

Suivi des TAVI. Thromboses et dégénérescences précoces: MYTHE ou REALITE?

C BARBEY



Cardiologie
Interventionnelle
Imagerie
Cardiaque,



Clinique Saint Gatien TOURS, France
Dr Bar, Dr Chassaing, Dr Barbey, Dr Arnould

DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

Intervenant : **Christophe BARBEY, TOURS**

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

Thromboses TAVI: MYTHE ou REALITE?

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Stented porcine valves



Medtronic Hancock® II



Medtronic Mosaic®



St. Jude Medical Biocor™

Stentless porcine valves



St. Jude Medical Toronto SPV™



Medtronic Freestyle®

Stented pericardial valves



Carpentier-Edwards Magna Ease™



Sorin group Mitroflow™



St. Jude Medical Trifecta™

Stentless pericardial valves

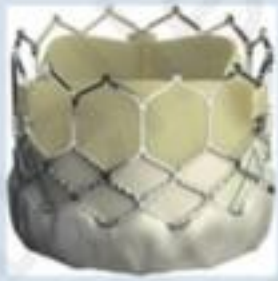


Sorin group Pericarbon Freedom™



Medtronic 3 Enable®

Transcatheter heart valves



Edwards SAPIEN® 3



Medtronic CoreValve Evolut R



Boston Scientific Lotus™



Direct Flow Medical®



St. Jude Medical Portico™



Symetis ACURATE neo™

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Am Coll Cardiol 2014;64:2605-15)

Thrombose Bioprothèses

SAVR

- 0,03% par an.

BPVT represented 11.6% of indications of bioprosthetic explanations

BPVT prevalence was similar for the 4 positions, ranging from 10.9% to 12.7%

Median time to explantation was 24 months for BPVT vs. 108 months for structural deterioration ($p < 0.001$)

Possible BPVT was mentioned in only 2 of 42 TTEs (5%) and in 6 of 45 TEEs (13%)

Paroxysmal AF, subtherapeutic INR on OAC, 50% increase in gradient within 5 yrs, increased cusp thickness (>2 mm, commonly on the downstream aspect of the valve), and abnormal cusp mobility were independent predictors of BPVT

(J Am Coll Cardiol 2015;66:2285-94)

TAVI

- SOUCE XT, France 2, PARTNER (US)

0

- PARTNER (EU)

1 (9 mois)

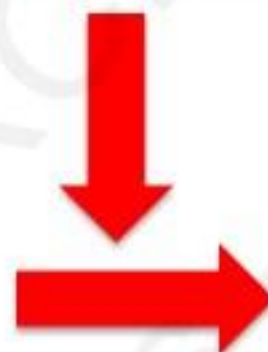
- Homme de 63 ans
 - RAO serré symptomatique à FE basse
 - FE 25%
 - Gradient moyen 40 mmhg
 - Sao 0,3 cm²
 - ATCD :
 - AOMI , avec un AAA thrombosé non opéré
 - IRCO sévère (PO² de repos 43 mmhg)
 - Août 2011:
 - **Sapien Edwards 29 mm TA**
 - Sortie sous 160 mg de Kardegic

ETT	Gradient moyen (mmhg)	FE (%)	NT pro BNP (pg/ml)
Avant TAVI	40	25	> 10000
J4 Après TAVI	7	30	> 10000
Suivi 1 mois	7	35	2511
Suivi 6 mois	6	65	432
Suivi 1 an	55	55	4559

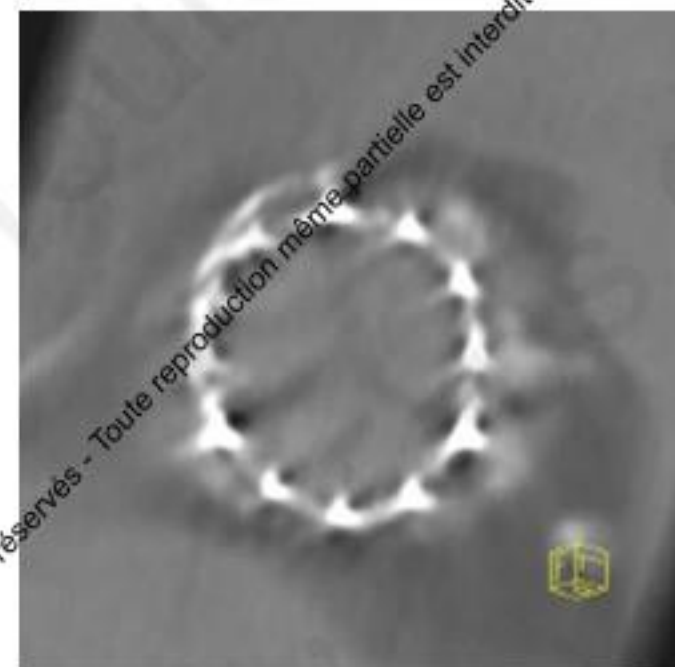
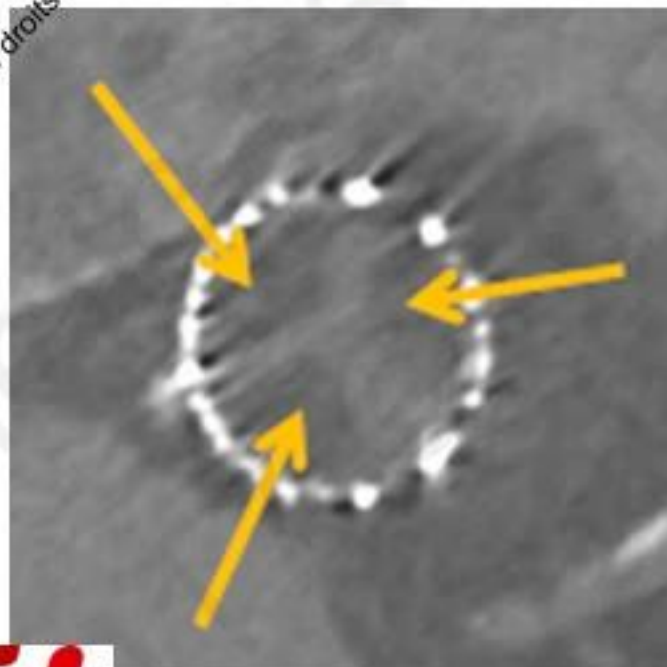
ETO



