

Session controversée

Le TAVI pour tous : Contre !

L. Labrousse
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CHU de Bordeaux



Disclosure

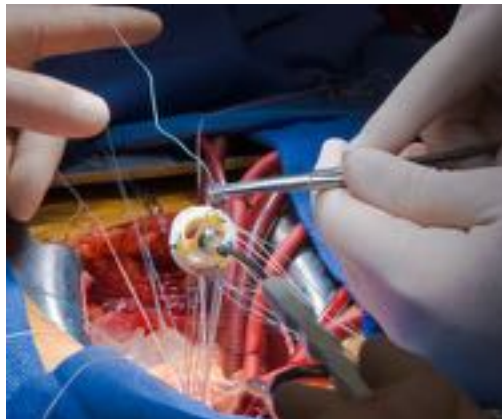
- Proctor pour Abbott
- Investigateur et Investigateur principal pour Edwards et Medtronic

Disclosure

- Service médico-chirurgical de Valvulopathies et cardiomyopathies - Chirurgie cardiaque adulte et congénitale - Cardiologie Interventionnelle structurelle adulte



**Valvulopathies et
cardiomyopathies**



**Chirurgie
Cardiaque adulte
et congénitale**



**Cardiologie
Interventionnelle
structurelle adulte**

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Questions clés en 2018

- Définition du risque – population(s) à traiter
- AVC – dommages cérébraux
- Durabilité
- BBG – PM post implantation
- Fuites para-prothétiques

Définition Euroscore

Euroscore Logistic 2 (2011)

	Homme	Femme
55 ans	1,51 %	2,08 %
60 ans	1,61 %	2,22 %
65 ans	2,23 %	3,07 %
70 ans	3,08 %	4,24 %
75 ans	4,25 %	5,82 %
80 ans	5,83 %	7,94 %

Patients sans aucune co-morbidité

Euroscore 2 $\approx$ STS score x 2

Résultats en 2018

Activité Haut Lévéque 2016-2018 RVAo et RVAo+Pts

Euroscore	nb	Age	Score 2	DC (%)	AVC (%)
<3 %	251	60,5	2,1 %	0,4	0,4
< 5%	558	65,6	3,2 %	0,5	0,7
< 8%	975	70,1	4,6 %	0,8	1
>8 %	50	70,0	17,5 %	4,2	0,7
Global	1525	72,6	9,2 %	2	0,9

Population à traiter

Même traitement ?



VS



Espérance de vie

Espérance de vie en 2015 en France pour un âge donné

	Male	Female	Population
Âge x	Life expectancy at the age	Life expectancy at the age	Life expectancy at the age
60	22,84	27,40	25,13
65	19,04	23,03	21,08
70	15,38	18,75	17,14
71	14,67	17,91	16,37

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Rappel : risque intermédiaire

The PARTNER 2A and S3i Trial Lancet On-line



Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis



Research in context

Evidence before this study

Before we did the PARTNER 2A and S3i studies, clinical trial evidence comparing transcatheter aortic valve replacement (TAVR) to surgery was mainly limited to patients at high risk of death during surgery. Data from large national registries now indicated a global trend towards TAVR being used in lower-risk populations despite little rigorous clinical evidence for this practice. We searched for clinical evidence for this practice. We searched on Jan 31, 2015, with the terms "transcatheter aortic valve implantation", "transcatheter aortic valve replacement in low risk patients", "transcatheter aortic valve implantation in intermediate risk patients", "transcatheter aortic valve replacement in low risk patients", "transcatheter aortic valve replacement in intermediate risk patients", "surgical aortic valve replacement", and "surgical aortic valve replacement in intermediate risk patients" in English with no date limitations. The published studies include a small randomised trial and several non-adjusted comparisons between TAVR and surgery in intermediate-risk patients. These studies did not use

neurologists for stroke assessment, a clinical events committee to adjudicate outcomes, or core laboratories for analysis of imaging data.

Added value of this study

We show TAVR with SAPIEN 3 to be superior to surgery at 1 year follow-up with lower rates of all-cause mortality, stroke, and the composite endpoint of mortality, stroke, and moderate or severe aortic regurgitation, but higher rates of moderate or severe regurgitation. Our analysis is the first rigorously designed and carried out clinical study to compare TAVR with the SAPIEN 3 device with surgery in intermediate-risk patients. The prespecified propensity analysis allows for meaningful comparisons between the two groups.

Implications of all the available evidence

TAVR should be considered as the preferred alternative to surgery in intermediate-risk patients and future studies should consider depending the indications for TAVR.

"Preferred alternative"

Summary

CoreValve SURTAVI Trial

- SURTAVI met its primary endpoint demonstrating that TAVR with a self-expanding CoreValve or Evolut R bioprosthesis is noninferior to SAVR for all-cause mortality or disabling stroke at 24 months.

ORIGINAL ARTICLE

Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients

M.J. Beardon, N.M. Van Mieghem, J.J. Popma, N.S. Kleiman, L. Søndergaard, M. Mumtaz, D.H. Adams, G.M. Deeb, B. Maini, H. Gada, S. Chetcuti, T. Gleason, J. Heiser, R. Lange, W. Merhi, J.K. Oh, P.S. Olsen, N. Piazza, M. Williams, S. Windecker, S.J. Yakubov, E. Grube, R. Makkar, J.S. Lee, J. Conte, E. Yang, H. Nguyen, Y. Chang, A.S. Mugglin, P.W.J.C. Serruys, and A.P. Kappetein, for the SURTAVI Investigators*

**Propensity match
analysis**

Randomized study



Rappel : risque intermédiaire

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neurologists for stroke assessment, a clinical events committee to adjudicate outcomes, or core laboratories for analysis of imaging data.

Main results of this study

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Quid de la définition ?

Rappel : risque intermédiaire

Définition du risque intermédiaire



Baseline Patient Characteristics Demographics (AT)



Characteristic	TAVR (n = 1077)	Surgery (n = 944)	p-value
Age - yrs	81.6 ± 6.6	81.6 ± 6.8	0.23
Male - %	61.7	55.0	0.002
BMI - kg/m ²	28.7 ± 6.1	28.4 ± 6.2	0.32
Median STS Score - %	5.2 [4.3, 6.3]	5.4 [4.4, 6.7]	0.0002
NYHA Class III or IV - %	72.5	76.1	0.07

mean ± SD, median [IQR]

Baseline Characteristics*

CoreValve SURTAVT Trial

n [%] or mean ± SD	SAVR (n = 854)	SAVR (n = 796)
Age, years	79.7 ± 6.2	79.7 ± 6.1
Male sex	498 (57.6)	438 (55.0)
Body surface area, m ²	1.9 ± 0.2	1.9 ± 0.2
STS-PROM, %	4.4 ± 1.5	4.5 ± 1.6
Logistic EuroSCORE, %	11.9 ± 7.6	11.6 ± 8.0
Diabetes mellitus	295 (34.1)	277 (34.8)
Serum creatinine ×2 mg/dL	14 (1.6)	17 (2.1)
Prior stroke	57 (6.6)	57 (7.2)
Prior TIA	58 (6.7)	46 (5.8)
Peripheral vascular disease	266 (30.8)	238 (29.9)
Permanent pacemaker	84 (9.7)	72 (9.0)

*STT population; no significant differences in any baseline characteristics

Rappel : risque intermédiaire

Définition du risque intermédiaire



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mean ± SD, median [IQR]

