PALAIS DES CONGRES BIARRITZ 8/9/10 JUIN 2016
www.appac.fr

APPAC
ACTUALISATIONS ET PERSPECTIVES EN PATHOLOGIE CARDIOVASCULAIRE

BVS ABSORB
Synthèse des résultats cliniques

Jean Fajadet
Clinique Pasteur, Toulouse

BVS: les preuves cliniques

1. Etudes randomisées
2. Meta-analyses
3. Registres

BVS: les preuves cliniques

Etudes randomisées: n=6

Clinical primary endpoint

Absorb III - Ellis et al. *N Engl J Med* 2015; 373:1905-15

Absorb Japan - Kimura et al. *Eur Heart J* 2015

Non clinical primary endpoint

Absorb II - Serruys et al. *Lancet* 2015; 385: 43–54

Absorb China - Gao et al. *J Am Coll Cardiol* 2015; 66:2298–309

Everbio II - Puricel et al. *Am Coll Cardiol* 2015; 65: 791–801

Troffi II - Sabate et al. *Eur Heart J* 2016; 37, 229–240

Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease – ABSORB III

Ellis et al. *N Engl J Med* 2015;373:1905-15

2008 patients with stable or unstable angina

Randomisation in a 2:1 ratio
everolimus-eluting bioresorbable vascular (Absorb) scaffold: 1322 patients
or an everolimus-eluting cobalt– chromium (Xience) stent: 686 patients

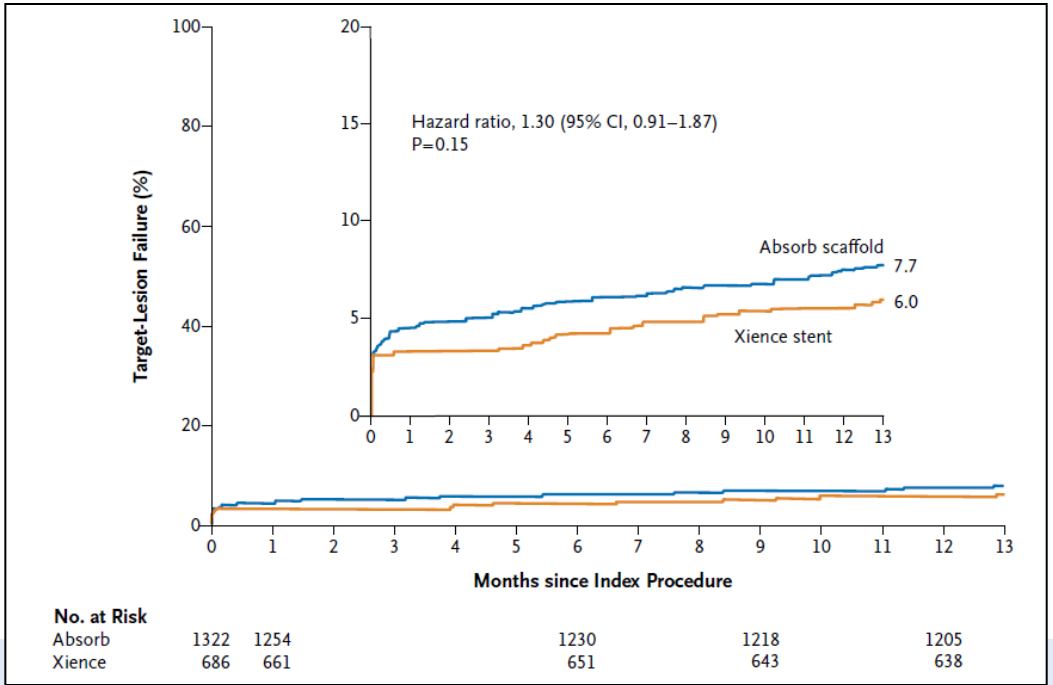
Primary end point: target-lesion failure (cardiac death, target-vessel myocardial infarction, or ischemia-driven target-lesion revascularization) **at 1 year**

Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease – ABSORB III

Ellis et al. *N Engl J Med* 2015;373:1905-15

Target-lesion failure at 1 year: 7.8% vs 6.1%

risk difference, 1.7 percentage points; 95% confidence interval [CI], −0.5 to 3.9; P = 0.007 for noninferiority and P = 0.16 for superiority



Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease – ABSORB III

Ellis et al. *N Engl J Med* 2015;373:1905-15

Repeat revascularisation

Adverse Event	Absorb Scaffold (N=1322)	Xience Stent (N=686)	Relative Risk (95% CI)	P Value
	no./total no. (%)			
Any revascularization	120/1313 (9.1)	55/677 (8.1)	1.12 (0.83–1.53)	0.45
Ischemia-driven	115/1313 (8.8)	54/677 (8.0)	1.10 (0.81–1.50)	0.55
Target vessel	66/1313 (5.0)	25/677 (3.7)	1.36 (0.87–2.14)	0.18
Nontarget vessel	71/1313 (5.4)	39/677 (5.8)	0.94 (0.64–1.37)	0.74
Not ischemia-driven	8/1313 (0.6)	5/677 (0.7)	0.82 (0.27–2.51)	0.77
Target lesion	2/1313 (0.2)	2/677 (0.3)	0.52 (0.07–3.65)	0.61
Target vessel	3/1313 (0.2)	3/677 (0.4)	0.52 (0.10–2.55)	0.42
Nontarget vessel	5/1313 (0.4)	2/677 (0.3)	1.29 (0.25–6.63)	1.00

Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease – ABSORB III

Ellis et al. *N Engl J Med* 2015;373:1905-15

Device thrombosis

Adverse Event	Absorb Scaffold (N=1322)	Xience Stent (N=686)	Relative Risk (95% CI)	P Value
	no./total no. (%)			
Definite or probable device thrombosis	20/1301 (1.5)	5/675 (0.7)	2.08 (0.78–5.51)	0.13
Early: 0 to 30 days	14/1315 (1.1)	5/686 (0.7)	1.46 (0.53–4.04)	0.46
Acute: ≤24 hr	2/1320 (0.2)	4/686 (0.6)	0.26 (0.05–1.42)	0.19
Subacute: >24 hr to 30 days	12/1315 (0.9)	1/686 (0.1)	6.26 (0.82–48.04)	0.04
Late: 31 days to 1 yr	6/1299 (0.5)	0/675	NA	0.10
Definite	18/1301 (1.4)	5/675 (0.7)	1.87 (0.70–5.01)	0.21
Probable	2/1301 (0.2)	0/675	NA	0.55

Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease – ABSORB III

Ellis et al. *N Engl J Med* 2015;373:1905-15

In this large-scale, randomized trial, treatment of noncomplex obstructive coronary artery disease with an everolimus-eluting bioresorbable vascular scaffold, as compared
with an everolimus-eluting cobalt–chromium stent, was within the prespecified margin for noninferiority with respect to target-lesion failure at 1 year.

A randomized trial evaluating everolimus-eluting Absorb bioresorbable scaffolds vs. Everolimuseluting metallic stents in patients with coronary artery disease: ABSORB Japan –

Kimura et al. *Eur Heart J* 2015

Single-blind, multicentre, active-controlled, randomized non-inferiority trial 2:1 ratio to Absorb BVS vs. cobalt-chromium everolimus-eluting stents (CoCr-EESs)

400 patients randomized to BVSs (266 patients and 275 lesions)
or CoCr-EESs (134 patients and 137 lesions)

Primary endpoint: Target Lesion Failure [TLF: a composite of cardiac death, myocardial infarction attributable to target vessel, or ischaemia-driven target lesion revascularization (ID-TLR)] at 12 months

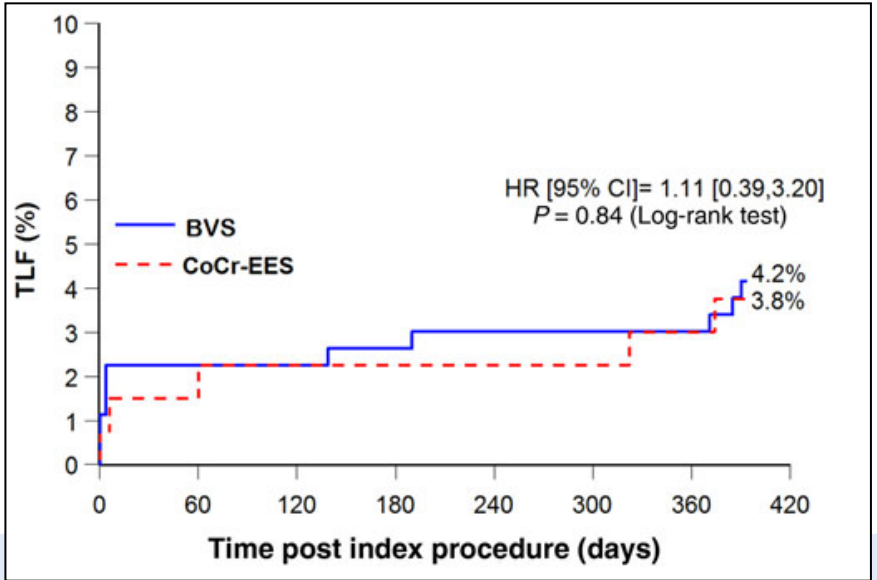
A randomized trial evaluating everolimus-eluting Absorb bioresorbable scaffolds vs. Everolimuseluting metallic stents in patients with coronary artery disease: ABSORB Japan –

