

Make BRS Great Again

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Declaration de Conflit d'interet

- Absence de conflit d'interet


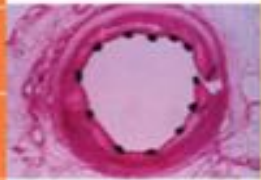



1. Metallic Coronary disease



Stanley Kubrick's
**FULL
METAL
JACKET**



Metallic Coronary disease

	BA	Dissection and intraparietal haemorrhage	BMS	Sealing of dissection with BMS	DES
Acute Occlusion	-		+		+
Acute ST	NA		-/+		+
Subacute ST			+		+
Acute recoil	-	Dissection Post-angioplasty	+		+
Constrictive remodelling	-		+	Neointimal hyperplasia making obstruction in the metallic stent	+
Neointimal hyperplasia	-		--		+
Expansive remodelling	+		-		-
Late Luminal Enlargement	+		-		-
Late and Very late ST	NA		-		-

Critère d'efficacité clinique : Target Lesion Failure

- ID-TLR : Ischemia Driven TLR
- TVMI : Target Vessel MI
- Cardiac Death

Critère de Sécurité :

- Stent Thrombosis

Metallic Coronary disease : Clinical Outcome

	EES	SES	PES
Death			
0 to 30 d	135 (3.2)	79 (2.1)	135 (3.1)
>30 d to 1 y	108 (2.7)	77 (2.1)	127 (3.1)
>1 y to 4 y	141 (6.6)	198 (6.5)	160 (6.5)
0 to 4 y	384 (12.0)	354 (10.3)	422 (12.1)
Cardiac death			
0 to 30 d	124 (2.9)	68 (1.8)	122 (2.8)
>30 d to 1 y	61 (1.5)	46 (1.2)	70 (1.7)
>1 y to 4 y	70 (3.2)	105 (3.5)	92 (4.0)
0 to 4 y	255 (7.5)	219 (6.4)	284 (8.2)
MI			
0 to 30 d	48 (1.2)	57 (1.5)	82 (1.9)
>30 d to 1 y	20 (0.5)	24 (0.7)	58 (1.5)
>1 y to 4 y	37 (1.9)	88 (2.9)	88 (3.7)
0 to 4 y	105 (3.5)	169 (5.0)	228 (7.0)

All comers

N = 12339

Follow Up : 4 ans

Décès de cause cardiaque après 4 FU:

Groupe EES : 7.5 / 100 patients / an

Metallic Coronary disease : Target Lesion Failure

No. of contributing patients/trials

Outcomes at 9–12 months

Median (IQR 25–75%) per 100 person-years

Cardiac death (%)

BMS	5891/15	1.57 (0.88–2.81)
DES	59 334/59	1.00 (0.53–1.69)
Early DES	29 149/48	0.98 (0.50–1.83)
New DES	30 185/32	1.00 (0.65–1.63)
FDA approved new DES	20 135/25	0.99 (0.58–1.39)

Target lesion revascularization (%)

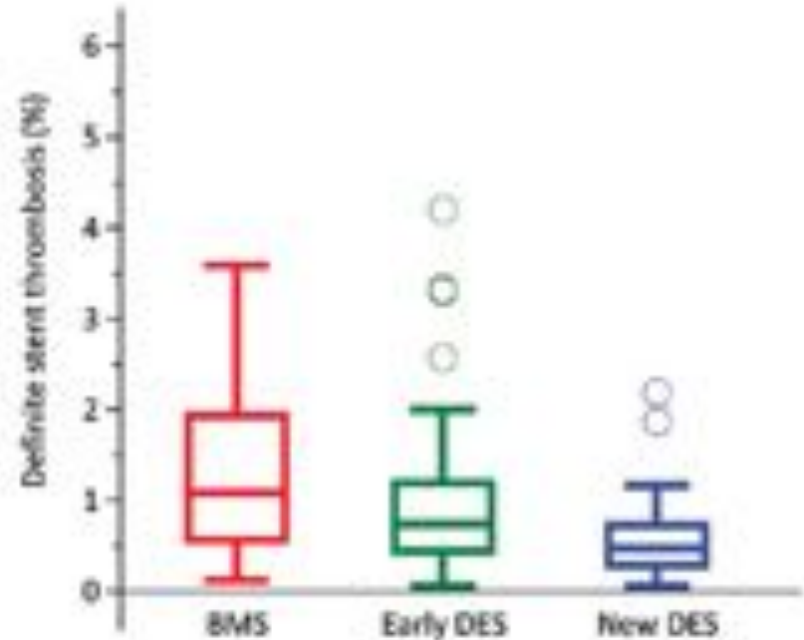
BMS	5557/17	12.32 (7.44–13.79)
DES	57 595/67	4.00 (2.05–6.40)
Early DES	26 729/56	4.34 (2.40–7.11)
New DES	30 866/35	2.91 (1.67–5.94)
FDA approved new DES	20 436/26	3.01 (1.75–4.72)

Myocardial infarction (%)

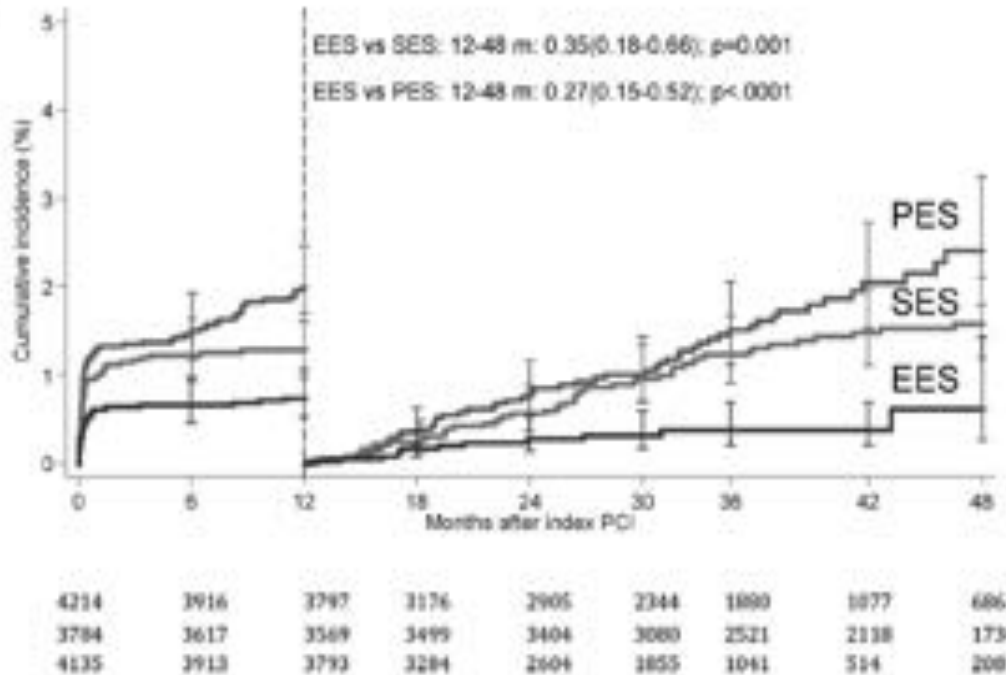
BMS	6315/19	3.29 (1.97–4.31)
DES	62 347/71	2.88 (1.41–4.57)
Early DES	30 976/59	2.88 (1.39–4.59)
New DES	31 371/36	2.89 (1.45–4.21)
FDA approved new DES	20 833/27	2.78 (1.33–4.26)

Metallic Coronary disease : Thombose de stent

	No. of contributing patients/trials	Outcomes at 9–12 months Median (IQR 25–75%) per 100 person-years
Definite stent thrombosis (%)		
BMS	6399/19	1.08 (0.57–1.94)
DES	54 393/58	0.61 (0.37–0.99)
Early DES	24 221/46	0.74 (0.45–1.19)
New DES	30 172/31	0.47 (0.28–0.72)
FDA approved new DES	19 634/22	0.43 (0.28–0.58)



