



BVS ABSORB Synthèse des résultats cliniques

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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 i	10. (%)		
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







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



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





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)





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)	<mark>0.69</mark>
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





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 <mark>(</mark> 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



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





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





Non inferiority trial 480 patients were randomized 241 BVS vs 239 CoCr-EES

Primary endpoint: In-segment Late Loss at 1 year





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)







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







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)





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



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–

BIARRIT7

8/9/10



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

Patient-oriented MACE rate

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





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 **N2016** of the randomized ABSORB STEMI — TROFI II trial

ARRIT7

8/9/10



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



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

of the randomized ABSORB STEMI — TROFI II trial

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 [®]	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



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



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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 deviceoriented adverse events at 1-year follow-up compared with CoCr-EES. Everolimus-eluting bioresorbable vascular scaffolds versus RRIZ 9/10 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 EVITZ Provide trials – Cassese et al. *Lancet* 2016; 387: 537–44



(1·20 [0·90–1·60]; p=0·21)

	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)	
TROFIII	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:	v ² =2.71 df	$=5 \cdot n = 0.74$	· 1 ² =0%				
Test for overall	effect: 7=1	.25 n=0.21	,				
Pandom offect	e odde rat	io 1 20 (0)		1 60)			

Everolimus-eluting bioresorbable vascular scaffolds versus BIARRITZ 8/9/10 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% Cl 1.00–3.98]; p=0.05)



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, everolimuseluting 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.



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Study/First Author

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



101 ABSORB 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 MI: 2.1%, EVERBIO II 238 1.536 GABI-R TLR: 2.0% 1,189 GHOST-EU 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%

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)

Definite or Pr	Definite or Probable Scaffold Thrombosis							Acute and Su	ıbacu	te S	caffol	d T	hrom	bosis			
	BVS		DES			Odds Ratio	Odds Ratio		DV		DEC			Odda Datia		Odda Datia	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl	Otente en Octomore	DVa	, 	DES	T - 4 - 1	147-1-1-4	Odds Ratio		Odds Ratio	
1.8.1 RCT								Study or Subgroup	Events	Total	Events	otal	Weight	M-H, Random, 95% C	M-F	, Random, 95% Cl	
ABSORB II	3	329	0	164	4.9%	3 53 10 18 68 681		1.9.1 RCT									
EVERBIO II	1	78	ő	160	4.2%	6 21 [0.25, 154 27]		ABSORB II	2	329	0	164	12.6%	2.51 [0.12, 52.61]			
Subtotal (95% CI)		407	-	324	9.1%	4.58 [0.52, 40.51]		EVERBIO II	0	78	0	160		Not estimable			
Total events	4		0					Subtotal (95% CI)		407		324	12.6%	2.51 [0.12, 52.61]			
Heterogeneity; Tau ² =	0.00; Chi2 =	= 0.07.	df = 1 (P	= 0.80); ² = 0%			Total events	2		0						
Test for overall effect:	Z = 1.37 (P	= 0.17)					Heterogeneity: Not app	olicable								
								Test for overall effect:	Z = 0.59 (P = 0.55	5)						
1.8.2 Non-RCT																	
ABSORB EXTEND	8	812	2	812	17.9%	4.03 [0.85, 19.04]		1.9.2 Non-RCT									
BVS EXAMINATION	7	290	4	290	28.1%	1.77 [0.51, 6.11]		BVS EXAMINATION	6	290	1	290	25.8%	6.11 [0.73, 51.04]			
BVS-RAI	3	122	6	441	22.0%	1.83 [0.45, 7.42]		Costopoulos et al	0	92	0	92		Not estimable			
Costopoulos et al	0	92	0	92		Not estimable		Gori et al	4	150	3	103	50.5%	0 91 [0 20 4 17]		_	
Gori et al	4	150	3	103	18.7%	0.91 [0.20, 4.17]		Mattesini et al	0	35	0	31		Not estimable			
Mattesini et al	0	35	0	31		Not estimable		PRAGUE-19	1	40	ő	57	11.2%	4 37 [0 17 109 97]	-		
PRAGUE-19	1	40	0	57	4.1%	4.37 [0.17, 109.97]		Subtotal (95% CI)		607	0	573	87.4%	2.10 [0.57, 7.73]			
Subtotal (95% CI)		1541		1826	90.9%	1.91 [0.96, 3.80]	-	Total events	11		4						
Total events	23		15					Hotorogonoity: Tour =	0.22. Chiz	- 2 27	df = 2 /D	- 0.24)	12 - 150				
Heterogeneity: Tau ² =	0.00; Chi ² =	= 2.08,	df = 4 (P	= 0.72); I ² = 0%			Test for everall effect:	7 = 1 12 /	= 2.37, D = 0.26	ui = 2 (F ·	- 0.31)	, 1 = 137	2			
Test for overall effect: 2	Z = 1.84 (P	= 0.07)					rescion overall effect.	2 - 1.12 (1	0.20	5)						
Total (95% CI)		1948		2150	100.0%	2.06 [1.07, 3.98]	◆	Total (95% CI)		1014		897	100.0%	2.02 [0.69, 5.93]		-	
Total events	27		15					Total events	13		4						
Heterogeneity: Tau ² =	0.00; Chi ² =	= 2.72,	df = 6 (P	= 0.84); l ² = 0%	L		Heterogeneity: Tau ² =	0.00; Chi ²	= 2.38,	df = 3 (P =	= 0.50)	; l ² = 0%			1 10	100
Test for overall effect:	Z = 2.16 (P	= 0.03)			0.01	U.1 1 10 100	Test for overall effect:	Z = 1.27 (P = 0.20	D)				0.01 0.1	1 10 DVC Equation DEC	100
Test for subgroup diffe	rences: Ch	i² = 0.5	6, df = 1	(P = 0.4	45), l ² = 0	%	Favours DVS Favours DES	Test for subgroup diffe	rences: C	hi ² = 0.0	01, df = 1 (P = 0.9	92), l ² = 0	%	Favou	S DVO Favours DES	