Kimura et al. *Eur Heart J* 2015

Similar TLF between BVS and CoCr-EES at 12 months

4.2% vs 3.8%

difference (upper one-sided 95% confidence limit) = 0.39% (3.95%); P non-inferiority , 0.0001

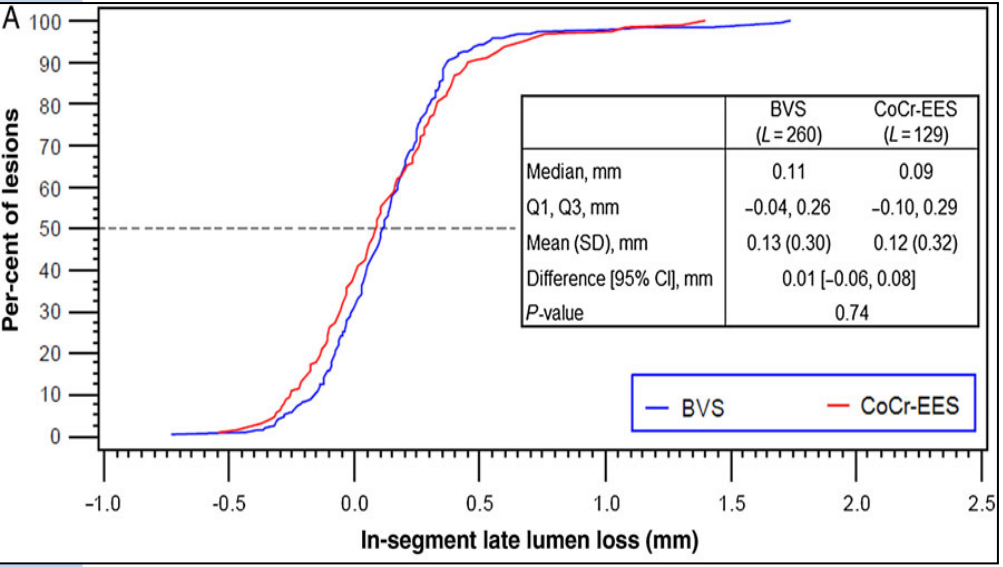


A randomized trial evaluating everolimus-eluting Absorb bioresorbable scaffolds vs. Everolimuseluting metallic stents in patients with coronary artery disease: ABSORB Japan –

Kimura et al. *Eur Heart J* 2015

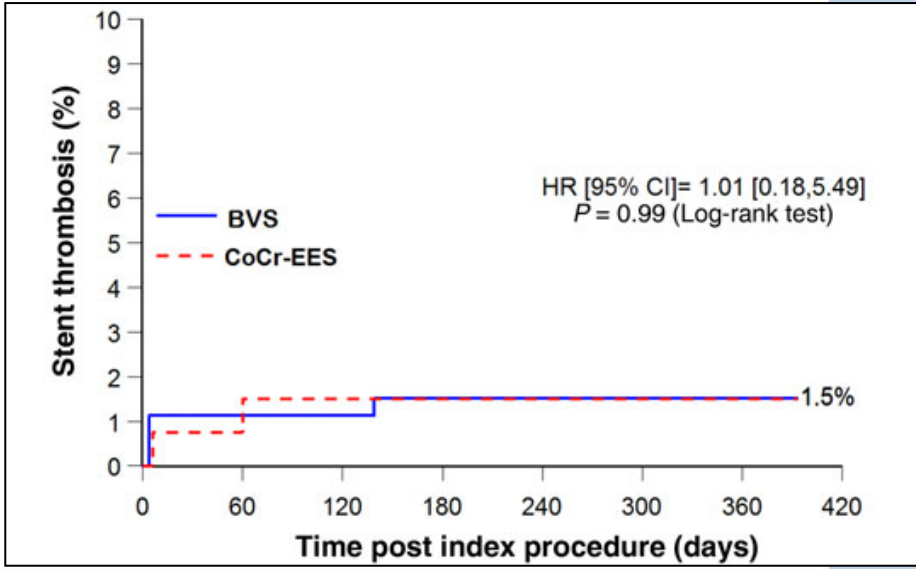
Similar in-segment Late Lumen Loss

0.13+0.30 mm vs 0.12+0.32 mm



Similar device thrombosis

1.5% vs 1.5%



A randomized trial evaluating everolimus-eluting Absorb bioresorbable scaffolds vs. Everolimuseluting metallic stents in patients with coronary artery disease: ABSORB Japan –

Kimura et al. *Eur Heart J* 2015

In the ABSORB Japan randomized trial, 12-month clinical and 13-month angiographic outcomes of BVSs were comparable to CoCr-EESs.

ABSORB II: an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial –

Serruys et al. *Lancet* 2015; 385: 43–54

Single-blind, multicentre, randomised trial
Randomisation in a 2:1 ratio, BVS vs Xience

Co-primary endpoints:

vasomotion (change in mean lumen diameter before and after nitrate administration at 3 years)
and difference between minimum lumen diameter (after nitrate administration) after the index procedure and at 3 years

501 patients: bioresorbable scaffold group (335 patients, 364 lesions)
or the metallic stent group (166 patients, 182 lesions)

ABSORB II: an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial –

Serruys et al. *Lancet* 2015; 385: 43–54

Clinical outcome

All deaths	0	1 (1%)	−0·61% (−3·35 to 0·65)	0·33
Cardiac deaths	0	0	0·00% (NA)	1·00
Myocardial infarction per protocol	15 (4%)	2 (1%)	3·32% (−0·25 to 6·26)	0·06
Q-wave	2 (1%)	0	0·60% (−1·71 to 2·18)	1·00
Non-Q-wave	13 (4%)	2 (1%)	2·72% (−0·78 to 5·53)	0·16
All target-lesion revascularisation	4 (1%)	3 (2%)	−0·61% (−4·08 to 1·60)	0·69
Clinically indicated target-lesion revascularisation	4 (1%)	3 (2%)	−0·61% (−4·08 to 1·60)	0·69
All target-vessel revascularisation	8 (2%)	8 (5%)	−2·43% (−7·01 to 0·86)	0·15
All revascularisation	12 (4%)	12 (7%)	−3·65% (−8·89 to 0·37)	0·08

ABSORB II: an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial –

Serruys et al. *Lancet* 2015; 385: 43–54

Similar Composite End-points outcome

	BVS (n=335)	Xience (n=166)	Difference (95% CI)	p value
Cardiac death, all myocardial infarction, clinically indicated target-vessel revascularisation (target-vessel failure)	18 (5%)	8 (5%)	0·59% (–4·26 to 4·41)	0·78
Cardiac death, target-vessel myocardial infarction, and clinically indicated target-lesion revascularisation (target-lesion failure; device-oriented composite endpoint)	16 (5%)	5 (3%)	1·80% (–2·48 to 5·16)	0·35
Cardiac death, all myocardial infarction, and clinically indicated target-lesion revascularisation (major adverse cardiac events)	17 (5%)	5 (3%)	2·11% (–2·20 to 5·51)	0·28
All death, all myocardial infarction, and all revascularisation (patient-oriented composite endpoint)	24 (7%)	15 (9%)	–1·84% (–7·69 to 2·98)	0·47

ABSORB II: an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial –

Serruys et al. *Lancet* 2015; 385: 43–54

Low and similar Device Thrombosis

	BVS (n=335)	Xience (n=166)	Difference (95% CI)	p value
Definite scaffold or stent thrombosis	2 (0·6%)	0	0·61% (–1·72 to 2·19)	1·00
Acute (0–1 day)	1 (0·3%)	0	0·30% (–1·98 to 1·67)	1·00
Sub-acute (2–30 days)	1 (0·3%)	0	0·30% (–1·98 to 1·68)	1·00
Late (31–365 days)	0	0	0·00% (NA)	1·00
Definite or probable scaffold or stent thrombosis	3 (0·9%)	0	0·91% (–1·45 to 2·65)	0·55

ABSORB II: an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial –

Serruys et al. *Lancet* 2015; 385: 43–54

The everolimus-eluting bioresorbable scaffold showed similar 1-year composite secondary clinical outcomes to the everolimus-eluting metallic stent

Bioresorbable Vascular Scaffolds Versus Metallic Stents in Patients With Coronary Artery Disease - ABSORB China Trial

