères d'exclusion

- Fragilité
- Bicuspidie
- CAD sévère
- Choc cardiogénique
- Valvulopathie
- CMH obstructive
- CI aux 2 traitements

Essais randomisés comparant TAVI au remplacement chirurgical (mortalité)

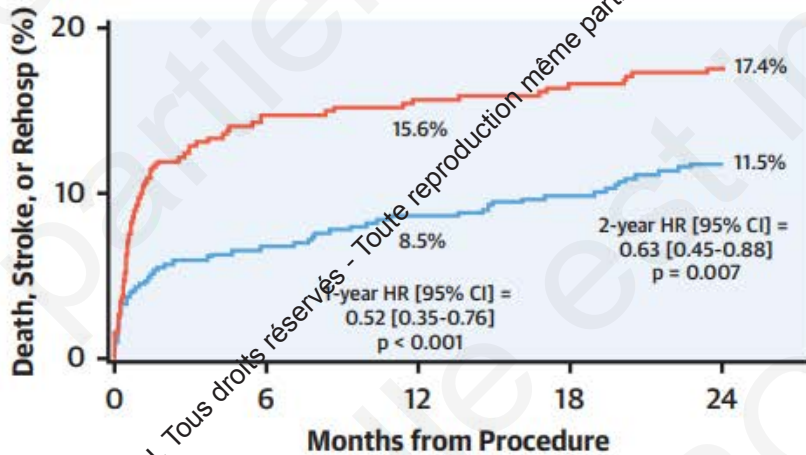


Essais randomisés comparant TAVI au remplacement chirurgical (long-terme)

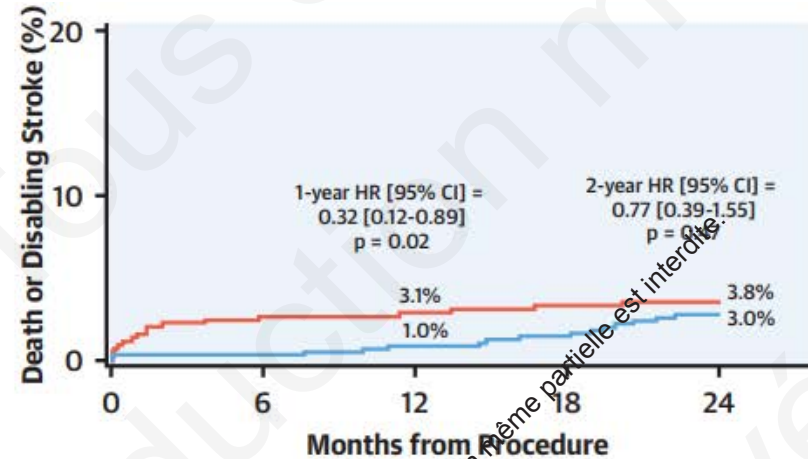


PARTNER 3 – Suivi à 2 ans

Death, stroke, Rehosp



Death or disabling stroke



Number at risk:

	0	6	12	18	24
— Surgery	454	379	371	357	345
— TAVR	496	462	453	444	431

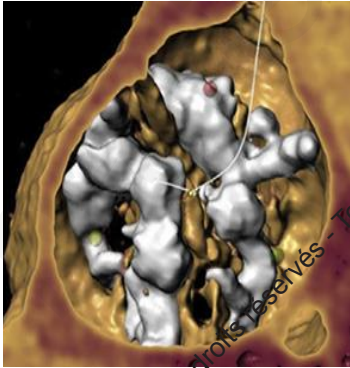
Number at risk:

	0	6	12	18	24
— Surgery	454	431	424	410	400
— TAVR	496	493	490	483	472

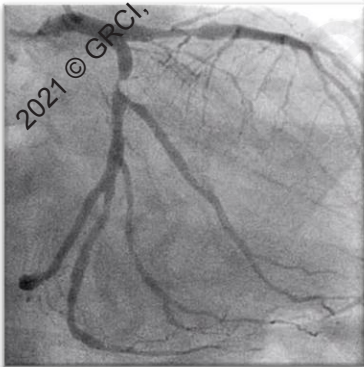
CONCLUSIONS At 2 years, the primary endpoint remained significantly lower with TAVR versus surgery, but initial differences in death and stroke favoring TAVR were diminished and patients who underwent TAVR had increased valve thrombosis. (Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients With Aortic Stenosis [PARTNER 3]; [NCT02675114](https://clinicaltrials.gov/ct2/show/study/NCT02675114)) (J Am Coll Cardiol 2021;77:1149-61) © 2021 by the American College of Cardiology Foundation.

Questions ouvertes ?

BICUSPID VALVE



CONCOMITANT CAD



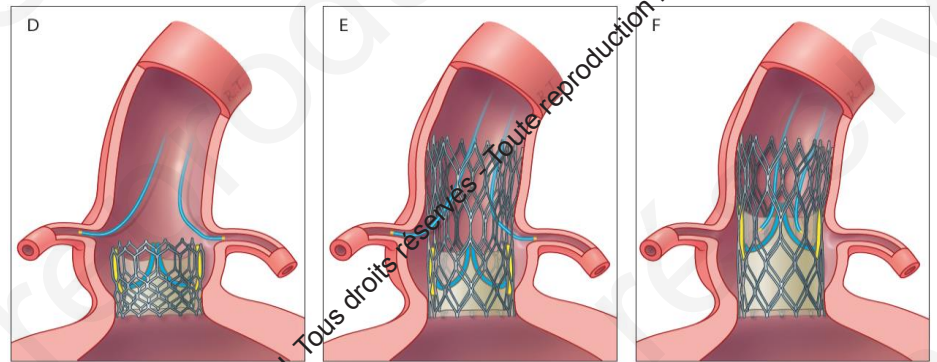
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PPM & CONDUCTION DISTURBANCES