Metallic Coronary disease : Thrombose Tres tardive de stent



All comers

N = 12339

Follow Up : 4 ans

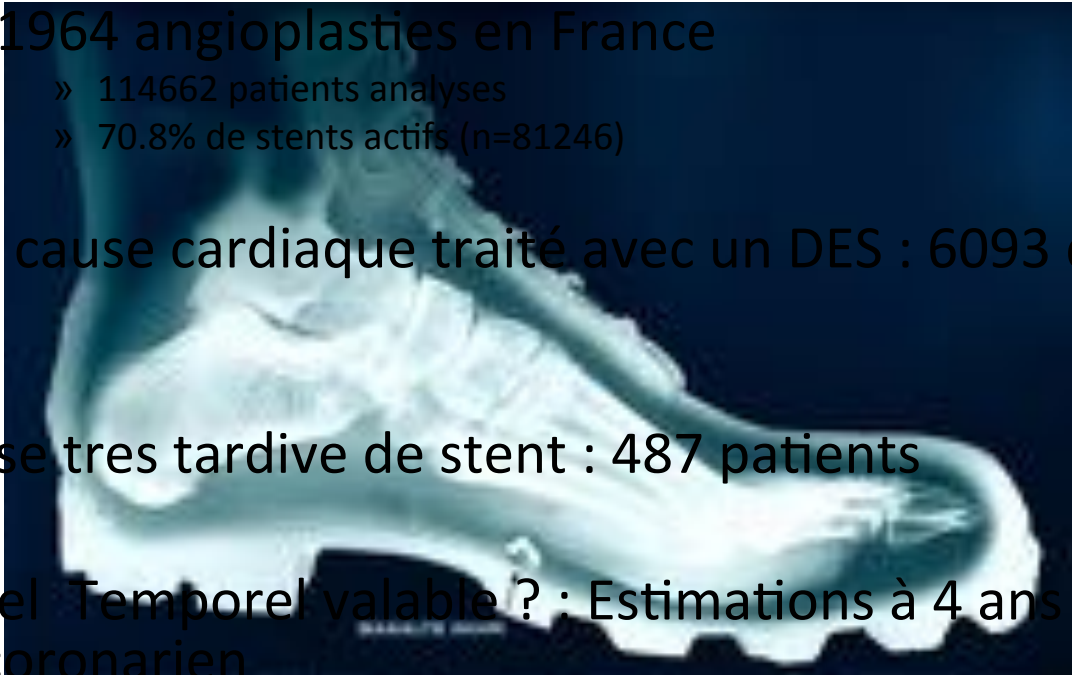
**EES : Thrombose tres tardive de stent : 0.6 / 100 patients / an
 Deces de cause cardiaque : 7.5 /100 patients / an**

Metallic Coronary disease en France

Utilisation des endoprothèses (stents) coronaires en France en 2014 :

Étude à partir des données du SNIIRAM

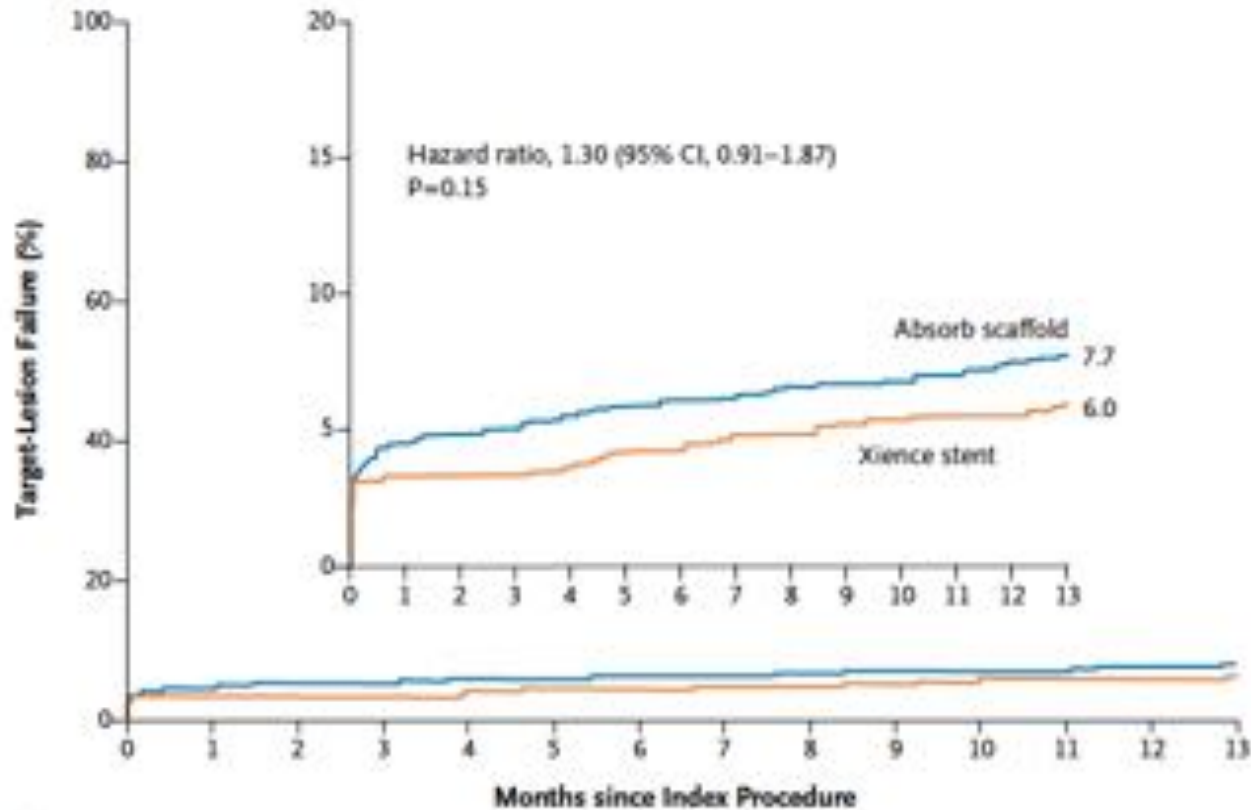
- 2014 : 121964 angioplasties en France
 - » 114662 patients analysés
 - » 70.8% de stents actifs (n=81246)
- Mortalité cause cardiaque traité avec un DES : 6093 décès à 4 ans
- Thrombose très tardive de stent : 487 patients
- Référentiel Temporel valable ? : Estimations à 4 ans vs durée de vie d'un coronarien



