

La fuite aortique résiduelle après TAVI : une histoire réglée ?

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DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

Intervenant : Michael Angioi, Essey-lès-Nancy

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

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Incidence

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Table 1. Studies reporting paravalvular leak rates post procedure, 30 days, 6 months and one year post TAVI

Author	Journal	Year	Patients	Valve	Male n (%)	Age	Logistic EUROSCORE	Significant PVR n (%)
D'Onofrio et al (19)	J Thorac and CardiovascSurg	2012	468	ES, SXT	190 (40)	82±4	26±14.4	3 (0.6)
Tamburino et al (8)	Circulation	2011	663	MCV	292 (44)	81±7.3	23±13.7	139 (20.9)
Gotzmann et al (5)	Am J Cardiol	2012	198	MCV	93 (47)	80±6	22±16	28 (13.8)
Nuis et al (20)	Am J Cardiol	2012	211	MCV	107 (50)	80±8	13.8±8.2	24 (12)
Vasa-Nicotera et al (4)	JACC CardiovascInterv	2012	122	ES, MCV	65 (53.3)	81.7±6.8	22.4±13	20 (16.4)
Nombela-Franco et al (21)	JACC CardiovascInterv	2012	211	ES, SXT	86 (40.8)	79±8	24.9±15.2	59 (27.9)
Bagur et al (9)	JACC Cardiovasc Imaging	2011	100	ES, SXT	41 (41)	79±9	25.8±17.6	0
Masson et al (22)	Catheter cardiovascinterv	2010	136	CE, ES	69 (50.7)	85.1±6.9	29±12.5	11 (8.08)
Unbehaun et al (23)	J Am CollCardiol	2012	358	ES	120 (34)	79.5±8.3	38.2±20.7	2 (0.6)
Drews et al (24)	An ThoracSurg	2013	186	ES	64 (34.4)	81±8	63±16	2 (1.07)
Fraccaro et al (25)	Circ CardiovascInterv	2012	384	ES, MCV, SXT	185 (48)	80±7	24±15.6	16 (4.1)
Panico et al*(26)	Minerva Cardioangiol	2012	118	ES, MCV	55 (46.6)	82.5±5.87	25.8±15.4	24 (20.4)
Haensig et al*(27)	Eur J CardiothoracSurg	2012	120	ES	30 (25)	82.6±6.2	30.1±11.5	4 (3.33)
Gilard et al*(28)	N Engl J Med	May 2012	3195	MCV, ES	1630 (51)	82.7±7.2	21.9±14.3	316 (9.89)
Moat et al*(29)	J Am CollCardiol	2011	870	MCV, ES	456 (52.4)	81.9±7.1	18.5±9.4	118 (13.6)
D'Errigo et al (30)	Int J Cardiol	2012	133	MCV, SXT	83 (62.4)	79±7.4	18.8±9.5	8 (6.01)
Leon et al*(1)	N Engl J Med	2010	179	ES	82 (45.8)	83.1±8.6	26.4±17.2	21 (11.8)
Gotzmann et al (7)	Am Heart J	2011	145	MCV	NS	79.1±6.2	21±16.2	25 (17.2)
Gilard et al*(28)	N Engl J Med	2012	3195	MCV, ES	1630 (51)	82.7±7.2	21.9±14.3	316 (9.89)
Ussia et al (31)	Eur Heart J	2012	181	MCV	80 (44.2)	80±6.1	24±13.5	32 (17.7)
Gilard et al*(28)	N Engl J Med	2012	3195	MCV, ES	1630 (51)	82.7±7.2	21.9±14.3	316 (9.89)
Leon et al*(1)	N Engl J Med	2010	179	ES	82 (45.8)	83.1±8.6	26.4±17.2	21 (11.8)
Panico et al*(26)	Minerva Cardioangiol	2012	118	ES, MCV	55 (46.6)	82.5±5.87	25.8±15.4	24 (20.4)

ES Edward Sapien, MCV Medtronic CoreValve, SXT Sapien XT, ECHO echocardiography, PP post procedure, NS not specified, * included at more than one time point.

Dans les premières études

Incidence de la fuite paraprothétique après TAVI très variable : de 0,6 à 27,9 %

Dans France 2012 : 9,89 %

Impact pronostic

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Impact pronostic d'une fuite paraprothétique dans PARTNER

