DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

Intervenant : Dr Saïd GHOSTINE, le Plessis Robinson

☑ Je n'ai pas de lien d'intérêt à déclarer

Sauf les 3 C

GRCI 2017
France

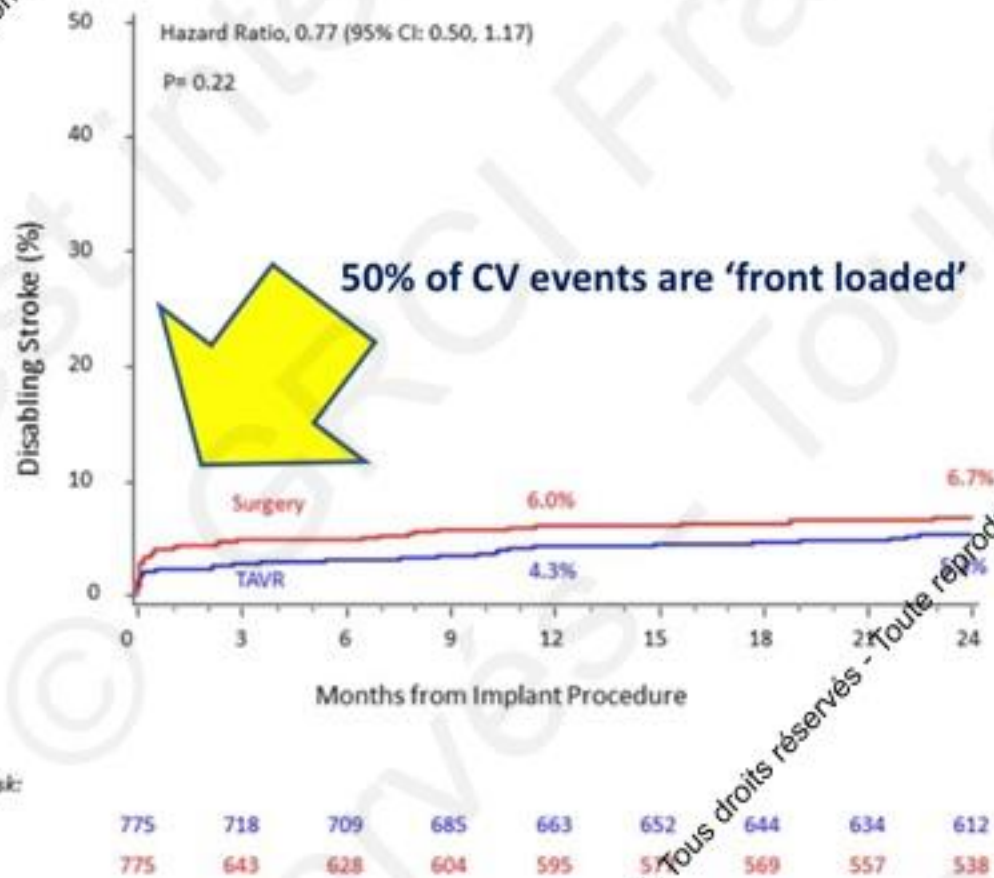
6 AU 8 DÉCEMBRE 2017
Novotel Paris Tour Eiffel

Passion Communication Education

Quel traitement antithrombotique post TAVI

SAID GHOSTINE
Hôpital Marie Lannelongue

AVC post TAVI % chirurgie



TAVI transfémorale

Leon MB et al. N Engl J Med 2016;374:1609-1620.