AVK 3 mois



CT Scan



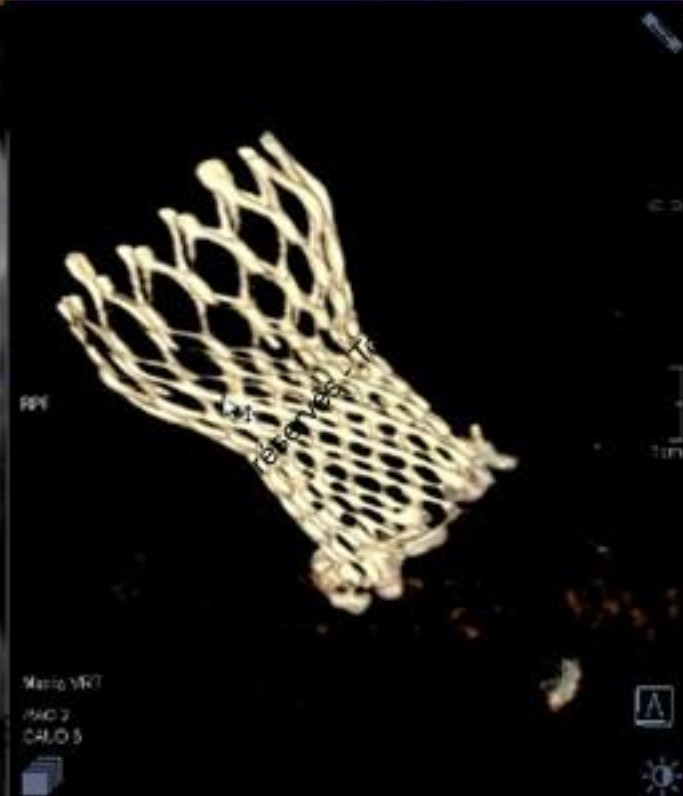
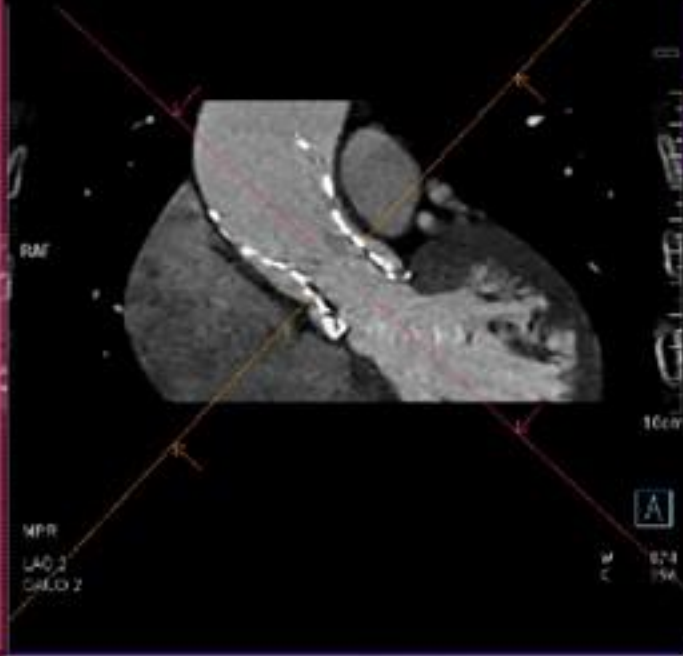
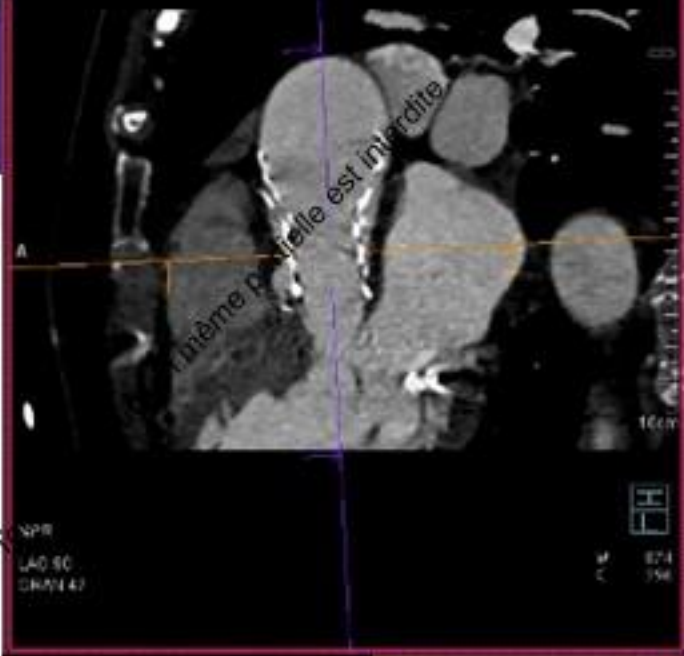
Avril 2014

- Mme S, 88 ans
 - Dyspnée d'effort
 - ECG:RS/QRS fins
- ETT:FeVG 70%. Sp 17 mm. **Gdt moy 63 mmHg. Vmax 4.9 m/s.**
- **COREVALVE 26 mm**
- ETT:FeVG 60%. Gdt 9/18 mmHg. IAO minime.
- Sortie J4
- KDG/PLAVIX