2. Preuves scientifiques BRS

Efficacité
Target Lesion Failure

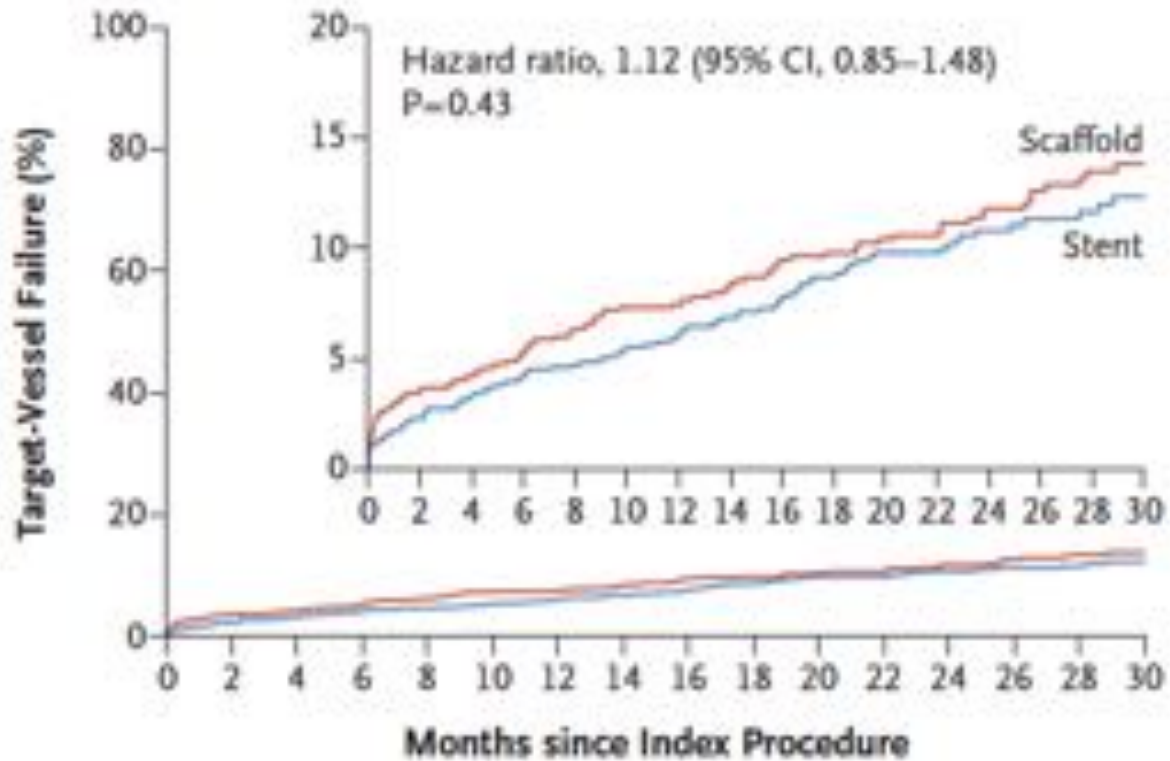
ABSORB III: Clinical Outcome - TLF



No. at Risk

Absorb	1322	1254	1230	1218	1205
Xience	686	661	651	643	638

All Comers BRS : Clinical Outcome -TLF



No. at Risk

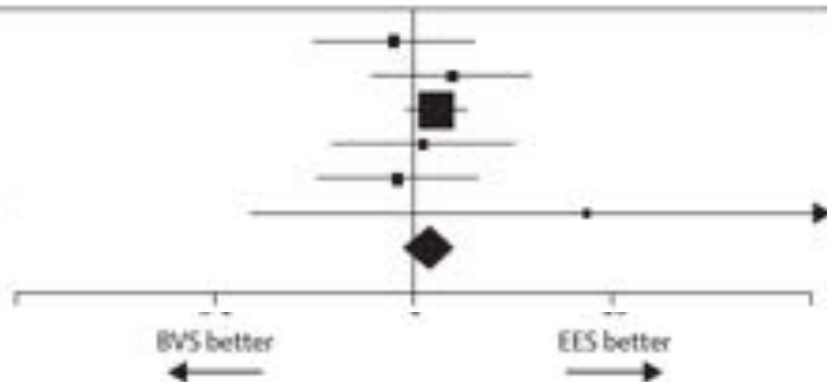
Scaffold	924	870	776	594	385	196
Stent	921	873	792	599	388	188

Metanalyse etudes Randomisées : Clinical Outcome -TLF

Target lesion failure

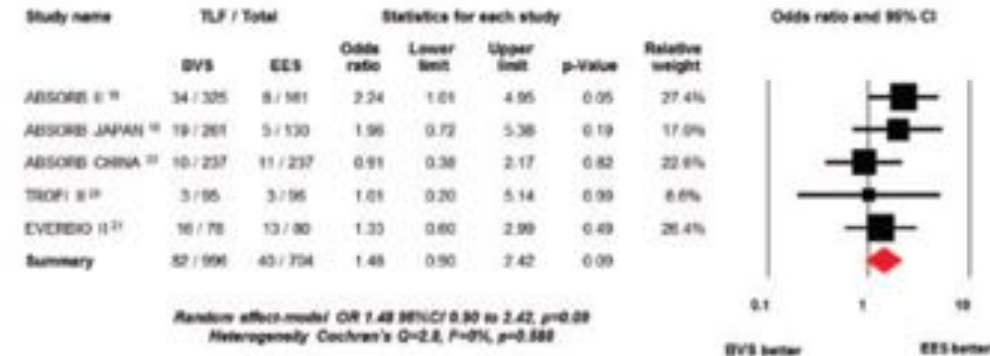
	BVS		EES		Weight (%)	Fixed-effects odds ratio (95% CI)
	Events	Total	Events	Total		
ABSORB China	8	238	10	237	9.3	0.79 (0.31-2.03)
ABSORB II	16	335	5	166	9.6	1.55 (0.61-3.92)
ABSORB III	102	1313	41	677	63.9	1.29 (0.09-1.85)
ABSORB Japan	11	265	5	133	7.3	1.11 (0.38-3.19)
EVERBIO II	9	78	11	80	9.4	0.82 (0.32-2.09)
TROFI II	1	95	0	96	0.5	7.47 (0.15-376.35)
Overall	147	2324	72	1389	100	1.20 (0.90-1.60)

(OR 1.20 [0.90–1.60]; p=0.21)



Cassese et al. Lancet. 2016

Target Lesion Failure



(OR 1.48 [0.90–2.2] ; p=0.09)

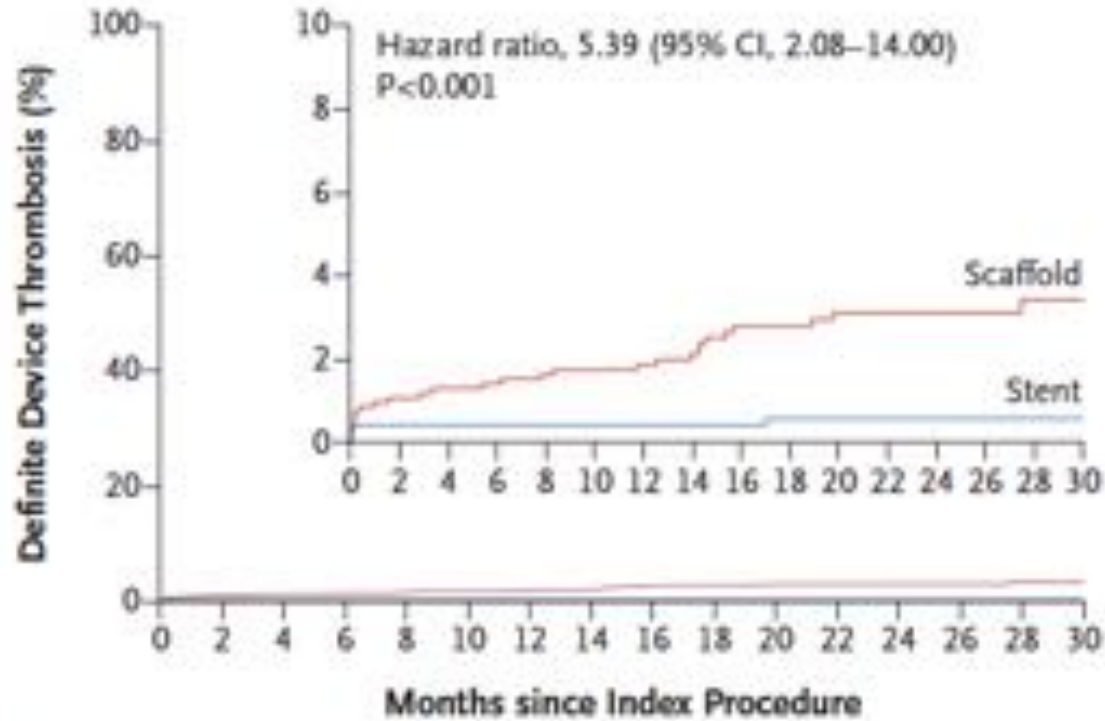
**PAS DE DIFFERENCE TLF entre
BVS ET EES**