Gao et al. *J Am Coll Cardiol* 2015;66:2298–309

Non inferiority trial

480 patients were randomized

241 BVS vs 239 CoCr-EES

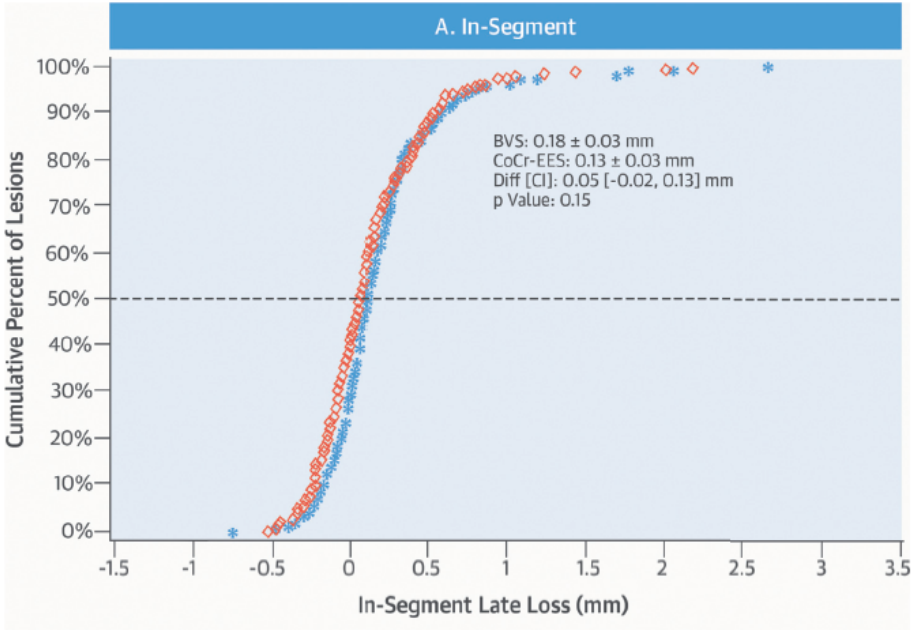
Primary endpoint: In-segment Late Loss at 1 year

Bioresorbable Vascular Scaffolds Versus Metallic Stents in Patients With Coronary Artery Disease - ABSORB China Trial

Gao et al. *J Am Coll Cardiol* 2015;66:2298–309

Primary endpoint: In-segment Late Loss at 1 year

0.19 ± 0.38 mm versus 0.13 ± 0.38 mm (p non inferiority = 0.01)



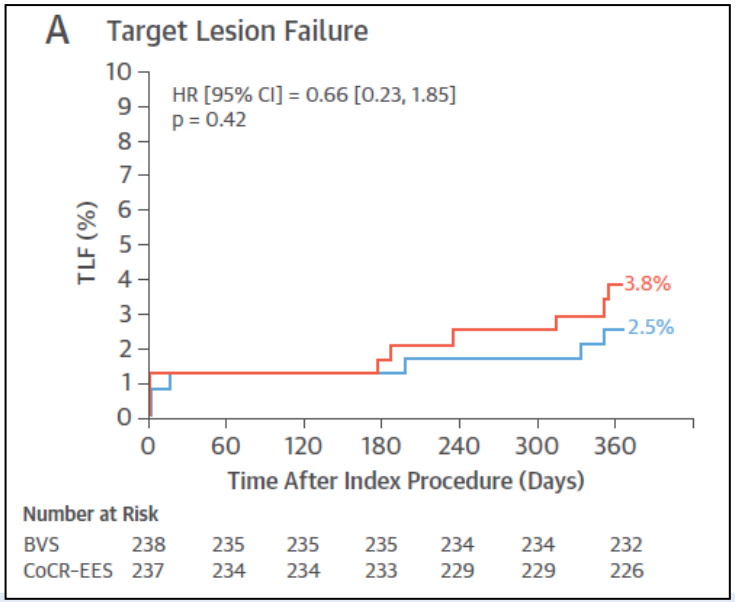
Bioresorbable Vascular Scaffolds Versus Metallic Stents in Patients With Coronary Artery Disease - ABSORB China Trial

Gao et al. *J Am Coll Cardiol* 2015;66:2298–309

Similar 1-year rates of Target Lesion Failure

(cardiac death, target vessel myocardial infarction, or ischemia-driven target lesion revascularization)

3.4% vs. 4.2%, p = 0.62



Bioresorbable Vascular Scaffolds Versus Metallic Stents in Patients With Coronary Artery Disease - ABSORB China Trial

Gao et al. *J Am Coll Cardiol* 2015;66:2298–309

Similar 1-year rates of Definite/Probable Scaffold/Stent Thrombosis

0.4% vs. 0.0%, p =1.00

Scaffold/stent thrombosis‡			
All (0-365 days)	0.4 (1/238)	0.0 (0/232)	0.4 (–1.2 to 2.3)
Definite	0.0 (0/238)	0.0 (0/232)	0.0 (–1.6 to 1.6)
Probable	0.4 (1/238)	0.0 (0/232)	0.4 (–1.2 to 2.3)
Acute (≤1 day)	0.0 (0/238)	0.0 (0/236)	0.0 (–1.6 to 1.6)
Subacute (>1-30 days)	0.4 (1/238)	0.0 (0/236)	0.4 (–1.2 to 2.3)
Late (31-365 days)	0.0 (0/238)	0.0 (0/232)	0.0 (–1.6 to 1.6)

Bioresorbable Vascular Scaffolds Versus Metallic Stents in Patients With Coronary Artery Disease - ABSORB China Trial

Gao et al. *J Am Coll Cardiol* 2015;66:2298–309

In the present multicenter randomized trial,
BVS was noninferior to CoCr-EES
for the primary endpoint of in-segment LL at 1 year

Comparison of Everolimus- and Biolimus-Eluting Coronary Stents With Everolimus-Eluting Bioresorbable Vascular Scaffolds EVERBIO II - Puricel et al. *J Am Coll Cardiol* 2015;65:791–801

240 patients randomly assigned in a 1:1:1 ratio to EES, BES, or BVS

Primary endpoint:

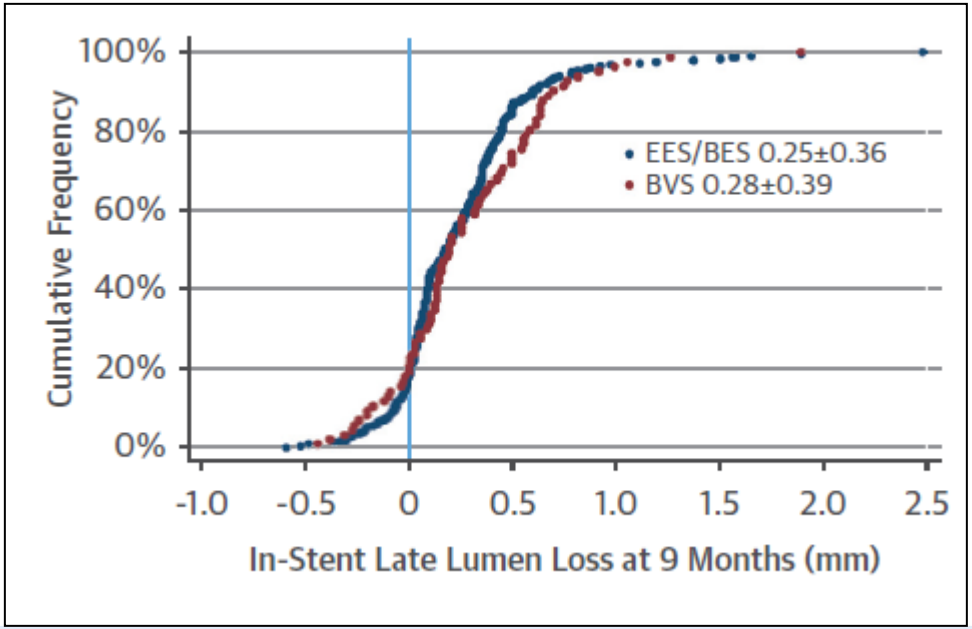
Angiographic Late Lumen Loss (LLL) at 9 months

Follow-up angiography was performed in 216 patients (90.7%) at 9 months

Comparison of Everolimus- and Biolimus-Eluting Coronary Stents With Everolimus-Eluting Bioresorbable Vascular Scaffolds EVERBIO II - Puricel et al. *J Am Coll Cardiol* 2015;65:791–801

Similar In-stent LLL between BVS and EES/BES

0.28 ± 0.39 mm vs 0.25 ± 0.36 mm; p= 0.30

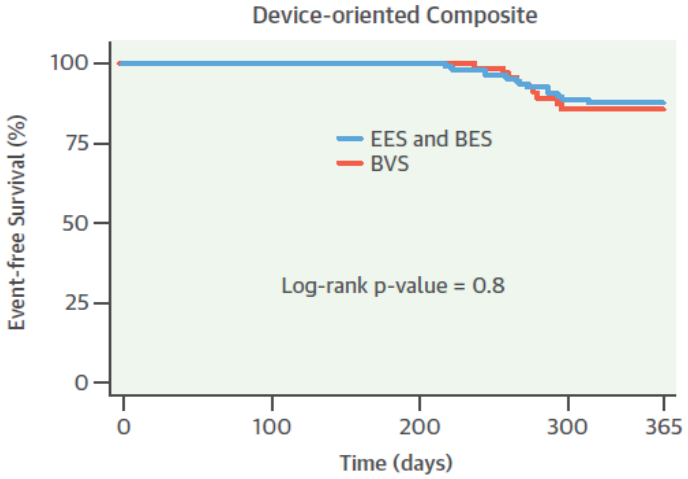


Comparison of Everolimus- and Biolimus-Eluting Coronary Stents With Everolimus-Eluting Bioresorbable Vascular Scaffolds EVERBIO II - Puricel et al. *J Am Coll Cardiol* 2015;65:791–801

