

Revue de la littérature

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*« On se sert des statistiques comme un ivrogne
le fait d'un lampadaire,*



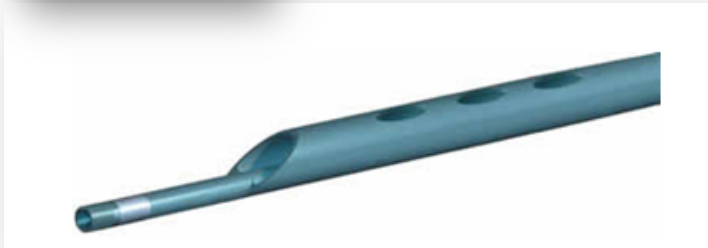
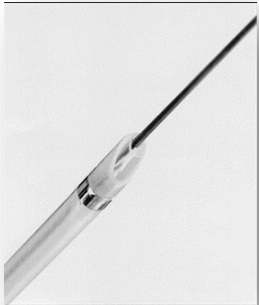
Pr David Holmes (Mayo Clinic)

*« On se sert des statistiques comme un ivrogne
le fait d'un lampadaire, **plus pour tenir debout
que pour s'éclairer !** »*



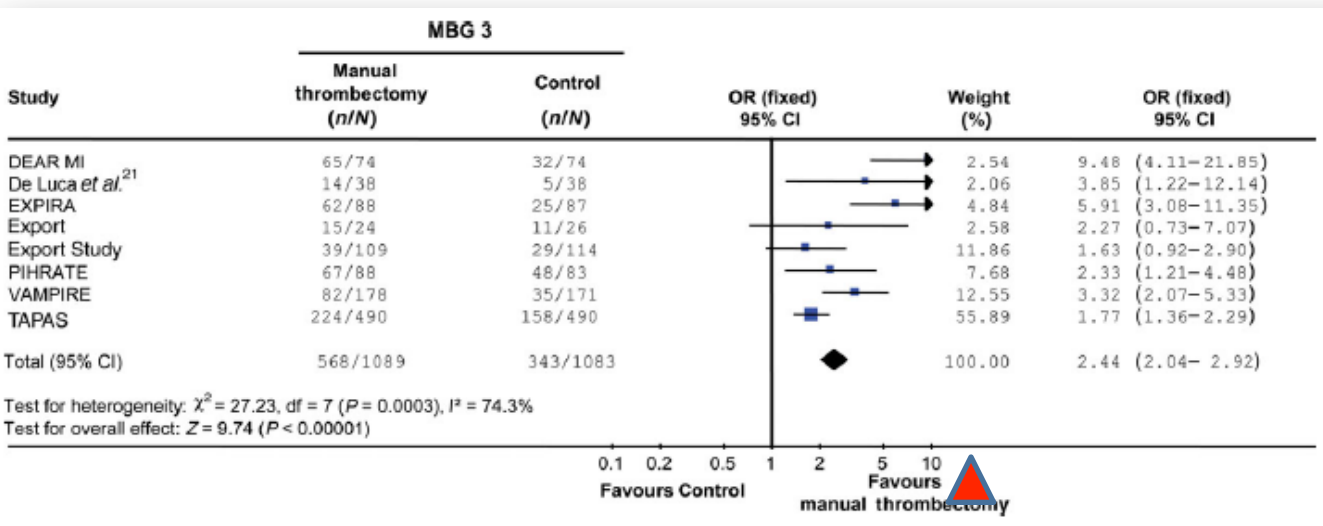
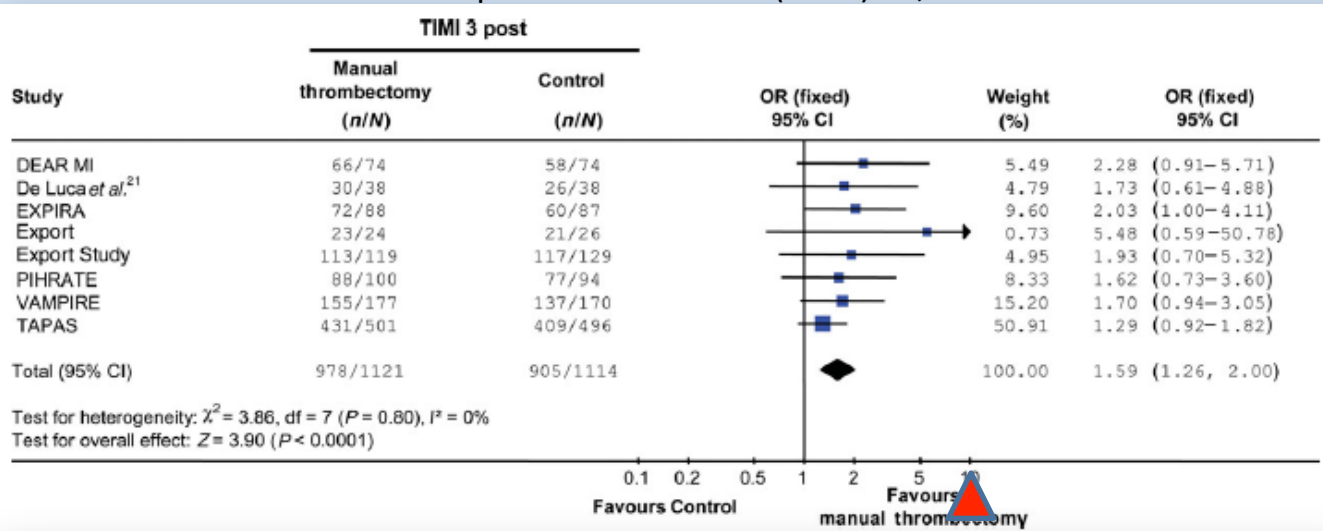
Pr David Holmes (Mayo Clinic)

- Pendant des années j'ai cru que « thrombo-aspirer », c'était bien



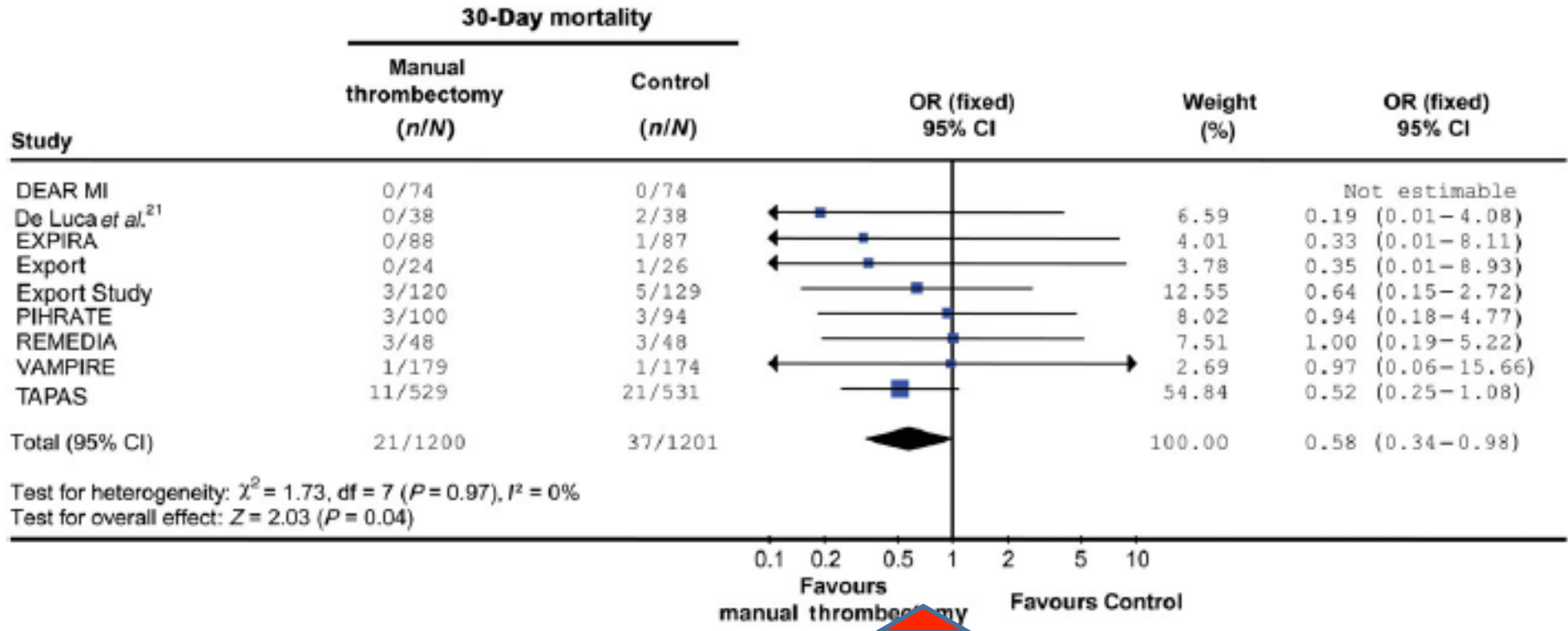
Meta analysis Manual Thrombectomy

Deluca G et al European Heart Journal (2008) 29, 3002–3010



Meta analysis Manual Thrombectomy

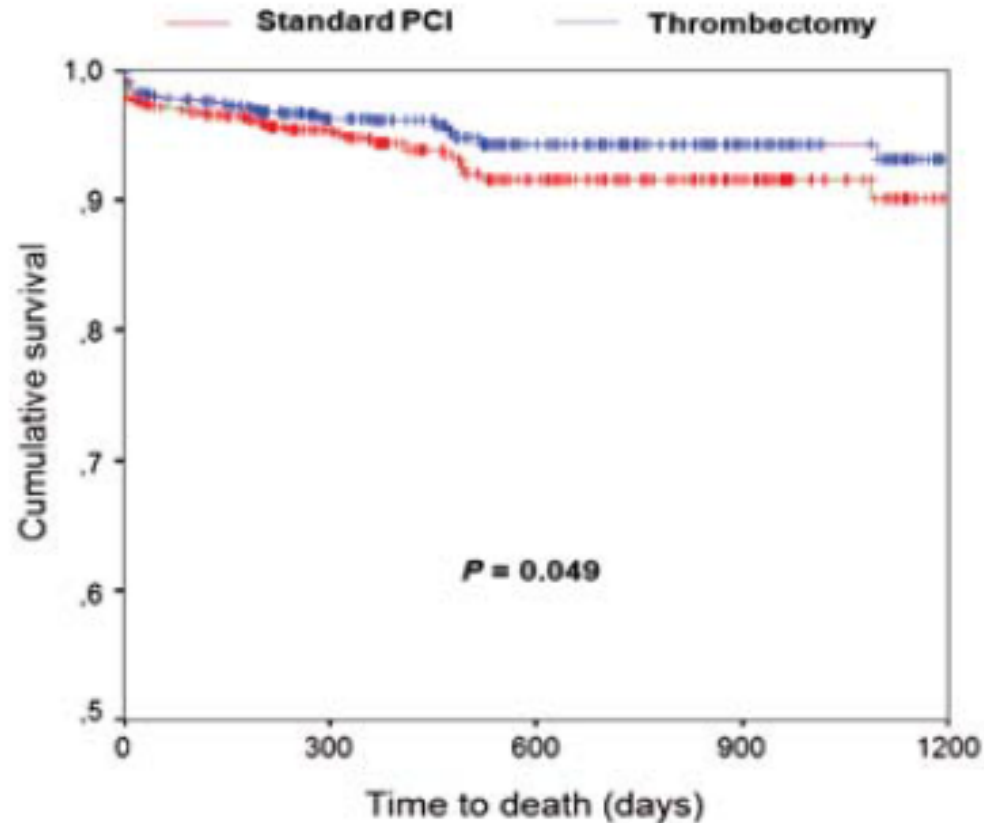
Deluca G et al European Heart Journal (2008) 29, 3002–3010