Collet et al. Eur Heart J. 2017

2. Preuves scientifiques BRS

Securité :
Thrombose de Scaffold

All Comers BRS : Thrombose de Scaffold

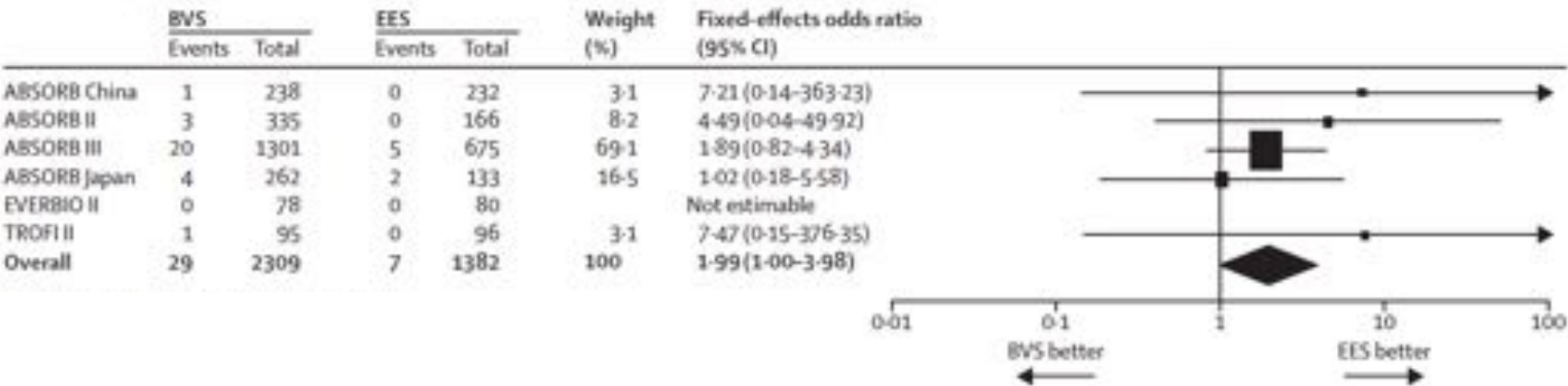


No. at Risk

Scaffold	924	898	812	632	416	211
Stent	921	903	828	635	421	207

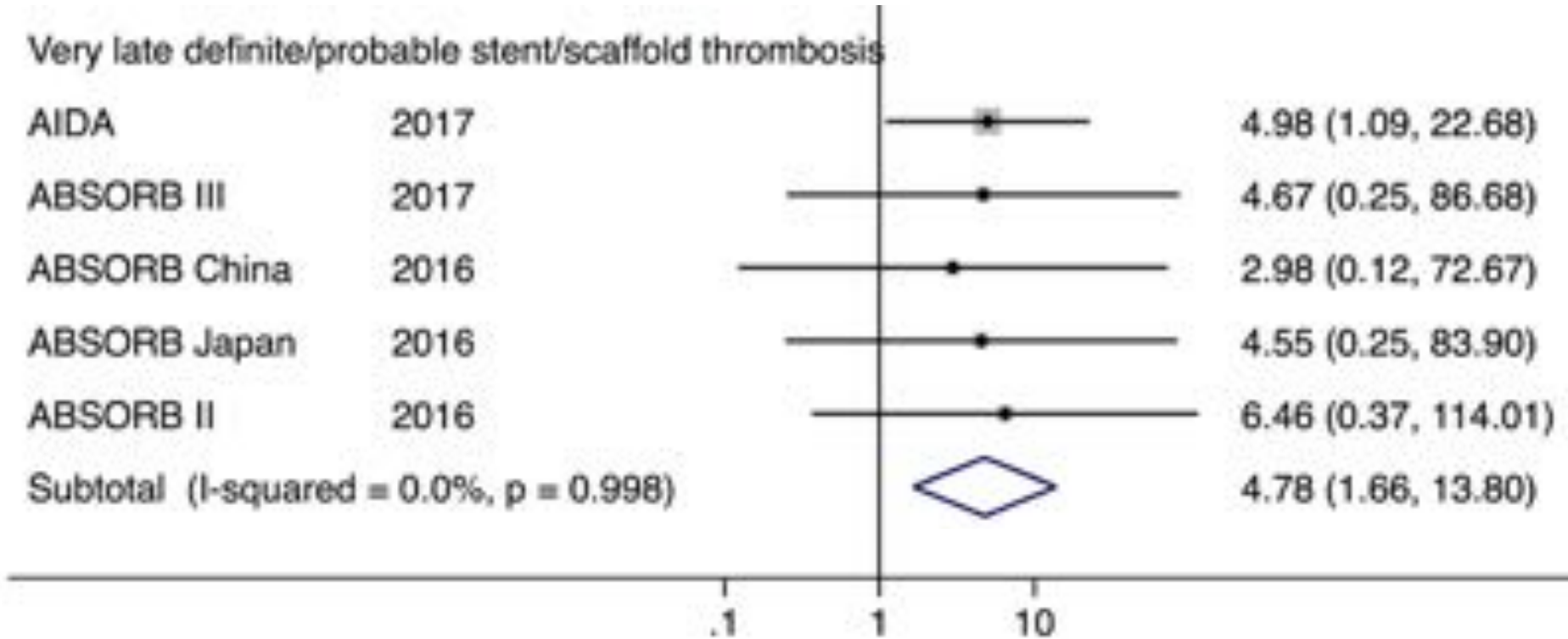
Metanalyse : Thrombose de Scaffold

Definite or probable stent thrombosis



OR : 1.99 (1.00 – 3.98) p=0.05

Metanalyse : Sécurité - Thrombose tres tardive de Scaffold

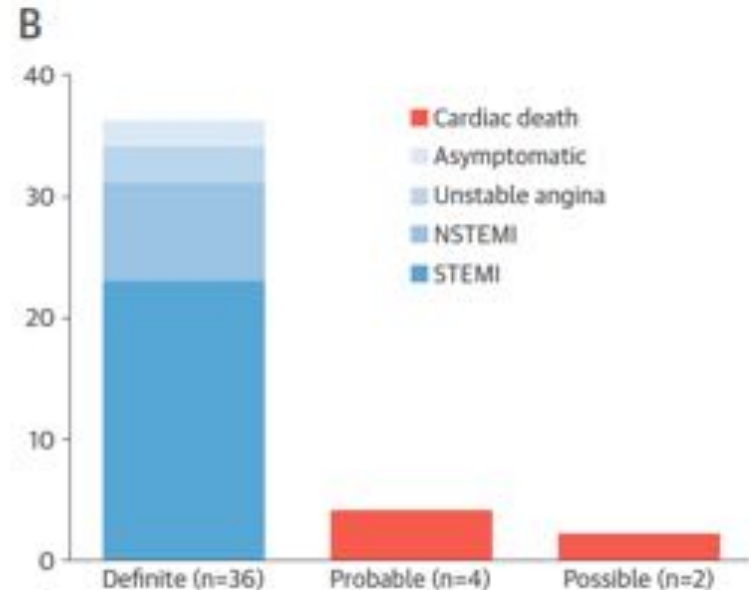
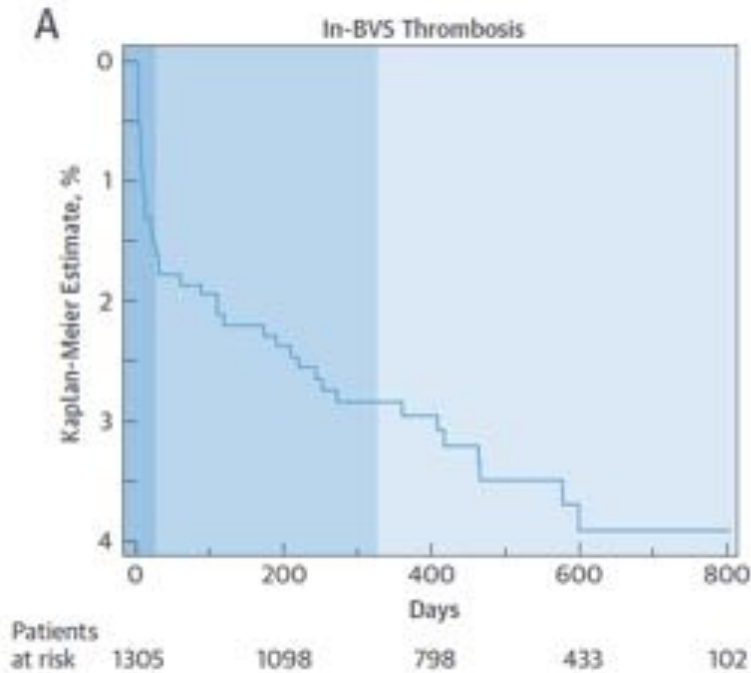