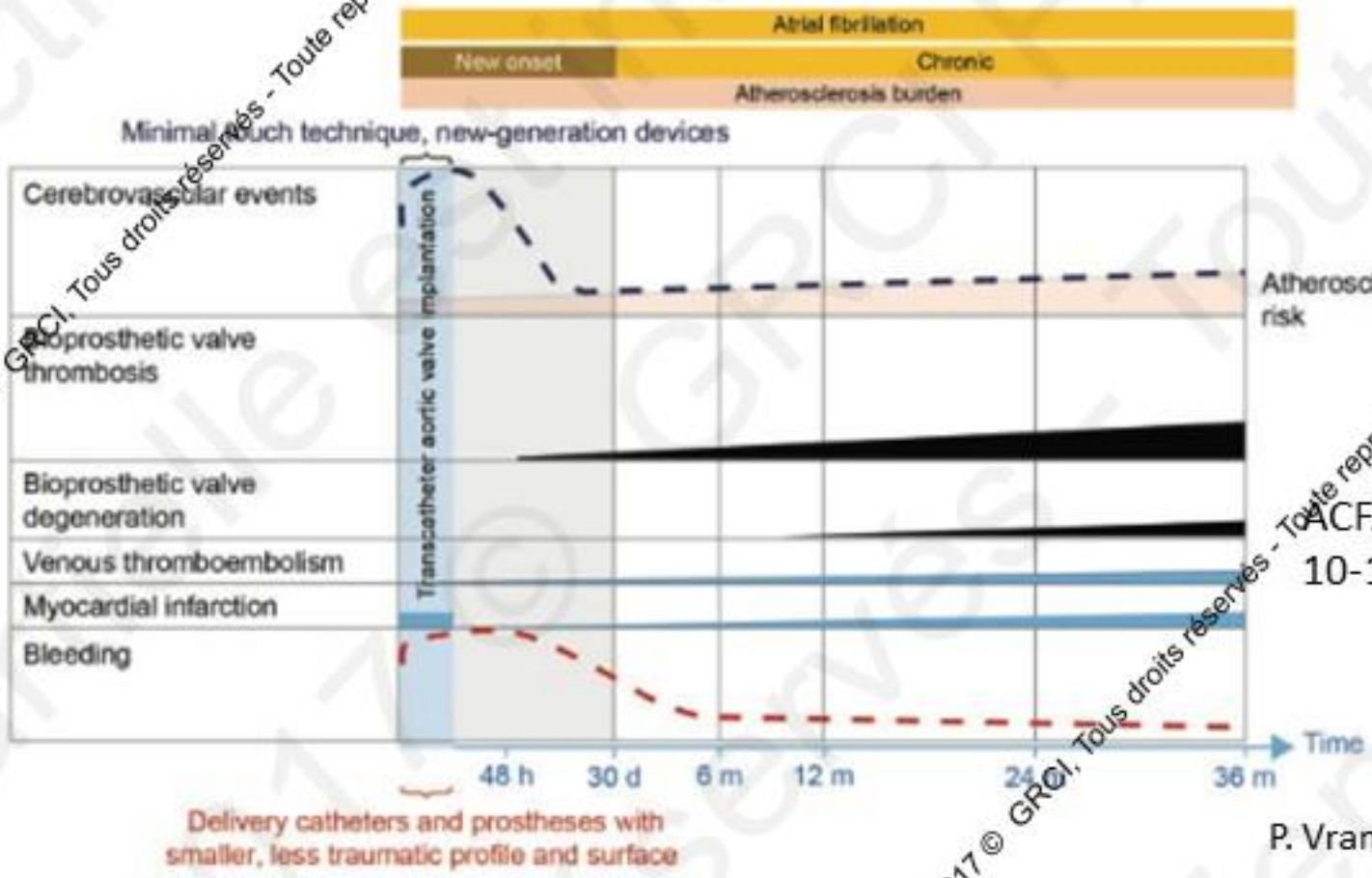
Ischemic and bleeding post TAVI

	<30 days	1 year	2 years
Life-threatening/or disabling or major bleeding complications[a] (%)	10.2 (±3.5)	15.95 (±0.9)	17.6 (±0.7)
Stroke (%)	4.1 (±0.7)	7.0 (±1.7)	8.5 (±2.3)
Disabling stroke (%)	2.4 (±1.3)	4.1 (±1.8)	4.9 (±2.1)
Nondisabling stroke (%)	1.6 (±0.6)	3.2 (±0.5)	3.9 (±0.6)
TIA (%)	1.1 (±0.4)	2.1 (±0.5)	3.5 (±0.9)
Systemic embolism	Unreported	Unreported	Unreported
Deep vein thrombosis	Unreported	Unreported	Unreported
New onset atrial fibrillation (%)	11.2 (±1.9)	13 (±4.3)	15.4 (±5.7)
Valve thrombosis (clinical)	0.03–0.07%/year		
Myocardial infarction (%)	0.9 (±0.1)	1.1 (±0.3)	2.7 (±0.8)
Coronary obstruction requiring intervention (%)	0.3 (±0.1)	0.3 (±0.1)	0.3 (±0.1)
All-cause mortality (%)	2.8 (± 0.6)	10.3 (± 3.7)	15.9 (± 5.6)
Cardiovascular mortality (%)	2.6 (± 0.6)	7.1 (± 2.9)	10.7 (± 4.1)

Rates of events were calculated as the number of events divided by the number of treated patients with available data for the Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI), the Placement of Aortic Transcatheter Valves (PARTNER) 2 cohort and the US CoreValve high risk study.[3,6–8] Results are presented as weighted mean ± 1 standard deviation.[9]
TIA, transient ischaemic attack.
[a]According to the modified Valve Academic Research Consortium definitions.

P. Vranckxs EHJ (2017) 38, 3341–3350

Risque thrombotique et saignement



AVC essentiellement les 2 1er jours
Surtout per procédurale
Mais 25% AVC > 30 jours

FACFA 30-50% des sujets âgés
10-15% nouvel épisode post TAVI

P. Vranckxs EHJ (2017) 38, 3341–3350

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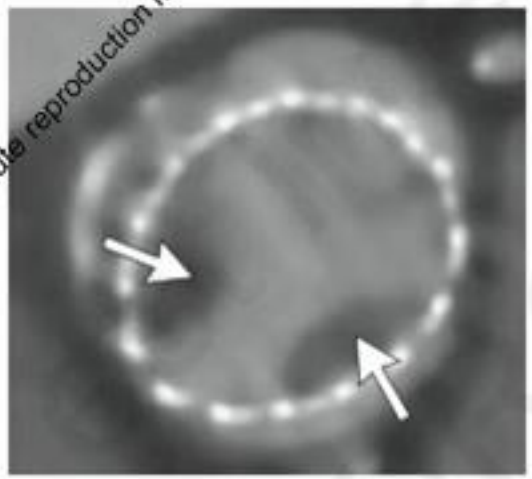
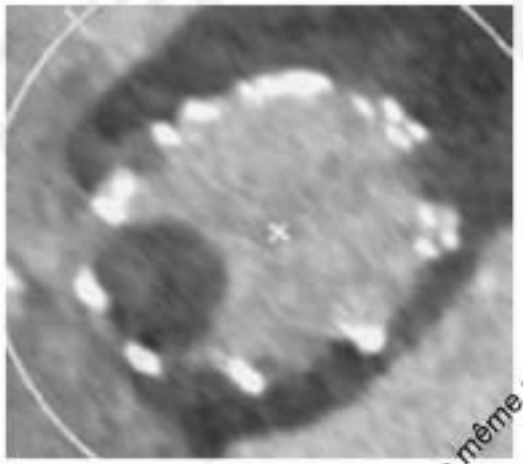
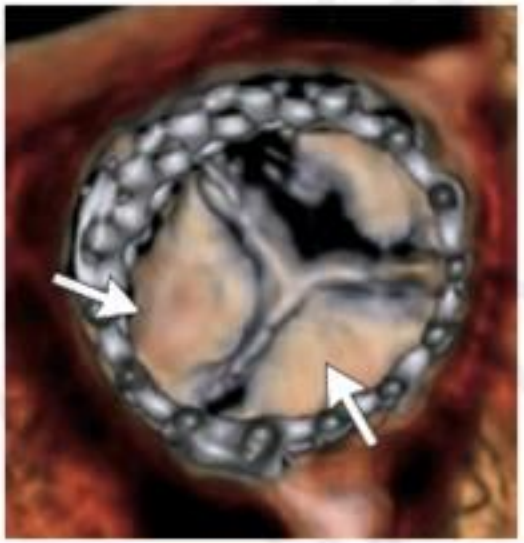
Thromboses bioprothèses