1,7 % vs 3,1 %

ATTEMPT

Burzotta et al EHJ 2009 30;2193-2203

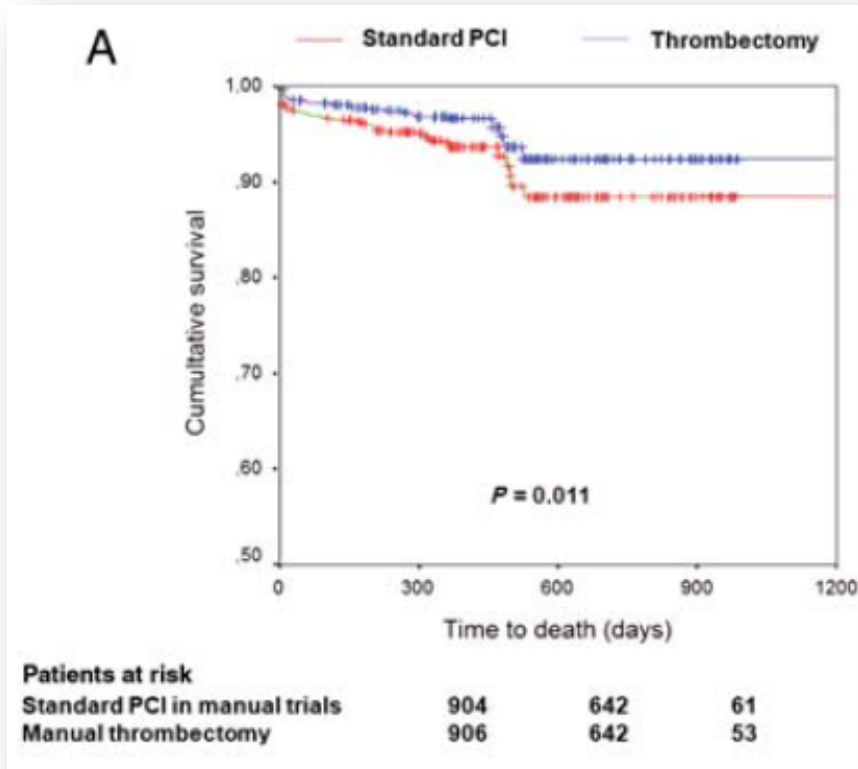


Patients at risk

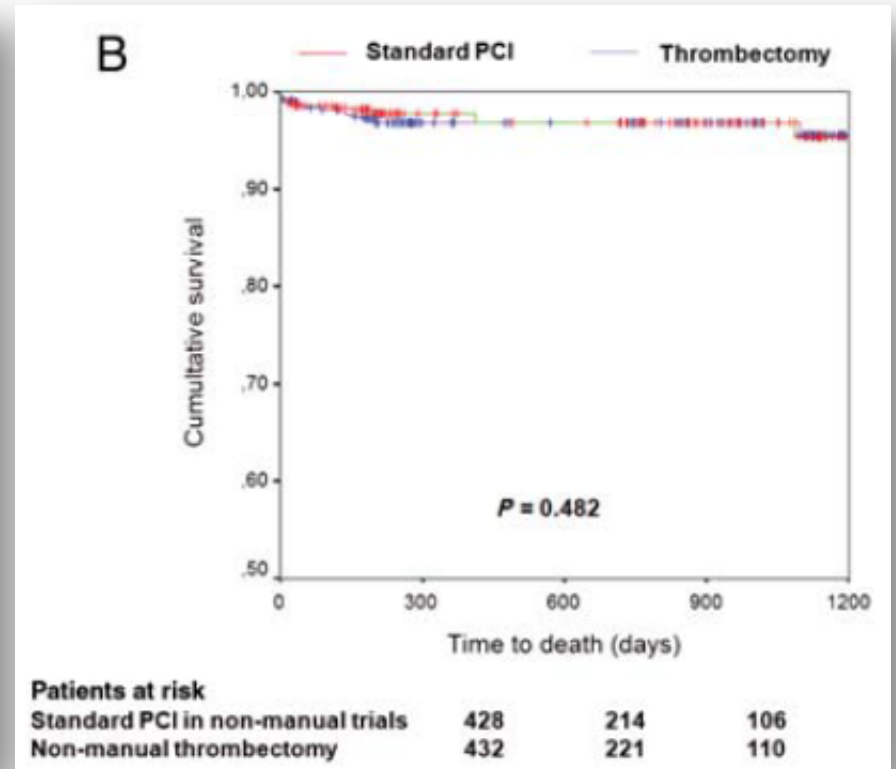
Standard PCI	1333	857	167	97	37
PCI with thrombectomy	1339	864	164	101	48

ATTEMPT

Burzotta et al EHJ 2009 30;2193-2203



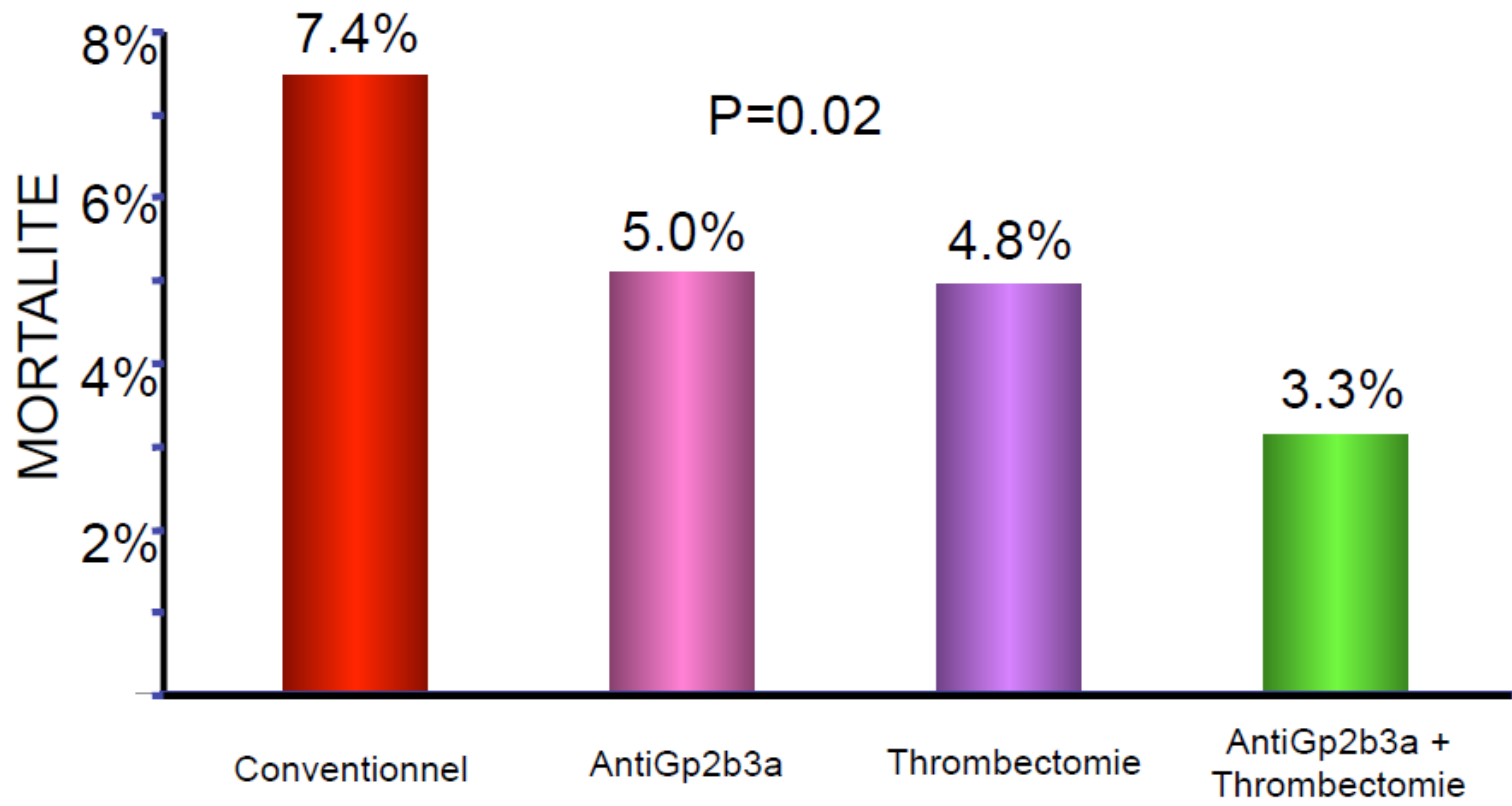
Manual thrombectomy



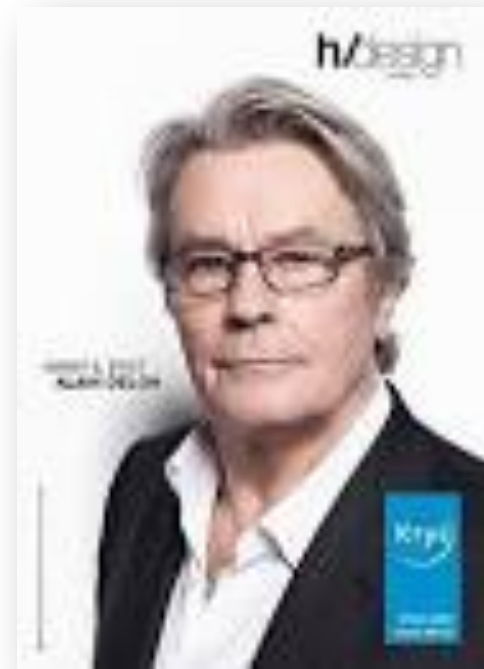
Mechanical thrombectomy

ATTEMPT

Burzotta et al EHI 2009 30;2193-2203



- Mais ça c'était avant



TASTE

The NEW ENGLAND
JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

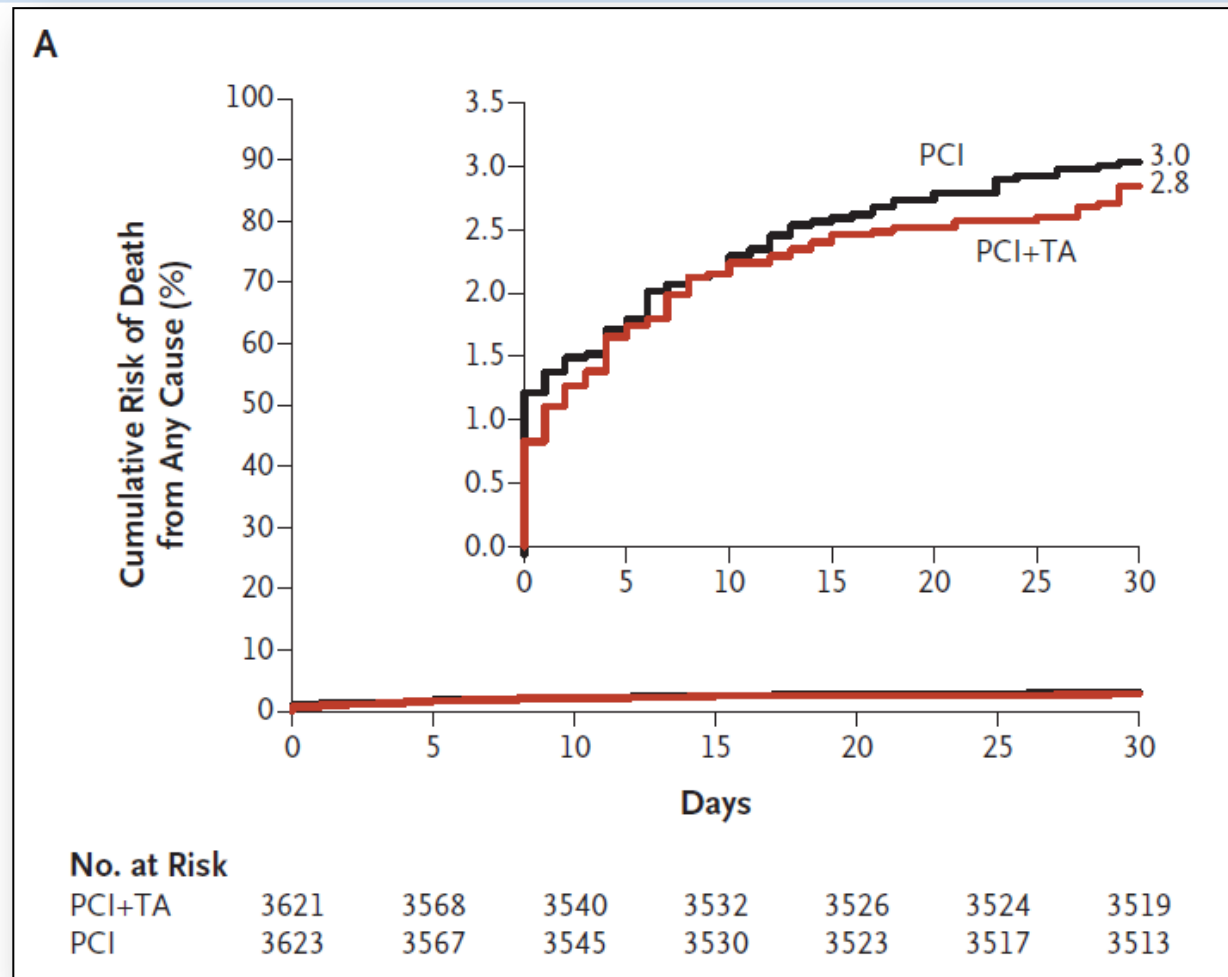
OCTOBER 24, 2013

VOL. 369 NO. 17

Thrombus Aspiration during ST-Segment Elevation
Myocardial Infarction

Ole Fröbert, M.D., Ph.D., Bo Lagerqvist, M.D., Ph.D., Göran K. Olivecrona, M.D., Ph.D., Elmir Omerovic, M.D., Ph.D., Thorarinn Gudnason, M.D., Ph.D., Michael Maeng, M.D., Ph.D., Mikael Aasa, M.D., Ph.D., Oskar Angerås, M.D., Fredrik Calais, M.D., Mikael Danielewicz, M.D., David Erlinge, M.D., Ph.D., Lars Hellsten, M.D., Ulf Jensen, M.D., Ph.D., Agneta C. Johansson, M.D., Amra Kåregren, M.D., Johan Nilsson, M.D., Ph.D., Lotta Robertson, M.D., Lennart Sandhall, M.D., Iwar Sjögren, M.D., Ollie Östlund, Ph.D., Jan Harnek, M.D., Ph.D., and Stefan K. James, M.D., Ph.D.

La thrombo-aspiration ne marche pas en Suède !