	09/14	11/15
FeV ₆ (%)	60	60
Gdt Moy (mmHg)	8	13
Gdt Max (mmHg)	12	23
IAO	+	+

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AVK

TABLE 1 Case Reports of TAV Thrombosis

TABLE 1 Continued

Case #	First Author (Ref. #)	Age, yrs	Sex	Type of THV	Duration	Symptom	Examination	After TAVR	Treatment	Outcome/Histology
1	Trepels et al. (16)	84	Female	Edwards Sapien	8 months	Dyspnea	TEE: thickened restricted leaflets	DAPT discontinued after 6 weeks	THV retrieval and Antiplatlet Therapy	Thrombus with fibrous organization. Thrombus with fibrous organization, protein S reduction
2	Kefer et al. (16)	11	Male	Edwards Sapien	6 months	Dyspnea	TEE: thickened restricted NYHA II to III THV leaflets without thrombus	Discontinuing DAPT after 4 months	DAPT	Symptomatic improvement
3	Pergolini et al.	12	Male	Edwards Sapien, 23 mm	3 days	Cardiac arrest	TEE: thrombus on the THV at post-implantation	DAPT	Heparin continued post-TAVR	Deceased Autopsy: normal THV position and good leaflet mobility with thrombi on the stent
4	Greasi									
5	Cota et al.									
6	Cota et al.									
7	Cota et al.									
8	Latib et al. (20)									
9	Latib et al. (20)	17	NA	NA	Edwards Sapien XT, 29 mm	1 month	Bleeding problems	NA	DAPT, started monotherapy after 1 month due to bleeding problems	Deceased on day 137 Autopsy: thickened, stiff and with fibrosis on both sides of the leaflets
10	Latib et al. (20)									
11	Orbach et al. (30)	81	Female	Edwards Sapien, 26 mm	21 months	Heart failure	TEE: thickened and restricted prosthetic aortic-valve leaflets	Mean PG increased to 53 mm Hg	Aspirin Enoxaparin and warfarin	Symptomatic improvement Mean PG decreased to 10 mm Hg

Transcatheter heart valves



Edwards SAPIEN[®] 3

Medtronic CoreValve Evolut R

Boston Scientific Lotus[™]

Direct Flow Medical[®]

St. Jude Medical Portico[™]

Symetis ACURATE neo

Thromboses TAVI

- La première année (6 mois)
 - 1/3 asymptomatique
 - 65% Dyspnée
 - AIT.
- ETT: Gdient moy > 20 mmHg (90%)

Thromboses TAVI

- Balloon Self expandable
- Malgré DAPT
- 100% RESOLUTIF sous ACO(40 jours)

Frequency of reduced leaflet motion (n=106)

Transcatheter valves	101/752 (13%)
Edwards	63/453 (14%)
Edwards-Sapien	1/22 (5%)
Sapien XT	12/122 (10%)
Sapien 3	50/309 (16%)
Evolut or CoreValve	9/145 (6%)
CoreValve	3/70 (4%)
Evolut	6/75 (8%)
Lotus	12/83 (14%)
Portico	15/50 (30%)
Direct flow	0/6
Centera	1/7 (14%)
Symetis	1/8 (12%)
Surgical valves	5/118 (4%)
Epic	0/16
Freestyle	0/2
Magna	4/37 (11%)
Mitroflow	0/11
Perimount	1/39 (3%)
Trifecta	0/33

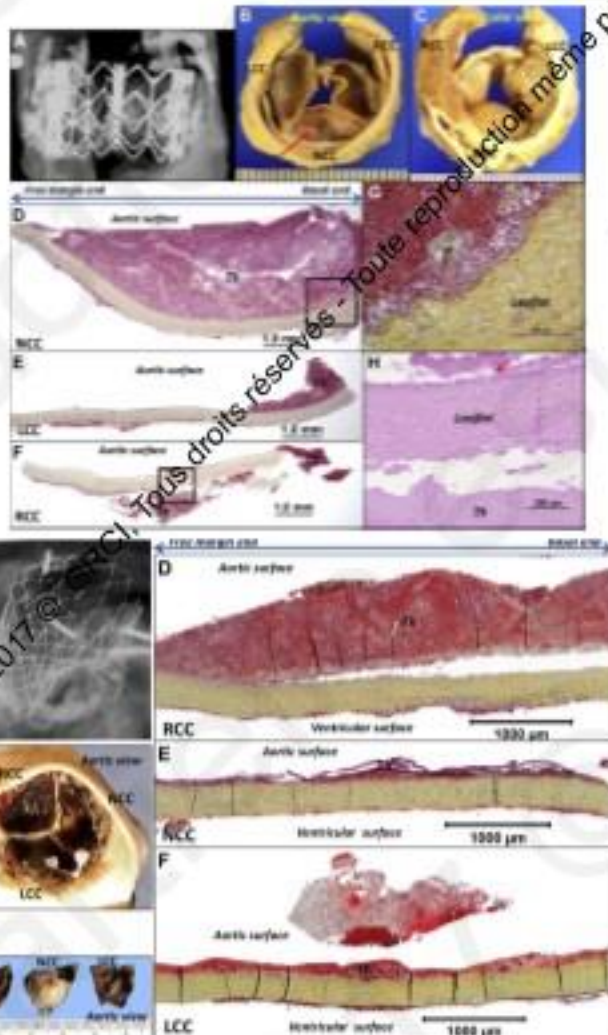
Pathogénie Comorbidités

- Anémie
- Tabac actif
- Diabète/Obésité
- Insuffisance rénale
- FeVG basse

Thrombus Formation Following Transcatheter Aortic Valve Replacement

(J Am Coll Cardiol Intv 2015;8:728-39)

Eduardo De Marchena, MD,* Julian Mesa, MD,* Sydney Pomenti, BS,* Christian Marin y Kall, MD,* Ximena Marincic, BS,* Kazuaki Yahagi, MD,† Elena Ladich, MD,† Robert Kutys, MS,† Yaar Aga, BS,* Michael Ragosta, MD,‡ Anil Chawla, MD,§ Michael E. Ring, MD,|| Renu Virmani, MD†



- Absence de microfractures/ détérioration leaflets
- Infiltrat Macrophage (>Balloon Exp)
- Absence d'infiltrat lymphocytaire

SAVR

- 0,03% par an.