Baseline Characteristics*

Correlative SURTAVI Trial

n [%] or mean ± SD	TAVR (N=854)	SAVR (N=794)
Age, years	79.9 ± 6.2	79.7 ± 6.2
Male sex	498 (57.6)	438 (55.0)
Body surface area, m ²	1.9 ± 0.2	1.9 ± 0.2
STS PROM, %	4.6 ± 1.5	4.5 ± 1.6
Logistic EuroSCORE, %	11.9 ± 7.6	11.6 ± 8.0
Diabetes mellitus	215 (24.1)	277 (34.8)
Serum creatinine >2 mg/dL	14 (1.6)	17 (2.1)
Prior stroke	57 (6.5)	57 (7.2)
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Rappel : risque intermédiaire

Définition du risque intermédiaire



Baseline Patient Characteristics Other Co-morbidities (AT)



Characteristic (%)	TAVR (n = 1077)	Surgery (n = 944)	p-value
CAD	69.6	66.5	0.14
Previous CABG	27.9	25.7	0.27
Cerebrovascular Disease	9.0	10.3	0.36
PVD	28.2	32.2	0.05
COPD	30.0	30.2	0.92
Cr level > 2 mg/dL	7.5	5.4	0.06
Atrial Fibrillation	36.0	34.9	0.61
Permanent Pacemaker	13.2	12.0	0.42
15 ft Walk Test > 7s	41.3	45.7	0.06

Baseline Cardiac Risk Factors*

CoronArtery SURTAVL Trial

n (%)	TAVR (n=944)	Surgery (n=796)
Coronary artery disease	541 (57.3)	511 (64.2)
Prior CABG	136 (14.4)	137 (17.2)
Prior PCI	184 (19.5)	167 (21.0)
Prior myocardial infarction	125 (13.2)	111 (13.9)
Chronic heart failure	824 (87.3)	709 (89.1)
History of angina	275 (29.1)	250 (31.4)
Atrial fibrillation	343 (36.3)	311 (39.1)
NYHA Class III/IV	520 (55.2)	461 (58.0)

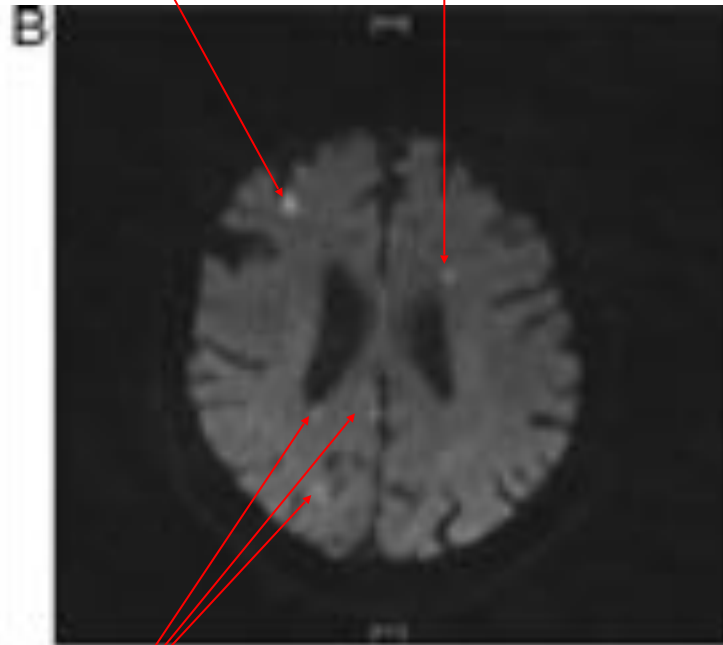
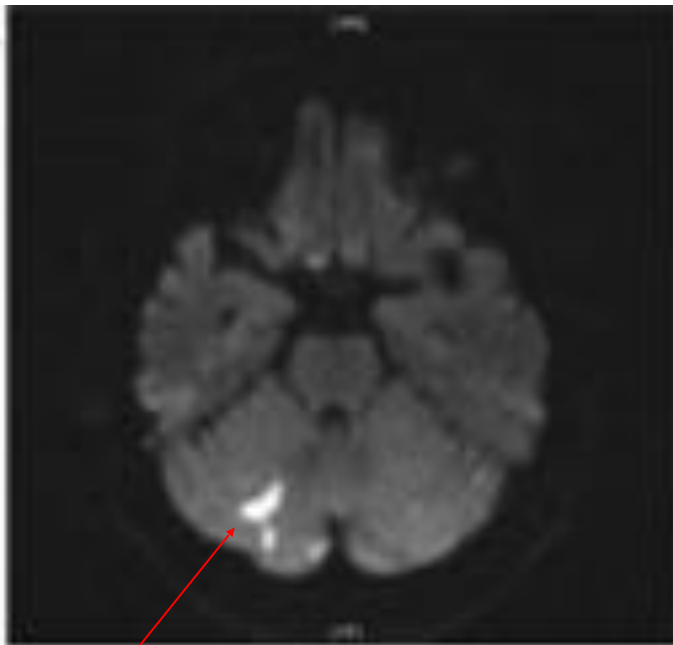
*p < 0.05 indicates significant difference in any baseline characteristics



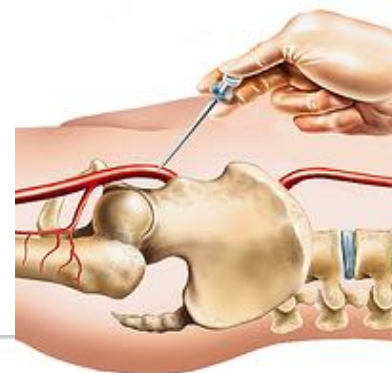
Stephen Hawking

Trous blancs cérébraux

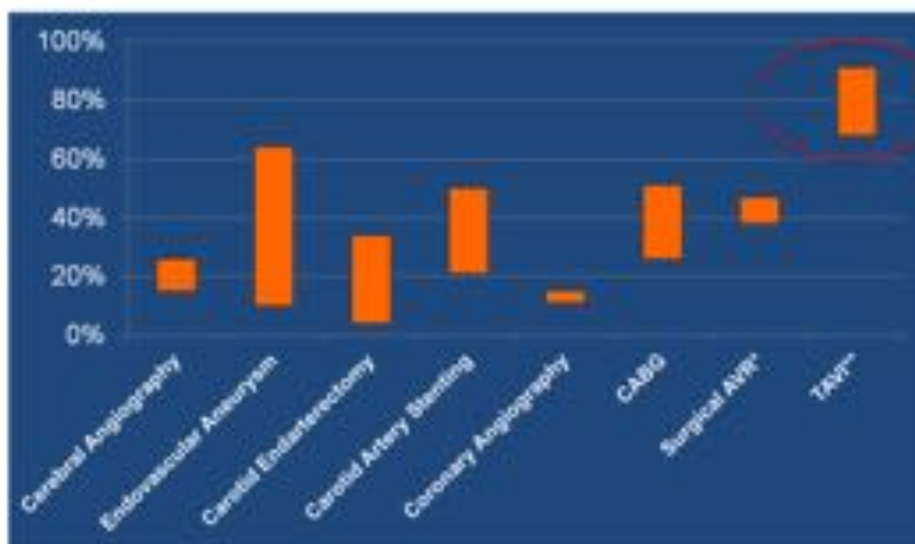
IRM de diffusion



Trous blancs cérébraux



Incidence of New DW MRI Brain Lesions





Trous blancs cérébraux

Les embols cérébraux mis en évidence en DWI MRI sont habituels après TAVI et apparaissent dans 68-98% des cas. (1, 2-4)

Les embols cérébraux mis en évidence en DWI MRI augmentent le risque d'AVC clinique par 2 à 4 fois et sont associés **A LONG TERME** aux troubles cognitifs, à la dépression, aux troubles de la mobilité, à la démence et augmentent la mortalité à long terme. (5-6)

Le volume des lésions visualisées en IRM est corélé avec l'importance du risque de dysfonction cognitif et de démence à long terme. (5-6)

¹Kahlert, *Circulation*. 2012;216:1245-1255. ²Arnold S, *J Am Coll Cardiol Interv*. 2010;3:1126. ³Haussig S, *JAMA*. 2016;316:592.
⁴Lansky AJ, *Eur Heart J*. 2015;36:2070. ⁵Sacco RL, *Stroke*. 2013;44:00. ⁶Vermeer SE, *Lancet Neurol* 2007;6:611.