TASTE

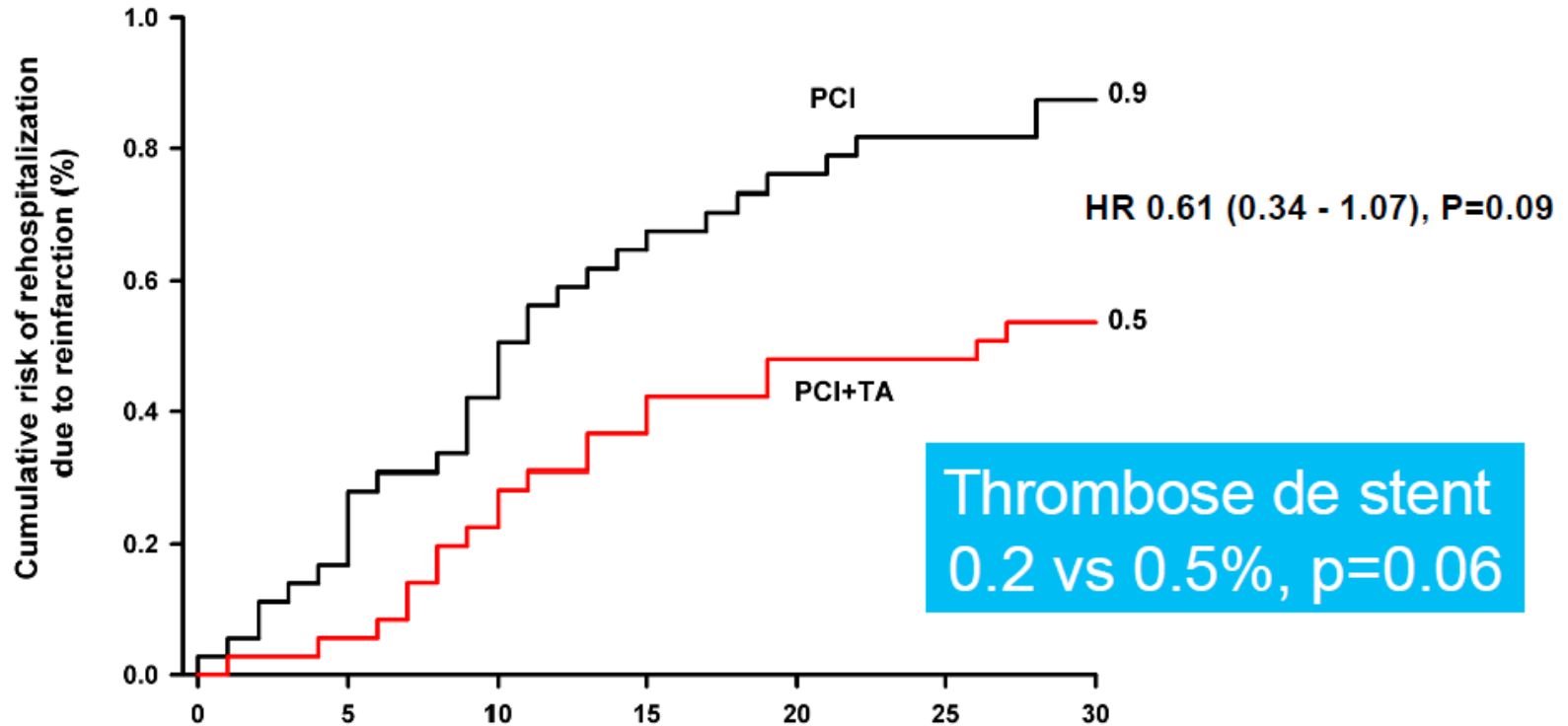
TASTE

Alors on a dit que....

Contrairement à TAPAS les patients étaient randomisés après l'angiographie

- ✓ Thrombectomie non standardisée
- ✓ Angioplastie non standardisée
- ✓ Pas de monitoring
- ✓ Pas de comité pour les évènements
- ✓ Pas de Corelab (Thrombus, ECG, Blush, Timi, embolies ...)

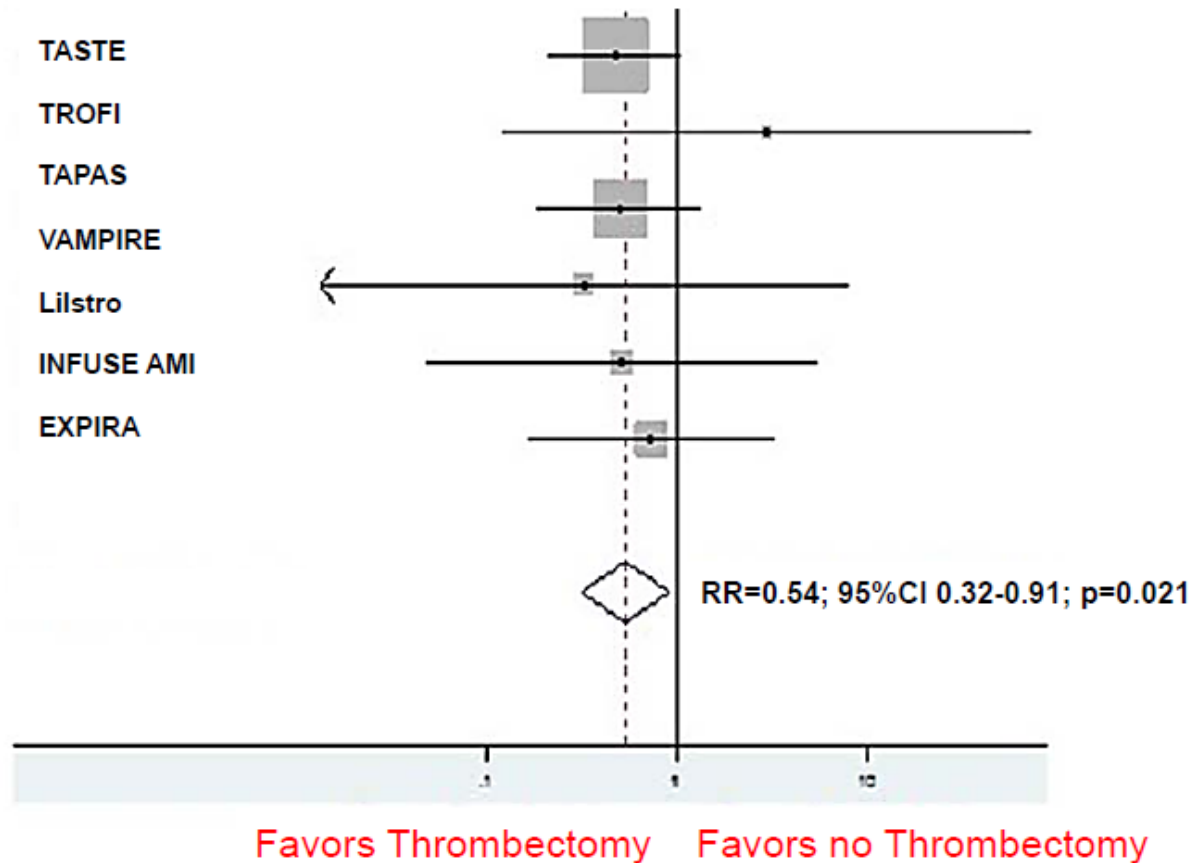
Et puis, peut-être pas si négative



No. at Risk

PCI+TA	3621	3567	3533	3520	3512	3508	3501
PCI	3623	3562	3533	3509	3498	3489	3483

Sur les thromboses de stents



Et puis c'était en Suède ...



9 avril 2015 !

TOTAL

The NEW ENGLAND
JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

APRIL 9, 2015

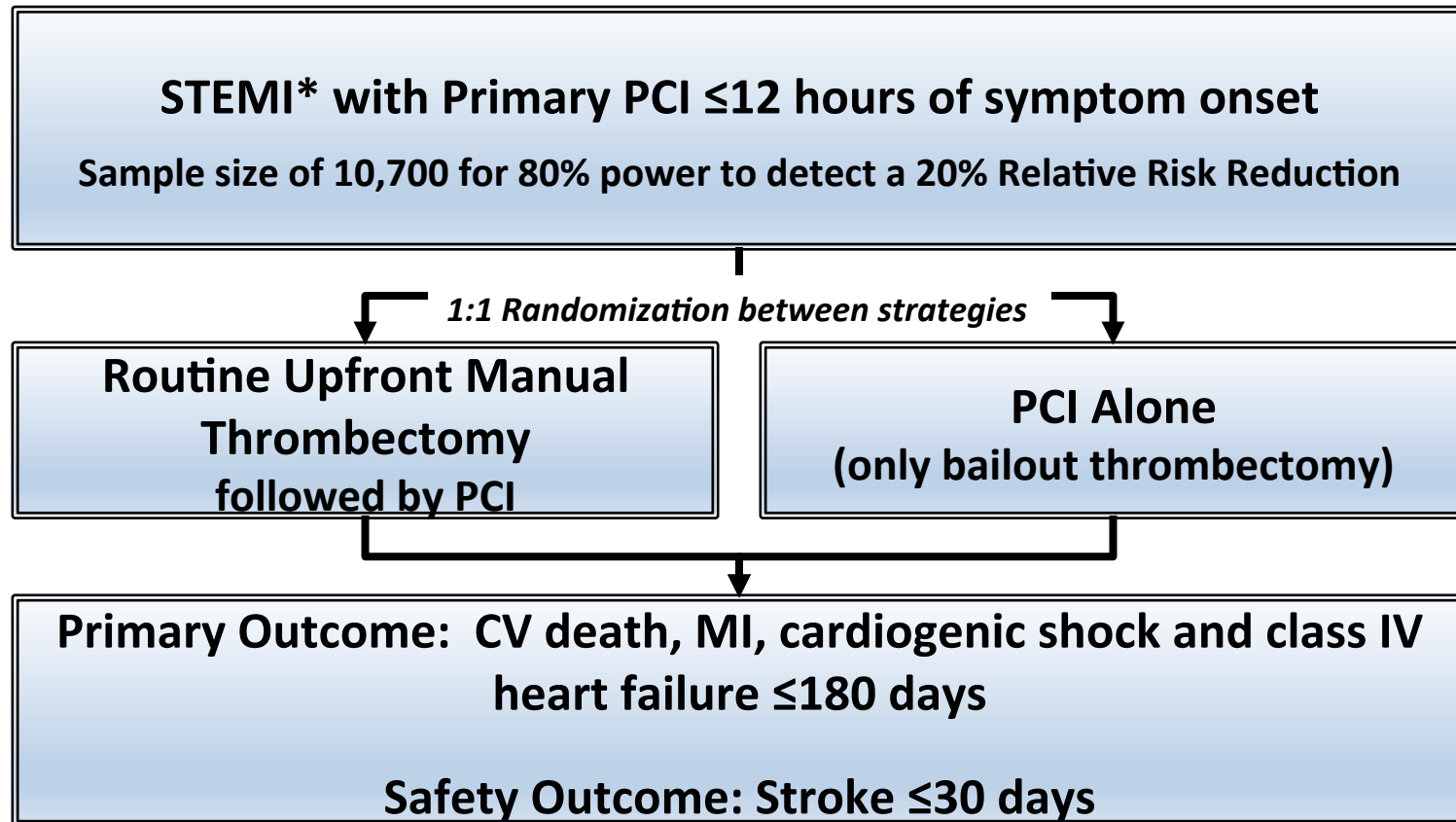
VOL. 372 NO. 15

Randomized Trial of Primary PCI with or without Routine
Manual Thrombectomy

S.S. Jolly, J.A. Cairns, S. Yusuf, B. Meeks, J. Pogue, M.J. Rokoss, S. Kedev, L. Thabane, G. Stankovic, R. Moreno, A. Gershlick, S. Chowdhary, S. Lavi, K. Niemelä, P.G. Steg, I. Bernat, Y. Xu, W.J. Cantor, C.B. Overgaard, C.K. Naber, A.N. Cheema, R.C. Welsh, O.F. Bertrand, A. Avezum, R. Bhindi, S. Pancholy, S.V. Rao, M.K. Natarajan, J.M. ten Berg, O. Shestakovska, P. Gao, P. Widimsky, and V. Džavík, for the TOTAL Investigators*