TAVI

- SOUCE XT, France 2, PARTNER (US)

Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves: an observational study

Lancet 2017; 389: 2383-92

Tarun Chakravarty, Lars Søndergaard, John Friedman, Ole De Backer, Daniel Berman, Klaus F Kofoed, Hasaan Jilani, Takahiro Shiota, Yigal Abramowitz, Troels H Jørgensen, Tanya Rami, Sharjeel Israr, Gregory Fontana, Martina de Knecht, Andreas Fuchs, Patrick Lyden, Alfredo Trento, Deepak L Bhatt, Martin B Leon, Raj R Makkar, on behalf of the RESOLVE and SAVORY Investigators*

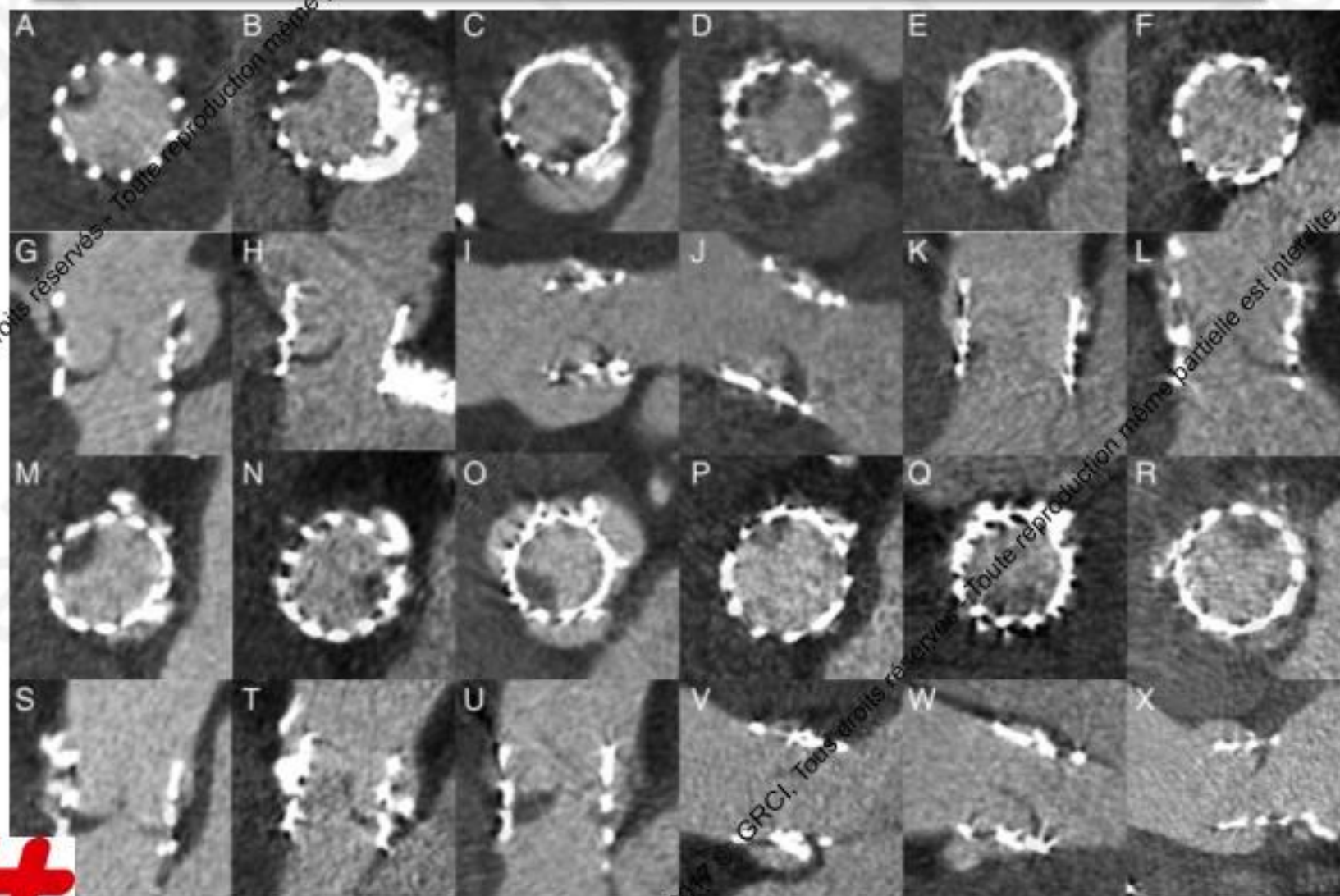
- **RESOLVE (US)/SAVORY (Dan)**
4%

- **RESOLVE (US)/SAVORY (Dan)**
13%

Early hypo-attenuated leaflet thickening in balloon-expandable transcatheter aortic heart valves

European Heart Journal (2016) 37, 2263–2271

Gregor Pache^{1*}, Simon Schoechl², Philipp Blanke³, Stephan Dorfs², Nikolaus Jander²,
Chesnal D. Arepalli³, Michael Gick², Heinz-Joachim Buettner², Jonathan Leipsic³,
Matthias Langer¹, Franz-Josef Neumann², and Philipp Ruile²



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TABLE 3 Summary of Clinical and Subclinical Findings of Patients With Suspected Bioprosthetic Valve Thrombosis Post-Surgical Aortic Valve Replacement and Post-Transcatheter Aortic Valve Replacement in Studies That Performed Systematic Computed Tomographic Evaluations

First Author (Ref. #)	TAVR		SAVR		Median Time Between TAVR/SAVR and CT, days	MTG ^(m) or PTG ^(p) , mm Hg		Post-TAVR/SAVR DAPT, Resolution With OAC, TIA/Stroke		
	HALT	RLM	HALT	RLM		Discharge	Follow-up	Suspected BPVT	Suspected BPVT	TIA/Stroke
Leetma et al. (46)	4/140 (3)	5/140 (4)	-	-	91 (66-92)	14.2 ^(p)	19.2 ^(p)	3/5 (60)	4/5 (90)	0 (0)
Makkar et al. (50)	22/55 (40)*	37/177 (23)	-	2/27 (7)	PORTICO IDE: 32 (28-37) Pooled registries: 30±10	9.1 ^(m)	9.6 ^(m)	21/39 (54)	11/11 (100)	5 (13)
Pache et al. (45)	16/156 (10)	8/156 (5)	-	-	5 (5-6)	8.2 ^(m)	12.8 ^(m)	10/16 (63)	4/4 (100)	0 (0)
Hansson et al. (47)	28/405 (7)	-	-	-	42 (25-59)	10 ^(m)	10 ^(m)	19/28 (68)	-	2/17 (12)
Yanagisawa et al. (49)	10/70 (14)†	-	-	-	-	=10 ^(m)	=10 ^(m)	3/10 (30)	-	0/10 (0)
Dooley et al. (48)	11/70 (16)	11/70 (16)	-	-	-	12 ^(m)	21 ^(m)	-	-	0/11 (0)
Chakravarty et al. (51)	101/752 (13)	101/752 (13)	5/138 (4)	5/138 (4)	83 (33-281)	9.8 ^(m)	13.8 ^(m)	6/208 (15)	36/36 (100)	4/4 (4)