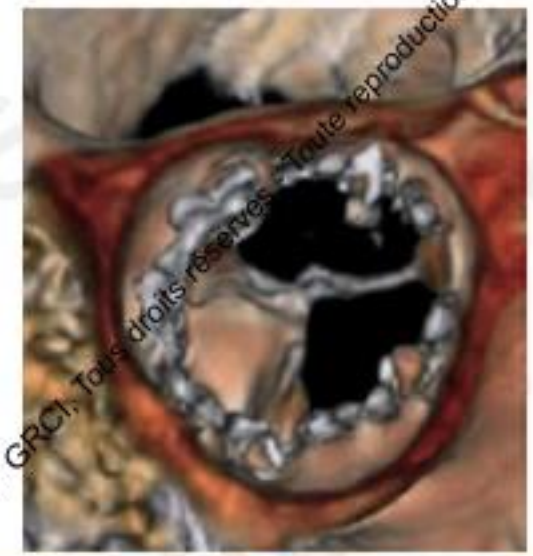
Hypodensités





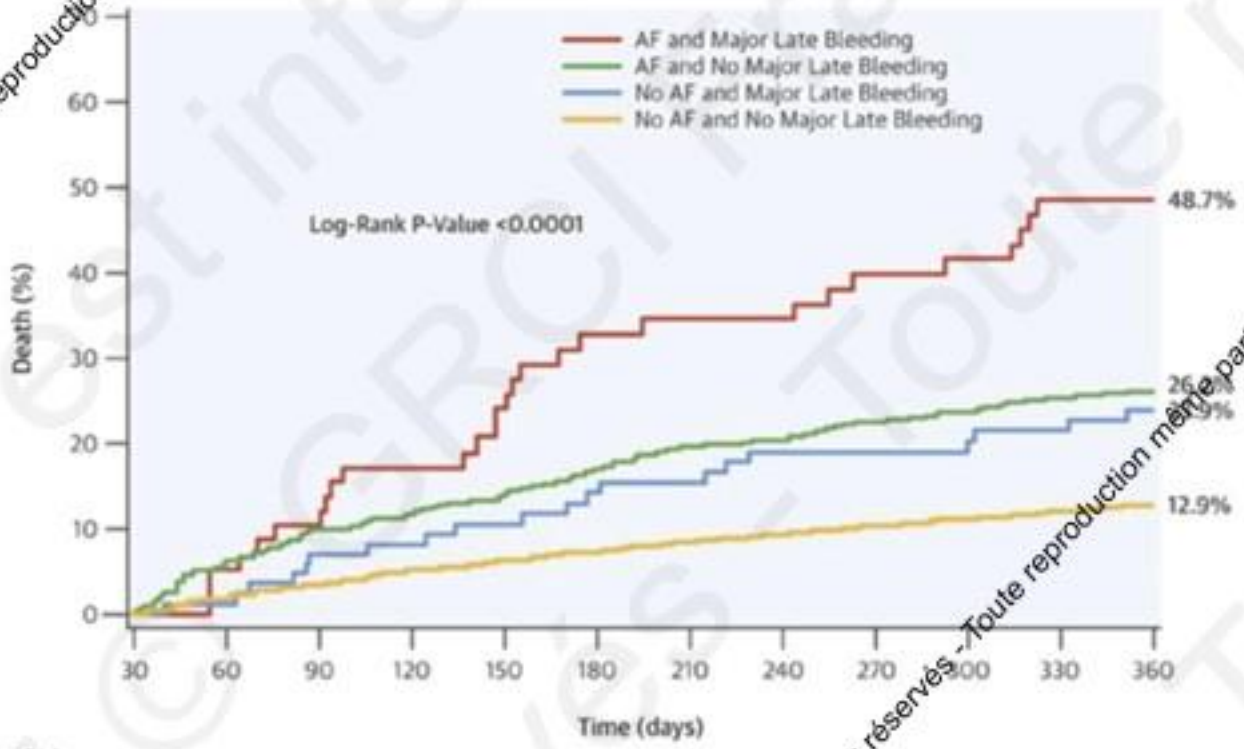
Diminution du mouvement valvulaire au Scanner 4D





N Engl J Med 2015; 373:2015-2024

Saignement post TAVI : RR x2 Mortalité



Number at Risk:

AF and MLB	58	52	38	34	26
AF and No MLB	613	551	498	459	394
No AF and MLB	84	78	72	67	60
No AF and No MLB	1,646	1,577	1,497	1,435	1,279