Plus de 10 000 patients randomisés

The TOTAL Trial Study Design

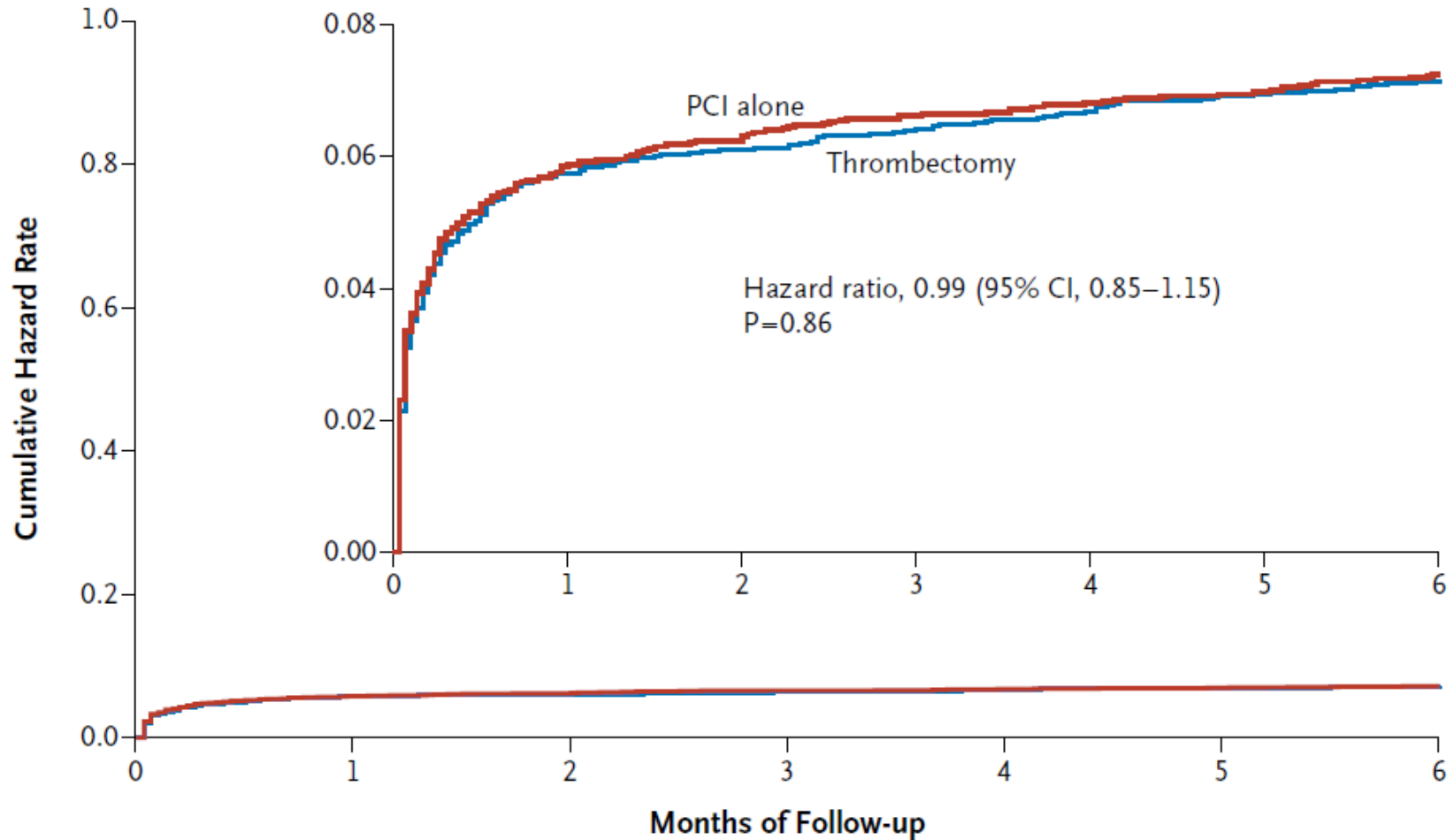


Bailout Thrombectomy allowed if PCI alone strategy fails:

- Persistent TIMI 0 or 1 flow with large thrombus after balloon pre-dilatation
 - Persistent large thrombus after stent deployment at target lesion

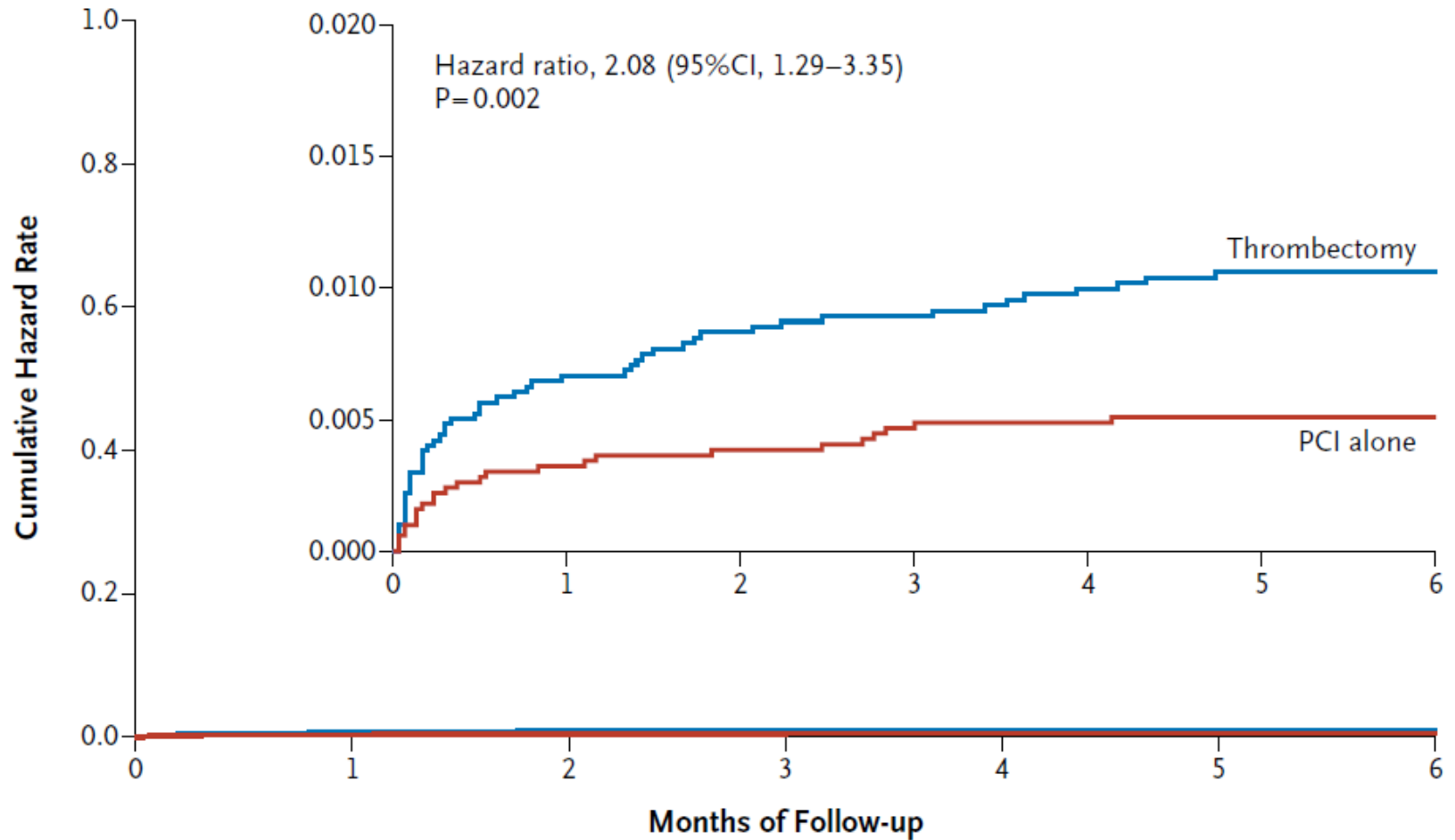
Décès CV, IDM, Choc, Classe IV

A Primary Outcome



Stroke

B Stroke



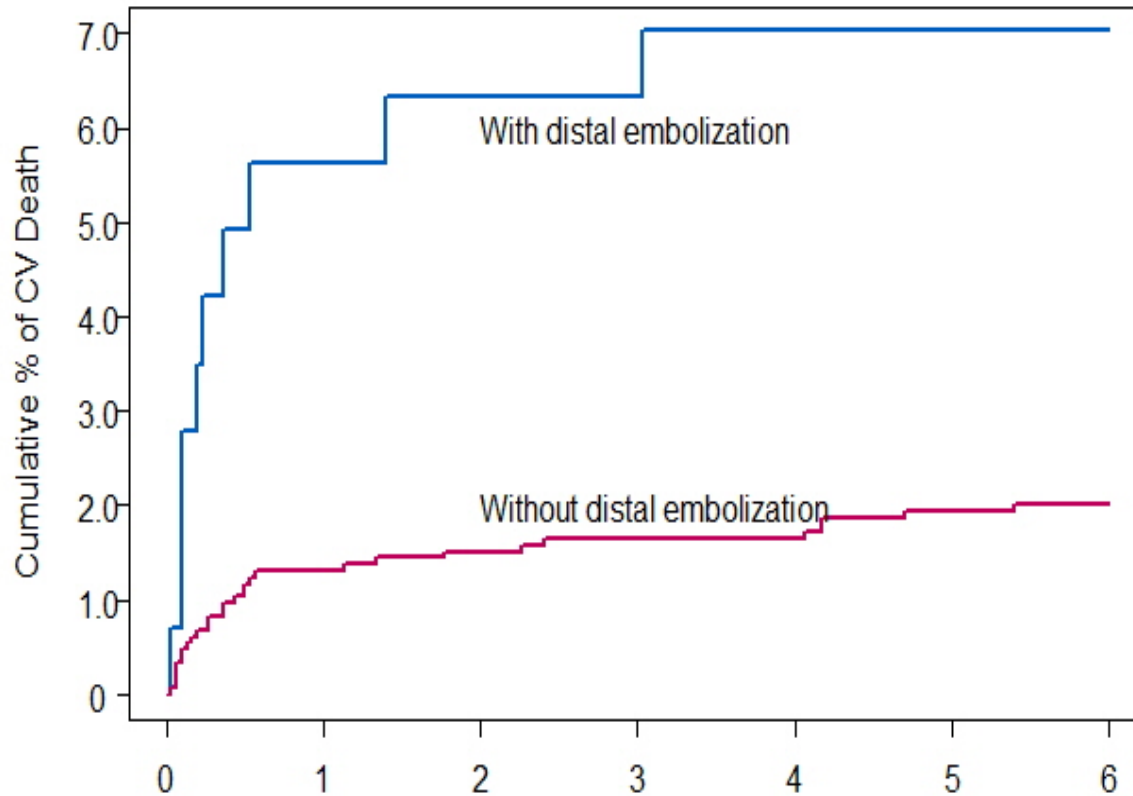
Sous étude angiographique

	Thrombectomy (N=791) (%)	PCI alone (N=819) (%)	p value
Myocardial Blush Grade 0,1	221 (28%)	246 (30%)	0.38
Myocardial Blush Grade 2,3	567 (72%)	573 (70%)	0.38
Post PCI TIMI Flow 0	9 (1.1%)	6 (0.7%)	0.4
Post PCI TIMI Flow 1	11 (1.4%)	10 (1.2%)	0.76
Post PCI TIMI Flow 2	59(7.5%)	70 (8.5%)	0.42
Post PCI TIMI Flow 3	712 (90%)	733 (89.5%)	0.73

Sous étude angiographique

	Thrombectomy (N=791) (%)	PCI alone (N=819) (%)	p value
Distal Embolization	56 (7.1%)	87 (10.7%)	0.01
Abrupt IRA Closure	7 (0.9%)	1 (0.1%)	0.02

Distal Embolization and Mortality



HR 3.63
(95%CI
1.77-7.46)
P=0.01

	Months of Follow-up						
No. at Risk	0	1	2	3	4	5	6
With distal embolization	143	134	133	133	132	132	132
Without distal embolization	1460	1431	1424	1420	1420	1416	1413

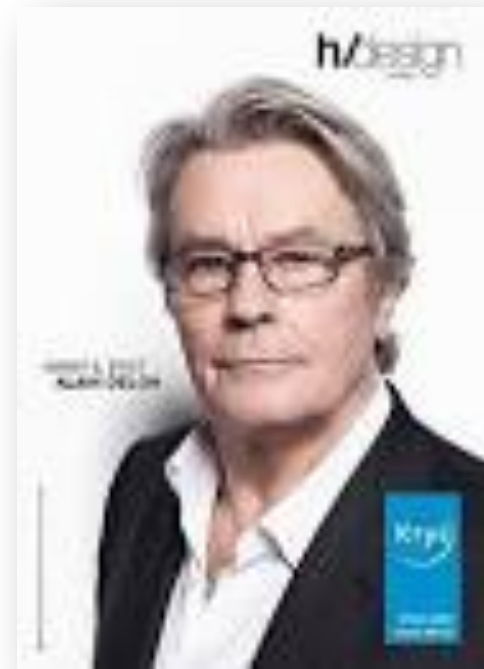
Sous étude Présentée à Euro PCR

- **Routine thrombectomy did not result in an improvement in final myocardial blush or TIMI Flow following PPCI for STEMI**
- **Routine thrombectomy reduced angiographic distal embolization**
- **Distal embolization was independently associated with mortality in multivariable analysis while myocardial blush was not**

Alors on continue ?