Recommandations post RVAO/TAVI

	ACC/AHA Guidelines (19)	ESC/EACTS Guidelines (57)	ACCP Guidelines (56)	ACCF/AATS/SCAI/STS Expert Consensus (59)	SCCS Position Statement (58)
SAVR MVR or repair	ASA 75-100 mg/d lifelong (IIa B) + VKA (INR of 2.5) for the first 3 months (IIa C for MVR or repair; IIb B for SAVR)	Low-dose ASA (IIa C) or VKA (IIb C) for the first 3 months post-SAVR VKA for the first 3 months after MVR or repair (IIa C)	ASA (50-100 mg/day) over VKA in the first 3 months post-SAVR (grade 2C) VKA (INR of 2.5) for the first 3 months post-MVR ASA over no therapy after 3 months in all cases (grade 2C)		
TAVR	ASA 75-100 mg/day lifelong + clopidogrel 75 mg/day for the first 6 months post-TAVR (IIb C)	DAPT (duration unspecified) In setting of OAC, avoid triple therapy and use warfarin with either ASA or clopidogrel	DAPT over VKA therapy and over no antiplatelet therapy in the first 3 months (grade 2C)	IV heparin with an ACT goal of 300 s during the procedure DAPT for 3-6 months, then ASA 81 mg indefinitely In setting of OAC, continue ASA, but not clopidogrel	DAPT for 1-3 months, then ASA 81 mg indefinitely In setting of OAC, avoid triple therapy

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Thromboses TAVI

- Prévalence THROMBOSES faible MAIS SOUS ESTIMÉE à l'heure actuelle.
- Dyspnée/Élévation des GRADIENTS TRANSVALVULAIRES: **SCANNER 4D+++**
- Guidelines (...): **DAPT** 1 mois à ..?
- Intérêt **NACO** en cours d'évaluation (ATLANTIS/GALILEO)

Dégénérescences précoces: MYTHE ou REALITE?

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5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

MBRE 2017
Tour Eiffel
Education

Michael J Mack, Martin B Leon, Craig R Smith, Craig Miller, Jeffrey W Moses, E Murat Tuzcu, John G Webb, Pamela S Douglas, William N Anderson, Eugene H Blackstone, Susheel K Kodali, Raj R Makkar, Gregory P Fontana, Samir Kapadia, Joseph Bavaria, Rebecca T Hahn, Vinod H Thourani, Vasilis Babaliaros, Augusto Pichard, Howard C Herrmann, David L Brown, Mathew Williams, Jodi Akin*, Michael J Davidson†, Lars G Svensson, for the PARTNER 1 trial investigators

Background The Placement of Aortic Transcatheter Valves (PARTNER) trial showed that mortality at 1 year, 2 years, and 3 years is much the same with transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR) for high-risk patients with aortic stenosis. We report here the 5-year outcomes.

Methods We did this randomised controlled trial at 25 hospitals, in Canada (two), Germany (one), and the USA (23). We used a computer-generated randomisation sequence to randomly assign high-risk patients with severe aortic stenosis to either SAVR or TAVR with a balloon-expandable bovine pericardial tissue valve by either a transfemoral or transapical approach. Patients and their treating physicians were not masked to treatment allocation. The primary outcome of the trial was all-cause mortality in the intention-to-treat population at 1 year, we present here predefined outcomes at 5 years. The study is registered with ClinicalTrials.gov, number NCT00530894.

Findings We screened 3105 patients, of whom 699 were enrolled (348 assigned to TAVR, 351 assigned to SAVR). Overall mean Society of Thoracic Surgeons Predicted Risk of Mortality score was 11.7%. At 5 years, risk of death was 67.8% in the TAVR group compared with 62.4% in the SAVR group (hazard ratio 1.04, 95% CI 0.86–1.24; $p=0.76$).

We recorded no structural valve deterioration requiring surgical valve replacement in either group.