Trous blancs cérébraux

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**1-mm³ voxel on DW-MRI:
at least 80,000 neurons
4.5 million synapses**

**Post TAVI (100-300 mm³)
At least 2 million neurons
And 1 billion synapses**

From Choi Neurology 2000, Kahlert 2010, Ghanem 2011, Astarci 2011, Stolz 2004, Rodes Cabau 2011

Trous blancs cérébraux

Protecteurs cérébraux



(A) Montage™ 2 Capture Device (Claret); (B) Embrella Embolic Deflector System (Edwards Lifesciences); and (C) TriGuard™ Cerebral Protection Device (Keystone Heart). Adapted from Fanning et al., 2014¹⁸ with permission from Wolters Kluwer Health, Inc. © 2014.

Trous blancs cérébraux

Cerebral Protection During Transcatheter Aortic Valve Implantation: An Updated Systematic Review and Meta-Analysis

Luca Testa, MD, PhD; Azeem Latib, MD; Matteo Casenghi, MD; Riccardo Gorla, MD; Antonio Colombo, MD; Francesco Bedogni, MD

Background—The use of embolic protection devices (EPD) may theoretically reduce the occurrence of cerebral embolic lesions during transcatheter aortic valve implantation. Available evidence from single studies is inconclusive. The aim of the present meta-analysis was to assess the safety and efficacy profile of current EPD.

Methods and Results—Major medical databases were searched up to December 2017 for studies that evaluated patients undergoing transcatheter aortic valve implantation with or without EPD. End points of interest were 30-day mortality, 30-day stroke, the total number of new lesions, the ischemic volume per lesion, and the total volume of lesions. Eight studies involving 1285 patients were included. The EPD delivery success rate was reported in all studies and was achieved in 94.5% of patients. The use of EPD was not associated with significant differences in terms of 30-day mortality (odds ratio 0.43 [0.18–1.05], $P=0.3$) but it was associated with a lower rate of 30-day stroke (odds ratio 0.55 [0.31–0.98], $P=0.04$). No differences were detected with respect to the number of new lesions (standardized mean difference -0.19 [-0.71 to 0.34], $P=0.49$). The use of EPD was associated with a significantly smaller ischemic volume per lesion (standardized mean difference, -0.52 [-0.85 to -0.20], $P=0.002$) and smaller total volume of lesions (standardized mean difference, -0.23 [-0.42 to -0.03], $P=0.02$).

Conclusions—The use of EPD is not associated with a reduced rate of mortality and new ischemic cerebral lesions. The use of EPD during transcatheter aortic valve implantation seems to be associated with a lower 30-day stroke rate, although this result is driven by a single nonrandomized study. The use of EPD is associated with a smaller volume of ischemic lesions, and smaller total volume of ischemic lesions. (*J Am Heart Assoc.* 2018;7:e008463. DOI: 10.1161/JAHA.117.008463.)

Trous blancs cérébraux

Clean-TAVI randomized Clinical Trial

From Haussig et al. JAMA 2016;316(6):592-601.

	2 Days				7 Days			
	Filter (n = 49)	Control (n = 45)	Difference (95% CI) ^a	P Value	Filter (n = 45)	Control (n = 43)	Difference (95% CI) ^a	P Value
Entire Brain								
No. of new lesions, median (IQR)	8.00 (5.00-12.00)	16.00 (9.75-24.25)	6.00 (3.00-10.00)	.002	5.00 (2.75-8.00)	10.00 (3.00-18.00)	4.00 (1.00-8.00)	.009
Volume of new lesions, median (95% CI), mm ³	466 (349-711)	800 (594-1407)	311 (66-580)	.02	205 (115-335)	472 (385-909)	240 (51-393)	.009

Trous blancs cérébraux

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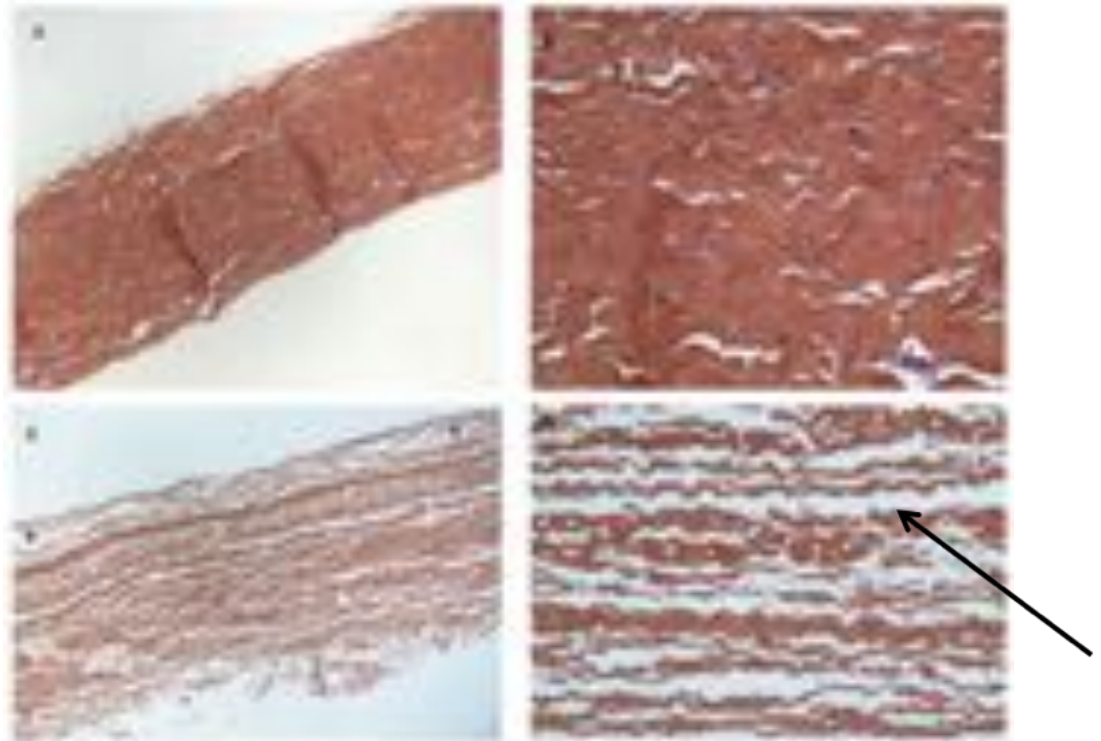
Surgical randomized Clinical Trial

CONCLUSIONS AND RELEVANCE Among patients undergoing SAVR, cerebral embolic protection devices compared with a standard aortic cannula did not significantly reduce the risk of CNS infarction at 7 days. Potential benefits for reduction in delirium, cognition, and symptomatic stroke merit larger trials with longer follow-up.