- Pendant des années, j'ai pensé qu'il fallait laisser au moins 12 mois la double AAP après stent actif !
- Mais ça c'était avant



6- Versus 24-Month Dual Antiplatelet Therapy After Implantation of Drug-Eluting Stents in Patients Nonresistant to Aspirin



The Randomized, Multicenter ITALIC Trial

Martine Gilard, MD, PhD,* Paul Barragan, MD,† Arif A.L. Noryani, MD,‡ Hussam A. Noor, MD,§ Talib Majwal, MD,|| Thomas Hovasse, MD,¶ Philippe Castellant, MD,* Michel Schneeberger, MD,# Luc Maillard, MD, PhD,** Erwan Bressolette, MD,†† Jaroslaw Wojcik, MD,‡‡ Nicolas Delarche, MD,§§ Didier Blanchard, MD,||| Bernard Jouve, MD,¶¶ Olivier Ormezzano, MD,## Franck Paganelli, MD,*** Gilles Levy, MD,††† Joël Sainsous, MD,†††† Didier Carrie, MD,§§§ Alain Furber, MD, PhD,|||| Jacques Berland, MD,¶¶¶ Oliver Darremont, MD,### Hervé Le Breton, MD,**** Anne Lyuycx-Bore, MD,†††† Antoine Gommeaux, MD,††††† Claude Cassat, MD,§§§§ Alain Kermarrec, MD,|||||| Pierre Cazaux, MD,¶¶¶¶ Philippe Druelles, MD,#### Raphael Dauphin, MD,***** Jean Armengaud, MD,††††† Patrick Dupouy, MD,†††††† Didier Champagnac, MD,§§§§§ Patrick Ohlmann, MD,||||||| Knut Endresen, MD,¶¶¶¶¶ Hakim Benamer, MD,##### Robert Gabor Kiss, MD,***** Imre Ungi, MD,†††††† Jacques Boschat, MD,* Marie-Claude Morice, MD¶

2,031 patients with implantation of Xience DES

Aspirin resistant
With or without dose adjustment
n=137

Good aspirin responders
Randomization
n=1,894

44 patients not randomized
Death = 13
MI = 10
TVR = 2
Other = 19 (7 with no consent validated)

Randomization applied
No events during first 6 months
n=1,850

Resistant group
Clopidogrel (prasugrel or ticagrelor) + aspirin, duration decided by the team
n=137

131 patients analyzed
on primary endpoint
(1-Year)

Group 1:
Dual oral antiplatelet regimen
for 24 months followed by
aspirin alone
n=924

910 patients analyzed
on primary endpoint
(1-Year)

Group 2:
Dual oral antiplatelet regimen
for 6 months followed by
aspirin alone
n=926

912 patients analyzed
on primary endpoint
(1-Year)

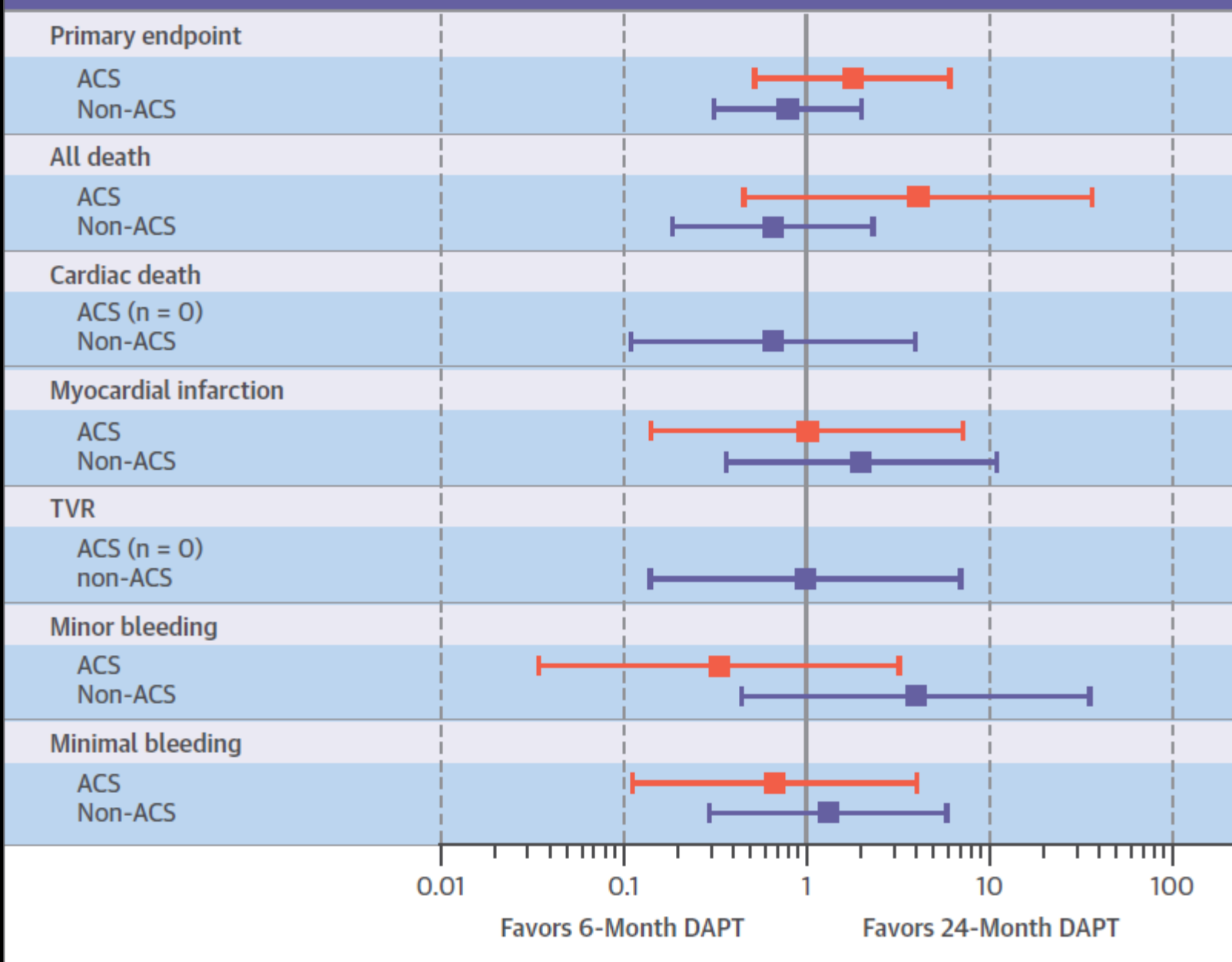
TABLE 3 1-Year Clinical Outcomes in the Intention-to-Treat Study Population

	Resistant Group (n = 131)	24-Month DAPT (n = 910)	6-Month DAPT (n = 912)	Hazard Ratio (95% CI)	p Value
Primary endpoint: death from any cause, MI, stroke, TVR, or major bleeding	2 (1.5)	14 (1.5)	15 (1.6)	1.072 (0.517–2.221)	0.85
Secondary endpoints					
Minor bleeding	0	4 (0.4)	5 (0.5)	1.247 (0.335–4.643)	0.74
Minimal bleeding	1 (0.8)	6 (0.7)	6 (0.7)	0.997 (0.321–3.090)	0.99
Death					
All deaths	1 (0.8)	7 (0.8)	8 (0.9)	1.143 (0.414–3.152)	0.80
Cardiac death	0	3 (0.3)	5 (0.5)	1.667 (0.398–6.974)	0.48
Myocardial infarction	0	4 (0.4)	6 (0.7)	1.500 (0.423–5.317)	0.53
Stroke	0	4 (0.4)	0	N/A	
TVR	1 (0.8)	2 (0.2)	5 (0.5)	2.499 (0.485–12.882)	0.27
Stent thrombosis	0	0	3 (0.3)	N/A	
Major bleeding	0	3 (0.3)	0	N/A	

Values are n (%) unless otherwise indicated.

CI = confidence interval; TVR = urgent target vessel revascularization; other abbreviations as in [Table 1](#).

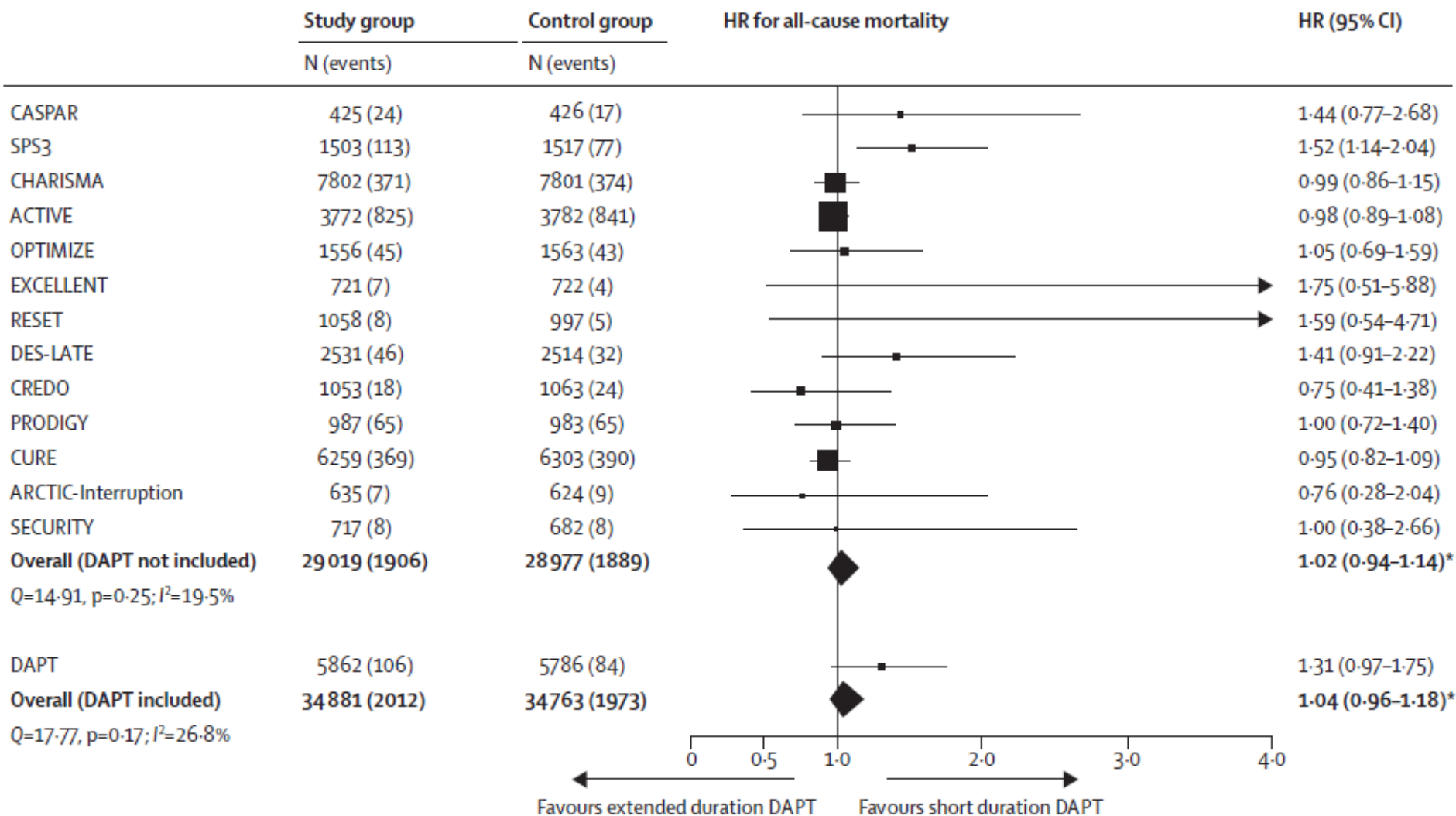
Hazard Ratio and 95% CI with p Value for DAPT ACS Interaction





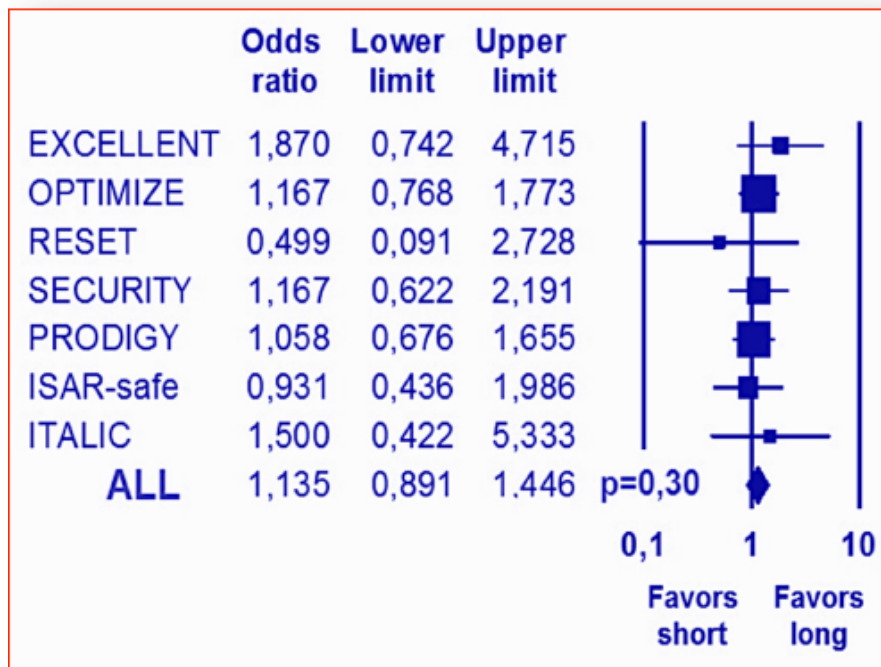
Extended duration dual antiplatelet therapy and mortality: a systematic review and meta-analysis

Sammy Elmariah, Laura Mauri, Gheorghe Doros, Benjamin Z Galper, Kelly E O'Neill, Philippe Gabriel Steg, Dean J Kereiakes, Robert W Yeh