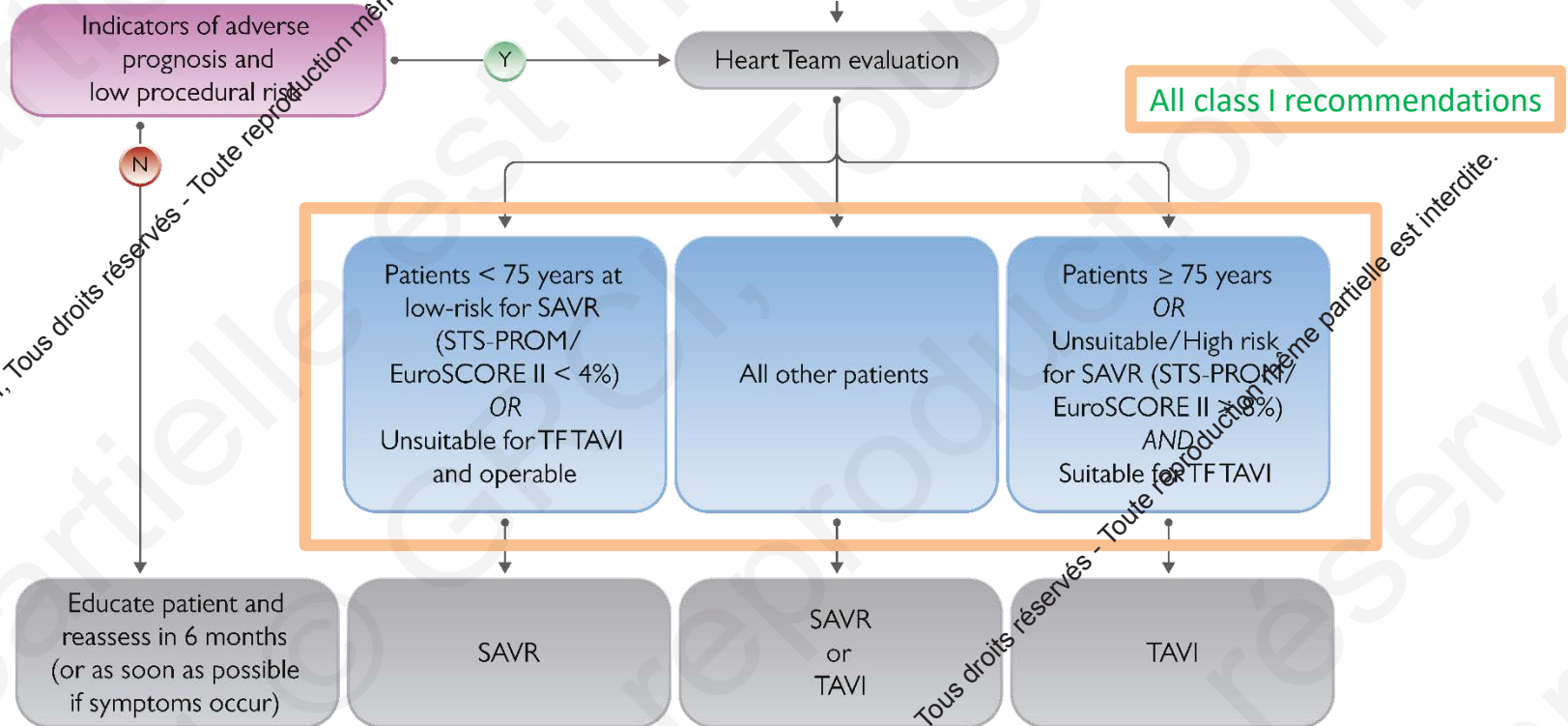
FUTURE CORONARY ACCESS



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Sténose aortique - recommandations

Severe AS and Indication for Intervention



Sténose aortique - recommandations

	Favours TAVI	Favours SAVR
Clinical characteristics		
Lower surgical risk	-	+
Higher surgical risk	+	-
Younger age	-	+
Older age	+	-
Previous cardiac surgery (particularly intact coronary artery bypass grafts at risk of injury during repeat sternotomy)	+	-
Severe frailty	+	-
Active or suspected endocarditis	-	+

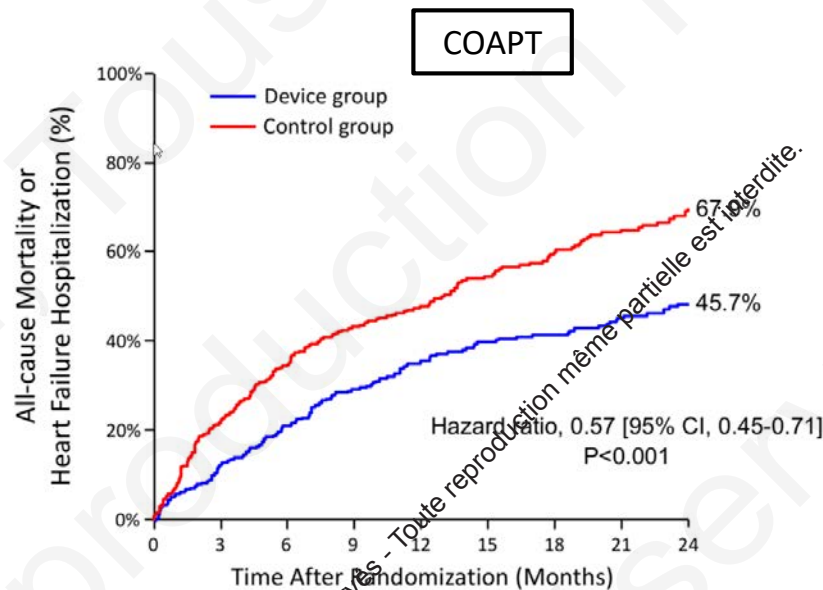
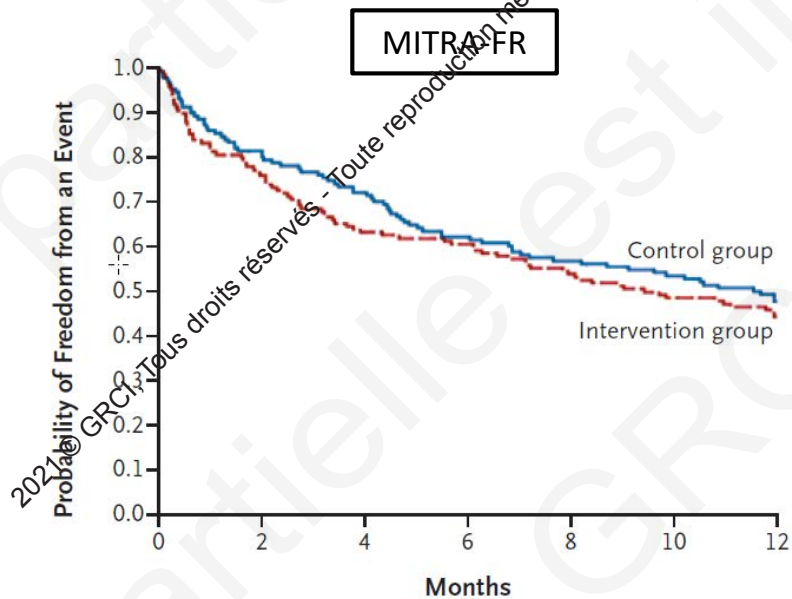
Traitement de l'insuffisance mitrale et tricuspide secondaires