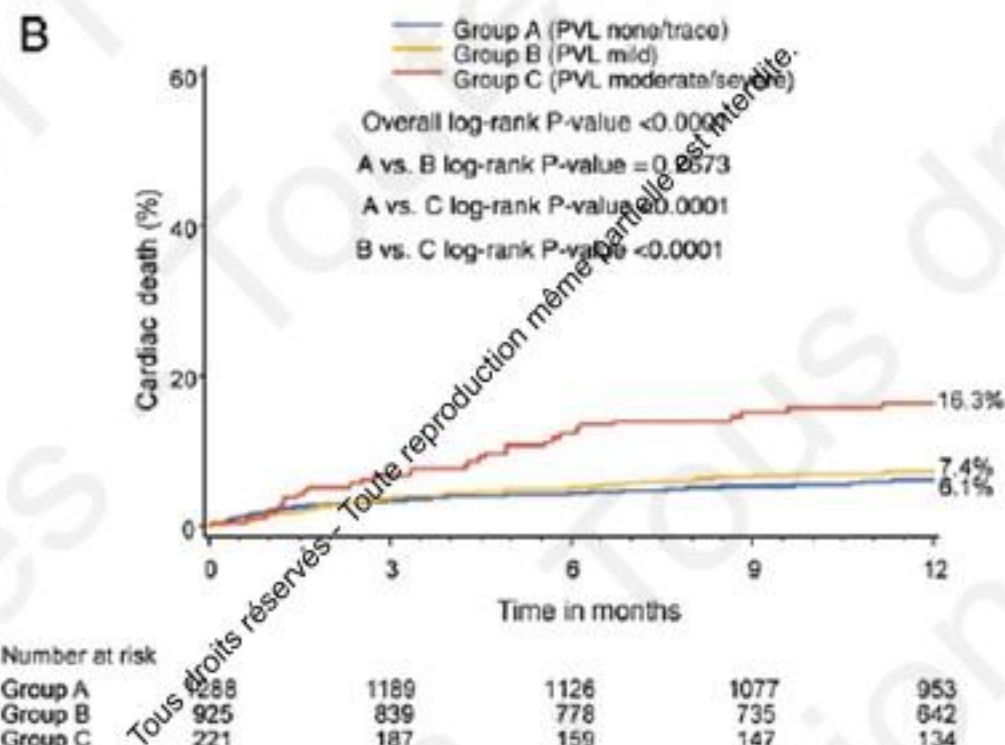
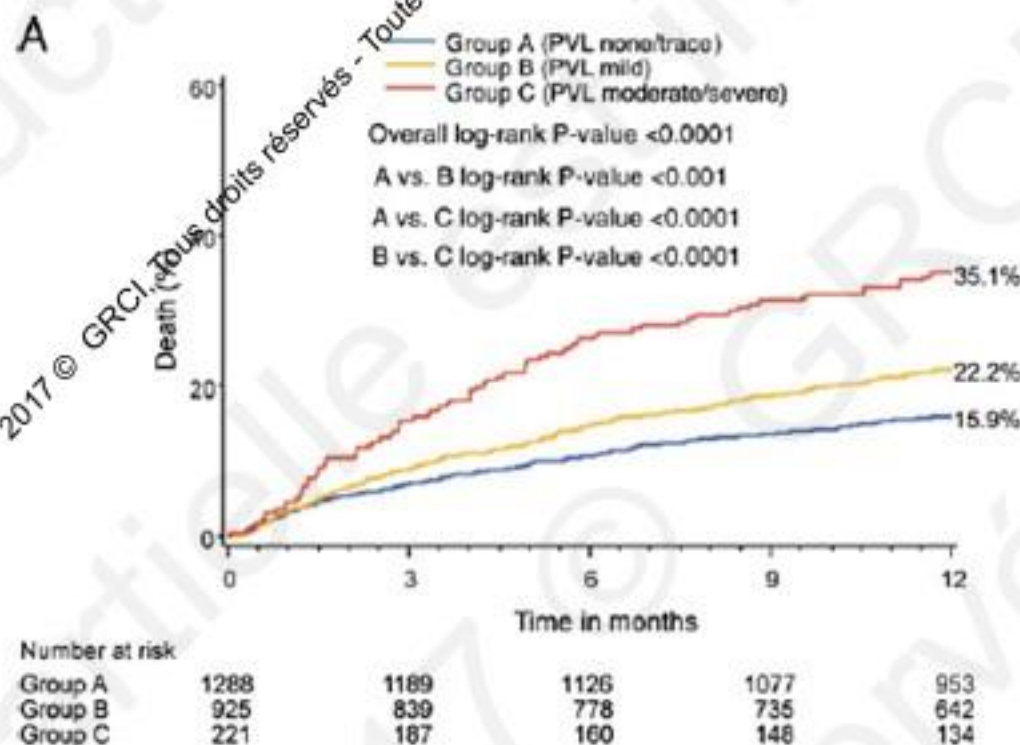


Table 4 Multivariable predictors of all-cause 1-year mortality

Multivariable analysis: baseline and procedural predictors of 1-year mortality

Variable	Hazard ratio	95% Confidence interval	P-value ^a
Major arrhythmia	1.41	1.14–1.75	0.002
TF vs. TA	0.73	0.59–0.91	0.005
AV annulus diameter (per 1 mm increase)	1.07	1.03–1.11	0.001
BMI (per 1 kg/m ² increase)	0.95	0.93–0.97	<0.0001
Total distance walked (per 10-m increase)	0.97	0.96–0.98	<0.0001
AV mean gradient (per 1 mmHg)	0.98	0.97–0.99	<0.0001
Paravalvular regurgitation			
None/trace	Referent	–	–
Mild	1.35	1.07–1.72	0.013
Moderate/severe	2.20	1.60–3.03	<0.0001
Renal disease (CR ≥ 2)	1.35	1.04–1.74	0.023

Potential covariates: age, sex, BMI, STS score, DM, smoking, prior CABG, prior BAV, frailty, renal disease, access route, major arrhythmia, pacemaker, chronic obstructive pulmonary disease, anaemia, 6 min walk, total distance walking (imputing 0 time for those who do not walk), LV ejection fraction, LV mass, LVED, LVES, AV annulus diameter, AV mean gradient, and baseline moderate/severe total AR.