J Am Coll Cardiol. 2014;64(24):2605-2615. doi:10.1016/j.jacc.2014.08.052

Guidelines ESC 2017

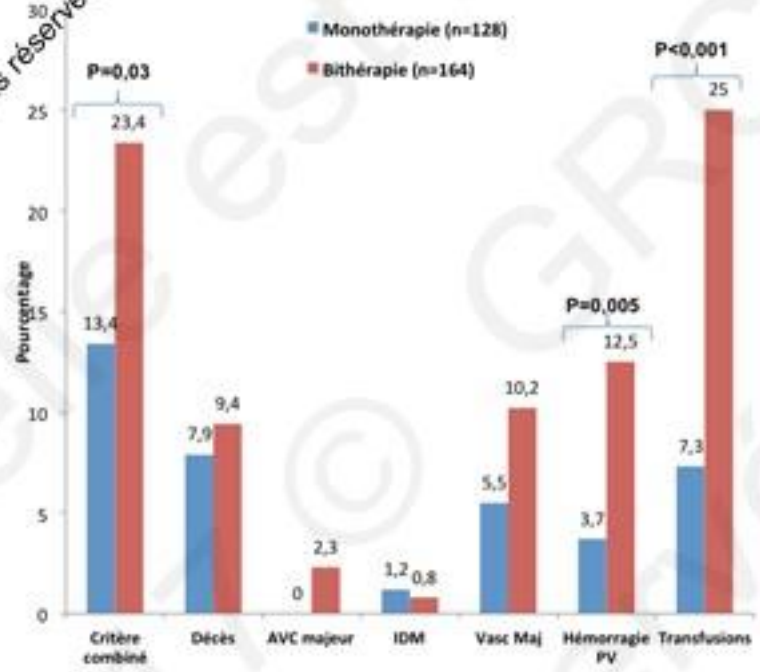
Indications for antithrombotic therapy for bioprostheses *(continued)*

Recommendations	Class	Level
Bioprostheses		
Oral anticoagulation is recommended lifelong for patients with surgical or transcatheter implanted bioprostheses who have other indications for anticoagulation.	I	
Dual antiplatelet therapy should be considered for the first 3-6 months after TAVI, followed by lifelong single antiplatelet therapy in patients who do not need oral anticoagulation for other reasons.	IIa	C
Single antiplatelet therapy may be considered after TAVI in the case of high bleeding risk.	IIb	C
Oral anticoagulation may be considered for the first 3 months after surgical implantation of an aortic bioprosthesis.	IIb	C

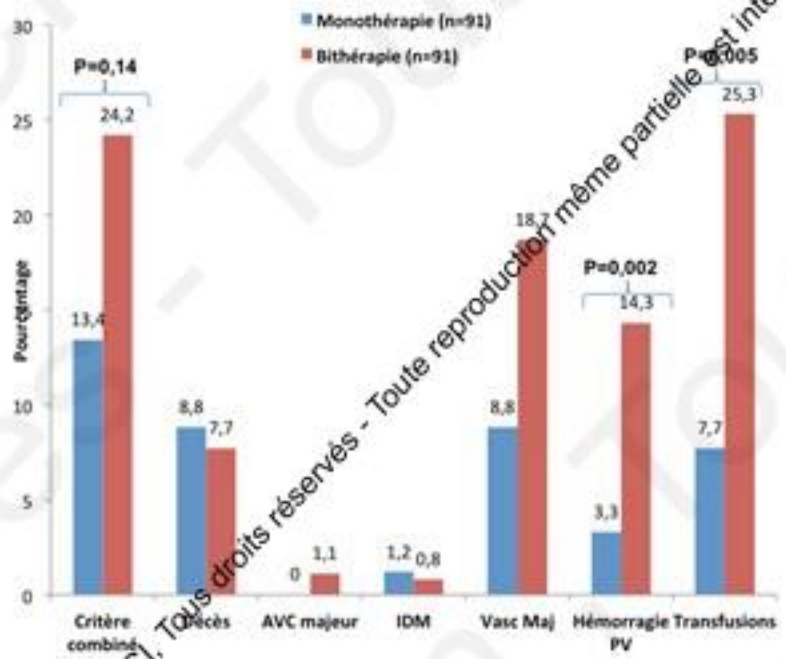
2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease
European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391

Registre France 2

Comparison of Two Antiplatelet Therapy Strategies in Patients Undergoing Transcatheter Aortic Valve Implantation