Thrombose Tres tardive de Scaffold

Thrombosis de Scaffold : Determinants

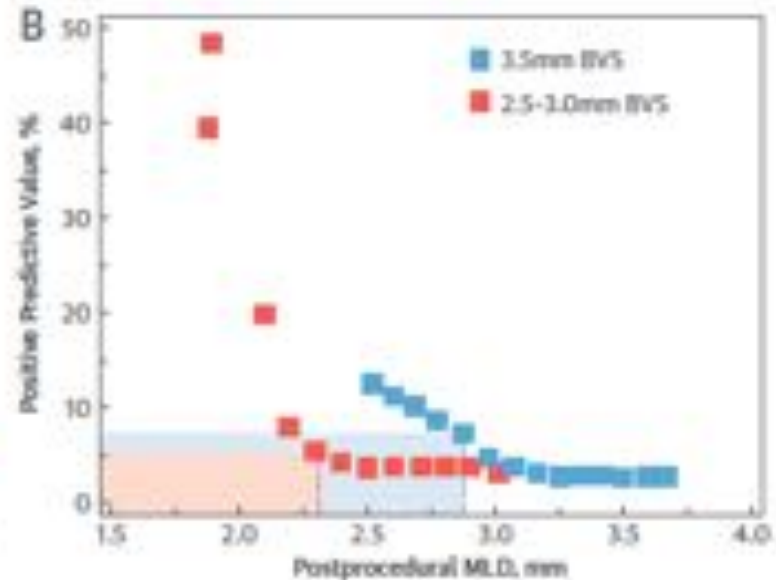
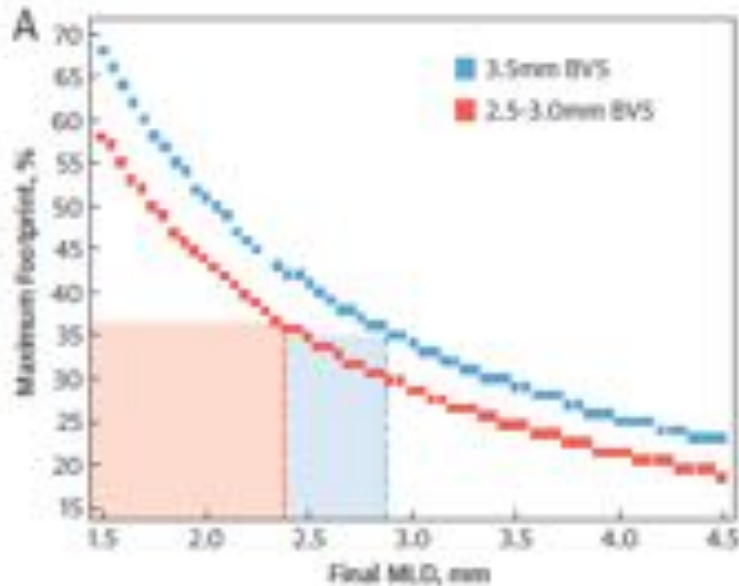
Bioresorbable Coronary Scaffold Thrombosis

Multicenter Comprehensive Analysis of Clinical Presentation, Mechanisms, and Predictors



Thrombose de Scaffold : Determinants

	Pre-Procedure				After BVS Implantation			
	BVS Thrombosis (n = 42)	Control (n = 84)	p Value for Risk	HR (95% CI)	BVS Thrombosis (n = 42)	Control (n = 84)	p Value for Risk	HR (95% CI)
MLD, mm	0.66 ± 0.59	0.68 ± 0.51	0.784	0.88 (0.35-2.22)	2.39 ± 0.58	2.85 ± 0.49	0.001	0.05 (0.01-0.28)
RVD, mm	2.77 ± 0.58	3.13 ± 0.66	0.014	0.27 (0.10-0.77)	2.93 ± 0.58	3.41 ± 0.52	0.002	0.13 (0.04-0.46)
% stenosis	76 ± 20	77 ± 16	0.815	1.00 (0.97-1.03)	19 ± 12	16 ± 7	0.071	1.05 (0.10-1.10)
Maximum footprint, %	–	–			43 ± 11	35 ± 6	0.001	1.20 (1.08-1.33)
Scaled residual stenosis	–	–			0.21 ± 0.18	0.07 ± 0.14	0.001	1,714 (20.07-146,454)

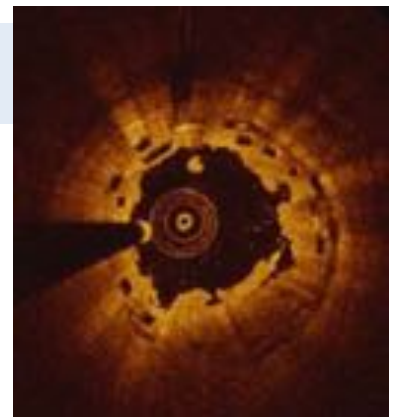


Thrombosis de Scaffold : Determinants

ABSORB III: Clinical endpoints by 2 years (25 months)

	Overall		QCA RVD \geq 2.25mm	
	Absorb (N=1322)	XIENCE (N=686)	Absorb (N=1074)	XIENCE (N=549)
TLF	11.0% (143)*	7.9% (53)*	9.4% (99)	7.0% (38)
Cardiac Death	1.1% (14)	0.6% (4)	0.9% (10)	0.4% (2)
TV-MI	7.3% (95)**	4.9% (33)**	6.5% (68)	4.8% (26)
ID-TLR	5.3% (69)	4.3% (29)	4.1% (43)	3.0% (16)
ST (Def/Prob)	1.9% (24)	0.8% (5)	1.3% (13)	0.6% (3)

Thrombose de Scaffold : OCT



Suboptimal implantation
underexpansion
malapposition
incomplete lesion coverage

early and late BVS thrombosis
similar to metallic stent thrombosis.

DAPT discontinuation

late BVS thrombosis

Number of potential triggers for BVS thrombosis could be avoided and might warrant prospective validation.

Technique d'Implantation : PSP

P PREPARE THE LESION

OBJECTIVE

- Prepare lesion to receive scaffold
- Facilitate delivery
- Enable full expansion of pre-dilatation balloon to facilitate full scaffold expansion

S SIZE APPROPRIATELY

OBJECTIVE

- Accurately size the vessel
- Select appropriate scaffold for "best fit"