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).

All-Cause Mo	All-Cause Mortality							ath					
							BVS		DES		Odds Ratio	Odds Ratio	
	BVS	DES		Odds Ratio	Odds Ratio	Study or Subgroup	Events	Total Ev	ents Total	Weight	M-H. Random, 95% Cl	M-H. Random, 95% Cl	
Study or Subgroup	Events Tota	Events Tota	I Weight	M-H, Random, 95% C	I M-H, Random, 95% Cl	1.2.1 RCT							
1.1.1 RCT						ABSORB II	0	329	1 164	4 3%	0 17 (0 01 4 08) 🗲		
ABSORB II	0 329	1 164	9.4%	0.17 [0.01, 4.08]	· · · · · · · · · · · · · · · · · · ·	EVERBIO II	1	78	0 160	4 2%	6 21 10 25 154 271		→
EVERBIO II	1 78	3 160	18.7%	0.68 [0.07, 6.64]		Subtotal (95% CI)	•	407	324	8.5%	1.01 [0.03, 35.36]		
Subtotal (95% CI)	407	324	28.1%	0.42 [0.07, 2.71]		Total events	1		1				
Total events	1	4				Heterogeneity: Tau ² =	3.89; Chi ² =	= 2.45, df =	= 1 (P = 0.12)); l ² = 599	0		
Heterogeneity: Tau ² =	0.00; Chi ² = 0.5	0, df = 1 (P = 0.4	8); 12 = 0%			Test for overall effect:	Z = 0.01 (P	= 0.99)					
Test for overall effect:	Z = 0.91 (P = 0.3	36)											
						1.2.2 Non-RCT							
1.1.2 Non-RCT						ABSORB EXTEND	6	812	5 812	30.9%	1.20 [0.37, 3.95]		
BVS-RAI	1 122	9 441	22.5%	0.40 [0.05, 3.16]		BVS EXAMINATION	6	290	6 290	33.5%	1.00 [0.32, 3.14]	+	
Costopoulos et al	0 92	2 92	10.4%	0.20 [0.01, 4.13]	· · · · · · · · · · · · · · · · · · ·	BVS-RAI	0	122	7 441	5.3%	0.24 [0.01, 4.17]		
Gori et al	2 150	3 103	29.7%	0.45 [0.07, 2.74]		Costopoulos et al	0	92	1 92	4.2%	0.33 [0.01, 8.20]		
Mattesini et al	0 35	0 31		Not estimable		Gori et al	2	150	3 103	13.4%	0.45 [0.07, 2.74]		
PRAGUE-19	0 40	1 57	9.3%	0.47 [0.02, 11,71]		Mattesini et al	0	35	0 31		Not estimable		
Subtotal (95% CI)	439	724	71.9%	0.39 [0.12, 1.23]		PRAGUE-19	0	40	1 57	4.2%	0.47 [0.02, 11.71]		
Total events	3	15				Subtotal (95% CI)		1541	1826	91.5%	0.80 [0.40, 1.59]	-	
Heterogeneity: Tau ² =	0.00 Chi2 = 0.2	3 df = 3/P = 0.0	7). 12 = 0%			Total events	14		23				
Tect for overall offect:	7 = 1 61 /P = 0	0, ui − 0 (i − 0.a 11)	//),1 = 0/0			Heterogeneity: Tau ² =	0.00; Chi ² =	= 2.11, df =	= 5 (P = 0.83)); l ² = 0%			
rest for overall effect.	2 - 1.01 (P - 0.	,				Test for overall effect:	Z = 0.64 (P	= 0.52)					
Total (95% CI)	846	1048	100.0%	0.40 [0.15, 1.06]	-	T-1-1 (OFA) OD		10.10	0450	400.00	0.04 10 40 4 501		
Total events	4	19				Total (95% CI)		1948	2150	100.0%	0.81 [0.42, 1.58]		
Heterogeneity: Tau? -	0.00 Chil - 0.7	4 df - 5 /P - 0 0	12 - 0%			Total events	15	1.00	24				
Test for everall effect	7 = 1 95 /D = 0.1	4, ui = 5 (F = 0.8	0), 1 - 0 /8		0.01 0.1 1 10 100	Heterogeneity: Tau ² =	0.00; Chi ² =	= 4.59, df =	= 7 (P = 0.71)); l ² = 0%	0.0	1 0.1 1 10	100
Test for subgroup diffs	2 - 1.03 (P = 0.0	001 df = 1 (D = 1	0.02) 12 = 0	w.	Favours BVS Favours DES	Test for overall effect:	Z = 0.61 (P	= 0.54)				Favours BVS Favours DES	
lest for subgroup diffe	erences: Chi* = 0	0.01, ar = 1 (P = 0)	0.93), 1* = 0	70		Test for subgroup diffe	rences: Ch	i ² = 0.02, (df = 1 (P = 0.9)	90), $ ^2 = 0$	%		