Cohorte Globale

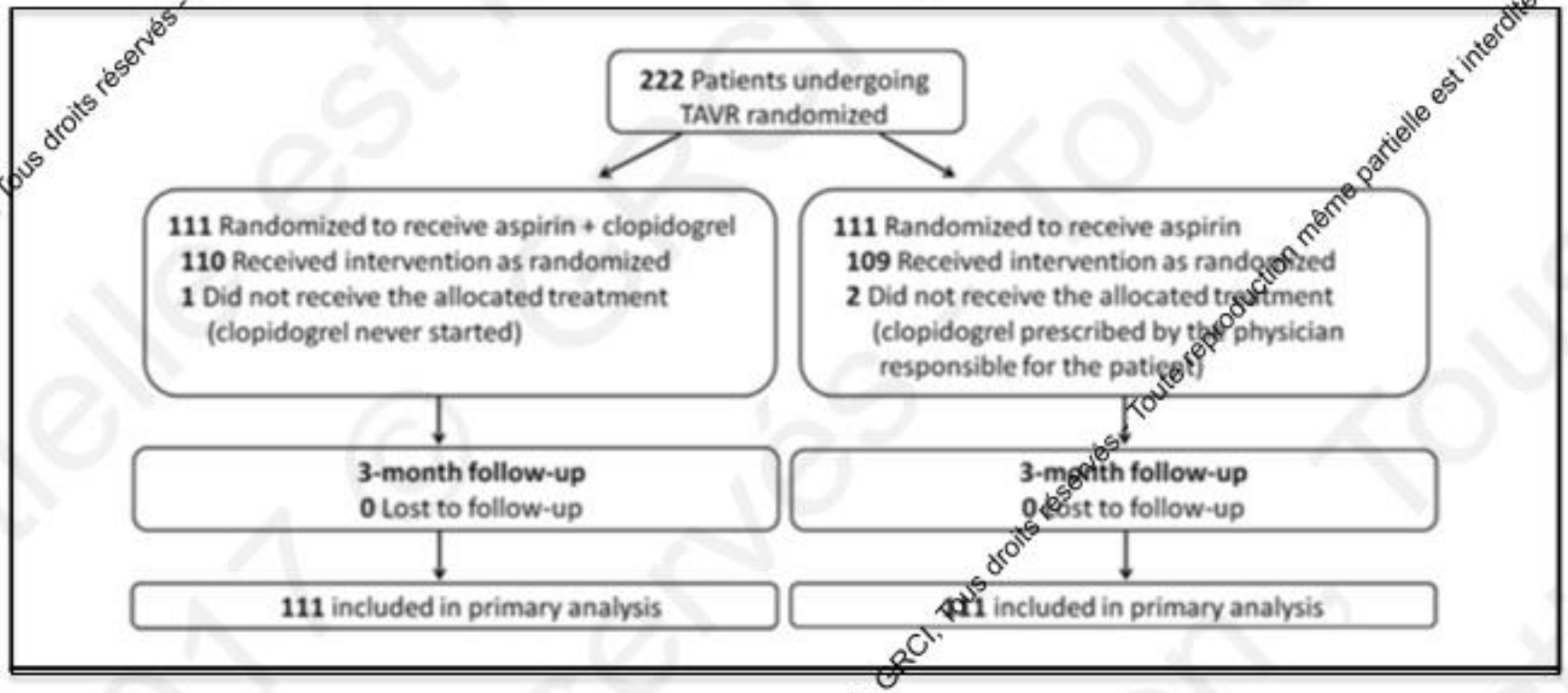


Cohorte matchée

Durand et al. Am J Cardiol 2014; 113:355-60

ARTE trial

Aspirine (SAPT) vs Aspirine et clopidogrel (DAPT) post Edwards TAVI



JACC interventions Vol.10, N°13, 2017

Caractéristique Population

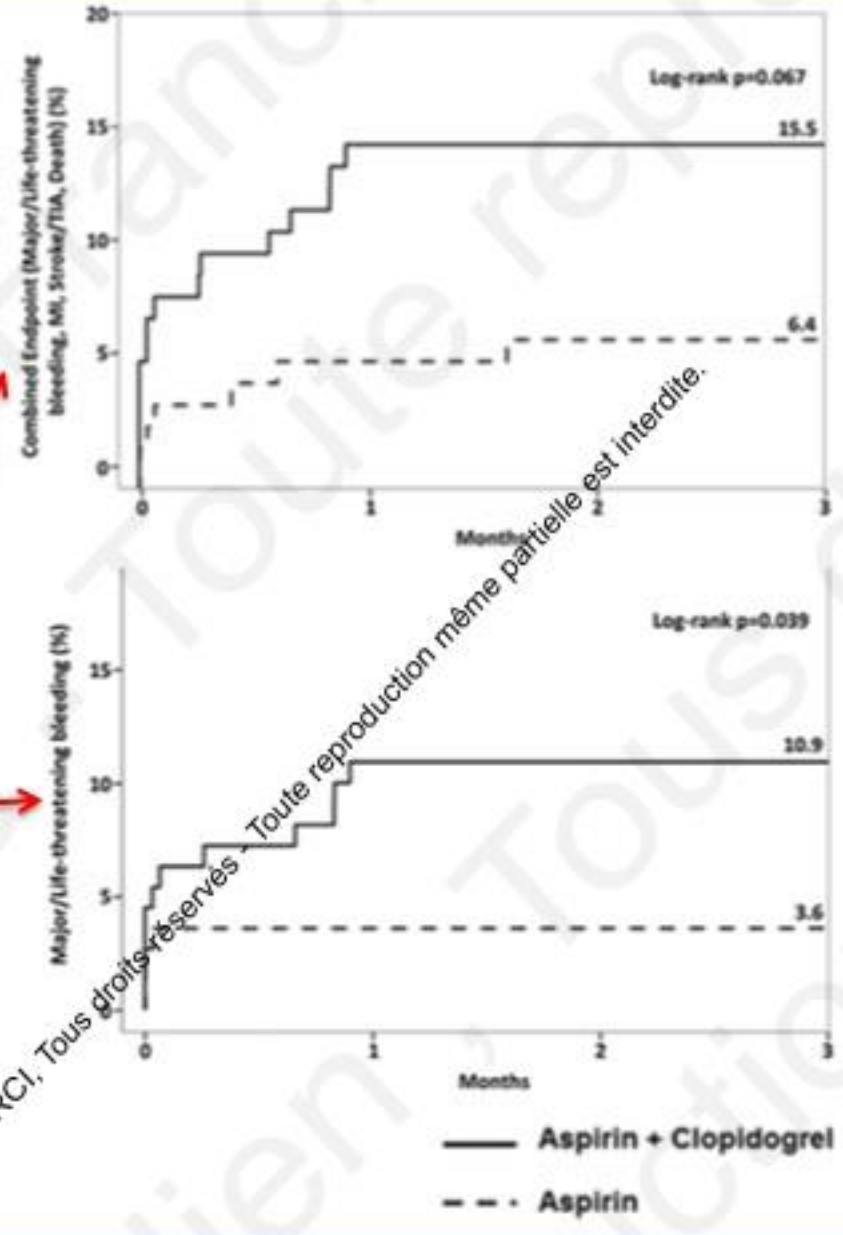
	Treatment		
	Aspirin Plus Clopidogrel (n = 111)	Aspirin (n = 111)	p Value
Baseline characteristics			
Age (yrs)	79 ± 9	79 ± 9	0.716
Male	70 (63.1)	59 (53.2)	0.174
Diabetes	41 (36.9)	36 (32.7)	0.573
Hypertension	86 (77.5)	87 (79.8)	0.743
Current smokers	3 (2.7)	2 (1.8)	0.504
Previous myocardial infarction	26 (23.4)	20 (18.4)	0.409
Previous coronary artery bypass graft	39 (35.1)	42 (38.5)	0.886
Peripheral vascular disease	28 (25.2)	22 (20.0)	0.422
COPD	28 (25.2)	33 (30.0)	0.455
Chronic renal failure (GFR <60 ml/min)	70 (63.1)	70 (63.1)	0.999
Porcelain aorta	18 (16.2)	11 (10.1)	0.232
STS-PROM score (%)	6.2 ± 4.4	6.4 ± 4.6	0.769
Echocardiographic variables			
Mean gradient (mm Hg)	43 ± 16	43 ± 15	0.713
Indexed AVA (cm^2/m^2)	0.42 ± 0.13	0.40 ± 0.11	0.095
Ejection fraction (%)	55 ± 12	54 ± 13	0.675
Aortic regurgitation			
None/trace	51 (48.1)	47 (45.6)	0.409
Mild	30 (28.3)	40 (38.8)	
Moderate/severe	25 (23.6)	16 (15.6)	