P POST-DILATE

OBJECTIVE

- Achieve **<10% final residual stenosis**
- Ensure full strut apposition

POST DILATATION

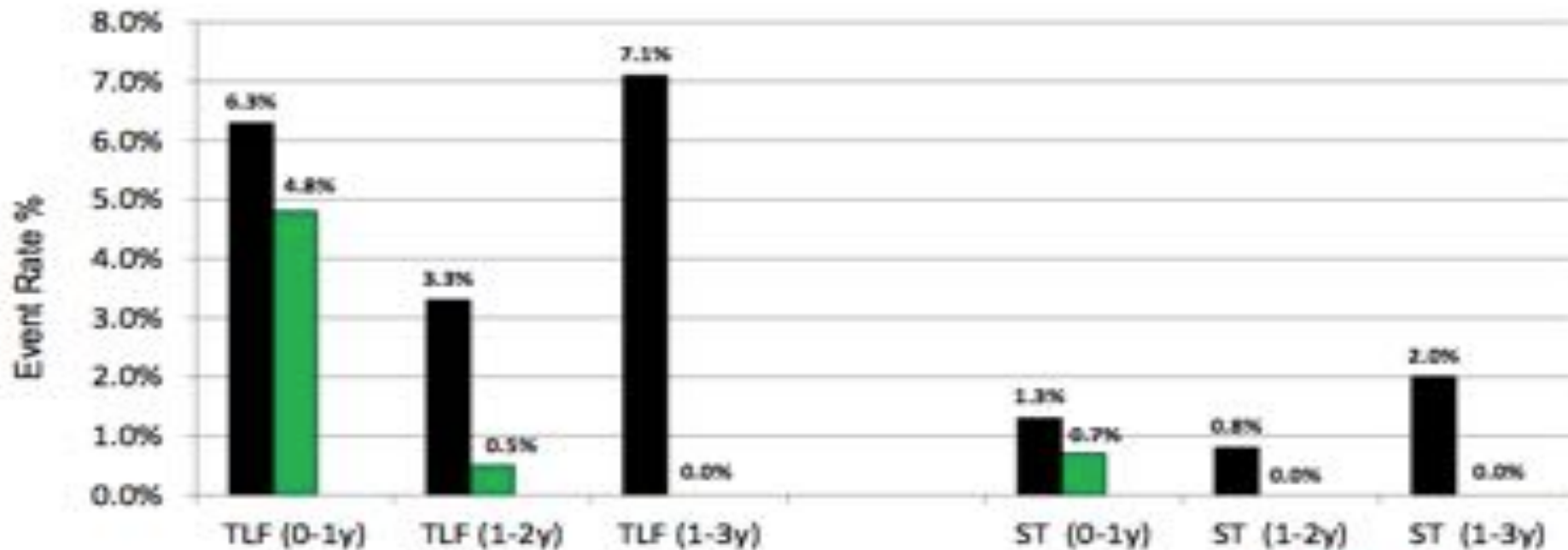
GHOST: 52%

ABSORB II: 60%

ABSORB III: 65%

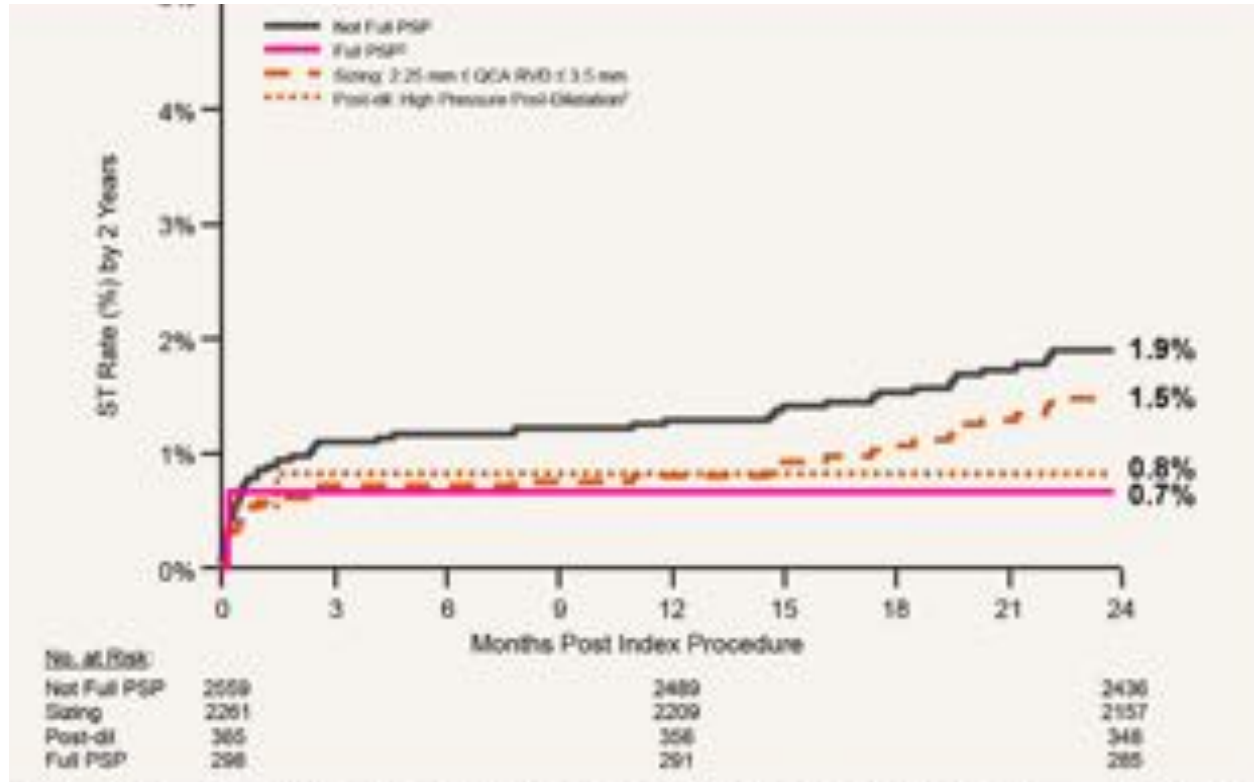
AIDA: 74% (63% during the 1st year)

Résultat Clinique Post HOC

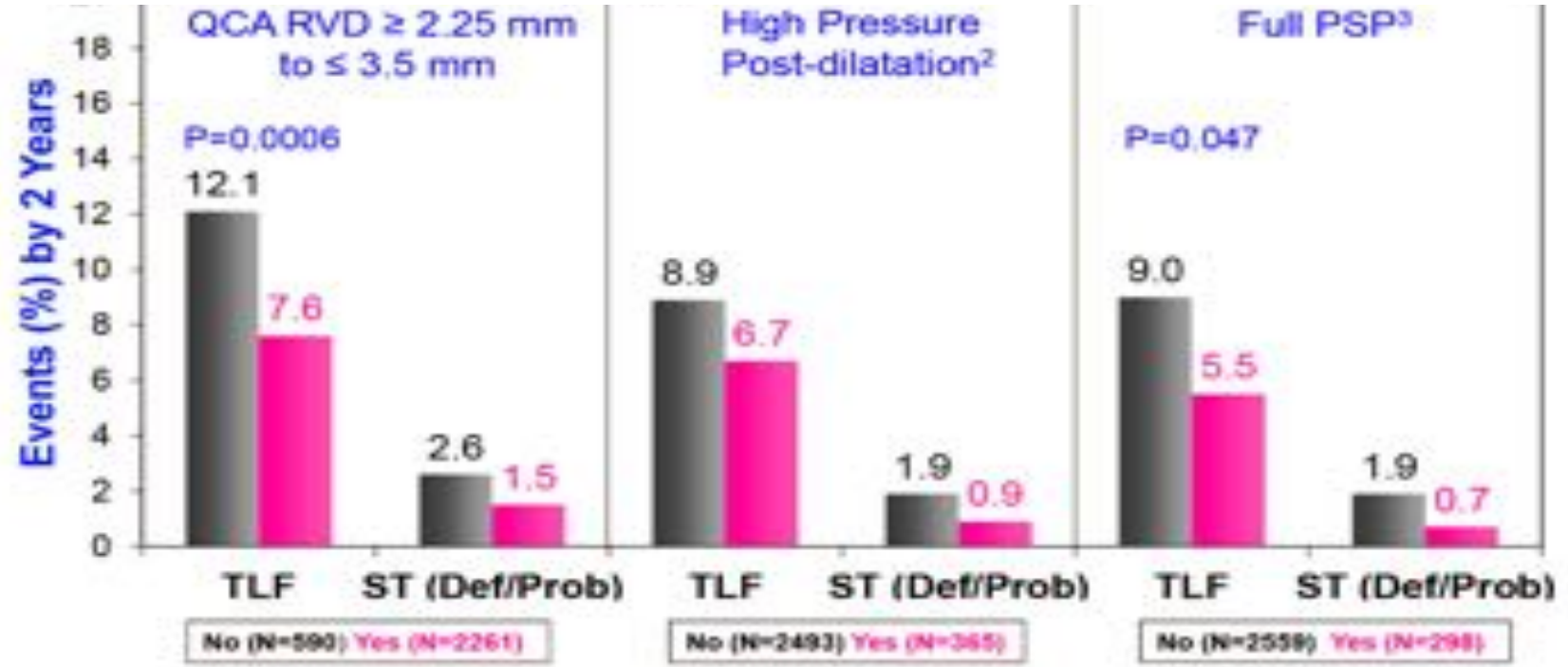


		Non-PSP	PSP
0-1y	A-EXTEND, A-II, A-Japan, A-China, A-III	N=2540	N=294
1-2y	A-EXTEND, A-II, A-Japan, A-China	N=1381	N=194
1-3y	A-II	N=297	N=21