^aAll results are from Cox regression.

La fuite paraprothétique est un facteur indépendant de mortalité à un an après TAVI



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Registre France 2

TABLE 2 Multivariable Predictors of 3-Year All-Cause Mortality

	Patients (n)	Events (n)	3-Yr Death Rate (%)	Univariable Analysis		Multivariable Analysis	
				Unadjusted HR (95% CI)	p Value	Adjusted HR (95% CI)	p Value
Post-implant periprosthetic AR grade							
0-1	3,072	1,085	36.0	1.00		1.00	
2-4	529	245	47.1	1.49 (1.29-1.71)	<0.001	1.50 (1.30-1.73)	<0.001
All patients	4,201	1,731					

AR – aortic regurgitation; CI – confidence interval; HR – hazard ratio; NYHA – New York Heart Association.

Evolution des fuites dans CoreValve US pivotal trial

FIGURE 2 Paired PVAR Data at Discharge and 1 Year

<i>Discharge</i>	<i>One Year</i>				
	None (N = 123)	Trivial (N = 143)	Mild (N = 102)	Moderate (N = 14)	Severe (N = 1)
None	49	18	7	1	0
Trivial	50	48	34	2	0
Mild	23	66	42	6	0
Moderate	1	11	18	5	1
Severe	0	0	1	0	0

■ Improvement in PVAR by at least 1 grade
■ Worsening in PVAR by at least 1 grade

Of 173 patients with mild (n = 137) or moderate (n = 36) paravalvular aortic regurgitation (PVAR) at discharge, 119 (69%) improved by at least 1 grade at 1-year follow-up. **Green** = improvement in PVAR by at least 1 grade, **brown** = worsening in PVAR by at least 1 grade.

Mécanismes et facteurs prédictifs

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Insuffisance aortique post-TAVI

Classification	Etiologie	Mécanisme
Paravalvulaire	Mismatch anneau-prothèse Apposition incomplète Implantation haute-basse	Mauvais sizing Calcifications (étendue, localisation) Bicuspidie, anneau excentrique Angle Ao/CCVG gros/petit anneau Mauvaise technique
Centrale	Mismatch anneau-prothèse Prothèse endommagée	Mauvais sizing Dysfonction prothétique

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FIGURE 1 Regions of the Aortic Valve Complex

The left ventricular outflow tract (LVOT) region (**blue bracket**) is defined as the cross-sectional region 5 mm inferior to the annular plane to the annular plane (**pink line**). The Annulus region (**green bracket**) is defined as the cross-sectional region 2 mm inferior to the annular plane to 3 mm superior to the annular plane. The Leaflet region (**red bracket**) is defined as the cross-sectional region 3 mm superior to the annular plane to the cranial portion of the leaflets. The AnnulusLVOT (not shown) section encompasses the Annulus and LVOT regions.

TABLE 3 AVC prediction of Greater Than or Equal to Mild PVR Using ROC Analysis

	AUC	Cutoff (mm ²)	Sensitivity	Specificity	p Value
LVOTCa	0.652	17.6	61	67	0.013
Δ LVOTCa	0.648	17.6	57	67	0.017
AnnulusCa	0.663	107.2	71	57	0.002
Δ AnnulusCa	0.687	19.9	71	64	0.002
AnnulusLVOTCa	0.666	107.2	79	57	0.0019
Δ AnnulusLVOTCa	0.689	69.9	71	62	0.0015
LeafletCa	0.635	988.9	64	67	0.025
Δ LeafletCa	0.571	NS	NS	NS	0.252

AUC = area under the curve; AVC = aortic valve calcification; NS = non-significant; ROC = receiver-operating characteristic; other abbreviations as in Tables 1 and 2.

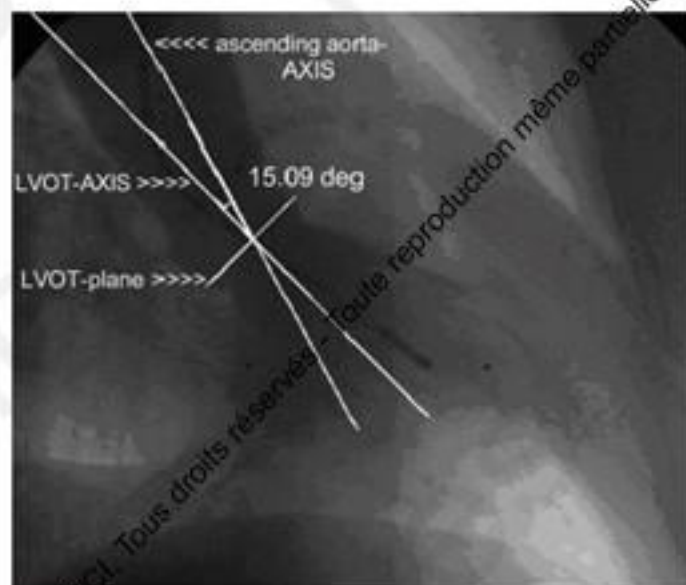


Figure 1 Measurement of \angle LVOT-AO Using Left Ventriculography in RAO 30°

The \angle LVOT-AO is the angle between the axis of the first 4 cm of the ascending aorta (AO), representing the contact surface with the upper part of the bioprosthesis, and the left ventricular outflow tract (LVOT) axis, representing the landing zone of the prosthesis. This angle was assessed using left ventriculography in right anterior oblique (RAO) projection 30° during preparation of the patients for the procedure.