	Treatment		
	Aspirin Plus Clopidogrel (n = 111)	Aspirin (n = 111)	p Value
Procedural characteristics			
Approach			
Femoral	80 (72.1)	73 (65.8)	0.788
Transapical	18 (16.2)	20 (18.0)	
Transaortic	10 (9.0)	14 (12.6)	
Transcarotid	3 (2.7)	4 (3.6)	
Valve type			
SAPIEN XT	104 (93.7)	101 (90.9)	0.615
SAPIEN 3	7 (6.3)	10 (9.0)	
Need for second valve	3 (2.7)	1 (0.9)	0.623
Conversion to open heart surgery	2 (1.8)	3 (2.7)	0.683
Major vascular complications	10 (9.0)	7 (6.4)	0.615
New-onset atrial fibrillation	12 (10.8)	12 (10.8)	0.999
Procedural success	101 (90.9)	94 (86.2)	0.294
Echocardiography at discharge			
Mean gradient (mm Hg)	10.8 ± 5.3	10.3 ± 5.7	0.539
Indexed AVA (cm^2/m^2)	0.95 ± 0.34	0.99 ± 0.34	0.991
Ejection fraction (%)	54 ± 11	54 ± 12	0.999
Aortic regurgitation			
None/trace	59 (61.4)	66 (68.7)	0.571
Mild	28 (29.2)	24 (25.0)	
Moderate/severe	9 (9.4)	6 (6.3)	

Résultats

TABLE 3 Study Outcomes According to Treatment Allocation

	Aspirin Plus Clopidogrel (n = 111)	Aspirin (n = 111)	OR (95% CI)	p Value
30-day outcomes				
Combined endpoint*	16 (14.4)	7 (6.3)	2.48 (0.98-6.31)	0.056
Life-threatening/major bleeding	12 (10.8)	4 (3.6)	3.22 (1.01-10.34)	0.038
Major bleeding	5 (4.5)	3 (2.7)	1.68 (0.39-7.21)	0.484
Life-threatening bleeding	7 (6.3)	1 (0.9)	7.34 (0.89-60.71)	0.065
Myocardial infarction	4 (3.6)	1 (0.9)	4.13 (0.45-37.60)	0.175
Stroke/TIA	3 (2.7)	1 (0.9)	3.11 (0.32-30.43)	0.313
Nondisabling stroke	2 (1.8)	0	–	–
Disabling stroke	1 (0.9)	1 (0.9)	0.97 (0.06-15.81)	0.983
TIA	0	0	–	–
Death	6 (5.4)	3 (2.7)	2.04 (0.50-8.37)	0.307
90-day outcomes				
Combined endpoint* (primary endpoint)	17 (15.3)	8 (7.2)	2.31 (0.95-5.62)	0.065
Life-threatening/major bleeding	12 (10.8)	4 (3.6)	3.22 (1.01-10.34)	0.038
Major bleeding	5 (4.5)	3 (2.7)	1.68 (0.39-7.21)	0.484
Life-threatening bleeding	7 (6.3)	1 (0.9)	7.34 (0.89-60.71)	0.065
Myocardial infarction	4 (3.6)	1 (0.9)	4.13 (0.45-37.60)	0.175
Stroke/TIA	3 (2.7)	1 (0.9)	3.11 (0.32-30.43)	0.313
Disabling stroke	1 (0.9)	1 (0.9)	0.97 (0.06-15.81)	0.983
Nondisabling stroke	2 (1.8)	0	–	–
TIA	0	0		
Death	7 (6.3)	4 (3.6)	1.78 (0.51-6.27)	0.370



Saignements majeurs

TABLE 4 Major or Life-Threatening Bleeding Events During the Study Period

Patient #	Treatment Allocation	Severity	Days From Procedure	Cause
1	Aspirin plus clopidogrel	Life-threatening	Periprocedural	Annular rupture
2	Aspirin plus clopidogrel	Life-threatening	27	GI bleeding
3	Aspirin plus clopidogrel	Major	Periprocedural	Femoral hematoma
4	Aspirin plus clopidogrel	Major	8	GI bleeding
5	Aspirin plus clopidogrel	Life-threatening	1	GI bleeding
6	Aspirin plus clopidogrel	Major	20	Access-site bleeding
7	Aspirin plus clopidogrel	Major	2	Femoral hematoma
8	Aspirin plus clopidogrel	Life-threatening	25	GI bleeding
9	Aspirin plus clopidogrel	Life-threatening	Periprocedural	Annular rupture
10	Aspirin plus clopidogrel	Major	Periprocedural	Femoral hematoma
11	Aspirin plus clopidogrel	Life-threatening	Periprocedural	Conversion to open heart surgery
12	Aspirin plus clopidogrel	Life-threatening	25	GI bleeding
13	Aspirin	Major	Periprocedural	Left ventricular perforation
14	Aspirin	Major	Periprocedural	Aortic hematoma
15	Aspirin	Major	1	Access-site bleeding
16	Aspirin	Life-threatening	Periprocedural	Annular rupture

GI = gastrointestinal.