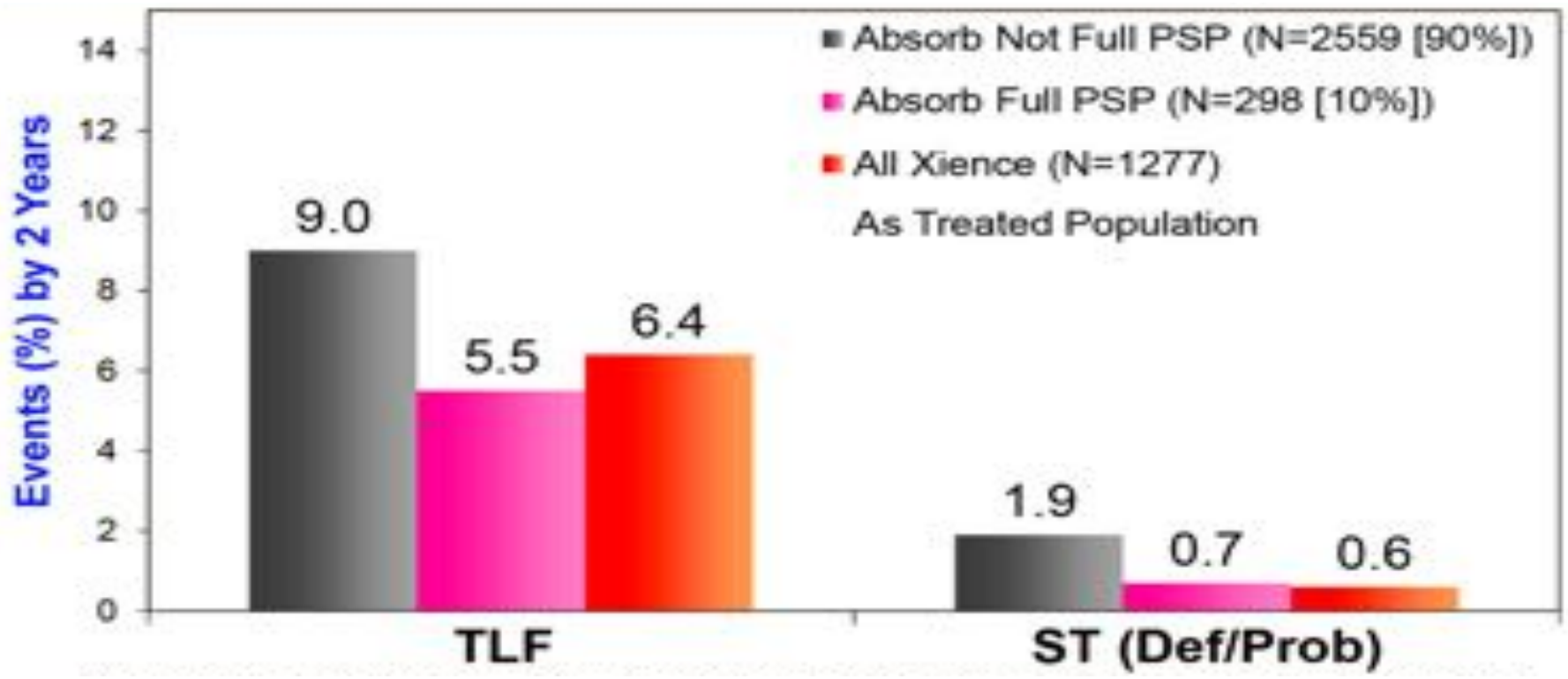
Impact of implantation technique on clinical outcomes by 2 years Pooled ABSORB trials ABSORB arm



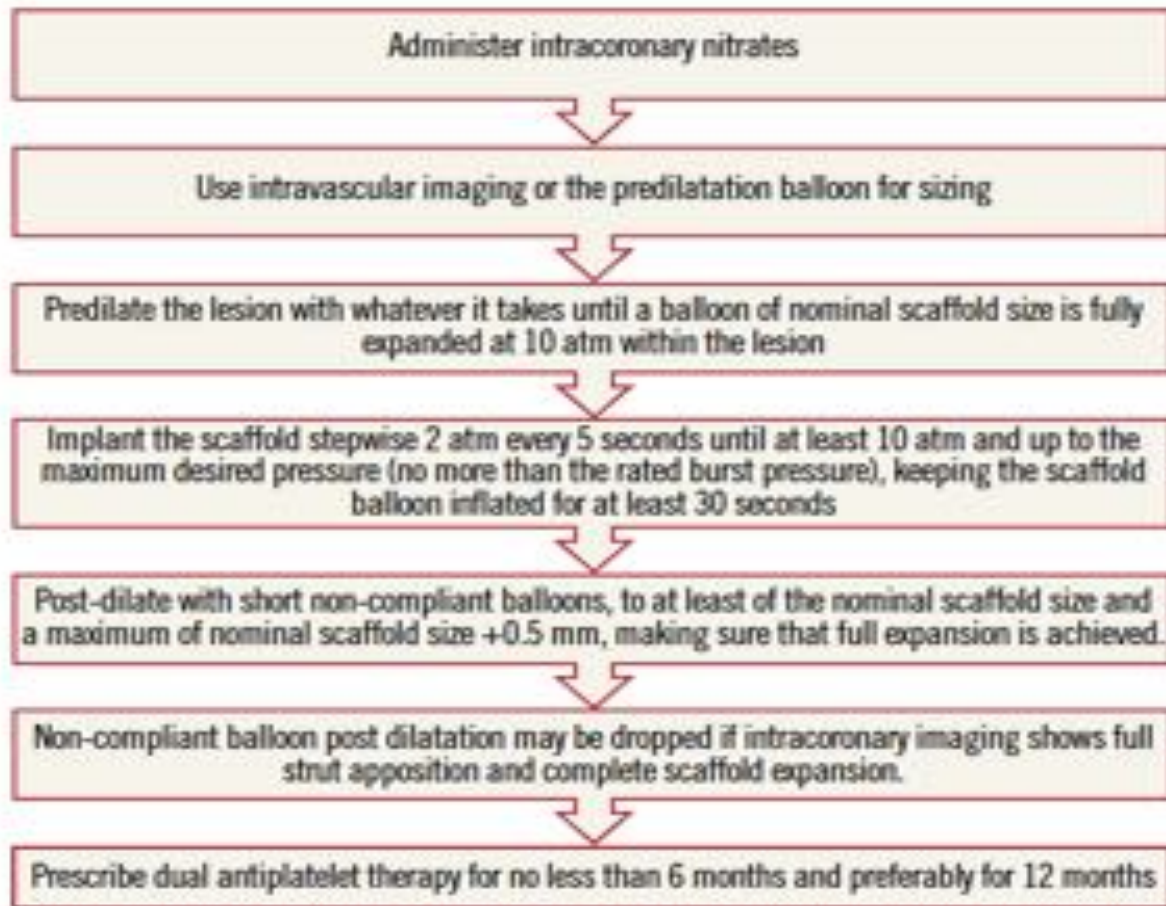
Impact of implantation technique on clinical outcomes by 2 years Pooled ABSORB trials ABSORB arm



Impact of implantation technique on clinical outcomes by 2 years Pooled ABSORB trials ABSORB arm