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

Major Adverse Cardiovascular Events											
	BVS		DES	5		Odds Ratio	Odds Ratio				
Study or Subgroup	up Events Total		al Events Total Weight		Weight	M-H, Random, 95% C	M-H, Random, 95% CI				
1.3.1 RCT											
ABSORB II	24	329	15	164	17.7%	0.78 [0.40, 1.53]					
EVERBIO II	9	78	15	160	10.5%	1.26 [0.53, 3.02]					
Subtotal (95% CI)		407		324	28.1%	0.93 [0.55, 1.59]	+				
Total events	33		30								
Heterogeneity: Tau ² = 0.00; Chi ² = 0.72, df = 1 (P = 0.40); l ² = 0%											
Test for overall effect:	Z = 0.25 (F	= 0.80	0)								
1.3.2 Non-RCT											
ABSORB EXTEND	41	812	39	812	39.7%	1.05 [0.67, 1.65]	+				
BVS-RAI	6	122	32	441	10.0%	0.66 [0.27, 1.62]					
Costopoulos et al	3	92	7	92	4.2%	0.41 [0.10, 1.63]					
Gori et al	16	150	16	103	14.5%	0.65 [0.31, 1.37]					
Mattesini et al	2	35	0	31	0.8%	4.70 [0.22, 101.79]					
PRAGUE-19	2	40	4	57	2.6%	0.70 [0.12, 4.00]					
Subtotal (95% CI)		1251		1536	71.9%	0.85 [0.61, 1.19]	•				
Total events	70		98								
Heterogeneity: Tau ² =	0.00; Chi ²	= 3.99,	df = 5 (F	P = 0.55	5); l² = 0%						
Test for overall effect:	Z = 0.95 (F	e = 0.34	4)								
Total (95% CI)		1658		1860	100.0%	0.87 [0.66, 1.16]	•				
Total events	103		128								
Heterogeneity: Tau ² =	0.00; Chi ²	= 4.80,	df = 7 (F	P = 0.68	3); I ² = 0%						
Test for overall effect:	Z = 0.94 (F	= 0.3	5)				Eavoure BVS Eavoure DES				
Test for subgroup diffe	rences: Ch	i ² = 0.0)9, df = 1	(P = 0	77), 12 = 0	1%	Tarous Deo Tarous DEO				