- Saignements gastrointestinaux (5)
  - Essentiellement dans groupe DAPT
  - IPP à la discrétion des centres
- Hématomes scarpa (3)
- Ruptures d'anneau (3)

Limites

- Petite étude n=222
- Effectif souhaité n=300
- Etude en ouvert
- Arrêt prématuré (74% effectif)
  - Inclusion lente Mars 2012-Février 2017
  - Manque de support financier
- Uniquement Valves Edwards

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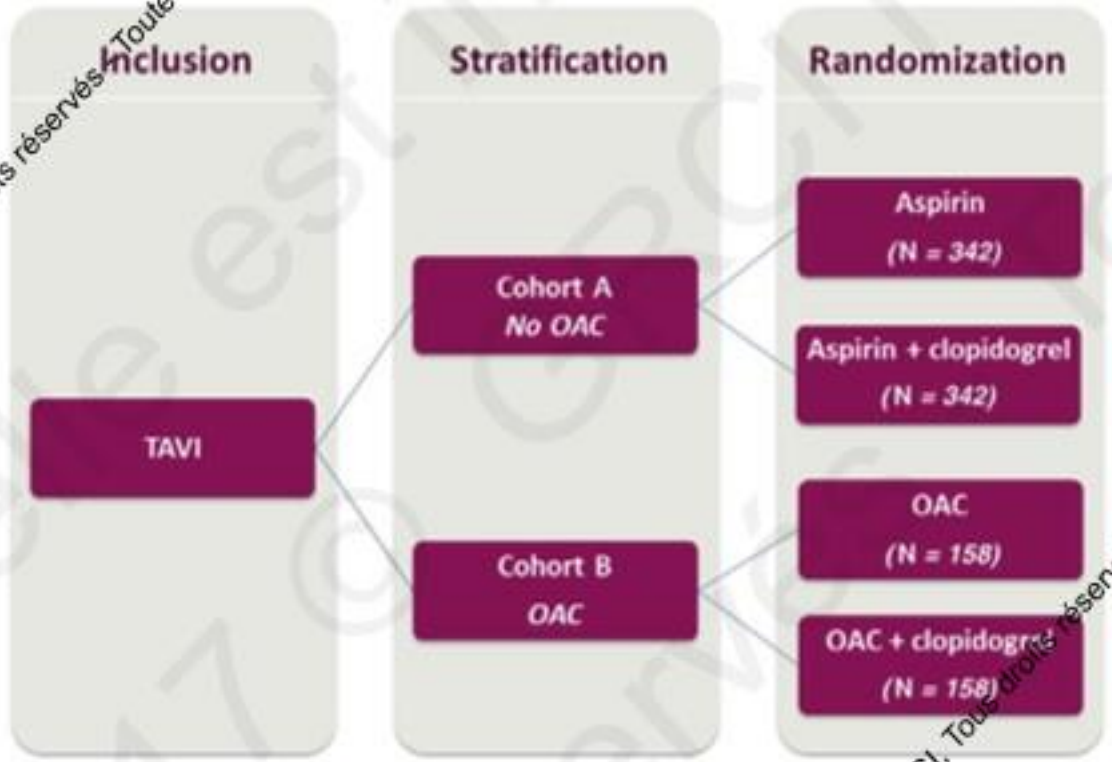
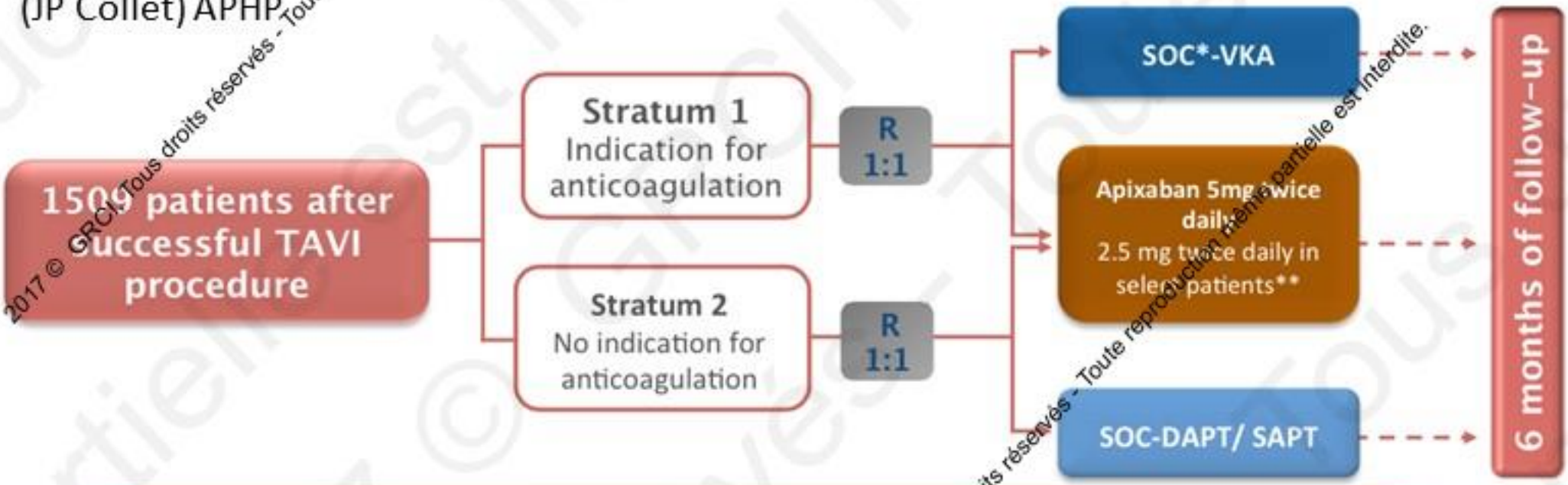
POPular-TAVI



POPular TAVI study design. After inclusion, patients are stratified according to the presence or absence of OAC therapy. The day before TAVI, patients are randomized in a 1:1 manner to clopidogrel or no clopidogrel in addition to aspirin (cohort A) or OAC (cohort B).