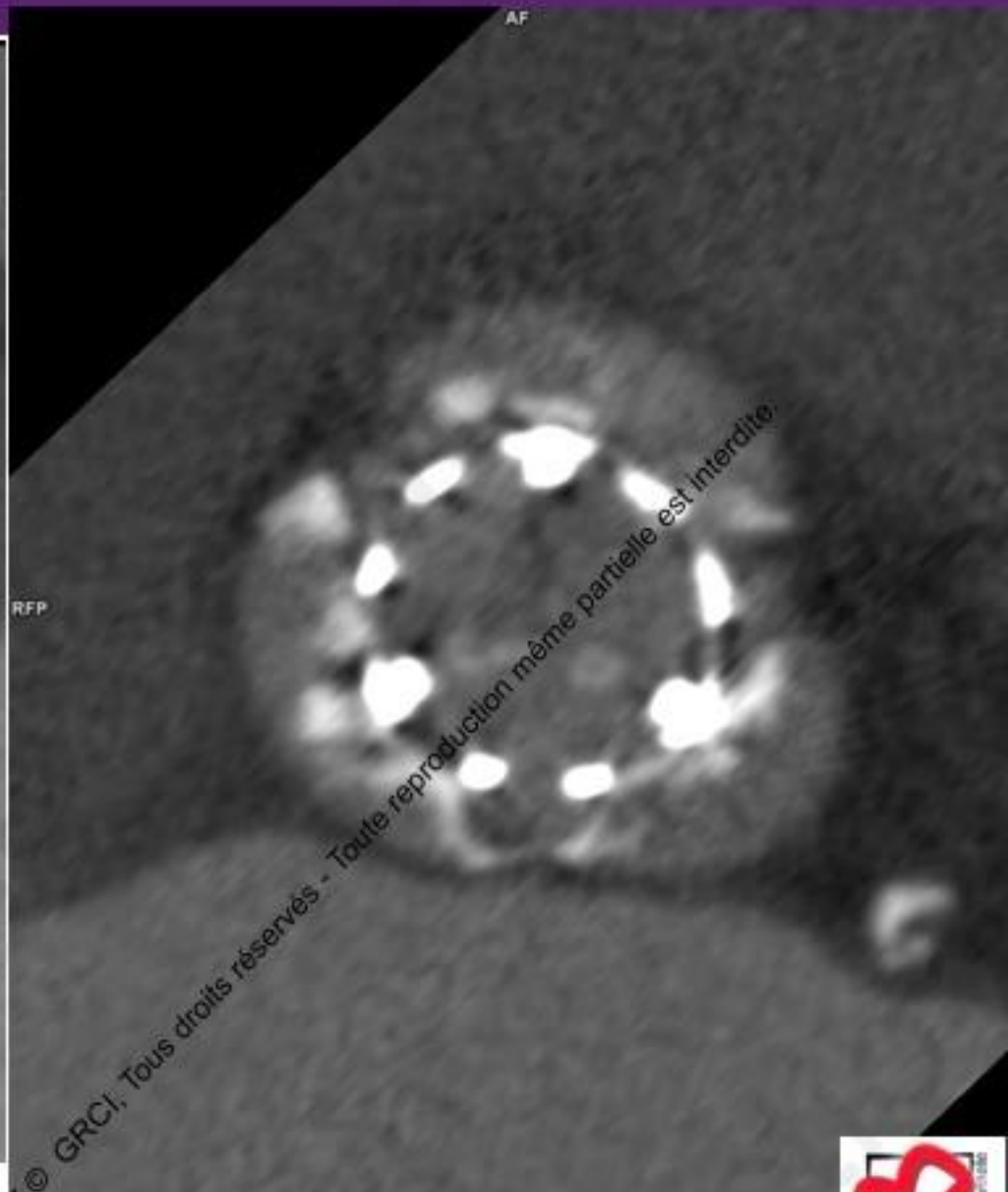
group ($p<0.0001$), and was associated with increased 5-year risk of mortality in the TAVR group (72.4% for moderate or severe aortic regurgitation vs 56.6% for those with mild aortic regurgitation or less; $p=0.003$).

Interpretation Our findings show that TAVR as an alternative to surgery for patients with high surgical risk results in similar clinical outcomes.

12/2010

- Mr L., 73 ans
- 1997: AMIG/IVA+Saph/Mg
- Dyspnée d'effort crescendo invalidante. EVA 60.
- ETT: **FeVG 35%. Gdt 45/70 mmHg.** IM moyenne Type 3 (VR 45 ml). Paps 65 mmHg.
- **EDWARDS 23 mm**

	12/10	01/11	05/11	11/11	11/12	08/14
FeVG (%)	40	40	43	48	48	30
Gdt Moy (mmHg)	9	9	13	15	15	38
Gdt Max (mmHg)	16	16	20	22	22	64
IAO	+	+	+	+	+	+ / ++



	08/14	09/14	01/15	01/16
FeVG (%)	30	35	50	50
Gdt Moy (mmHg)	38	23	20	18
IAO	64	+	0	0