Similar clinical outcomes at 9 months

Device-oriented MACE rate

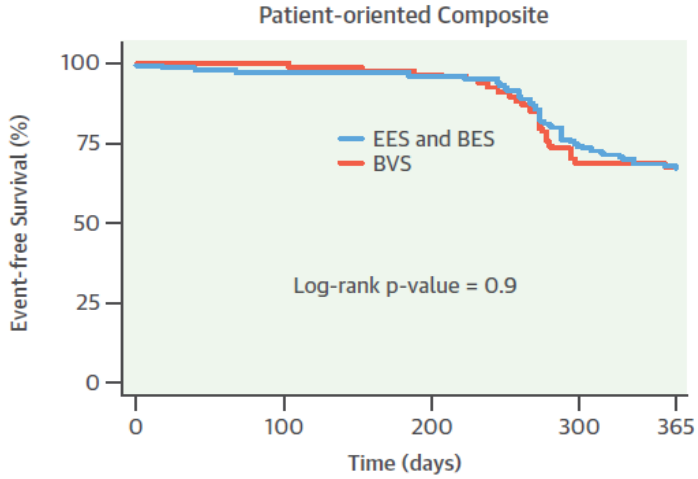
12% in BVS vs 9% in the EES/BES; p = 0.6



Number at risk					
BVS	78	78	78	49	48
EES and BES	160	158	158	91	87

Patient-oriented MACE rate

27% in BVS vs 26% in EES/BES; p = 0.83



Number at risk					
BVS	78	78	75	39	39
EES and BES	160	154	153	79	70

Comparison of Everolimus- and Biolimus-Eluting Coronary Stents With Everolimus-Eluting Bioresorbable Vascular Scaffolds EVERBIO II - Puricel et al. *J Am Coll Cardiol* 2015;65:791–801

New-generation metallic DES (EES/BES) were not superior to BVS in terms of angiographic LLL and clinical outcomes.

Everolimus-eluting bioresorbable stent vs. Durable polymer everolimus-eluting metallic stent in patients with STEMI: results of the randomized ABSORB STEMI — TROFI II trial

Sabate et al. *Eur Heart J* 2016; 37, 229–240

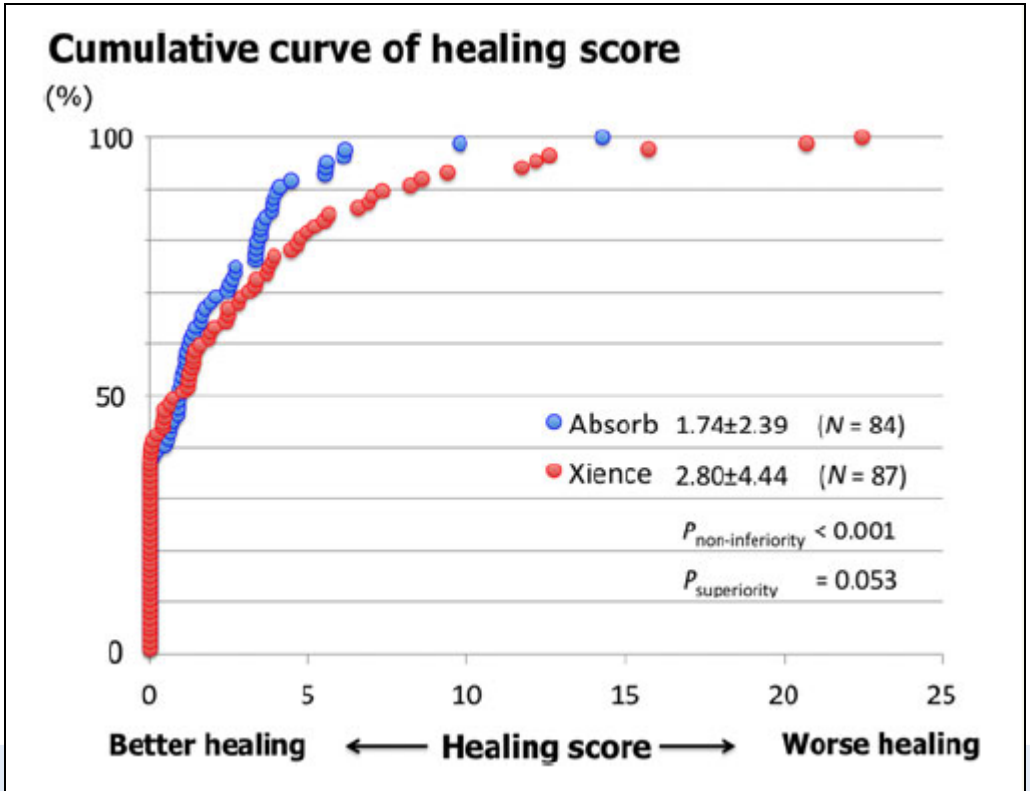
To compare the arterial healing response at short term, as a surrogate for safety and efficacy, between the Absorb and the metallic everolimus-eluting stent (EES) in patients with STEMI.

Multicentre, single-blind, non-inferiority, randomized controlled trial
191 patients: Absorb (n = 95) or EES (n = 96)

Primary endpoint: 6-month optical frequency domain imaging (OFDI) healing score (HS) based on the presence of uncovered and/or malapposed stent struts and intraluminal filling defects.

Everolimus-eluting bioresorbable stent vs. Durable polymer everolimus-eluting metallic stent in patients with STEMI: results of the randomized ABSORB STEMI — TROFI II trial

Sabate et al. *Eur Heart J* 2016; 37, 229–240



Everolimus-eluting bioresorbable stent vs. Durable polymer everolimus-eluting metallic stent in patients with STEMI: results of the randomized ABSORB STEMI — TROFI II trial

Sabate et al. *Eur Heart J* 2016 37, 229–240

Stenting of culprit lesions with Absorb in the setting of STEMI resulted in a nearly complete arterial healing which was comparable with that of metallic EES at 6 months.
These findings provide the basis for further exploration in clinically oriented outcome trials

BVS: les preuves cliniques

Méta-analyses

- Stone et al. - *Lancet* 2016; 387: 1277–89
- Lipinski et al. - *J Am Coll Cardiol Intv* 2016;9:12–24
- Cassese et al. - *Lancet* 2016; 387: 537–44
- Banach et al. - *EuroIntervention* 2016; 12:e175-e189

1-year outcomes with the Absorb bioresorbable scaff old in patients with coronary artery disease: a patient-level, pooled meta-analysis – Stone et al. *Lancet* 2016; 387: 1277–89

	ABSORB II[8]	ABSORB Japan[9]	ABSORB China[10]	ABSORB III[11]
ClinicalTrials.gov identifier	NCT01425281	NCT01844284	NCT01923740	NCT01751906
Centres, n	46	38	24	193
Randomised patients, n	501	400	480	2008
Assigned to BVS, n	335	266	241	1322
Assigned to CoCr-EES, n	166	134	239	686
Study lesions allowed, n	2	2	2	2
Study vessels allowed, n*	2	2	2	2
Target lesion reference vessel diameter	Maximum lumen diameter 2·25 to 3·8 mm by online QCA	≥2·5 to ≤3·75 mm by online QCA or visual assessment	≥2·5 to ≤3·75 mm by online QCA or visual assessment	≥2·5 to ≤3·75 mm by visual assessment (QCA or imaging allowed)
Target lesion length	≤48 mm	≤24 mm	≤24 mm	≤24 mm
Device overlap allowed?	Yes	For bailout only	For bailout only	For bailout only
1-year clinical follow-up complete	493 (98%)	397 (99%)	475 (99%)	1990 (99%)
Routine angiographic follow-up	At 3 years	At 13 months	At 1 year	No
Primary endpoint	Angiographic vasomotion at 3 years	Target lesion failure at 1 year	Angiographic in-segment late loss at 1 year	Target lesion failure at 1 year
Total duration of follow-up	5 years	5 years	5 years	5 years

1-year outcomes with the Absorb bioresorbable scaff old in patients with coronary artery disease: a patient-level, pooled meta-analysis –

Stone et al. *Lancet* 2016; 387: 1277–89

No differences in composite patient oriented adverse events

All-cause mortality, all MI, all revascularisation

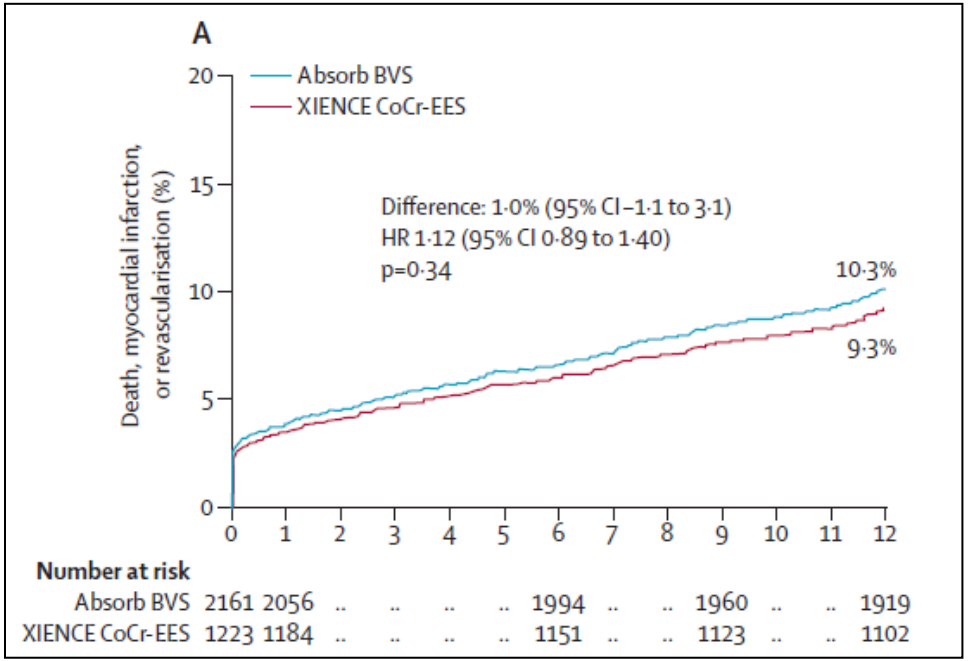
No differences in composite device oriented adverse events = TLF