7 days : Total infarct volume, mm³ : median 35 (0-168)

Trous blancs Valvulaires

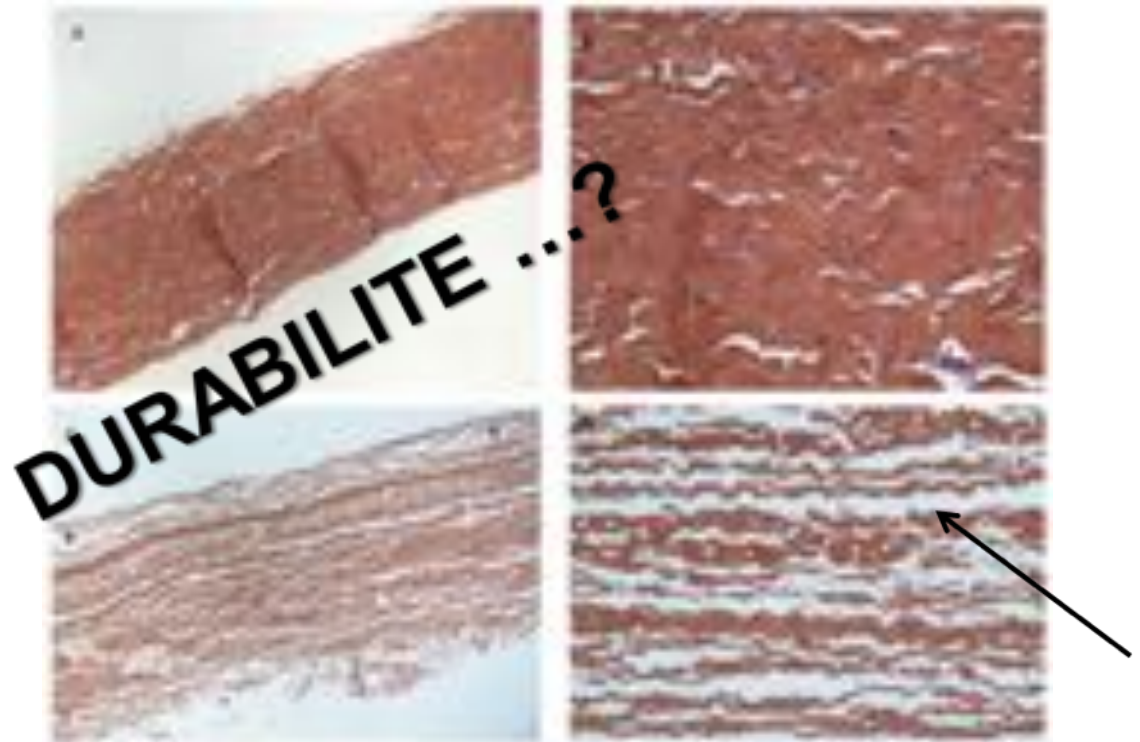
Spécificité du TAVI – Crimping...



Collagen fibers fragmentation and disruption
Increase plasmatic insudation of the pericardium

Trous blancs Valvulaires

Spécificité du TAVI – Crimping...



Collagen fibers fragmentation and disruption
Increase plasmatic insudation of the pericardium



Trous blancs Valvulaires

Que fait le compétiteur ?

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

(Ann Thorac Surg 2015;99:831-7)

2659 pts suivis pendant 24 ans !

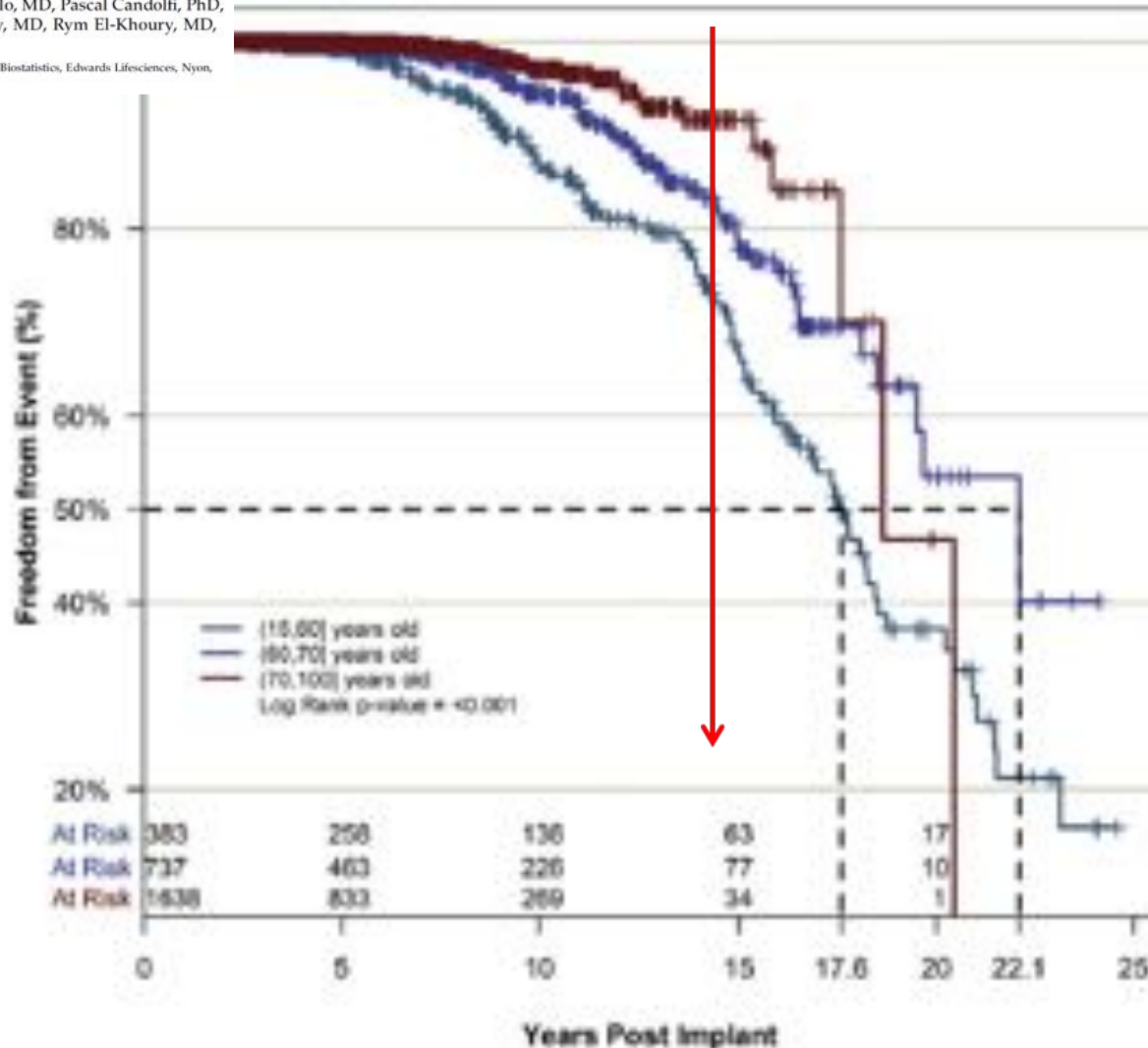
Trous blancs Valvulaires

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

Freedom from "dégénérescence structurelle"