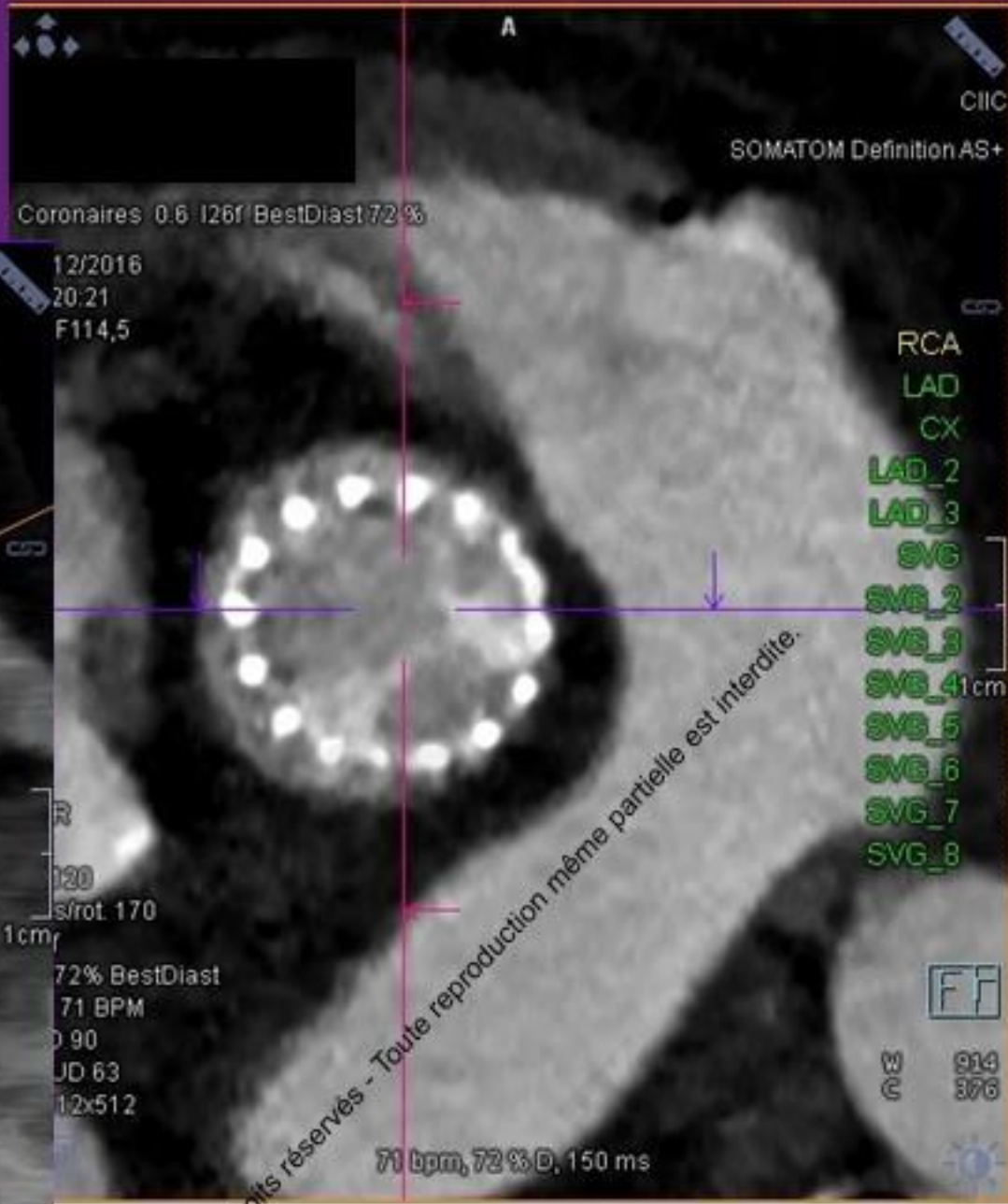


CoreValve 23 mm

Mars 2014

- Mme M, 74 ans
- 2005: néo sein droit: Chir/Chimio
- Troubles de la mémoire depuis 2009
- ETT: FeVG 45%. Sao 0.5. **Gdient 86/140 mmHg. Vmax 5.6m/s**
- **Corevalve 26 mm**
- KDG/PLAVIX
- Sortie convalescence J5

	04/14	05/14	04/16	12/16
FeVG (%)	65	65	65	55
Gdt Moy (mmHg)	11	9	11	64
Gdt Max (mmHg)	22	16	21	128
IAO	+	0	+	+ / ++



WL: 462 WW: 106

LA

RP



SI: 29.3
L-R: 141.0
PoR: 7.0



Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position

Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Candolfi, PhD, Alain Mirza, MD, Claudia Loardi, MD, Marc-Antoine May, MD, Rym El-Khoury, MD, Michel Marchand, MD, and Michel Aupart, MD

Department of Cardiac Surgery, Tours University Hospital, France; and Department of Biostatistics, Edwards Lifesciences, Nyon, Switzerland

Table 2. Summary of Main Events: Freedom From Event With Kaplan-Meier Estimates

Variable	Early Event ^a n (Rate)	Late Event n (Linearized Rate)	95% CI Linearized Rate	KM @ 10 Years	KM @ 15 Years	KM @ 20 Years	MST (Years)	AUC (Years)
Mortality	77 (2.7%)	1,098 (5.97%/vy)	[5.62%–6.33%]	52.4 ± 1.2%	31.1 ± 1.4%	14.4 ± 1.7%	10.4	11.4
Valve-related mortality	73 (2.65%)	255 (1.39%/vy)	[1.22%–1.56%]	84.0 ± 1.0%	75.3 ± 1.6%	64.1 ± 3.5%	19.4	19.4
Reoperation	4 (0.15%)	164 (0.89%/vy)	[0.76%–1.04%]	93.2 ± 0.8%	81.5 ± 1.9%	51.5 ± 4.6%	20.5	19.3
Endocarditis	3 (0.11%)	70 (0.38%/vy)	[0.30%–0.48%]	96.7 ± 0.4%	95.5 ± 0.8%	94.2 ± 1.2%	23.2	23.2
Thromboembolism	29 (1.05%)	133 (0.72%/vy)	[0.61%–0.85%]	92.2 ± 0.7%	86.9 ± 1.4%	84.5 ± 1.9%	22.1	22.1
Bleeding	9 (0.33%)	62 (0.34%/vy)	[0.26%–0.43%]	96.5 ± 0.5%	94.0 ± 1.0%	94.0 ± 1.0%	23.6	23.6
Perivalvular leak	5 (0.18%)	13 (0.07%/vy)	[0.04%–0.12%]	99.3 ± 0.2%	99.1 ± 0.2%	99.1 ± 0.2%	24.4	24.4
SVD	0 (0.0%)	157 (0.85%/vy)	[0.73%–0.99%]	94.2 ± 0.8%	78.6 ± 2.2%	48.5 ± 4.6%	19.7	19.0
Explant due to SVD	0 (0.0%)	123 (0.67%/vy)	[0.56%–0.79%]	95.4 ± 0.7%	84.0 ± 1.9%	54.3 ± 4.8%	20.7	19.8

^a Defines events occurring up to 30 days after surgery. ^b The survival curve does not cross the 50% line – MST not applicable.

AUC = area under the curve; CI = confidence interval limits; KM = Kaplan-Meier actuarial survival; MST = median survival time; SVD = structural valve deterioration; vy = valve-year.