Cardiac mortality, target vessel MI, ischemia-driven TLR

1-year outcomes with the Absorb bioresorbable scaff old in patients with coronary artery disease: a patient-level, pooled meta-analysis – Stone et al. *Lancet* 2016; 387: 1277–89

No differences in composite Patient oriented adverse events

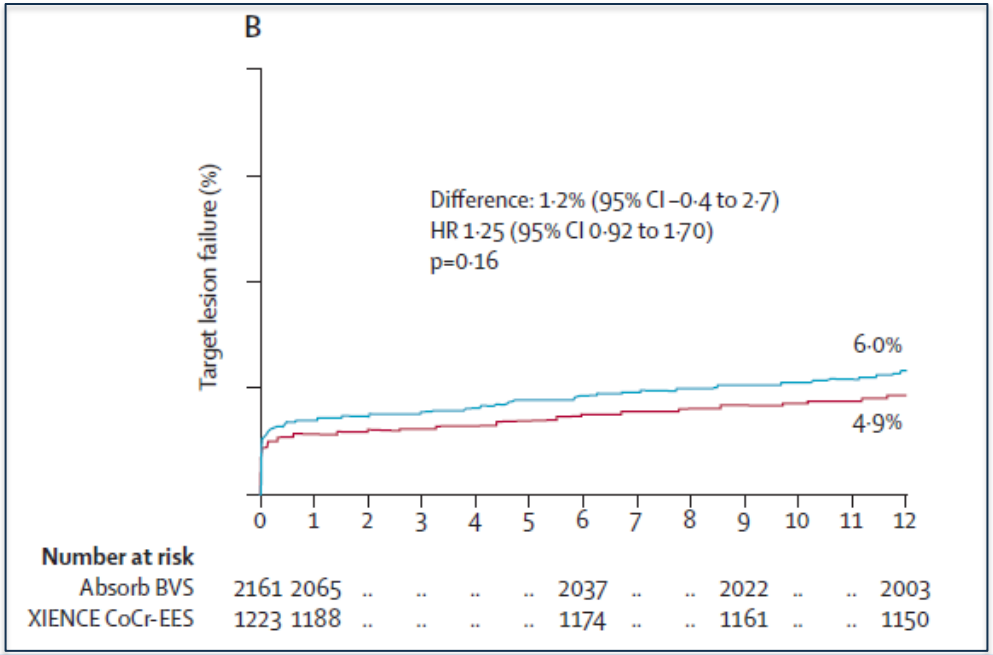
All-cause mortality, all MI, all revascularisation



1-year outcomes with the Absorb bioresorbable scaff old in patients with coronary artery disease: a patient-level, pooled meta-analysis – Stone et al. *Lancet* 2016; 387: 1277–89

No differences in composite Device oriented adverse events

= TLF: Cardiac mortality, target vessel MI, ischemia-driven TLR



1-year outcomes with the Absorb bioresorbable scaff old in patients with coronary artery disease: a patient-level, pooled meta-analysis – Stone et al. *Lancet* 2016; 387: 1277–89

Trend to higher Device Thrombosis

	BVS (n=2164)	CoCr-EES (n=1225)	Fixed-effects RR (95% CI)	p value
Device thrombosis (definite or probable)	30 (1·3%)	7/1204 (0·6%)	2·09 (0·92–4·75)	0·08
Definite	30 (1·1%)	6/1204 (0·5%)	2·06 (0·85–5·03)	0·11
Probable	30 (0·2%)	1/1204 (0·1%)	2·28 (0·28–18·51)	0·44
Early (0–30 days)	52 (0·9%)	6/1221 (0·5%)	1·76 (0·72–4·34)	0·22
Late (30 days–1 year; landmark)	28 (0·4%)	1/1204 (0·1%)	4·10 (0·52–32·56)	0·18

1-year outcomes with the Absorb bioresorbable scaff old in patients with coronary artery disease: a patient-level, pooled meta-analysis – Stone et al. *Lancet* 2016; 387: 1277–89

In this meta-analysis, BVS did not lead to different rates of composite patient-oriented and device-oriented adverse events at 1-year follow-up compared with CoCr-EES.

Everolimus-eluting bioresorbable vascular scaffolds versus everolimus-eluting metallic stents: a meta-analysis of randomised controlled trials – Cassese et al. *Lancet* 2016; 387: 537–44

3738 patients randomised

Everolimus-eluting BVS (n=2337)
or an everolimus-eluting metallic stent (n=1401)

in 6RCT's: ABSORB II
ABSORB III
ABSORB China
ABSORB Japan
EVERBIO II
TROFI II

Median follow-up was 12 months (IQR 9–12).

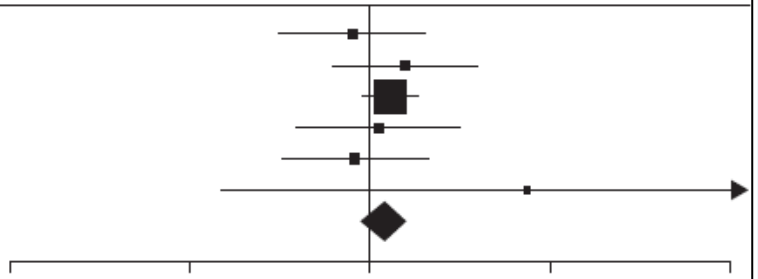
Everolimus-eluting bioresorbable vascular scaffolds versus everolimus-eluting metallic stents: a meta-analysis of randomised controlled trials – Cassese et al. *Lancet* 2016; 387: 537–44

Similar risk of Target Lesion Failure

(1·20 [0·90–1·60]; p=0·21)

A Target lesion failure

	BVS		EES		Weight	Fixed-effects odds ratio
	Events	Total	Events	Total	(%)	(95% CI)
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)**



Heterogeneity: χ^2=2·71, df=5; p=0·74; I^2=0%
Test for overall effect: Z=1·25; p=0·21
Random-effects odds ratio 1·20 (95% CI 0·90–1·60)

Everolimus-eluting bioresorbable vascular scaffolds versus everolimus-eluting metallic stents: a meta-analysis of randomised controlled trials – Cassese et al. *Lancet* 2016; 387: 537–44

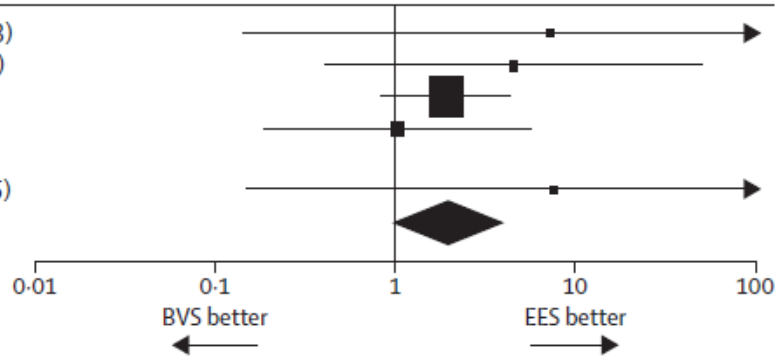
Higher risk of definite or probable Stent Thrombosis

(OR 1·99 [95% CI 1·00–3·98]; p=0·05)

B Definite or probable stent thrombosis

	BVS		EES		Weight	Fixed-effects odds ratio
	Events	Total	Events	Total	(%)	(95% CI)
ABSORB China	1	238	0	232	3·1	7·21 (0·14–363·23)
ABSORB II	3	335	0	166	8·2	4·49 (0·04–49·92)
ABSORB III	20	1301	5	675	69·1	1·89 (0·82–4·34)
ABSORB Japan	4	262	2	133	16·5	1·02 (0·18–5·58)
EVERBIO II	0	78	0	80		Not estimable
TROFI II	1	95	0	96	3·1	7·47 (0·15–376·35)
Overall	**29**	**2309**	**7**	**1382**	**100**	**1·99 (1·00–3·98)**

Heterogeneity: χ^2=1·90, df=4; p=0·75; I^2=0%
Test for overall effect: Z=1·96; p=0·05
Random-effects odds ratio 1·99 (95% CI 1·00–3·98)



Everolimus-eluting bioresorbable vascular scaffolds versus everolimus-eluting metallic stents: a meta-analysis of randomised controlled trials – Cassese et al. *Lancet* 2016; 387: 537–44

Compared with everolimus-eluting metallic stents, everolimus-eluting bioresorbable vascular scaff olds had similar rates of repeat revascularisation at 1 year of follow-up.

However, patients treated with a bioresorbable vascular scaffold had an increased risk of subacute stent thrombosis.