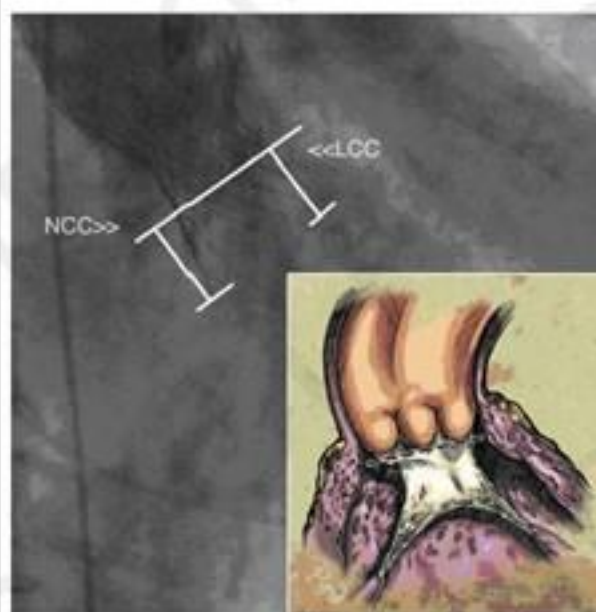


Figure 2 Measurement of Depth of Medtronic CoreValve Bioprosthesis Using Fluoroscopy in Relation to NCC and LCC

The depth of the final device position in the left ventricular outflow tract measured using the final aortogram of the deployed bioprosthesis in the right anterior oblique projection is shown. The depth of delivery is defined as the distance from the native aortic annular margin on the side of both the noncoronary cusp (NCC) and the left coronary cusp (LCC) to the most proximal edge of the corresponding side of the deployed stent frame. Figure was created by Craig Skaggs.

Multivariate regression model for the independent predictors

\angle LVOT-AO	0.21	0.06	1.26 (1.09-1.41)	<0.01
Depth to NCC, mm	-1.82	0.85	0.16 (0.03-0.85)	0.03
Depth to NCC squared	0.09	0.04	1.10 (1.01-1.19)	0.02

Predicteurs de fuite paravalvulaire avec la Medtronic CoreValve

Sherif MA et al

J Am Coll Cardiol 2010 ; 20

Un oversizing de 1 mm en diamètre ou de 10 % en surface réduit significativement les fuites paraprothétiques

Table 4

The Relationship Between Undersizing a THV Relative to the MDCT Annular Size and Increasing Grade of PAR

Grade of PAR	THV Diameter – Mean Annular Diameter (mm)	Percentage Difference Between the THV Area and Annular Area*
None/trivial	1.5 ± 1.8	14.2 ± 18.3
Mild	0.4 ± 1.8	4.3 ± 14.2
Moderate/severe	-0.7 ± 1.4	-7.0 ± 9.5
p value	<0.01	<0.01

Values are mean ± SD and measured in systole. *A positive percentage represents the amount that the THV area is greater than the annular area. Conversely, a negative percentage represents the amount that the THV area is less than the annular area. Calculated by (THV area/annular area - 1) × 100.

Abbreviations as in Table 3.

Analyse du scanner +++++
Sizing +++++
Choix de la prothèse +++++

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Influence des nouvelles prothèses sur l'incidence des fuites para-prothétiques

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Fig. 1. Compared to the traditional Medtronic CoreValve® prosthesis (left side), new features of the Medtronic Evolut R™ (right side) include a new design of the nitinol frame with a lower height and an extended sealing skirt (© Medtronic).