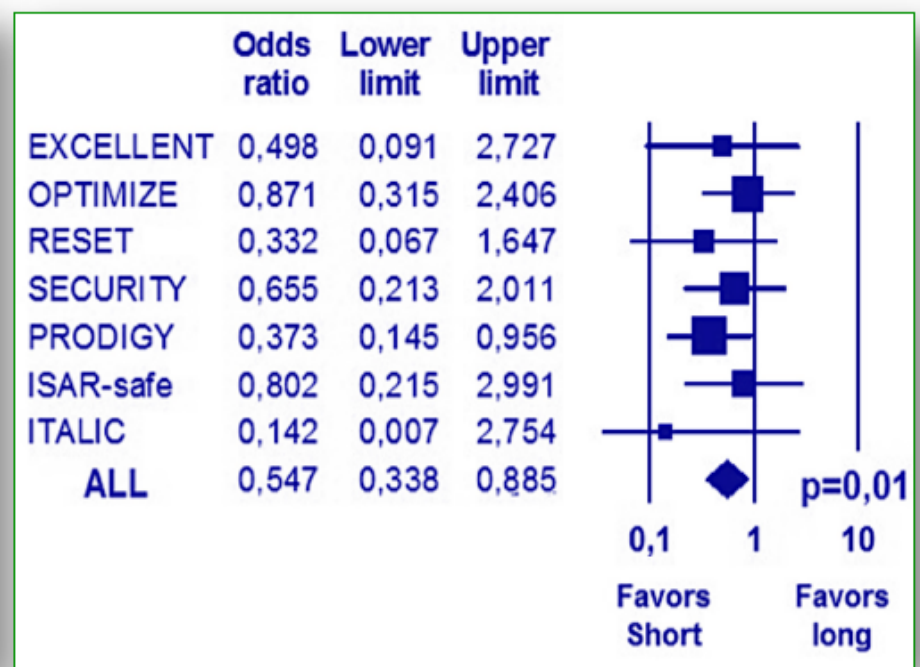
Meta analyse G Montalescot

IDM



EXCELLENT (Gwon et al. Circ 2014)
 OPTIMIZE (Feres et al. JAMA 2013)
 RESET (Kim et al. JACC 2013)
 SECURITY (Colombo et al. JACC 2014)

Saignements majeurs



PRODIGY (Valgimigli et al. Circ 2012)
 ISAR-safe (Schulz-Schüpke et al. AHA 2014)
 ITALIC (Gilard et al. JACC 2014)

Durée double AAP

La majorité des patients: 6 mois

Prolongation de la durée:

Patients ayant fait un événement thrombotique dans les
6 premiers mois

DES de première génération

SCA et BMS

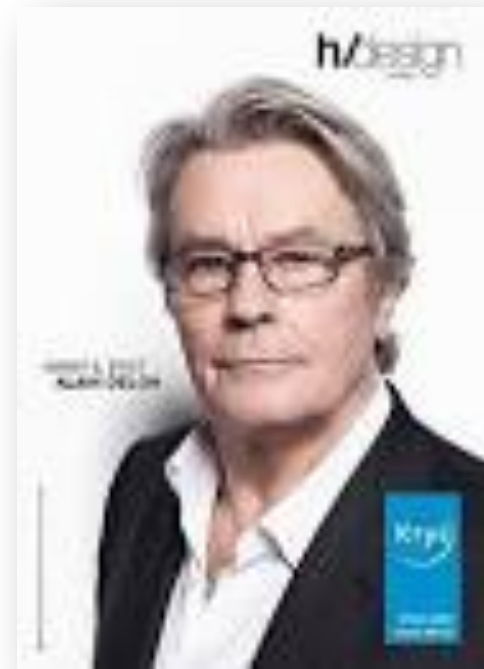
Patient à haut risque thrombotique et faible risque hémorragique

Patient à « haut risque anatomique »

Raccourcissement de la durée: après DES de nouvelle génération

Patients à haut risque hémorragique

- Avant, je pensais qu'on ne pouvait faire de TAVI qu'aux patients à haut risque chirurgical (sic)
- Mais ça c'était avant



Transcatheter Versus Surgical Aortic Valve Replacement in Patients with Severe Aortic Valve Stenosis: One-year Results from the All-comers Nordic Aortic Valve Intervention (NOTION) Randomized Clinical Trial

- Etude randomisée « all comers » entre TAVI(CoreValve) et chirurgie
- Pas de geste associé (coronaire ou valvulaire)

Patients 70 years or older with severe aortic valve stenosis and no significant coronary artery disease were recruited. Patients were randomized 1:1 to TAVR using a self-expanding bio-prosthesis versus SAVR. The primary outcome was the composite rate of death from any cause, stroke, or myocardial infarction at 1 year. The trial was non-blinded with the assumption that TAVR would be superior to SAVR.

Table 1. Patient Baseline Characteristics

Characteristic	Transcatheter* N=145	Surgical N=135
Age, years - mean±SD	79.2±4.9	79.0±4.7
Male – no./total no. (%)	78/145 (53.8)	71/135 (52.6)
NYHA classification – no./total no. (%)		
Class I	7/144 (4.9)	3/134 (2.2)
Class II	67/144 (46.5)	70/134 (52.2)
Class III	67/144 (46.5)	57/134 (42.5)
Class IV	3/144 (2.1)	4/134 (3.0)
STS Score, % – mean±SD	2.9±1.6	3.1±1.7
Logistic EuroSCORE, % – mean±SD	8.4±4.0	8.9±5.5
Logistic EuroSCORE II, % – mean±SD	1.9±1.2	2.0±1.3

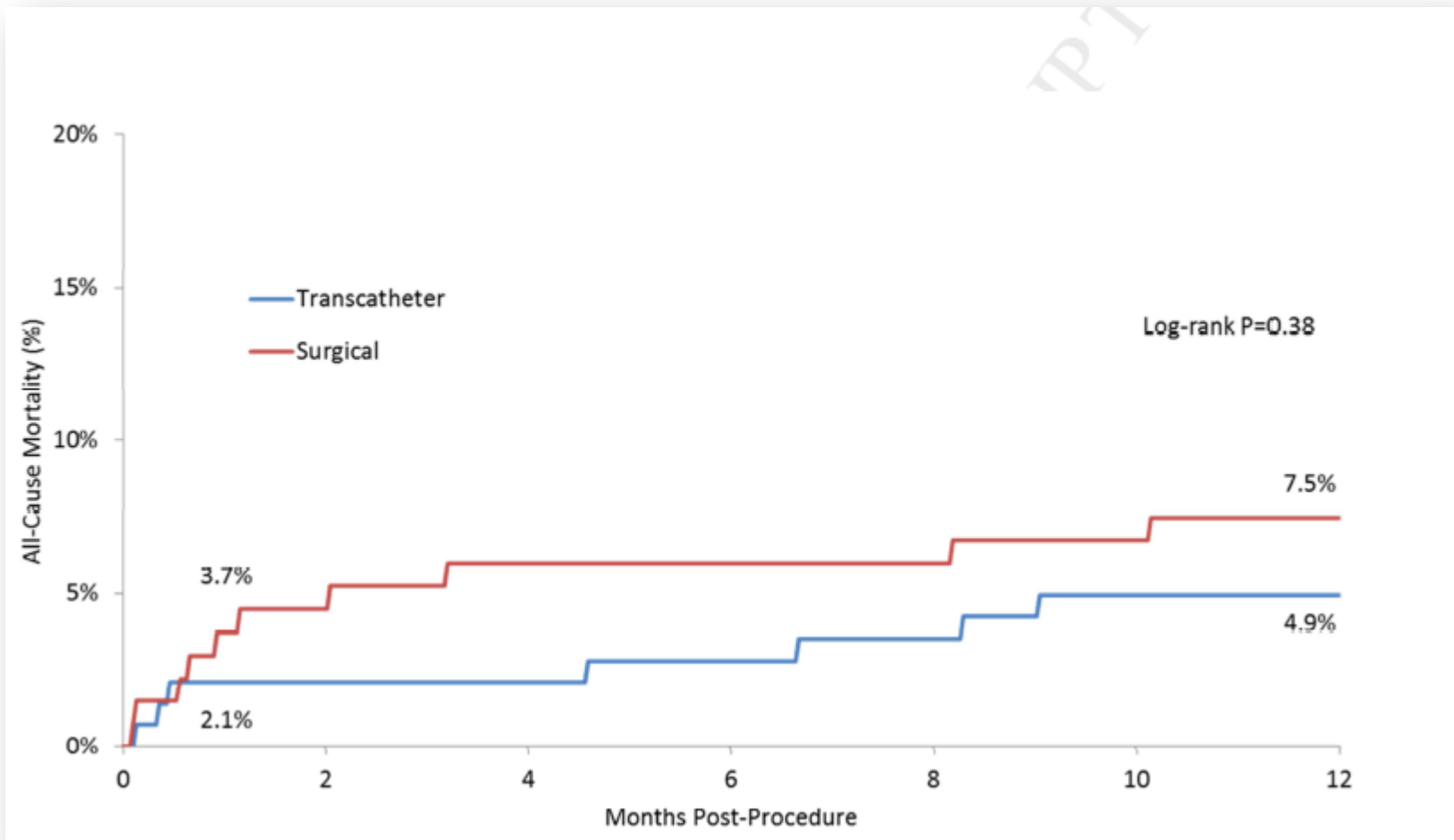
POPULATION RISQUE FAIBLE (Euroscore # 8%)

Diabetes mellitus – no./total no. (%)	26/145 (17.9)	28/135 (20.7)
Creatinine level >2 mg/dl – no./total no. (%)	2/145 (1.4)	1/135 (0.7)
History of hypertension – no./total no. (%)	103/145 (71.0)	103/135 (76.3)
Peripheral vascular disease – no./total no. (%)	6/145 (4.1)	9/135(6.7)
Prior cerebrovascular accident – no./total no. (%)	24/145 (16.6)	22/135 (16.3)
Chronic lung disease – no./total no. (%)	17/145 (11.7)	16/135 (11.9)
Cardiac Risk Factors		
Prior PCI – no./total no. (%)	11/145 (7.6)	12/135 (8.9)
Pre-existing pacemaker– no./total no. (%)	5/145 (3.4)	6/135 (4.4)
Prior myocardial infarction – no./total no. (%)	8/145 (5.5)	6/135 (4.4)
Prior atrial fibrillation/ atrial flutter – no./total no. (%)	40/144 (27.8)	34/133 (25.6)

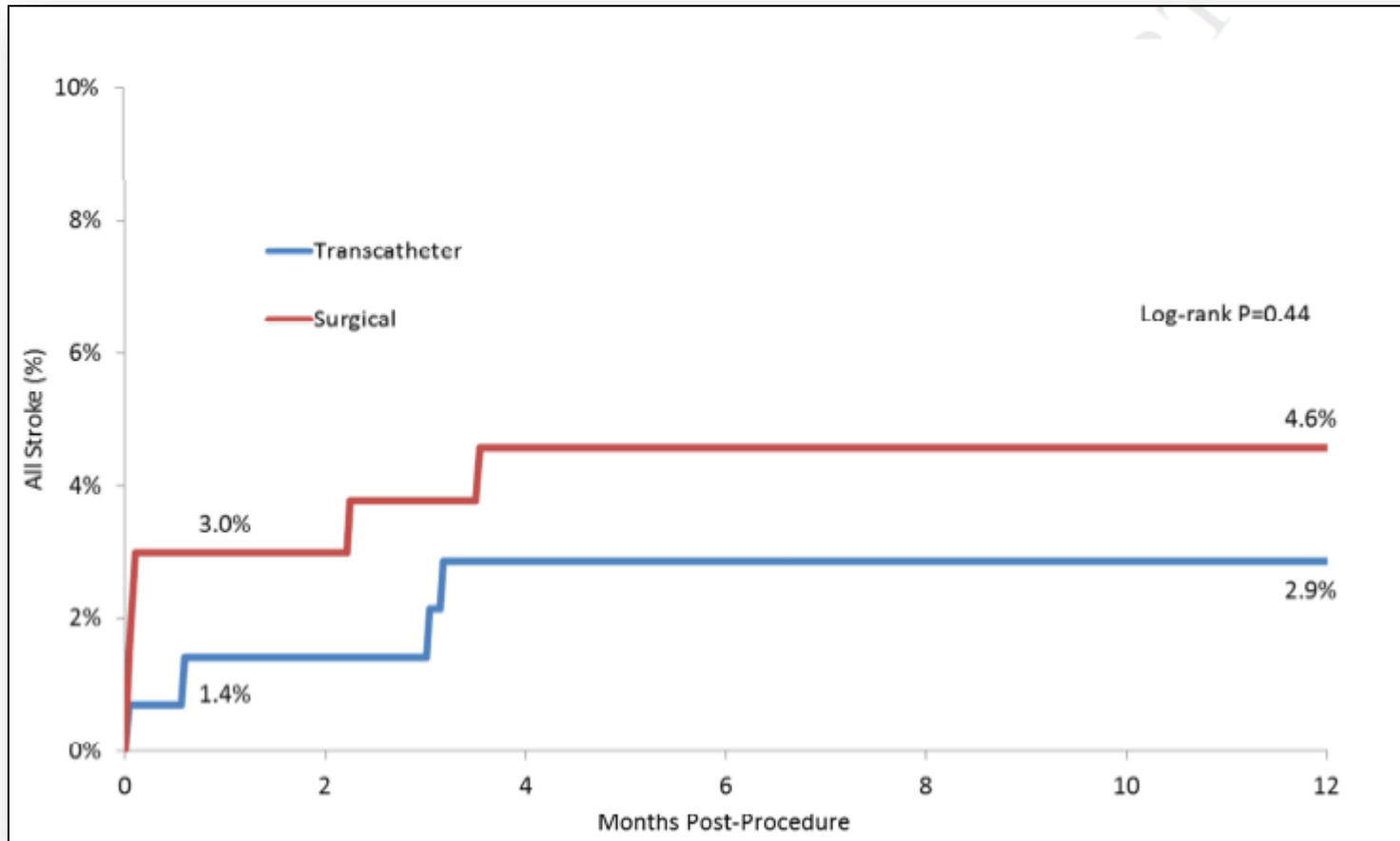
Table 3. Clinical Outcomes in the As-Treated Population