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MITRA-FR et COAPT – Suivi à 2 ans

Death or HF hospitalisation



No. at Risk:

Device group	302	264	238	215	194	154	145	126	97
Control group	312	244	206	174	153	117	90	75	55

Obadia J.-F. et al. *NEJM* 2018
Stone G. et al. *NEJM* 2018

No. at Risk

Control group	152	123	109	94	86	80	73
Intervention group	151	114	95	91	81	73	67

Critères d'inclusion/exclusion

	MITRA-FR	COAPT
Primary endpoint	All-cause death and hospitalization for CHF at 1 year	All hospitalizations for CHF within 2 years (including recurrent events)
Heart failure severity	NYHA class < II	NYHA class < II ACC/AHA stage D heart failure
Left ventricular dimensions	No exclusion criteria	LVESD >70mm
Coronary artery disease	CABG or PCI performed within 1 month	Untreated coronary artery disease requiring revascularisation
Right ventricle	No exclusion criteria	Right-sided congestive heart failure with moderate or severe right ventricular dysfunction Tricuspid valve disease requiring surgery
Pulmonary disease	No exclusion criteria	COPD with home oxygen therapy or chronic oral steroid use Estimated or measured PAP >70mmHg unresponsive to vasodilator therapy

Key exclusion criteria

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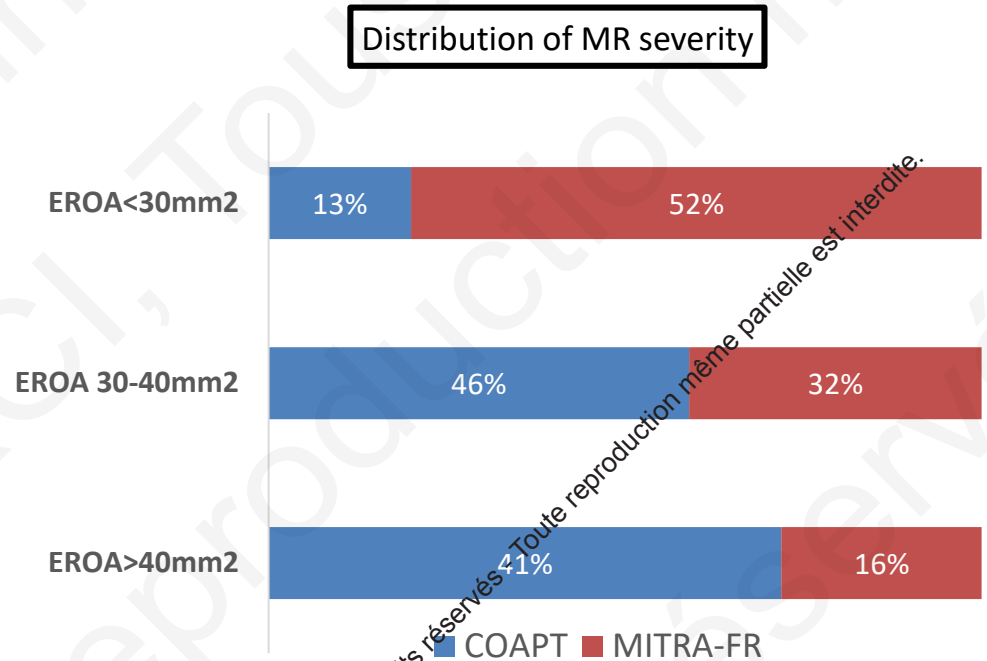
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F. Praz et al. Eur Heart J. 2019 Jul 14;40(27):2189-2193

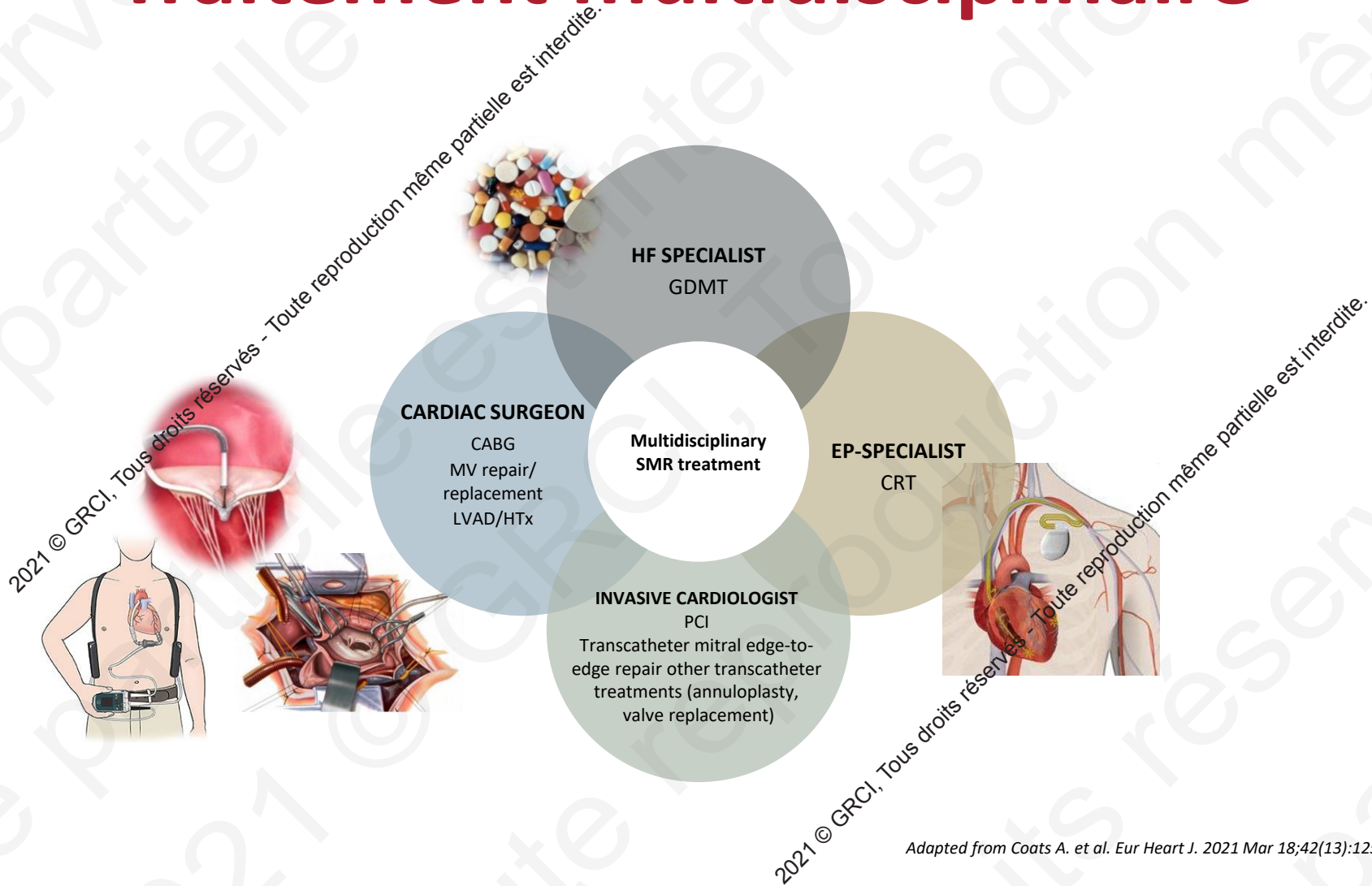
MITRA-FR/COAPT: caractéristiques des populations