Scaffold Thrombosis After Percutaneous Coronary Intervention With ABSORB Bioresorbable Vascular Scaffold - A Systematic Review and Meta-Analysis - Lipinski et al. *J Am Coll Cardiol Intv* 2016;9:12–24

Study/First Author	n
ABSORB	101
ABSORB II	501
ABSORB EXTEND	812
ABSORB FIRST	958
AMC	135
ASSURE	183
BVS-EXAMINATION	580
BVS EXPAND	200
BVS-RAI	563
BVS STEMI	49
CTO-ABSORB	35
EVERBIO II	238
GABI-R	1,536
GHOST-EU	1,189
POLAR-ACS	100
PRAGUE-19	97
REPARA	1,627
Robaei et al.	100
Costopoulos et al.	184
Gori et al.	253
Jaguszewski et al.	106
Kajiya et al.	11
Mattesini et al.	73
Ojeda et al.	42
Wiebe et al.	25
Weighted mean	368

10,510 patients: 8,351 with BVS, 2,159 with DES

follow-up: 6.4 ± 5.1 months, age: 60 ±11 years, ACS: 59%

Patients with BVS:

- CV death : 0.6%
- MI : 2.1%,
- TLR : 2.0%
- Definite/probable ST : 1.2% - *acute ST: 0.27%, subacute ST: 0.57%*

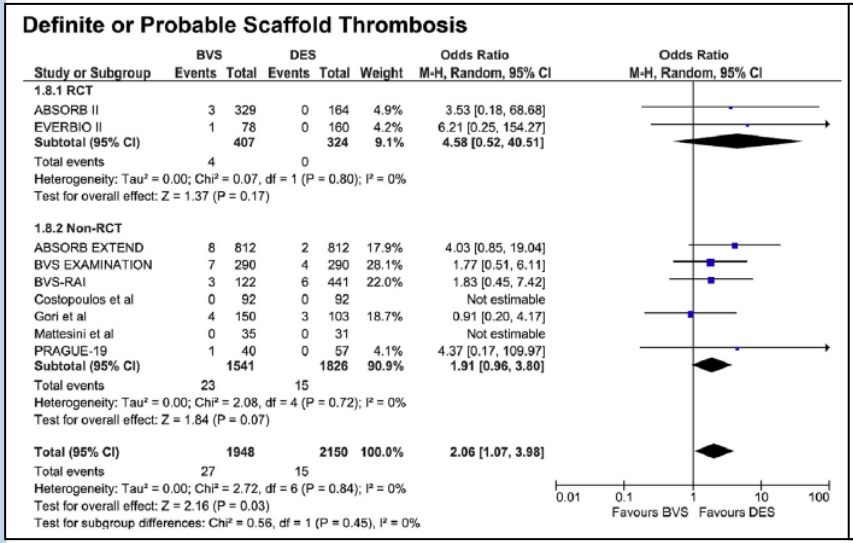
Meta-analysis:

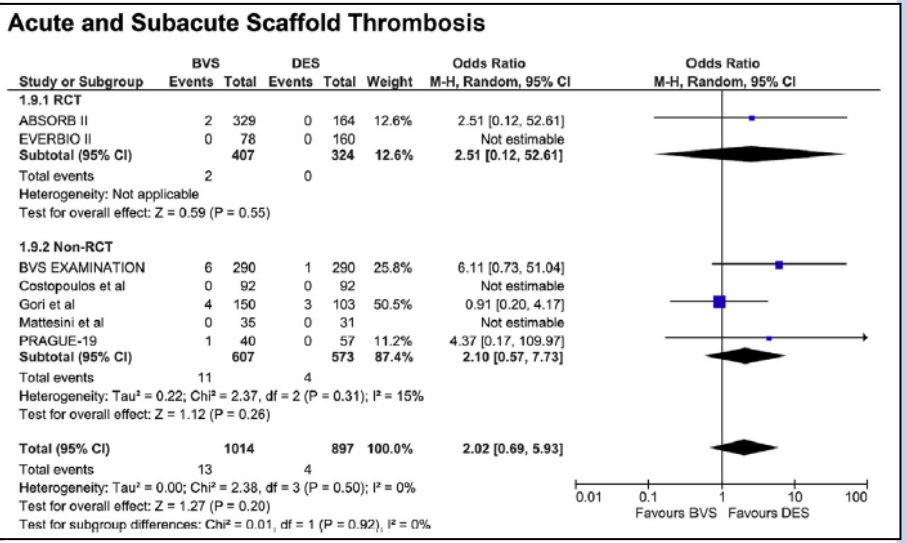
- Higher risk of MI *(OR:2.06, 95% CI: 1.31 to 3.22, p = 0.002)*
- Higher risk of definite/probable ST *(OR: 2.06, 95% CI: 1.07 to 3.98, p = 0.03)*
- Trend to lower all-cause mortality *(OR: 0.40,95% CI: 0.15 to 1.06, p = 0.06)*

Scaffold Thrombosis After Percutaneous Coronary Intervention With ABSORB Bioresorbable Vascular Scaffold - A Systematic Review and Meta-Analysis - Lipinski et al. *J Am Coll Cardiol Intv* 2016;9:12–24

Higher risk of definite/probable ST

(OR: 2.06, 95% CI: 1.07 to 3.98, p = 0.03)

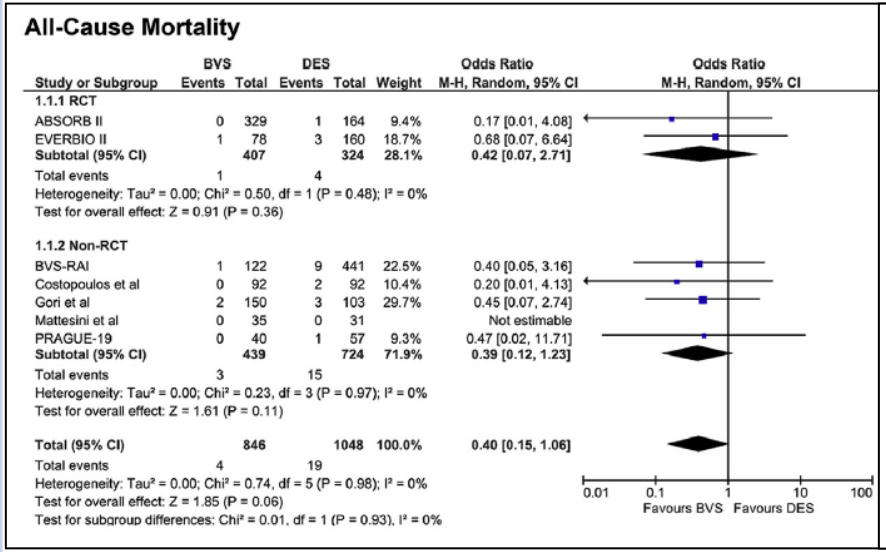


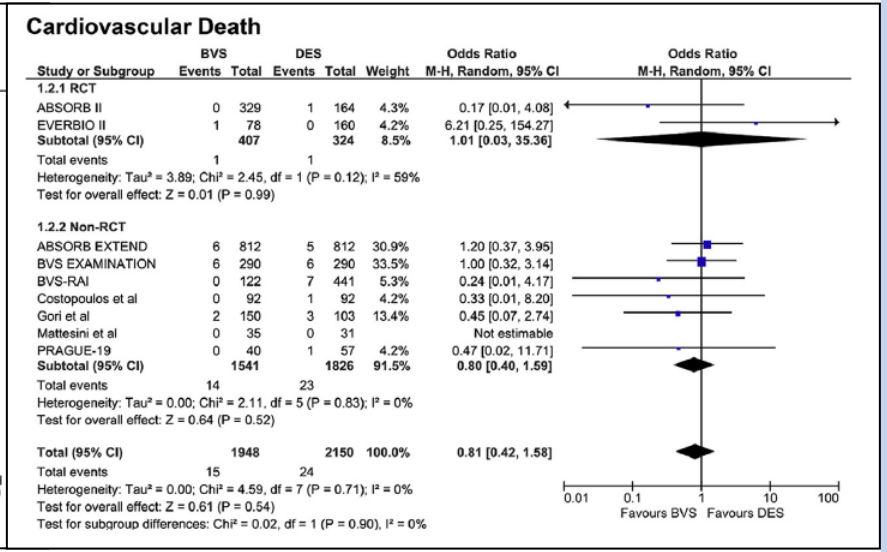


Scaffold Thrombosis After Percutaneous Coronary Intervention With ABSORB Bioresorbable Vascular Scaffold - A Systematic Review and Meta-Analysis - Lipinski et al. *J Am Coll Cardiol Intv* 2016;9:12–24

Trend to lower all-cause mortality

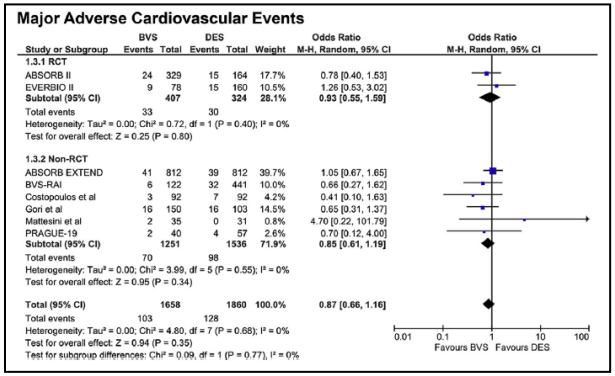
(OR: 0.40,95% CI: 0.15 to 1.06, p = 0.06).