Characteristic	Index Hospitalization* or 30 Days†			1 Year		
	Transcatheter	Surgical	P Value	Transcatheter	Surgical	P Value
Major, life threatening, or disabling bleeding*	16 (11.3)	28 (20.9)	0.03			
Cardiogenic shock*	6 (4.2)	14 (10.4)	0.05			
Major vascular complications*	8 (5.6)	2 (1.5)	0.10			
Acute kidney injury stage II or III*	1 (0.7)	9 (6.7)	0.01			
All-cause death†	3 (2.1)	5 (3.7)	0.43	7 (4.9)	10 (7.5)	0.38
Cardiovascular death†	3 (2.1)	5 (3.7)	0.43	6 (4.3)	10 (7.5)	0.25
Neurological events†	4 (2.8)	4 (3.0)	0.94	7 (5.0)	8 (6.2)	0.68
Stroke†	2 (1.4)	4 (3.0)	0.37	4 (2.9)	6 (4.6)	0.44
Transient ischemic attack†	2 (1.4)	0 (0)	0.17	3 (2.1)	2 (1.6)	0.71
Myocardial infarction†	4 (2.8)	8 (6.0)	0.20	5 (3.5)	8 (6.0)	0.33
Valve endocarditis†	1 (0.7)	0 (0)	0.33	4 (2.9)	2 (1.6)	0.47
New-onset or worsening atrial fibrillation†	24 (16.9)	77 (57.8)	<0.001	30 (21.2)	79 (59.4)	<0.001
Permanent pacemaker implantation†	46 (34.1)	2 (1.6)	<0.001	51 (38.0)	3 (2.4)	<0.001

Mortalité toutes causes

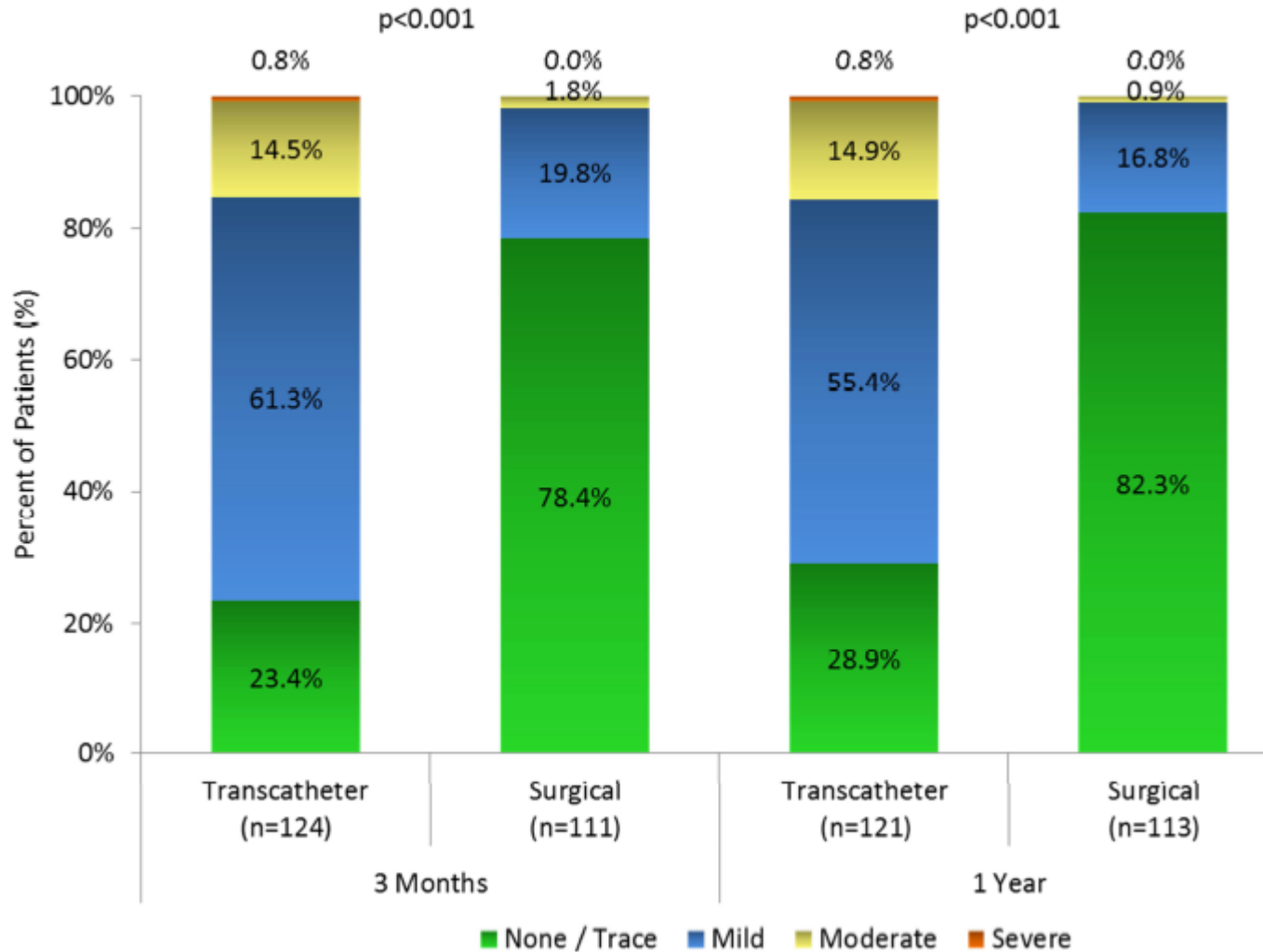


Stroke



Insuffisance aortique

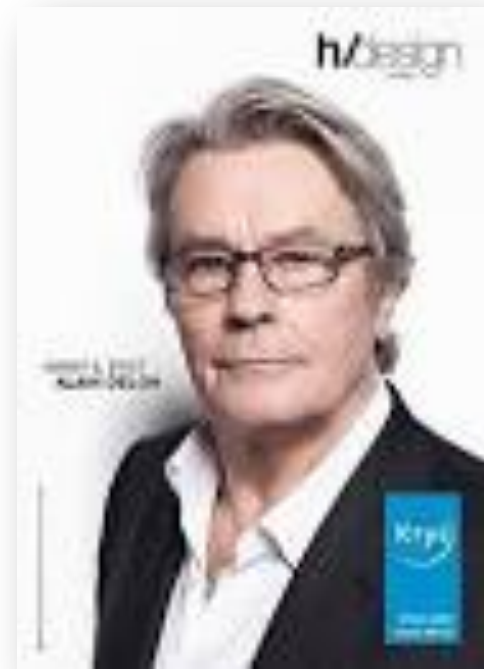
Figure 5: Changes in total aortic valve regurgitation over time



Jeu égal entre TAVI et RVAO
dans une population à faible
risque « all comers »

Mais incidence PM, fuites aortiques

- Jusqu'à présent je pensais que la fuite aortique post-TAVI était inéluctable !
- Mais ça c'était avant



JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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PUBLISHED BY ELSEVIER INC.

VOL. 64, NO. 21, 2014
ISSN 0735-1097/\$36.00
<http://dx.doi.org/10.1016/j.jacc.2014.09.026>

Multicenter Evaluation of a Next-Generation Balloon-Expandable Transcatheter Aortic Valve



John Webb, MD,* Gino Gerosa, MD,† Thierry Lefèvre, MD,‡ Jonathon Leipsic, MD,* Mark Spence, MD,§
Martyn Thomas, MD,|| Matthias Thielmann, MD,¶ Hendrik Treede, MD,# Olaf Wendler, MD,** Thomas Walther, MD††

TECHNOLOGICAL SOLUTION ?

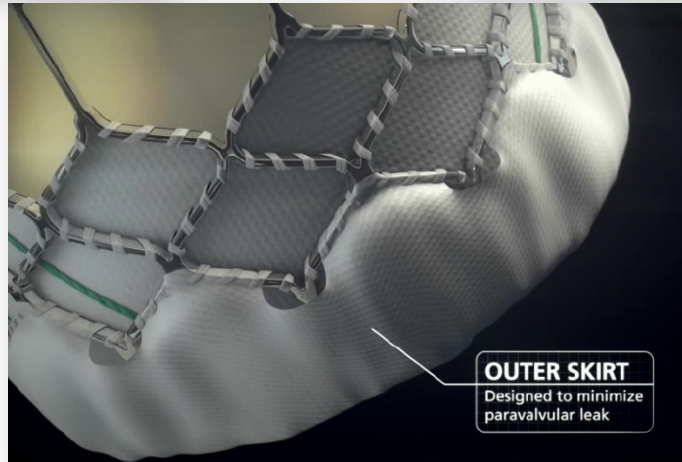
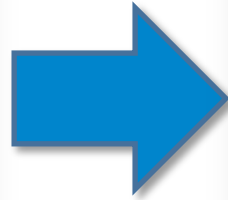
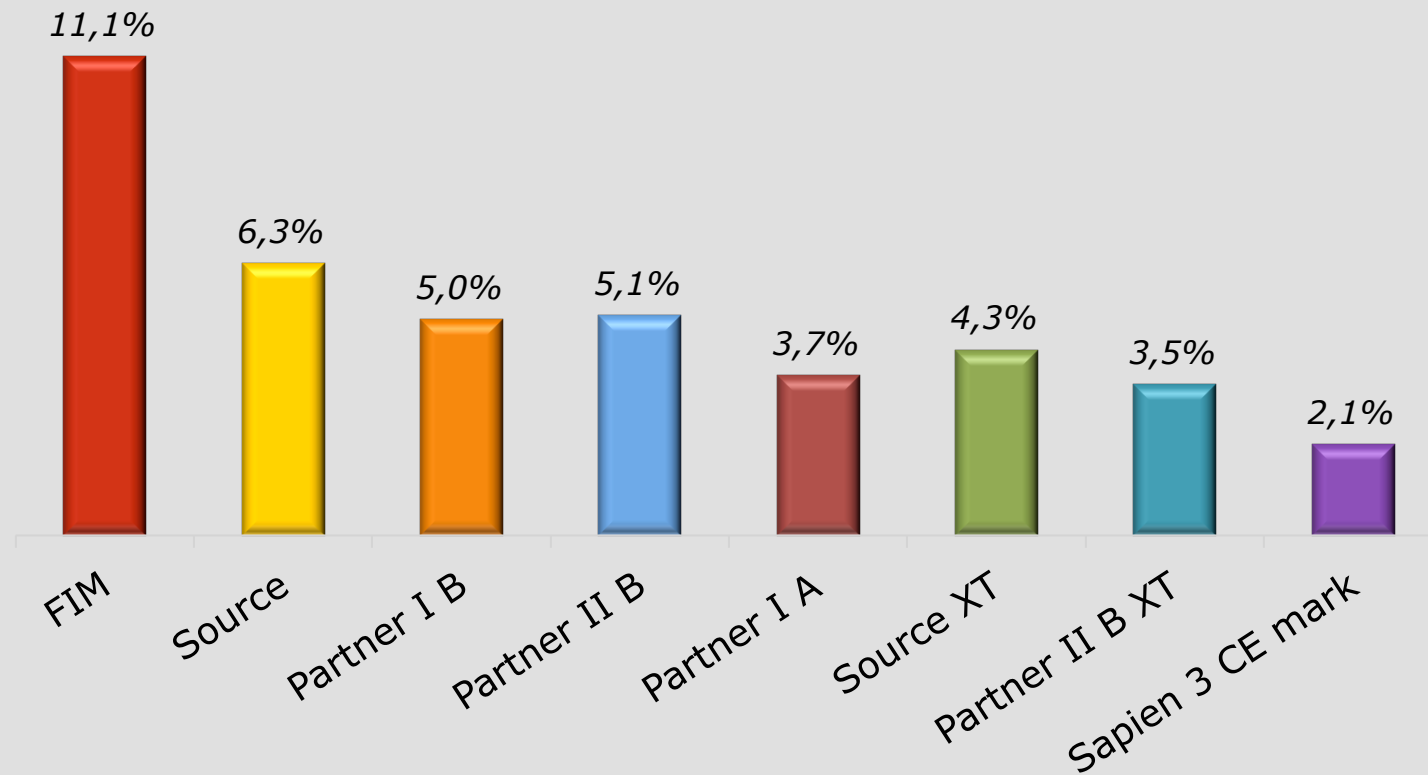