	MITRA-FR	COAPT	
Principal baseline characteristics	Number of patients (ITT)	304	614
	Mean age (years)	70±10	72±12
	Mean LVEF (%)	33±7	31±10
	MR severity (EROA, cm ²)	0.31±0.10	0.41±0.15
	Mean indexed LVEDV, ml/m ²	135±35	101±34
Safety and efficacy endpoints	Complications* (%)	14.6	8.5
	No implant (%)	9	5
	Implantation of multiple clips (%)	54	62
	Post-procedural MR grade ≤2+ (%)	92	95
	MR grade ≤2+ at 1 year (%)	83	95

Praz F. et al., Eur Heart J. 2019 Apr 2



Traitement multidisciplinaire



Adapted from Coats A. et al. Eur Heart J. 2021 Mar 18;42(13):1254-1269

Traitement de l'insuffisance mitrale secondaire

Recommendations	Class	Level
<i>Patients without concomitant coronary artery or other cardiac disease requiring treatment</i>		
TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment.	IIa	B
Valve surgery may be considered in symptomatic patients judged appropriate for surgery by the Heart Team.	IIb	C
In high-risk symptomatic patients not eligible for surgery and not fulfilling the criteria suggesting an increased chance of responding to TEER, the Heart Team may consider in selected cases a TEER procedure or other transcatheter valve therapy if applicable, after careful evaluation for ventricular assist device or heart transplant.	IIb	C