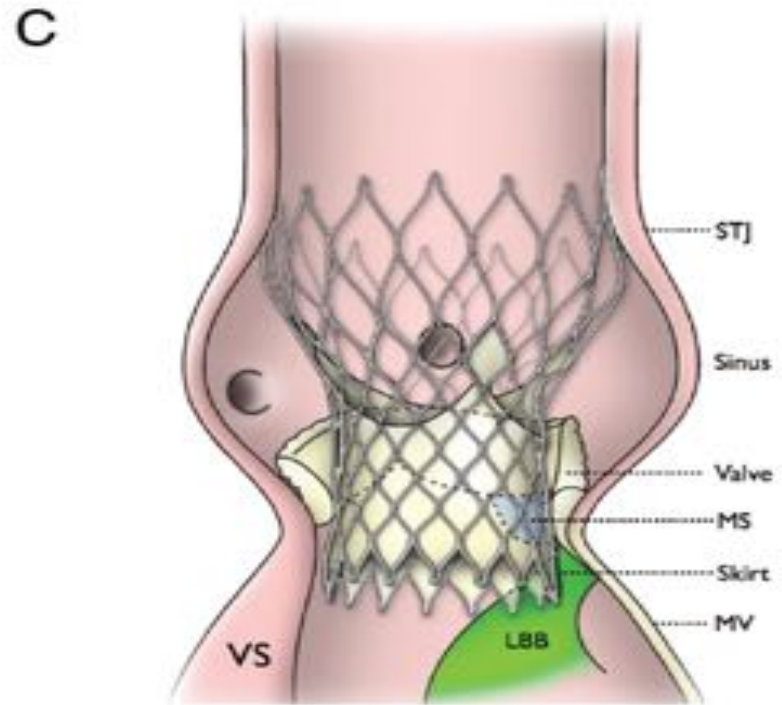
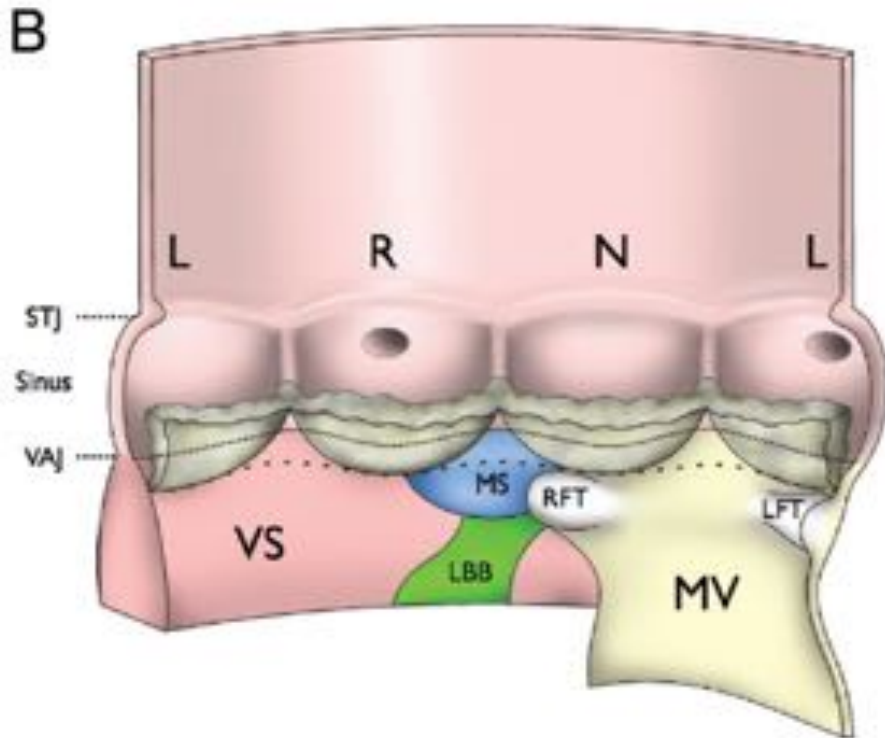
Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Candolfi, PhD, Alain Mirza, MD, Claudia Lardi, MD, Marc-Antoine May, MD, Rym El-Khoury, MD, Michel Marchand, MD, and Michel Aupart, MD

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



AUTRES PROBLEMES...

Bloc de Branche Gauche et BAV post implantation



Mechanical stress on the LV wall, septum and conduction system may lead to complete AV block or new LBBB

Bloc de Branche Gauche

Impact of New-Onset Left Bundle Branch Block and Periprocedural Permanent Pacemaker Implantation on Clinical Outcomes in Patients Undergoing Transcatheter Aortic Valve Replacement A Systematic Review and Meta-Analysis

Ander Regueiro, MD; Omar Abdul-Jawad Altisent, MD; María Del Trigo, MD;
Francisco Campelo-Parada, MD; Rishi Pari, MBBS, PhD; Marina Urena, MD, PhD;
François Philippon, MD; Josep Rodés-Cabau, MD

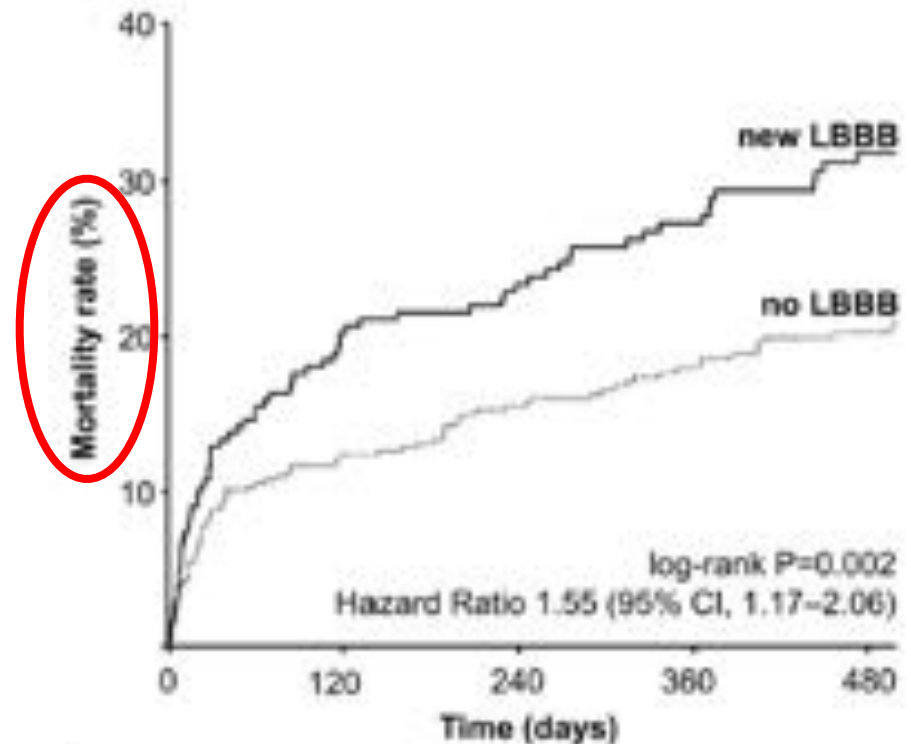
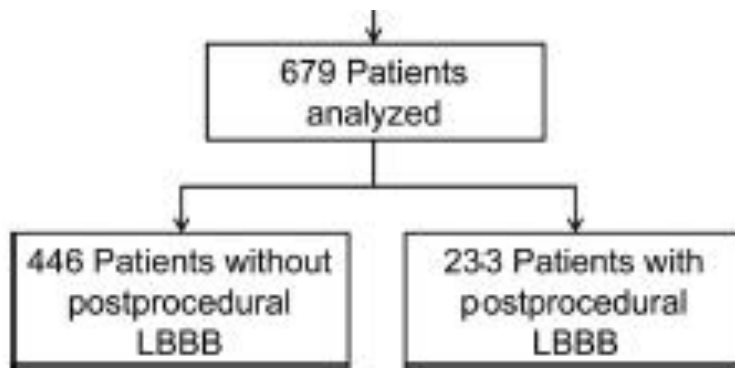
17 studies - > 11000 patients
New onset of LBBB: 10 – 37 %

Post chirurgie : 5%*

Bloc de Branche Gauche

Left Bundle-Branch Block Induced by Transcatheter Aortic Valve Implantation Increases Risk of Death

Patrick Houthuizen, MD*; Leen A.F.M. Van Garsse, MD*; Thomas T. Poels; Peter de Jaegere, MD, PhD; Robert M.A. van der Boon; Ben M. Swinkels, MD;