TABLE 1 Baseline Characteristics

	TF (n = 96)	TAA (n = 54)	Total (N = 150)	p Value TF Versus TAA
Age, yrs	96, 84.3 ± 4.8	54, 82.5 ± 5.3	150, 83.6 ± 5.0	0.0454
Female	50/96 (52.1)	31/54 (57.4)	81/150 (54.0)	0.6095
Logistic EuroSCORE	96, 19.8 ± 10.9	54, 24.9 ± 14.0	150, 21.6 ± 12.3	0.0215
EuroSCORE 2	96, 5.4 ± 3.3	54, 7.7 ± 7.9	150, 6.2 ± 5.5	0.0483
STS score	96, 7.5 ± 4.3	54, 7.3 ± 4.9	150, 7.4 ± 4.5	0.8130
NYHA functional class III/IV	82/96 (85.4)	48/54 (88.9)	130/150 (86.7)	0.6242
Chronic pulmonary disease	25/96 (26.0)	15/54 (27.8)	40/150 (26.7)	0.8489
Frailty index VARC-2 (yes or no)	75/89 (84.3)	37/41 (90.2)	112/130 (86.2)	0.4249
Carotid disease	24/95 (25.3)	14/54 (25.9)	38/149 (25.5)	1.0000
Periph				0.0032
Stroke				0.0000
Pacem				0.6354
Coronary artery disease	57/96 (59.4)	39/54 (72.2)	96/150 (64.0)	0.1561
Myocardial infarction	11/96 (11.5)	15/54 (27.8)	26/150 (17.3)	0.0142
Percutaneous coronary intervention	30/96 (31.3)	22/54 (40.7)	52/150 (34.7)	0.2846
Coronary artery bypass graft	14/96 (14.6)	15/54 (27.8)	29/150 (19.3)	0.0557
Atrial fibrillation	22/96 (22.9)	19/53 (35.8)	41/149 (27.5)	0.1247
RBBB	9/90 (10.0)	2/49 (4.1)	11/139 (7.9)	0.3279
Diabetes	31/96 (32.3)	17/54 (31.5)	48/150 (32.0)	1.0000
Renal insufficiency	39/96 (40.6)	21/54 (38.9)	60/150 (40.0)	0.8638
Moderate/severe mitral regurgitation	10/75 (13.3)	16/39 (41.0)	26/114 (22.8)	0.0018

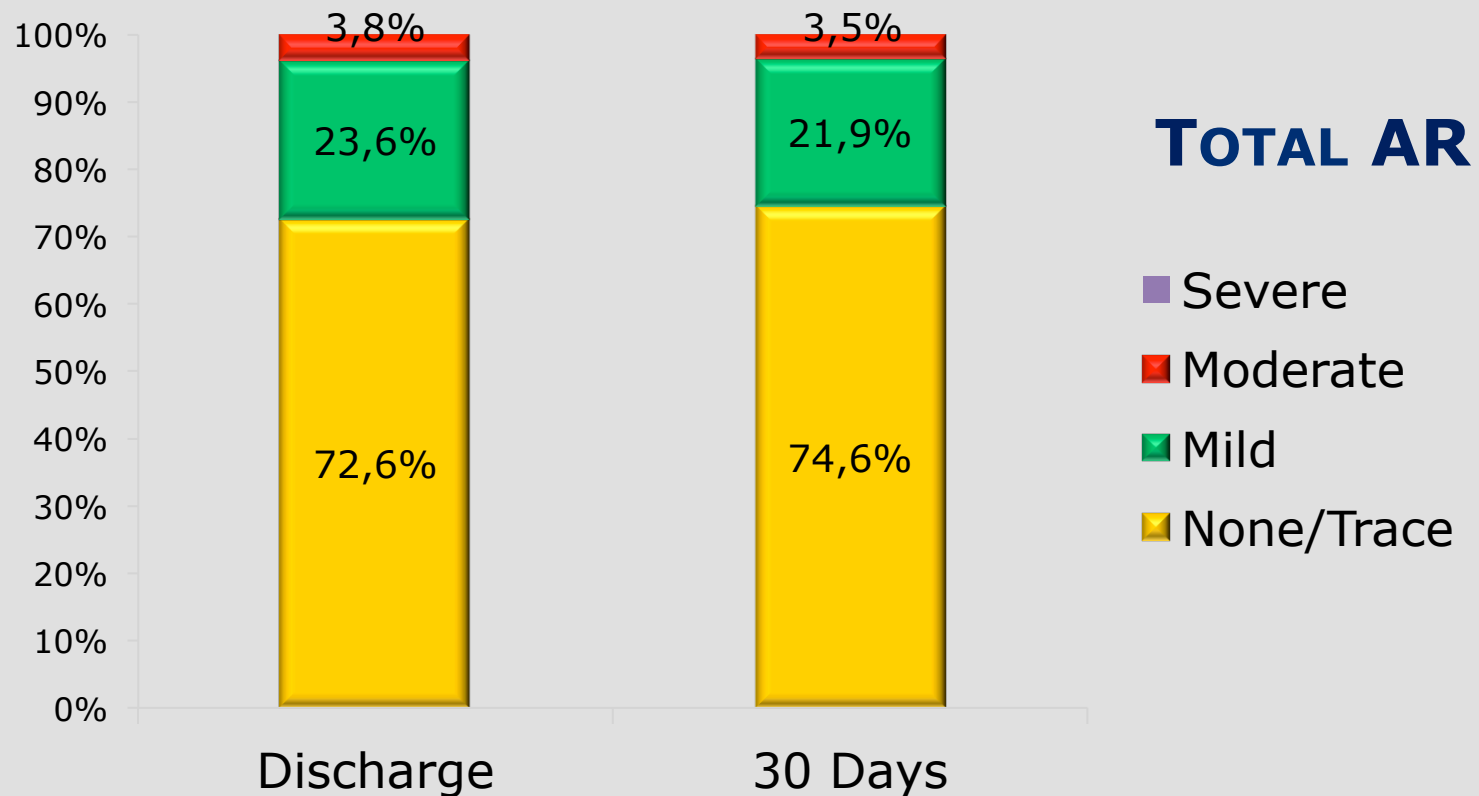
POPULATION RISQUE ELEVE (Euroscore # 20%)

30-DAY MORTALITY TRANSFEMORAL

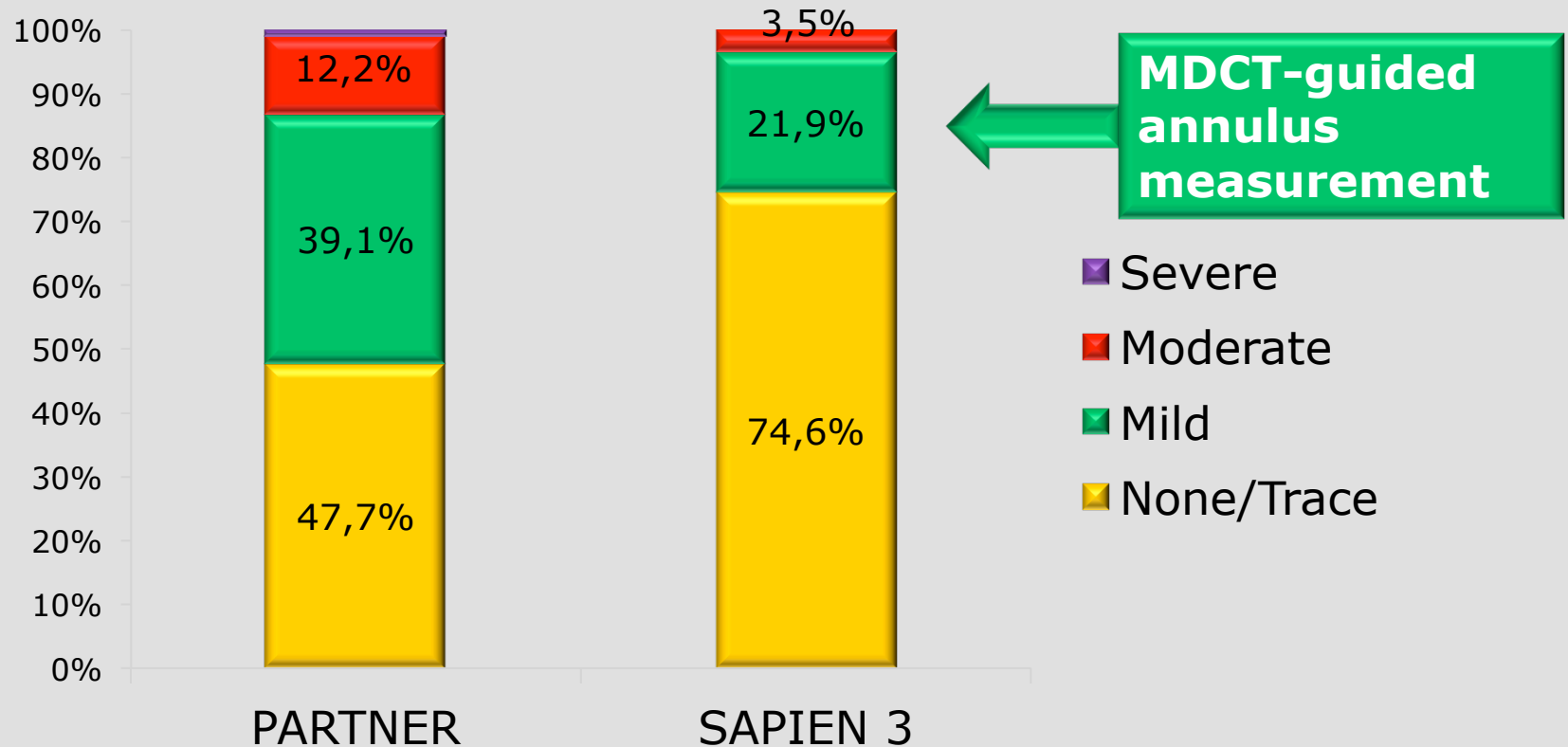


John Webb et col : Multicenter Evaluation of a Next-Generation Balloon-Expandable Transcatheter Aortic Valve JACC VOL . 64 , NO . 21 , 2014

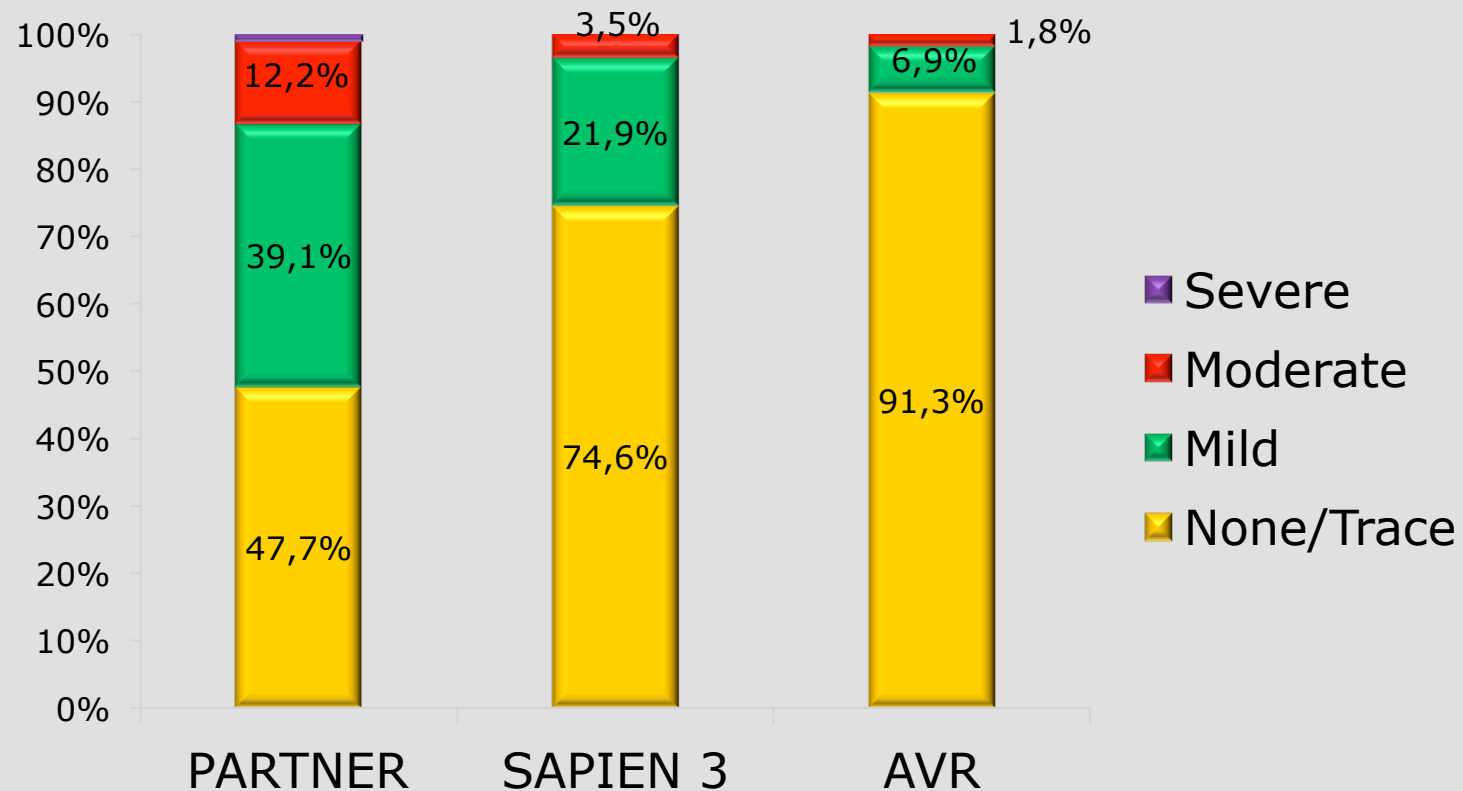
RESIDUAL AORTIC REGURGITATION



30-DAY RESIDUAL AORTIC REGURGITATION COMPARISON PARTNER VS SAPIEN-3



30-DAY RESIDUAL AORTIC REGURGITATION COMPARISON PARTNER VS SAPIEN 3



L'insuffisance aortique n'est plus
« obligatoire » après TAVI

Conclusions

- Et encore bien d'autres études qui ont changé ou conforté nos attitudes et nos habitudes

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PROGRAMME



Merci pour votre attention