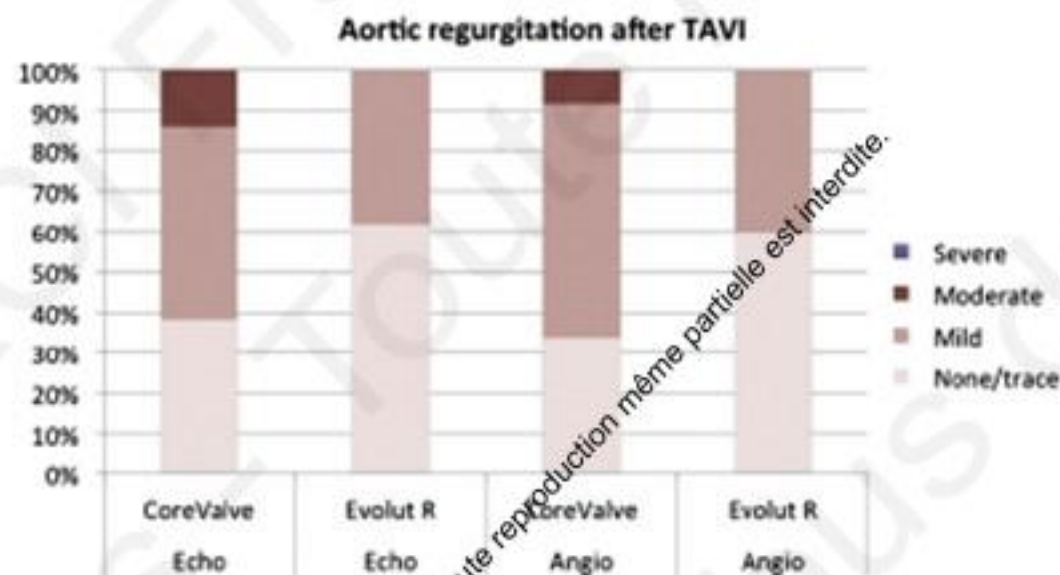


Fig. 2. Degree of residual aortic regurgitation after TAVI as assessed by transthoracic echocardiography (left columns) or aortic root angiography (right columns).

Taux de fuite modérée avec la CoreValve Evolut R



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Low Frame Height
• Respects the cardiac anatomy



Bovine Pericardial Tissue
• Scalloped leaflet shape
• Utilizes the same bovine pericardial tissue and processes as Edwards surgical valves

Inner Skirt
• Polyethylene terephthalate (PET)

Outer Sealing Skirt
• PET outer sealing skirt designed to minimize paravalvular leak

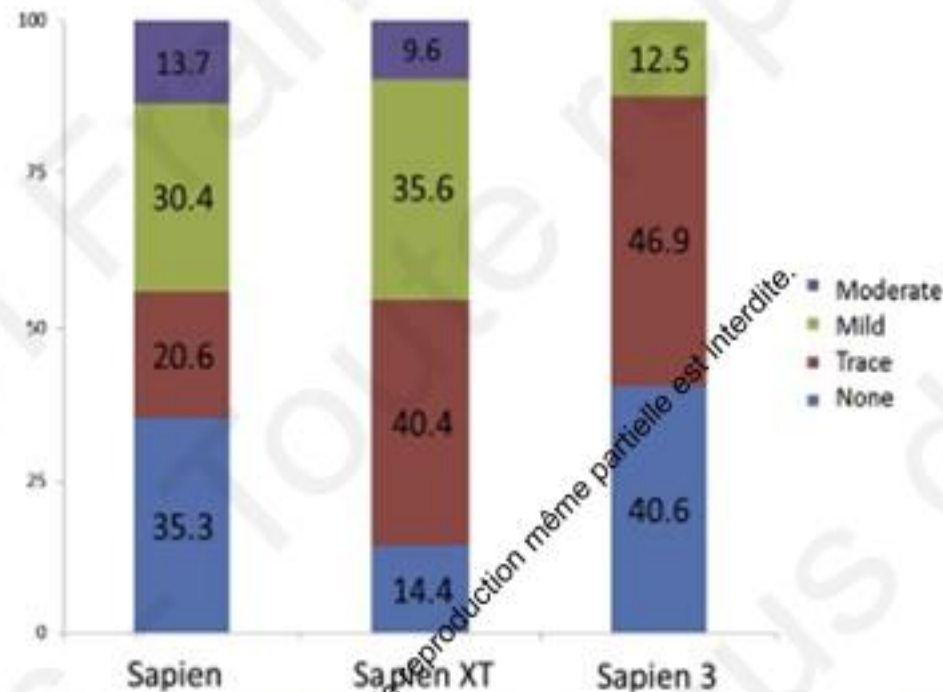
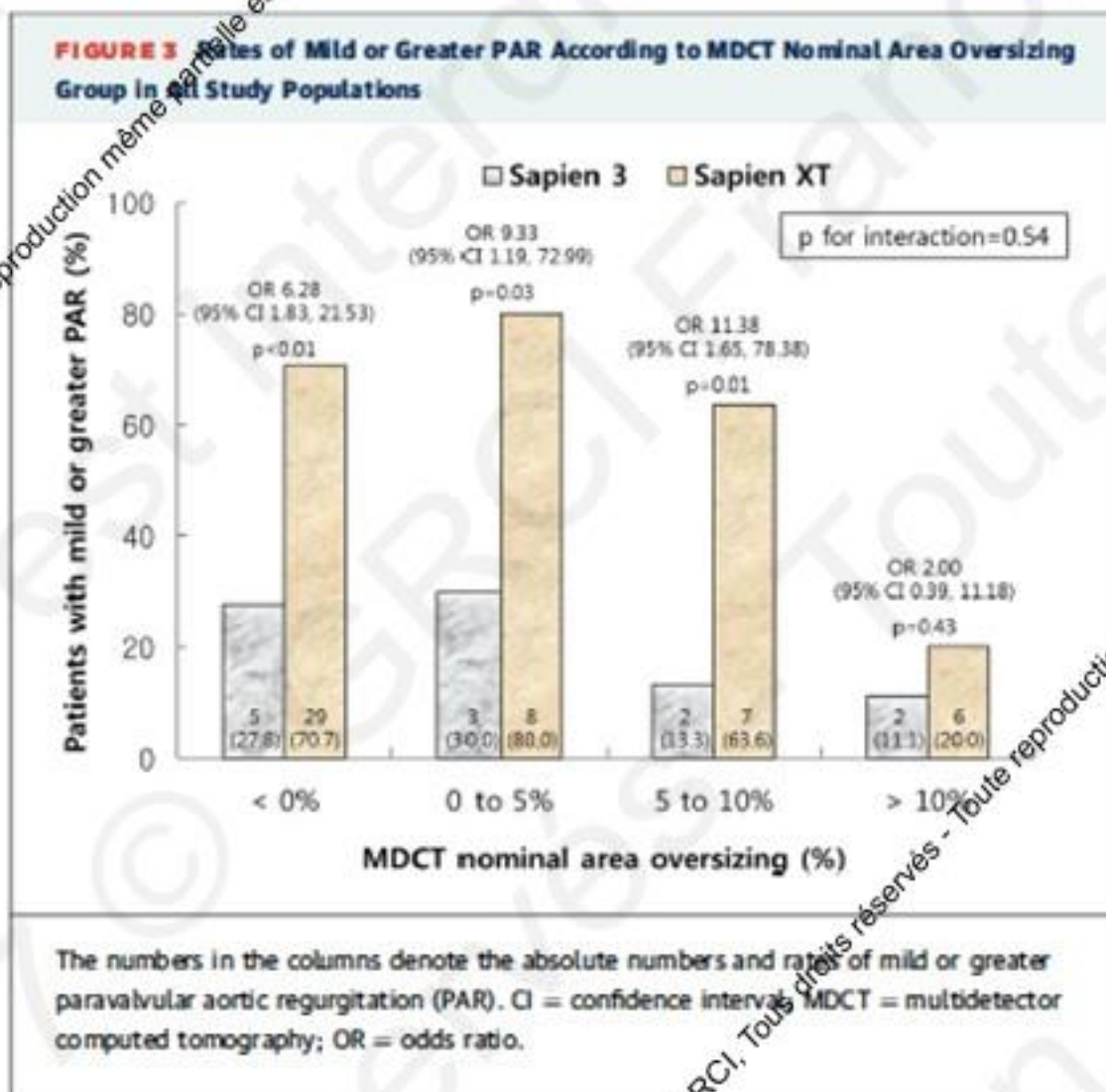