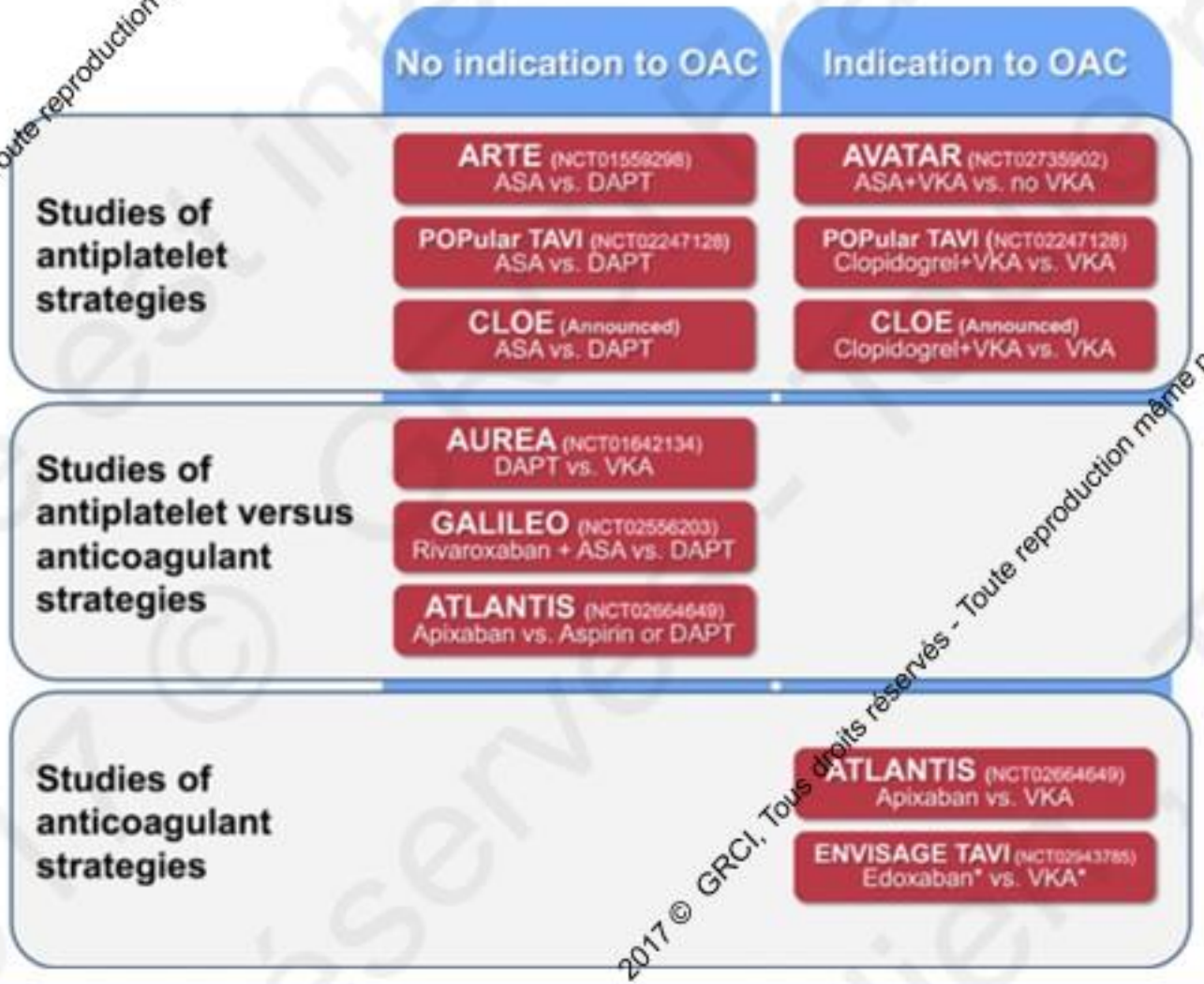
ATLANTIS trial

Etude supériorité Apixaban/SOC
(JP Collet) APHP



Primary endpoint
composite of death, myocardial Infarction, stroke/TIA/systemic emboli, intracardiac or bioprosthesis thrombus, episode of deep vein thrombosis or pulmonary embolism, major bleedings over 6 months of follow-up

Etudes en cours



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TAVI : Coronaropathie stentée et indication anticoagulante

Recommandations du traitement anti-thrombotique dans coronaropathie stable stentée et indication AVK		
Risque hémorragique	Risque AVC	Recommandations
Faible à modéré (HAS-BLED 0-2)	Modéré (CHA2DS2-VASC =1 chez homme	1-6 mois : Triple association (AVK+aspirine 75mg +clopidogrel 75 mg)
		puis jusqu'à 12 mois: AVK + clopidogrel 75 mg/j ou alternativement AVK + aspirine <100mg/j
		puis au long cours AVK
	Elevé (CHA2DS2-VASC ≥2)	1-6 mois : Triple association (AVK+aspirine 75mg +clopidogrel 75 mg)
		puis jusqu'à 12 mois: AVK + clopidogrel 75 mg/j ou alternativement AVK + aspirine <100mg/j
		puis au long cours AVK
Elevé (HAS-BLED ≥3)	Modéré (CHA2DS2-VASC =1 chez homme	Jusqu'à 12 mois : AVK + clopidogrel 75 mg/j
		puis au long cours AVK
	Elevé (CHA2DS2-VASC ≥2)	1 mois : Triple association (AVK+aspirine 75mg +clopidogrel 75 mg)
		puis jusqu'à 12 mois: AVK + clopidogrel 75 mg/j ou alternativement AVK + aspirine <100mg/j
		puis au long cours AVK

Conclusions

- Le traitement antithrombotique post TAVI reste controversé
- Recommandations : Consensus d'experts dérivés des Reco post PCI
- Peu d'études randomisées
- SAPT > DAPT en absence d'indication d'anticoagulant
- Attention au risque d'association AVK et antiagrégants
- Stratégies anticoagulantes en attente des études : ATLANTIS, GALILEO, POPular-TAVI