Importance de la technique d'implantation



Sizing

Préparation

Inflation prolongé

Post dilatation

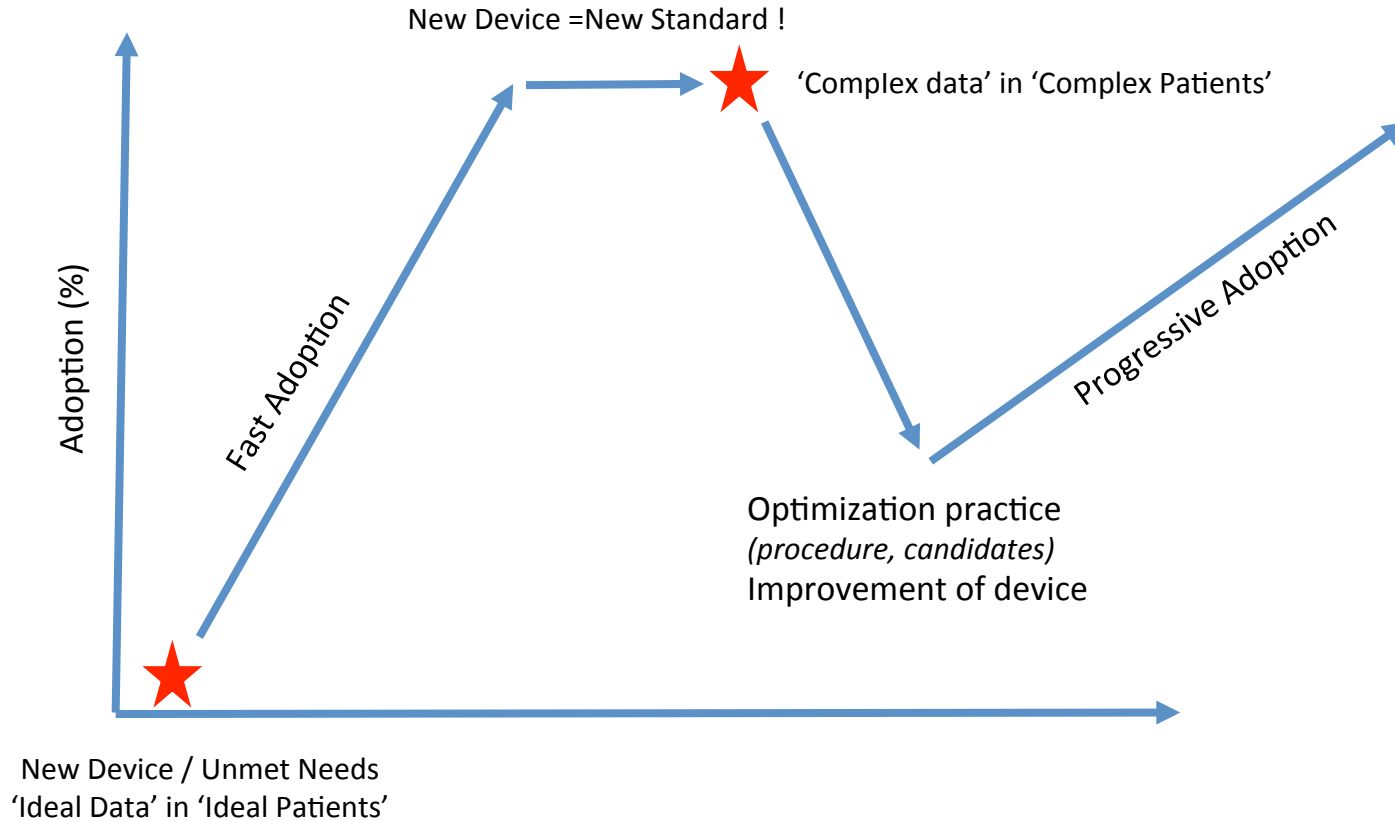
NC +0.5mm

Contrôle

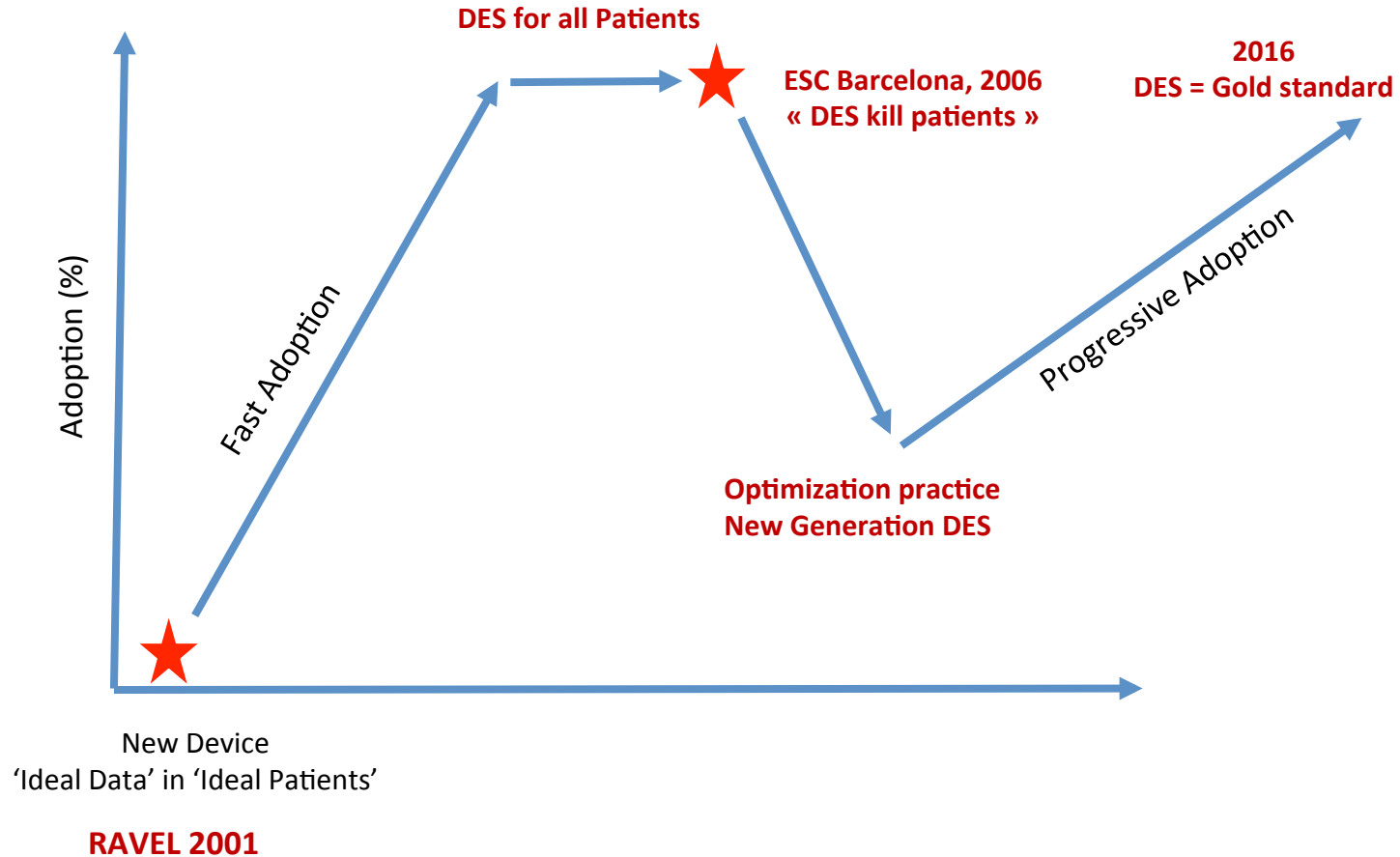
3. L'HISTOIRE



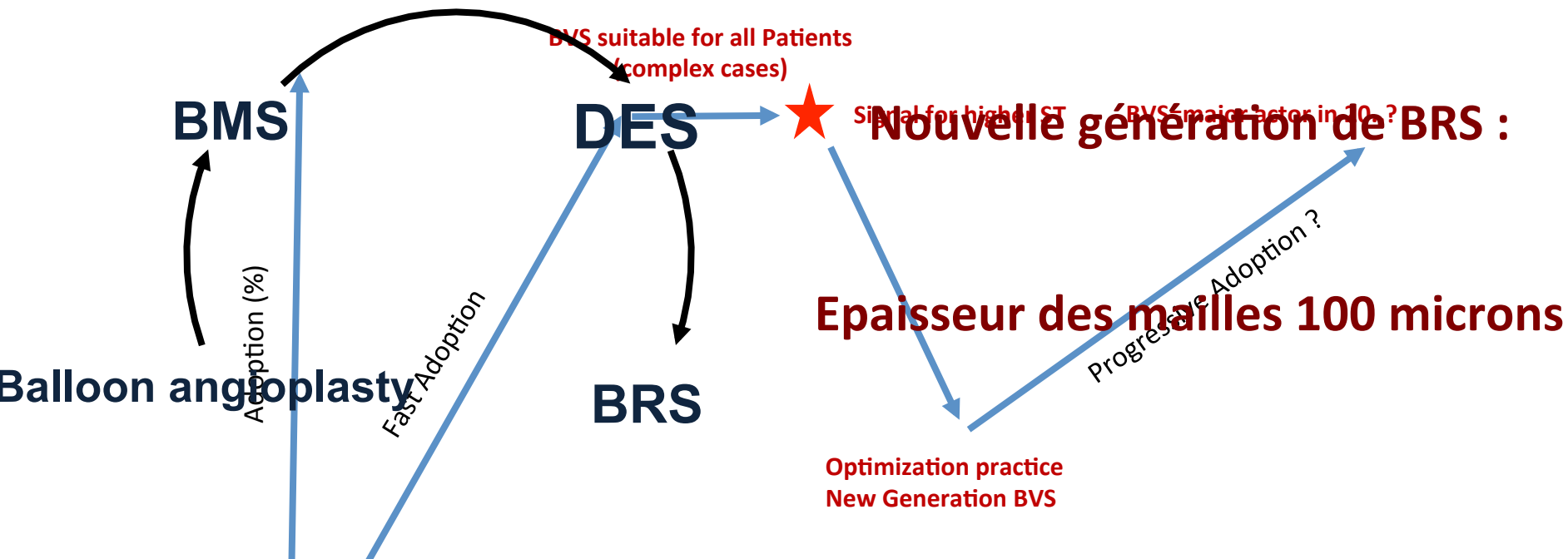
Timecourse d'un nouveau device



Timecourse d'un nouveau device



Timecourse d'un nouveau device



Quatrième revolution en angioplastie

New Device
'Ideal Data' in 'Ideal Patients'

Absorb A and B

Conclusion

- Concept révolutionnaire - 1^{ère} génération de BVS
- Améliorer nos résultats
 - Ne pas utiliser les BVS dans les petits vaisseaux
 - Role crucial de la technique d'implantation
 - Double antiagrégation prolongée ?
- ABSORB IV : PSP méthode