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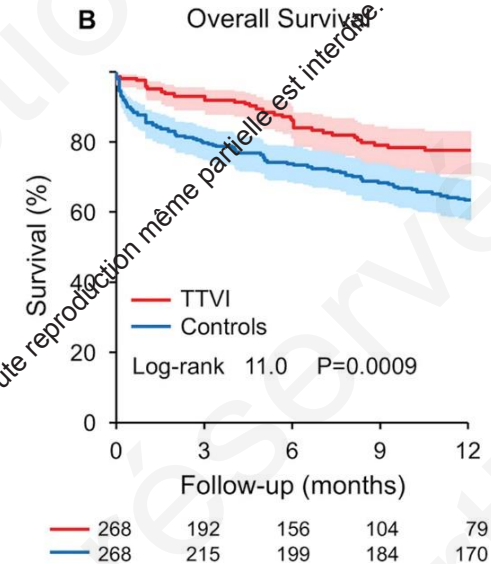
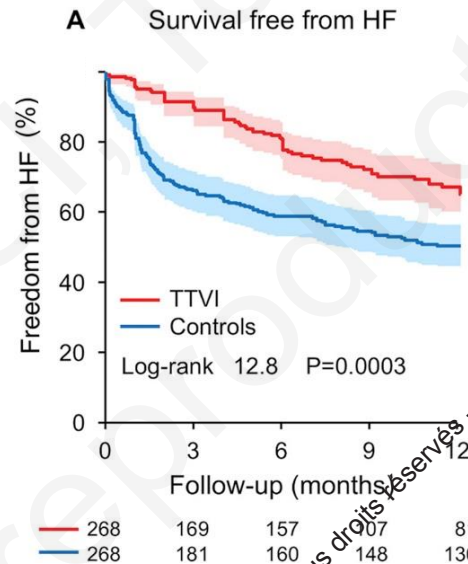
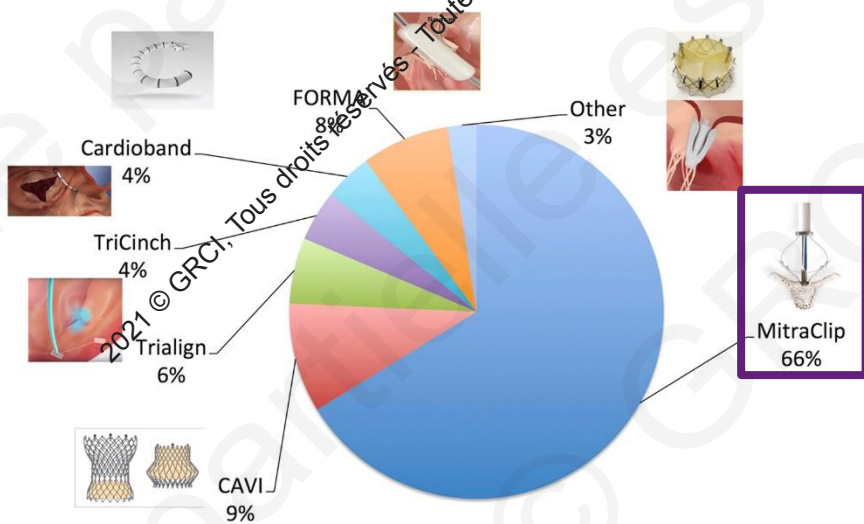
	Primary MR	Secondary MR
Quantitative		
EROA (2D PISA, mm ²)	≥40 mm ²	≥40 mm ² (may be ≥30 mm ² if elliptical regurgitant orifice area)
Regurgitant volume (mL/beat)	≥60 mL	≥60 mL (may be ≥45 mL if low flow conditions)
Regurgitant fraction (%)	≥50%	≥50%
Structural		
Left ventricle	Dilated (ESD ≥40 mm)	Dilated
Left atrium	Dilated (diameter ≥55 mm or volume ≥60 mL/m ²)	Dilated

Traitement percutané de la valve tricuspide

Transcatheter treatment of symptomatic secondary severe tricuspid regurgitation may be considered in inoperable patients at a Heart Valve Centre with expertise in the treatment of tricuspid valve disease.

IIb

C



Taramasso M. et al, JACC Cardiovasc Interv. 2019 Jan 28;12(2):155-165

Taramasso M. et al, JACC 2019 Sep 24

Conclusions

- Les recommandations 2021 ESC/EACTS pour la prise en charge des valvulopathies consolident le rôle du Heart Team et encouragent une prise en charge précoce des patients asymptomatiques
- Le choix du mode d'intervention pour les patients avec sténose aortique se base sur les caractéristiques anatomiques, l'âge et le risque chirurgical
- Une nouvelle définition de la sévérité de l'insuffisance mitrale secondaire est proposée ainsi qu'une mise à niveau de la recommandation pour TEER chez les patients de "type COAPT" (IIa)
- Une recommandation pour le traitement percutané de la valve tricuspide est introduite pour la première fois

Merci de votre attention

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