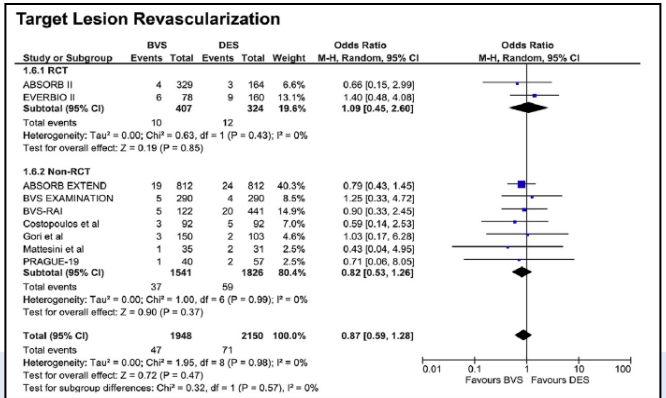


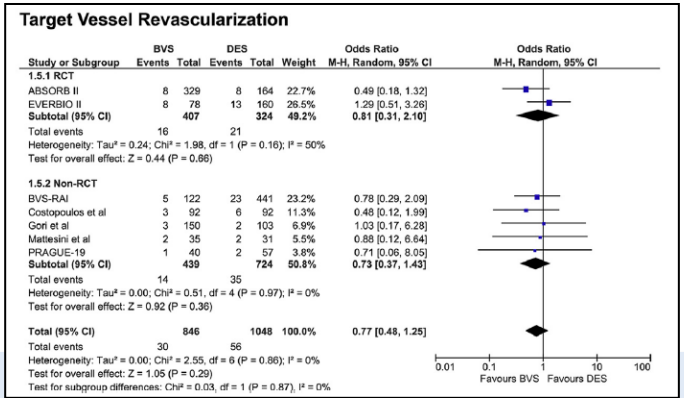


Scaffold Thrombosis After Percutaneous Coronary Intervention With ABSORB Bioresorbable Vascular Scaffold - A Systematic Review and Meta-Analysis - Lipinski et al. *J Am Coll Cardiol Intv* 2016;9:12–24

No differences in MACE, TLR, TVR







Scaffold Thrombosis After Percutaneous Coronary Intervention With ABSORB Bioresorbable Vascular Scaffold - A Systematic Review and Meta-Analysis - Lipinski et al. *J Am Coll Cardiol Intv* 2016;9:12–24

Patients undergoing PCI with a BVS had increased definite/ probable ST and MI during follow-up compared with DES. Further studies with long-term follow-up are needed to assess the risk of ST with a BVS.

BVS: les preuves cliniques

- Registres
  - ABSORB First
  - France ABSORB
  - GABI R
  - UK Registry
  - Repara
  - RAI registry
  - IT registry
  - GHOST…

2016 euroPCR

France Absorb Registry

In-hospital and 30 days Results

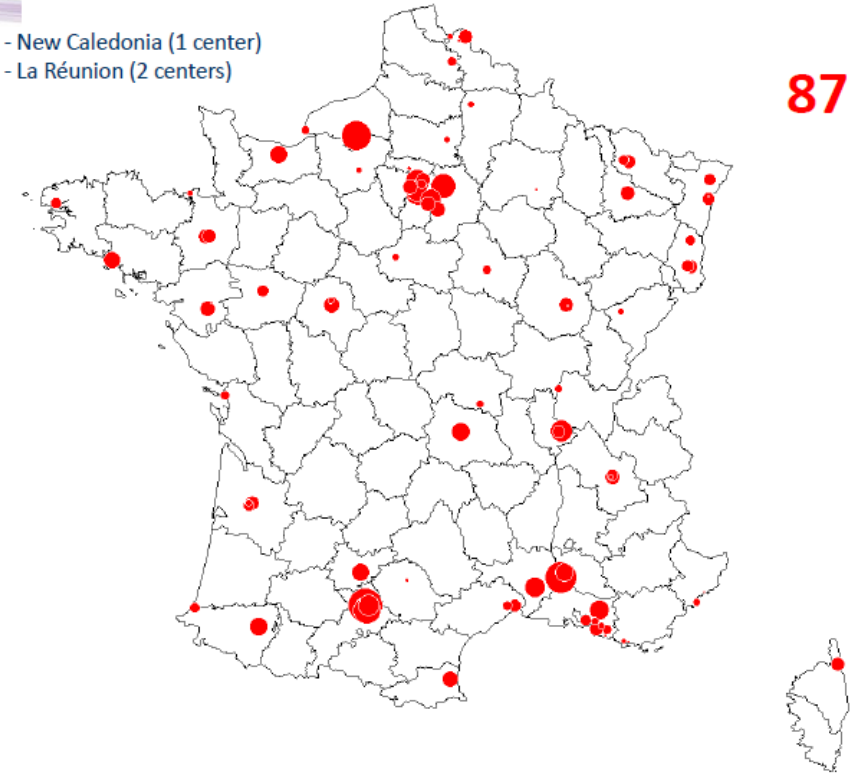
R. Koning, H. Le Breton

On behalf the French Cardiac Society

G.A.C.I

2089 Patients

- New Caledonia (1 center)
- La Réunion (2 centers)



87 centers

30 days MACCE (2%)

- Mortality: n=6/2089
  O.28%
- Myocardial Infarction : n=20
- Non fatal stroke n=2
- TLR: n=13