Figure 2. PVR evaluated by transeosophageal echocardiography immediately after TAVI. Note the significant reduction in moderate and severe PVR frequency after TAVI (13.7% in the SAPIEN group, 9.6% in the SAPIEN XT, and 0% in the SAPIEN 3 group; $p = 0.01$).

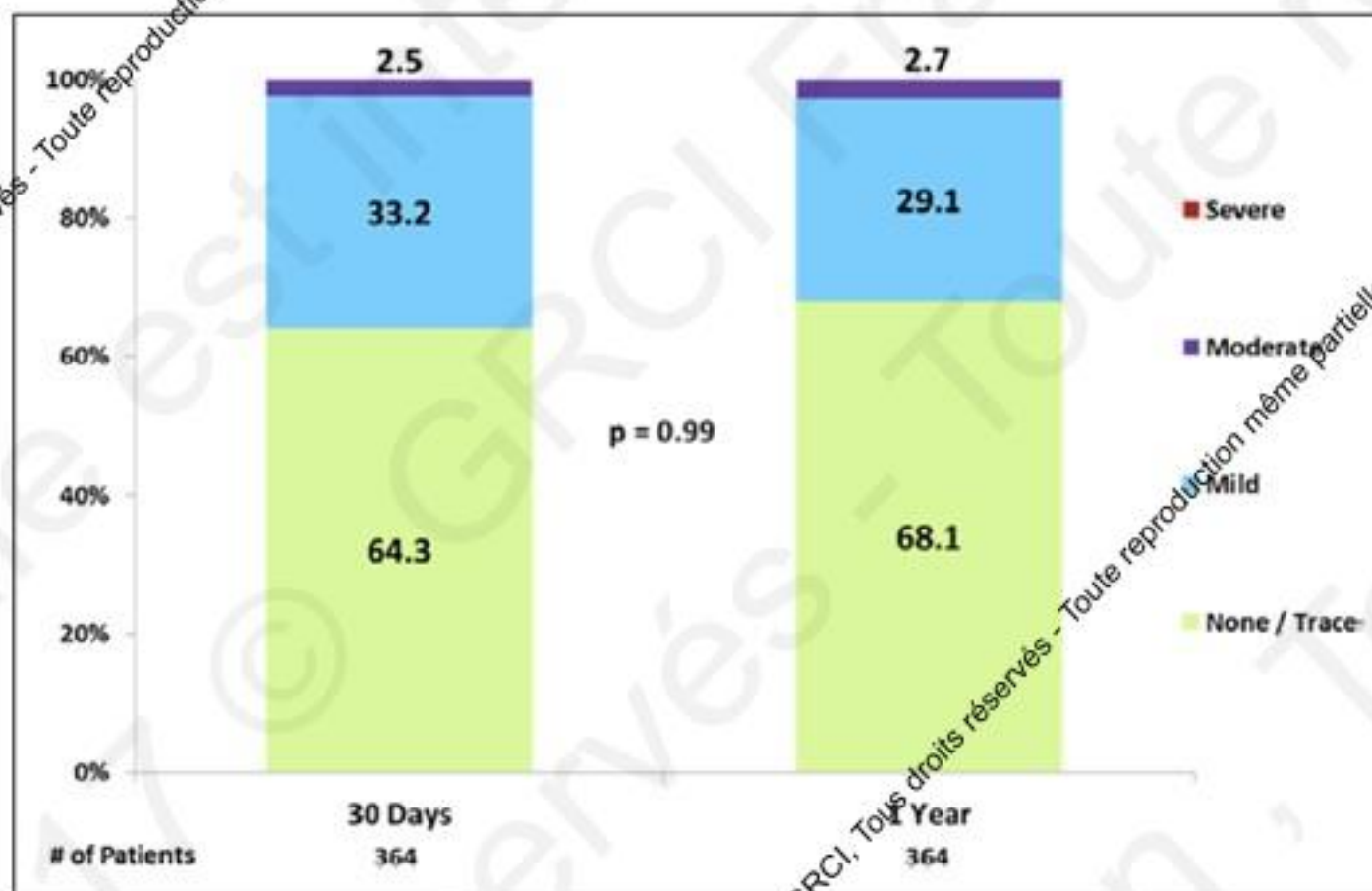
Table 3
Univariate and multivariate associations of PVR after TAVI