Target Vessel Revascularization

Target Lesi	on Revascu	larization
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	BVS		DES	5		Odds Ratio		Odds Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% C		M-H, Random, 95% CI	
1.6.1 RCT									_
ABSORB II	4	329	3	164	6.6%	0.66 [0.15, 2.99]			
EVERBIO II	6	78	9	160	13.1%	1.40 [0.48, 4.08]			
Subtotal (95% CI)		407		324	19.6%	1.09 [0.45, 2.60]		-	
Total events	10		12						
Heterogeneity: Tau ² =	0.00; Chi2	= 0.63	df = 1 (P	= 0.43); l ² = 0%				
Test for overall effect:	Z = 0.19 (F	P = 0.8	5)						
1.6.2 Non-RCT									
ABSORB EXTEND	19	812	24	812	40.3%	0.79 [0.43, 1.45]			
BVS EXAMINATION	5	290	4	290	8.5%	1.25 [0.33, 4.72]		_	
BVS-RAI	5	122	20	441	14.9%	0.90 [0.33, 2.45]			
Costopoulos et al	3	92	5	92	7.0%	0.59 [0.14, 2.53]			
Gori et al	3	150	2	103	4.6%	1.03 [0.17, 6.28]			
Mattesini et al	1	35	2	31	2.5%	0.43 [0.04, 4.95]			
PRAGUE-19	1	40	2	57	2.5%	0.71 [0.06, 8.05]			
Subtotal (95% CI)		1541		1826	80.4%	0.82 [0.53, 1.26]		+	
Total events	37		59						
Heterogeneity: Tau ² =	0.00; Chi2	= 1.00,	df = 6 (P	= 0.99); l ² = 0%				
Test for overall effect:	Z = 0.90 (F	P = 0.3	7)						
Total (95% CI)		1948		2150	100.0%	0.87 [0.59, 1.28]		•	
Total events	47		71						
Heterogeneity: Tau ² =	0.00; Chi2	= 1.95	df = 8 (P	= 0.98); ² = 0%		-		_
Test for overall effect:	Z = 0.72 (F	= 0.4	7)				0.01	U.1 1 10	100
Test for subgroup diffe	rences: Cl	ni² = 0.3	32, df = 1	(P = 0.	57), ² = 0 ⁴	%		Favous by 6 Favours DES	

	BVS		DES			Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% C	I M-H, Random, 95% Cl
1.5.1 RCT							
ABSORB II	8	329	8	164	22.7%	0.49 [0.18, 1.32]	
EVERBIO II	8	78	13	160	26.5%	1.29 [0.51, 3.26]	
Subtotal (95% CI)		407		324	49.2%	0.81 [0.31, 2.10]	-
Total events	16		21				
Heterogeneity: Tau ^a :	= 0.24; Chi ^a	= 1.98	. df = 1 (F	P = 0.16	3); l ² = 50%	6	
Test for overall effect	: Z = 0.44 (P = 0.6	6)				
1.5.2 Non-RCT							
BVS-RAI	5	122	23	441	23.2%	0.78 [0.29, 2.09]	
Costopoulos et al	3	92	6	92	11.3%	0.48 [0.12, 1.99]	
Gori et al	3	150	2	103	6.9%	1.03 [0.17, 6.28]	
Mattesini et al	2	35	2	31	5.5%	0.88 [0.12, 6.64]	
PRAGUE-19	1	40	2	57	3.8%	0.71 [0.06, 8.05]	
Subtotal (95% CI)		439		724	50.8%	0.73 [0.37, 1.43]	-
Total events	14		35				
Heterogeneity: Tau ² :	= 0.00; Chi ²	= 0.51	df = 4 (F	9 = 0.97); l ² = 0%		
Test for overall effect	: Z = 0.92 (P = 0.3	6)				
Total (95% CI)		846		1048	100.0%	0.77 [0.48, 1.25]	•
Total events	30		56				
Heterogeneity: Tau* :	= 0.00; Chi ²	= 2.55	df = 6 (F	9 = 0.86	3); I ² = 0%		
lest for overall effect	: Z = 1.05 (P = 0.2	9)				0.01 0.1 1 10 100
Test for subgroup diff	ferences. C	$h\vec{r} = 0$	03 df = 1	(P = 0)	87) 12 = 0	96	Favours Dyo Favours DES

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 ۲ **ABSORB** First France ABSORB GABI R **UK Registry** Repara **RAI** registry IT registry GHOST...



France Absorb Registry In-hospital and 30 days Results

8/9/10

R. Koning, H. Le Breton On behalf the French Cardiac Society G.A.C.I





PALAIS

8 CONGRES BIARRITZ 8/9/10 JUIN 2016









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





Scaffold Thrombosis Definite/probable





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. JAm 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)				



204

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191

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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