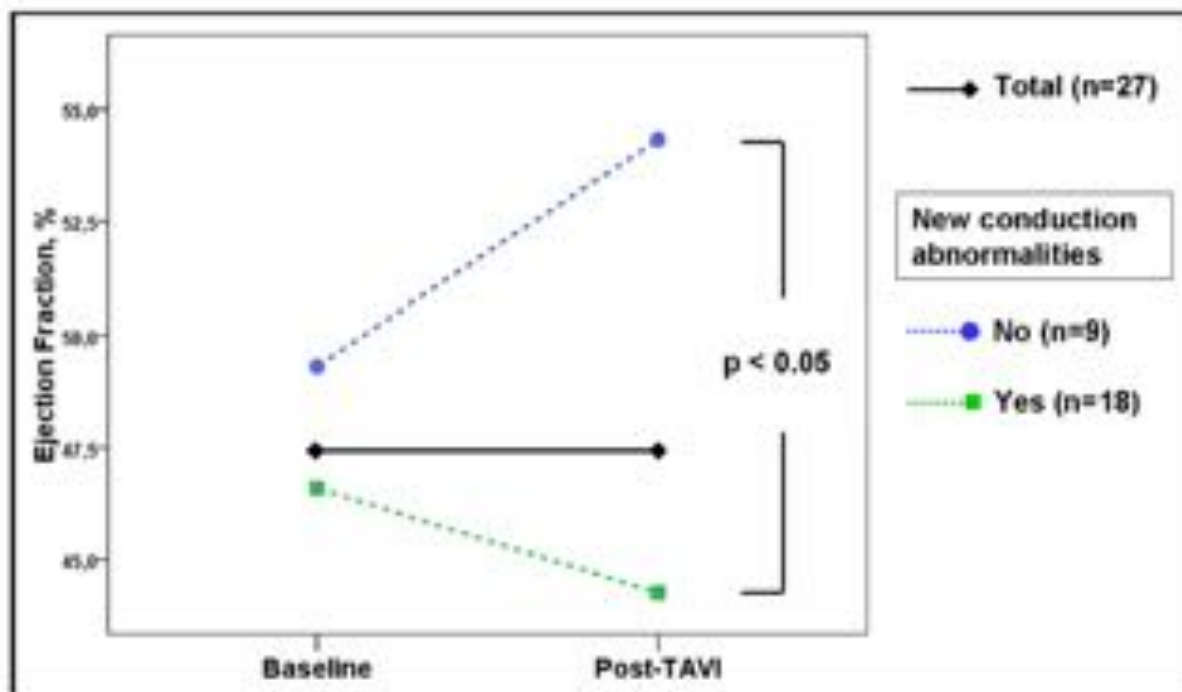


(*Circulation*. 2012;126:720-728.)

Bloc Branche Gauche

Frequency of Conduction Abnormalities After Transcatheter Aortic Valve Implantation With the Medtronic-CoreValve and the Effect on Left Ventricular Ejection Fraction

Apostolos Tzikas, MD*, Bas M. van Dalen, MD, PhD, Nicolas M. Van Mieghem, MD, Juan-Luis Gutierrez-Chico, MD, PhD, Rutger-Jan Nuis, MS, Floris Kauer, MD, (Am J Cardiol 2011;107:285–289)



Bloc de Branche Gauche

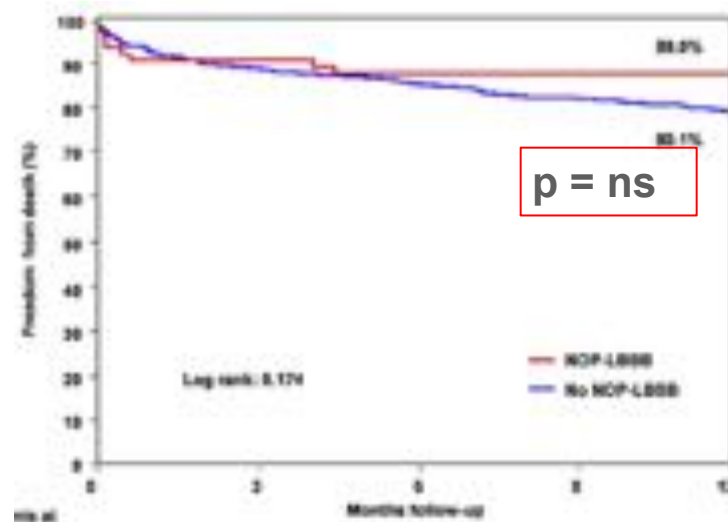
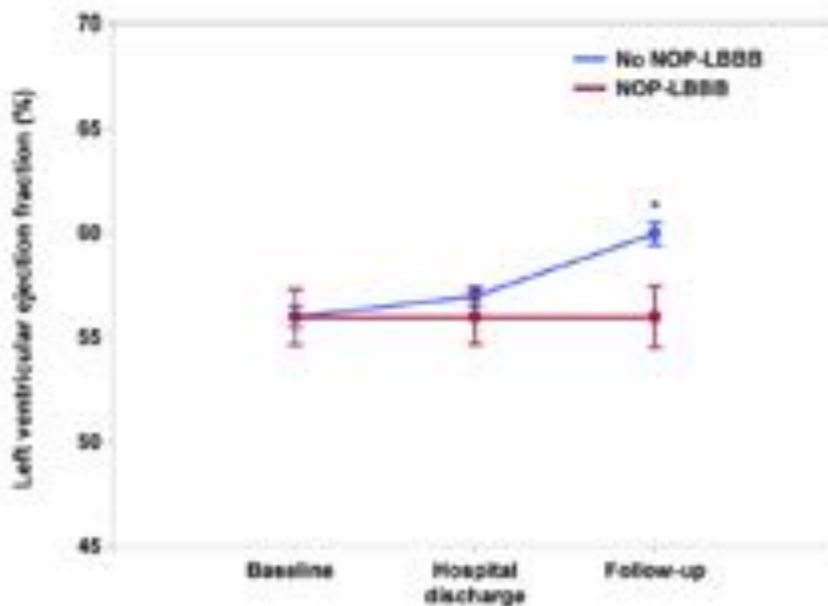
Impact of New-Onset Persistent Left Bundle Branch Block on Late Clinical Outcomes in Patients Undergoing Transcatheter Aortic Valve Implantation With a Balloon-Expandable Valve

Marina Urena, MD,* John G. Webb, MD,† Asim Cheema, MD,‡ Vicenç Serra, MD,§ Stefan Toggweiler, MD,|| Marco Barbanti, MD,|| Anson Cheung, MD,|| Jian Ye, MD,||