Variable	Univariate		Multivariate	
	Odds ratio (95% confidence interval)	p-value	Odds ratio (95% confidence interval)	p-value
Aortic annulus area derived from MDCT, (mm ²)	1.006 (1.000-1.011)	0.045	0.997 (0.988-1.006)	0.480
Cover index (%)	0.016 (0.001-0.387)	0.011	0.012 (0.000-2.038)	0.083
Log transformed Agatston calcium score	2.997 (1.318-6.817)	0.009	3.478 (1.424-8.498)	0.006
SAPIEN 3 valve	0.381 (0.194-0.749)	0.005	0.306 (0.146-0.642)	0.002

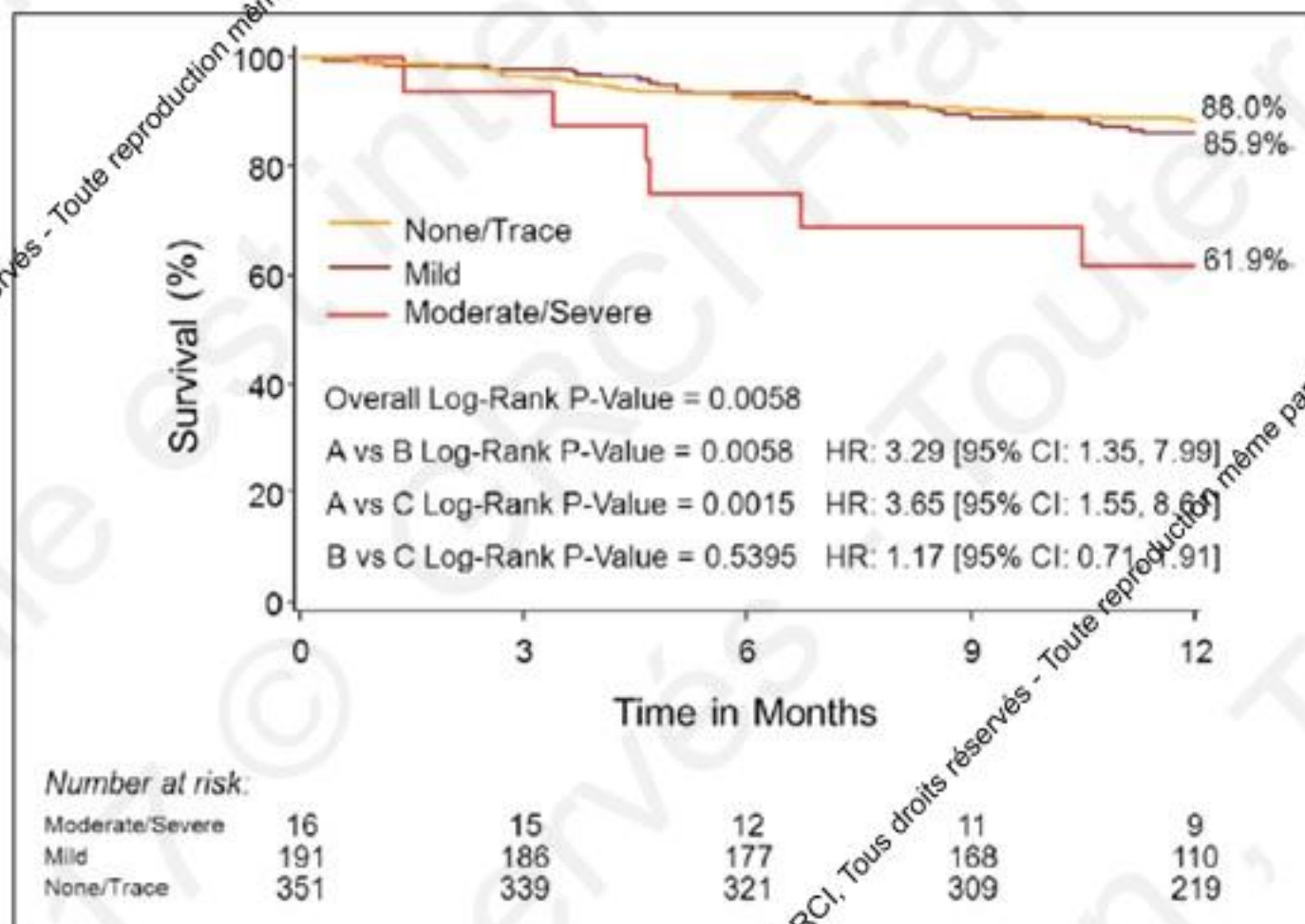
MDCT = multidetector row computed tomography.