BVS THROMBOSIS RATE

- **IN–HOSPITAL : 16 /2089 Pts**

  Acute: 11
  Sub-Acute: 5

  0.8 %

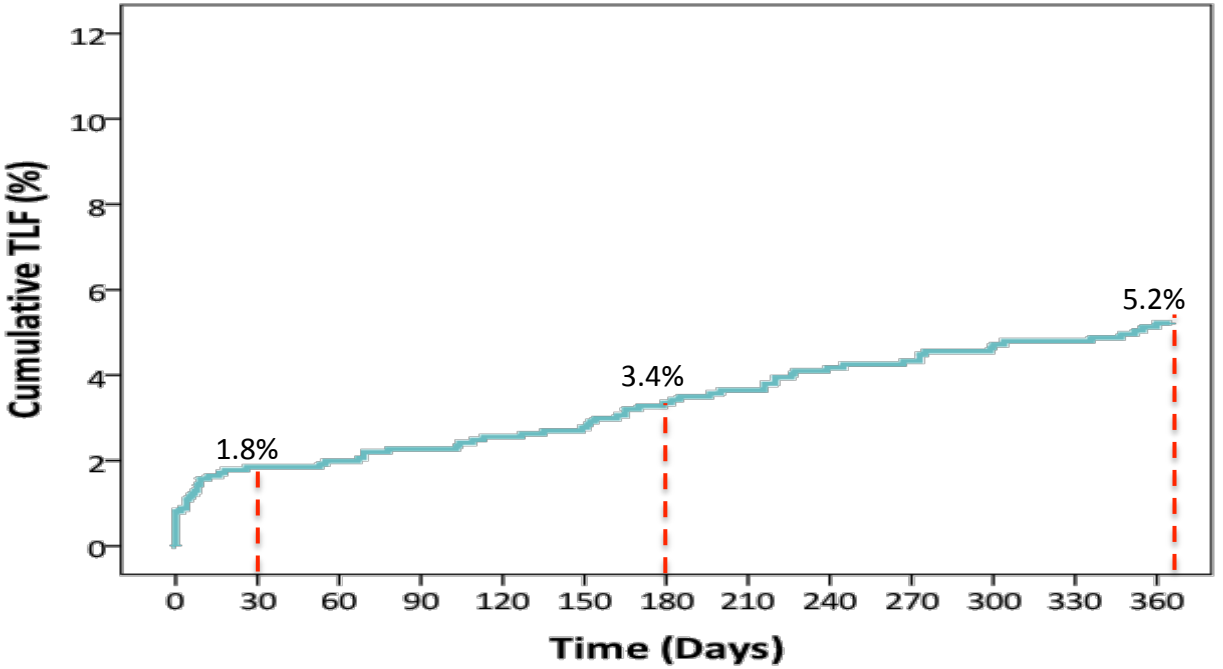
- **1 MONTH : 22/ 2089 Pts**

  (INCLUDING IN-HOSPITAL) **1.05%**

One-Year Outcomes

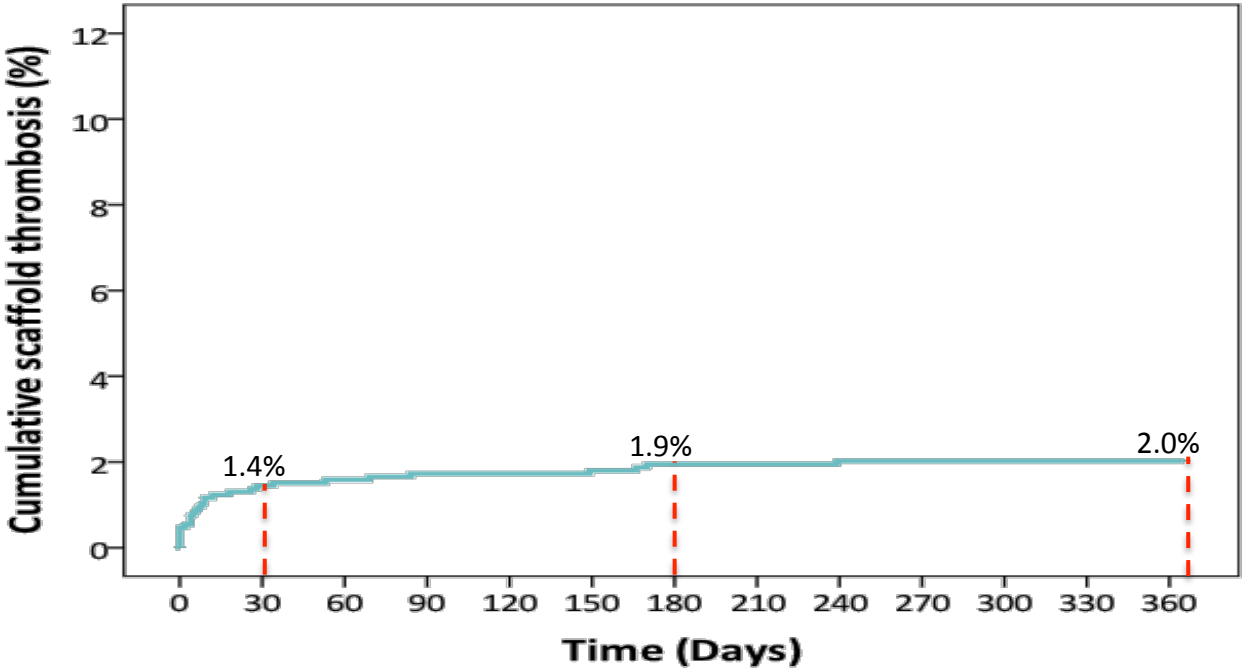
Target Lesion Failure

CV death, target-vessel MI, clinically-driven TLR



Days	0	90	180	365
Pts at risk	1,477	1,376	1,323	999

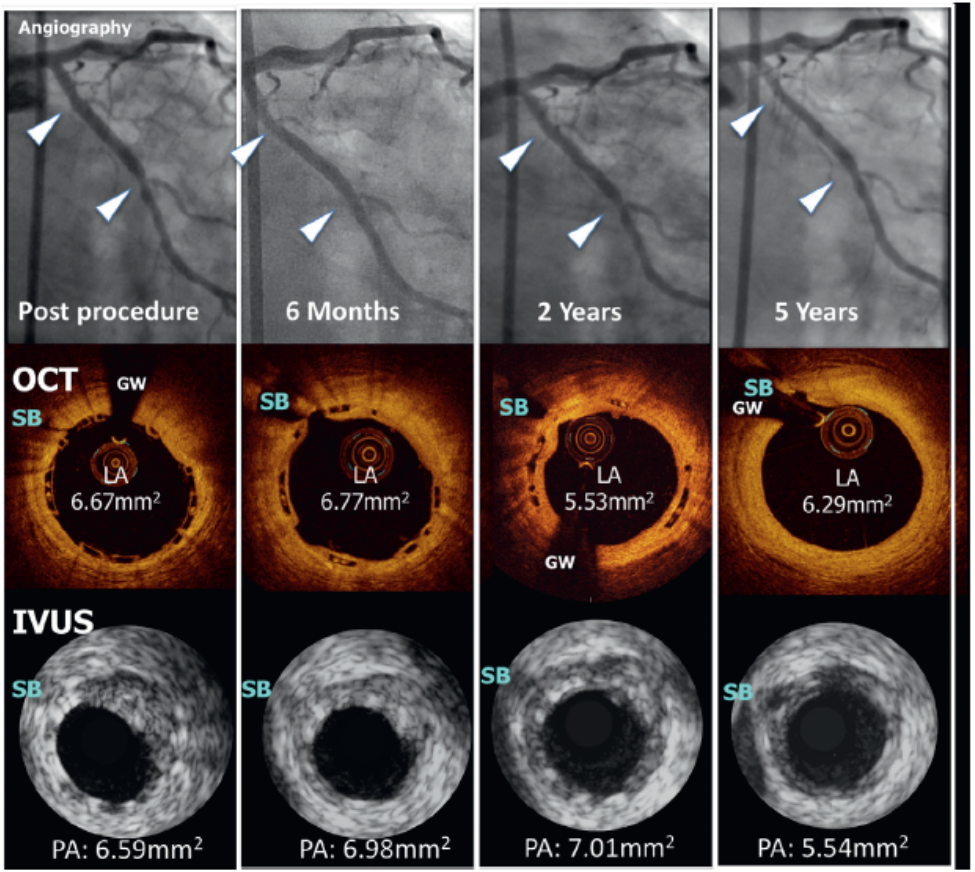
Scaffold Thrombosis
Definite/probable



Days	0	90	180	365
Pts at risk	1,477	1,376	1,332	1,012

A Polylactide Bioresorbable Scaffold Eluting Everolimus for Treatment of Coronary Stenosis - 5-Year Follow-Up

Serruys et al. *J Am Coll Cardiol* 2016;67:766–76

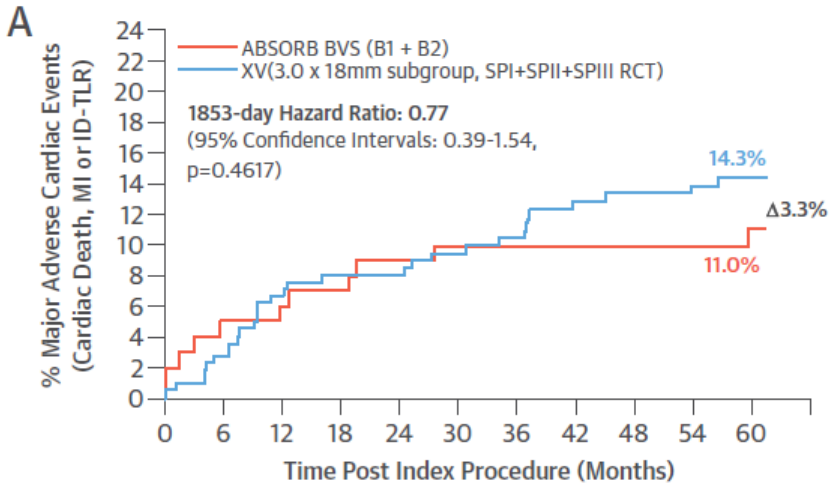


A Polylactide Bioresorbable Scaffold Eluting Everolimus for Treatment of Coronary Stenosis - 5-Year Follow-Up

Serruys et al. *J Am Coll Cardiol* 2016;67:766–76

TABLE 1 Nonhierarchical and Hierarchical Count of Clinical Events Over 5 Years (n = 101)

	30 Days (n = 101)	1 Yr (n = 101)	2 Yrs (n = 100)*	3 Yrs (n = 100)*	4 Yrs (n = 99)†	5 Yrs (n = 100)†
Nonhierarchical						
All death	0.0 (0)	0.0 (0)	0.0 (0)	1.0 (1)	3.0 (3)	3.0 (3)
Cardiac death	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
Noncardiac death	0.0 (0)	0.0 (0)	0.0 (0)	1.0 (1)	3.0 (3)	3.0 (3)
MI	2.0 (2)	3.0 (3)	3.0 (3)	3.0 (3)	3.0 (3)	3.0 (3)
Q-wave MI	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
Non-Q-wave MI	2.0 (2)	3.0 (3)	3.0 (3)	3.0 (3)	3.0 (3)	3.0 (3)
All TLR	0.0 (0)	5.0 (5)	9.0 (9)	10.0 (10)	10.0 (10)	11.0 (11)
ID-TLR	0.0 (0)	4.0 (4)	6.0 (6)	7.0 (7)	7.1 (7)	8.0 (8)
CABG	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
PCI	0.0 (0)	4.0 (4)	6.0 (6)	7.0 (7)	7.1 (7)	8.0 (8)
Non-ID-TLR	0.0 (0)	1.0 (1)	3.0 (3)	3.0 (3)	3.0 (3)	4.0 (4)
ID-TVR	0.0 (0)	4.0 (4)	8.0 (8)	10.0 (10)	10.0 (10)	11.0 (11)
Non-TL-ID-TVR	0.0 (0)	0.0 (0)	3.0 (3)	4.0 (4)	4.0 (4)	4.0 (4)
Non-TVR	0.0 (0)	5.0 (5)	7.0 (7)	10.0 (10)‡	10.0 (10)‡	13.0 (13)‡
Hierarchical						
MACE	2.0 (2)	6.9 (7)	9.0 (9)	10.0 (10)	10.1 (10)	11.0 (11)
TVF	2.0 (2)	6.9 (7)	11.0 (11)	13.0 (13)	13.1 (13)	14.0 (14)



Number of patients at Risk										
Time After Index Procedure (days)	0	37	194	284	393	573	758	1123	1488	1853
ABSORB	101	99	96	96	94	92	91	88	86	85
Xience V	227	224	219	211	204	202	191	182	174	169

Conclusion

Resultats cliniques similaires à 1 an

Tendance à un risque de thrombose de stent plus élevé

Potentiel pour moins d'évènements cliniques à long terme au dela de trois ans