1984-2008
2659 pts

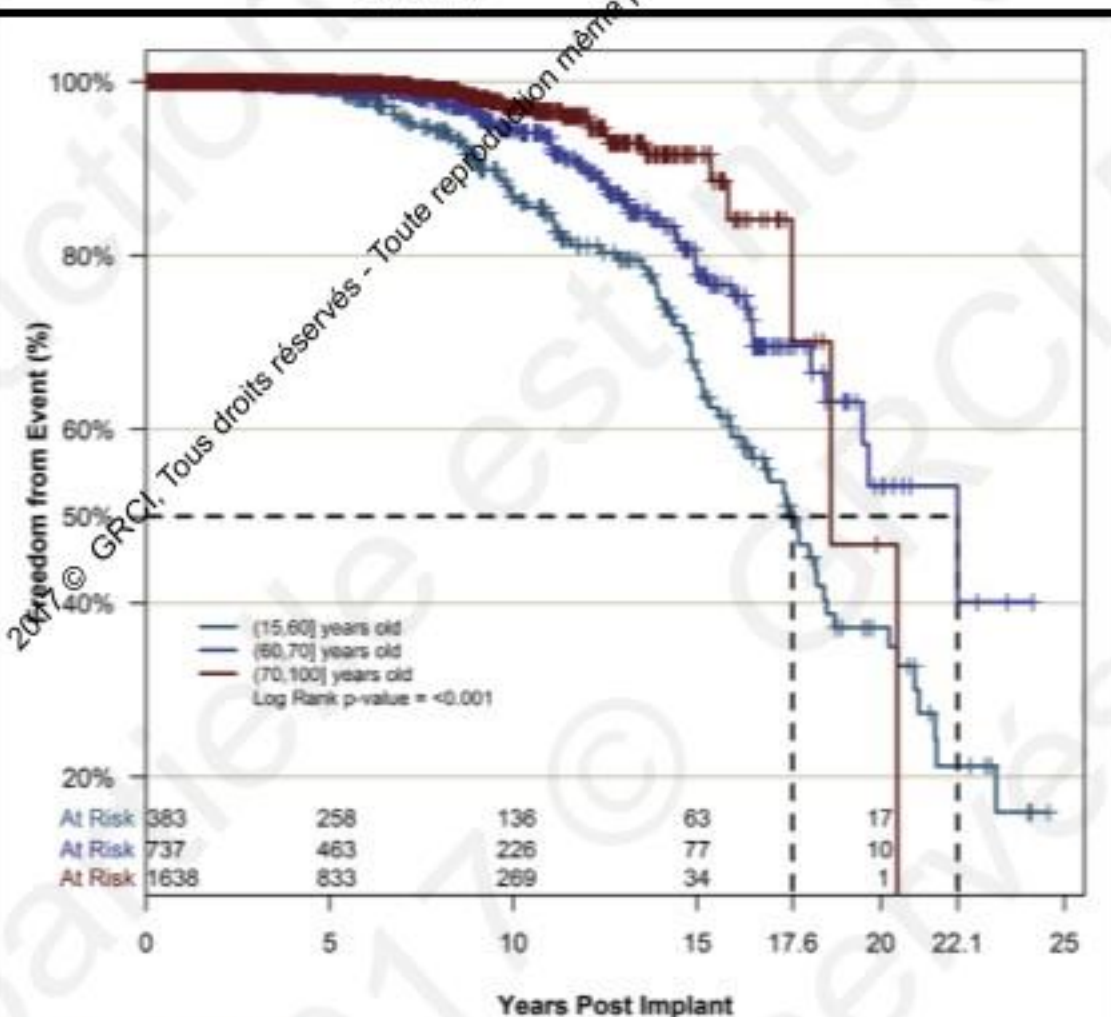
- 13,5 +/-5,6 ans.
- **0,85%/an. Seulement 6 cas avant 5 ans.**
- Calcifications (62%)
- Age à l'implantation est le seul facteur de risque (p<0,0001).

(Ann Thorac Surg 2015;■:■–■)

Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position

Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Candolfi, PhD, Alain Mirza, MD, Claudia Loardi, MD, Marc-Antoine May, MD, Rym El-Khoury, MD, Michel Marchand, MD, and Michel Aupart, MD

Department of Cardiac Surgery, Tours University Hospital, France; and Department of Biostatistics, Edwards Lifesciences, Nyon, Switzerland



1984-2008
2659 pts

- SVD à 15/20 ans
 - 33,2/62,8%
 - 22,3/47%
 - 8,4%
- Durée de vie Bioprothèse:
 - 17,6 ans
 - 22,1 ans

(Ann Thorac Surg 2015;■:■-■)

Table 2 Long-term durability after transcatheter aortic valve implantation

Author	Year	N	Prosthesis	Results
Toggweiler et al. ²¹	2013	88	Cribier-Edwards or Edwards Sapien	<ul style="list-style-type: none"> • Survival: 35% at 5 years
Mack et al. ²²	2015	348	Edwards Sapien	<ul style="list-style-type: none"> • Mortality: 68% at 5 years • Reintervention due to SVD³: 0% at 5 years
Barbanti et al. ²³	2015	353	Medtronic CoreValve	<ul style="list-style-type: none"> • Mortality: 55% at 5 years • Bioprosthetic valve dysfunction: 1.4% at 5 years

SVD	Rouen*	Canada	Italie
5 ans (%)	2,4	3,4	4,2
10 ans (%)	3,7	15,4*	

*Non publié



EUROPEAN
SOCIETY OF
CARDIOLOGY®

Guido Capodanno^{1*}, Anna S. Petronio^{2†}, Bernard Prendergast³,
Helene Eltchaninoff⁴, Alec Vahanian⁵, Thomas Modine⁶, Patrizio Lancellotti⁷,
Lars Sondergaard⁸, Peter F. Ludman⁹, Corrado Tamburino¹, Nicolò Piazza¹⁰,
Jane Hancock³, Julinda Mehilli¹¹, Robert A. Byrne¹², Andreas Baumbach¹³,
Arie Pieter Kappetein¹⁴, Stephan Windecker¹⁵, Jeroen Bax¹⁴, and Michael Haude¹⁷

European Heart Journal (2017) **0**, 1–10
doi:10.1093/eurheartj/ehx303

- **Dégénérescence Structurale Hémodynamique Modérée**
 - **20 < Gdt Moy < 40 mmHg**
 - Et/ou Majoration du Gdt Moy 10 mmHg
 - Et/ou Majoration ou nouvelle **IAO > 1/4**
- **Dégénérescence Structurale Hémodynamique Sévère**
 - **Gdt Moy > 40 mmHg**
 - Et/ou Majoration du Gdt Moy 10 mmHg
 - Et/ou Majoration ou nouvelle **IAO > 2/4**
- **Dysfonction de Bioprothèse (Bioprosthetic Valve Failure)**
 - Anomalie fonctionnelle **symptomatique** de la valve prothétique
 - **Remplacement** valvulaire ou seconde implantation
 - Quelle que soit la cause (dégénérescence, endocardite, thrombose...)

Registre 5 centres Français

Définition SVD	Risque SVD À 6 ans	IC 95%
EHI 2017	5,4	(3,6-7,6)
Bourguignon 2015	2,6	(1,5-4,2)
Chirurgie	0,7	(0,2-1,8)

Courtesy Dr H Eltchaninoff

Dégénérescence TAVI

- A 5 ANS (PARTNER/France 2): jusqu'ici tout va bien!
- Mais c'est au delà que les bioprothèses chirurgicales font généralement parler d'elles!
- Pour l'instant PAS D'ALERTE sur la durabilité des bioprothèses percutanées au delà de 5 ANS.