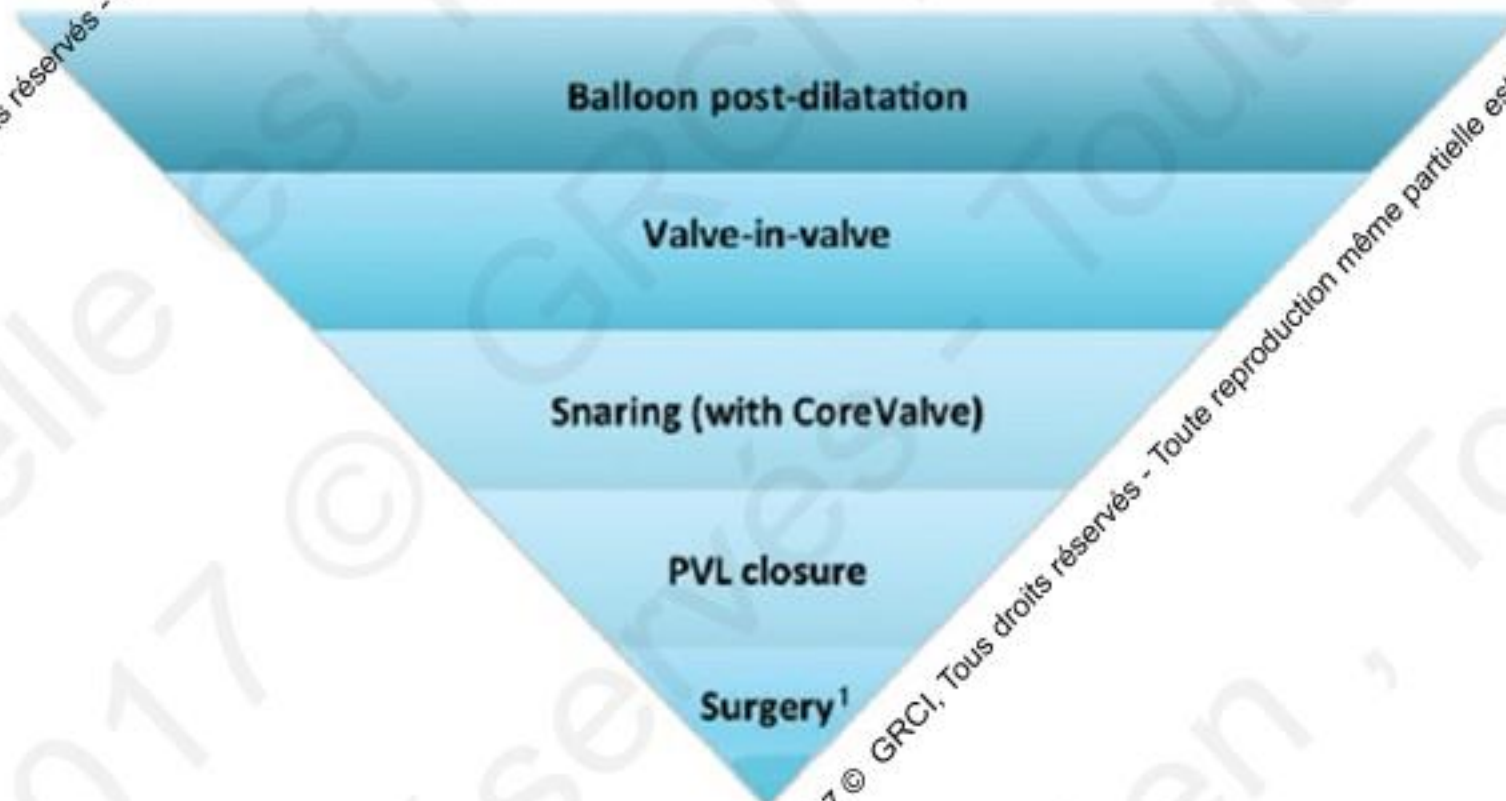
Résultats Partner II S3 High risk cohort



Incidence sur la mortalité



Traitement de la fuite paraprothétique



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Conclusion

- Diminution importante de l'incidence des fuites par amélioration du matériel
- Impact pronostic toujours présent
- Préparation de la procédure +++
 - Facteurs prédictifs, scanner
 - Sizing et choix de la prothèse
- Correction en salle

**Merci de votre
attention !**



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