JACC: CARDIOVASCULAR INTERVENTIONS 2013

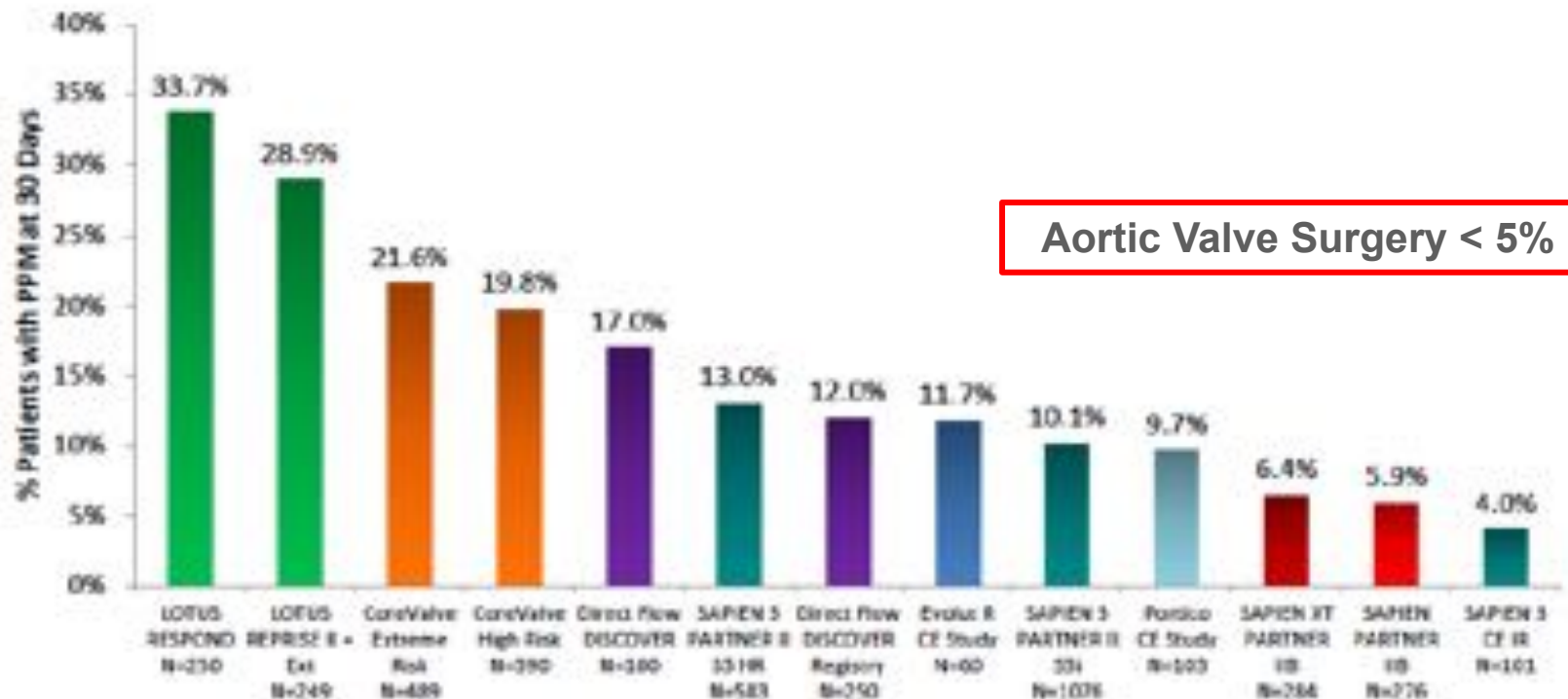


New LBB associated to poorer functional status



Pace maker

New Pace Maker Implantation

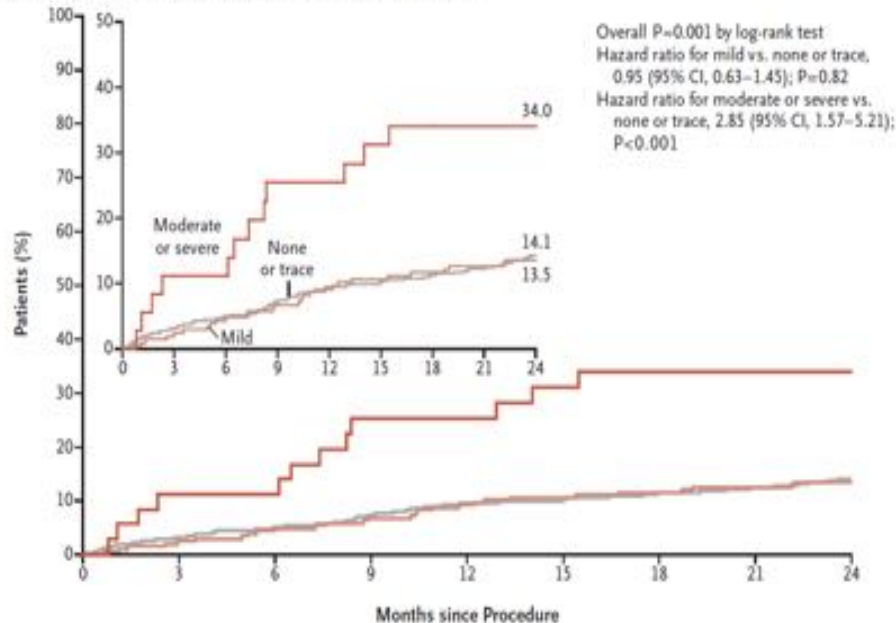


Aortic Valve Surgery < 5%

¹Van Mieghem, et al., presented at EuroPCR 2015; ²Meredith, et al., presented at PCR London Valves 2014; ³Yogme, et al., / Am Coll Cardiol 2014, 63: 1972-81; ⁴Adams, et al., N Engl J Med 2014; 370: 1790-8; ⁵Schofer, et al., / Am Coll Cardiol 2014, 63: 753-8; ⁶Kodali, et al., presented at ACC 2015; ⁷Naber, et al., presented at EuroPCR 2015; ⁸Meredith, et al., presented at ACC 2015; ⁹Kodali, et al., presented at ACC 2015; ¹⁰Manoharan, et al., et al. presented at TCT 2014; ¹¹Leon, et al. presented at ACC 2013; ¹²Vaharian, et al., presented at EuroPCR 2015

Fuites para-valvulaires

C Death from Any Cause, According to Severity of Paravalvular Aortic Regurgitation

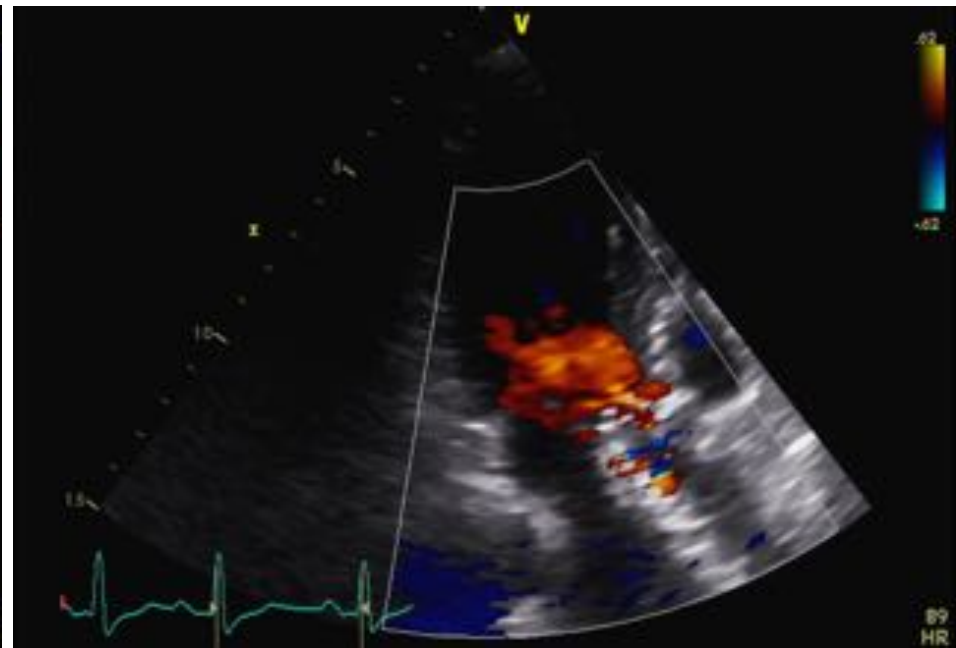
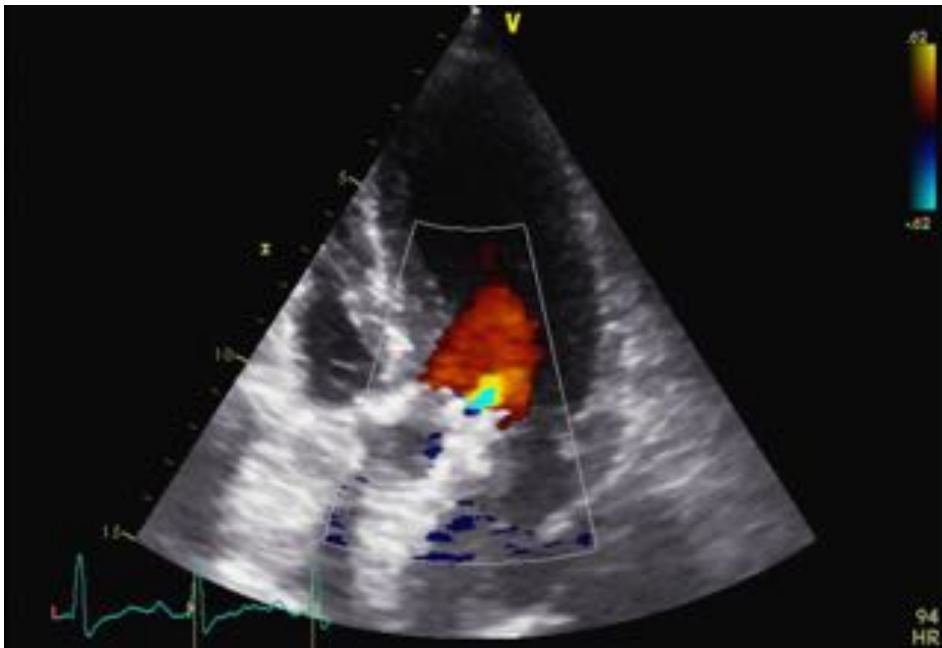


No. at Risk									
None or trace	701	678	664	647	628	621	612	605	585
Mild	210	204	199	194	188	184	182	180	175
Moderate or severe	36	32	32	26	26	24	22	22	21

Intermediate and low risk patients are expected to have 10 to 20 years of life expectancy !

Fuites para-valvulaires

Quid de la quantification ?



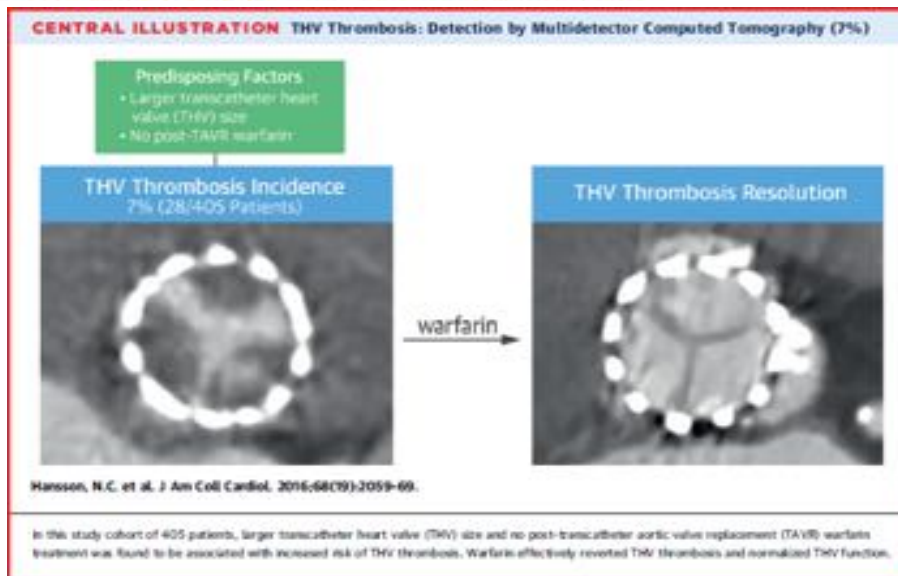
Autres problèmes...

Specificité du TAVI : La thrombose!

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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PUBLISHED BY ELSEVIER

VOL. 68, NO. 19, 2016
ISSN 0735-1097/\$36.00
<http://dx.doi.org/10.1016/j.jacc.2016.08.010>

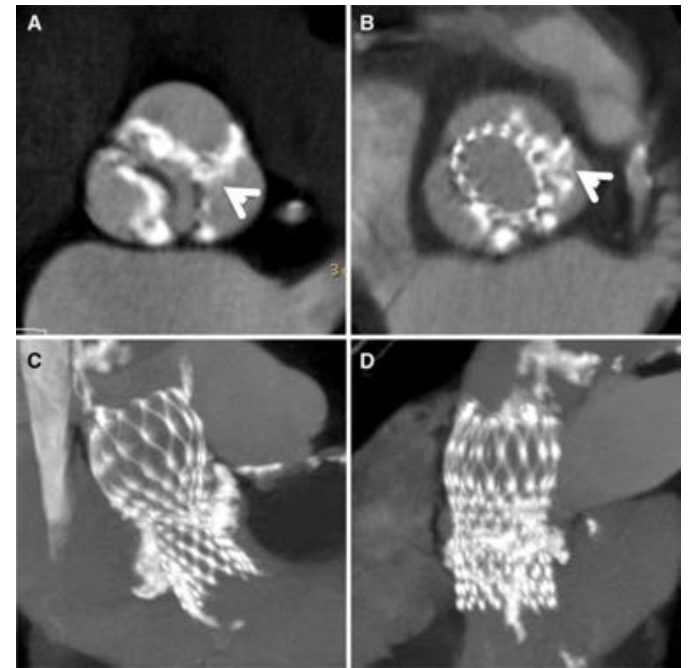
Transcatheter Aortic Valve Thrombosis Incidence, Predisposing Factors, and Clinical Implications



Prévention – traitement – Anticoagulants...

Autres problèmes...

Bicuspidie...



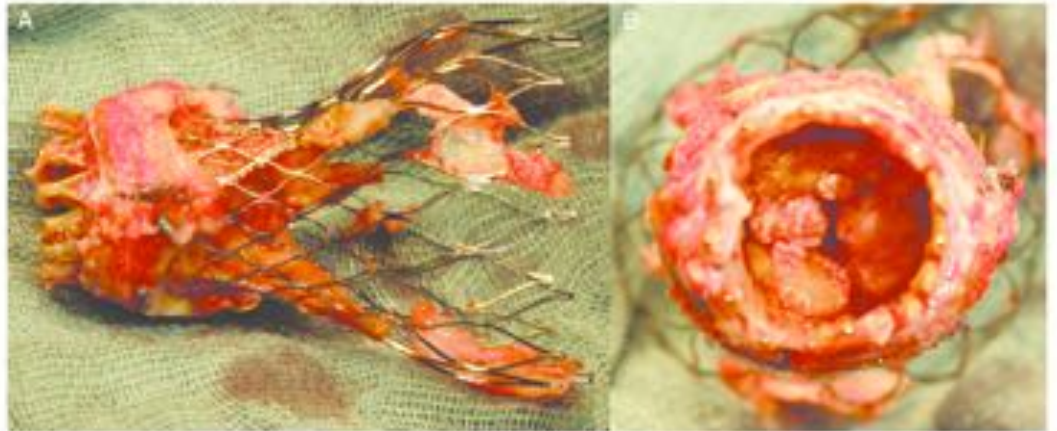
Autres problèmes...

Bicuspidie...
Accès coronaire +++



Autres problèmes...

Bicuspidie...
Accès coronaire +++
Endocardite ?!



Autres problèmes...

Bicuspidie...

Accès coronaire +++

Endocardite?!

TAVI in TAVI???

Conclusion



State of the art in TAVI

A revolution in patient care is taking place, but there is much still to learn as discussed by Dr Miles Dalby

We must however remain cautious regarding the related issues of longer-term outcomes and lower risk patients focusing in parallel on both mechanistic studies and clinical outcome trials. Transcatheter aortic valve implantation is a revolution, but we have a long way to go to approach the incredible efficiency of the native aortic root and valve.

LE TAVI POUR PERSONNE



CARDIAWAVE

