The 4-year Clinical Outcomes of the ABSORB II Trial: First Randomized Comparison between the Absorb Everolimus Eluting Bioresorbable Vascular Scaffold and the XIENCE Everolimus Eluting Stent

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on behalf of the ABSORB II Investigators

Presentor Disclosures

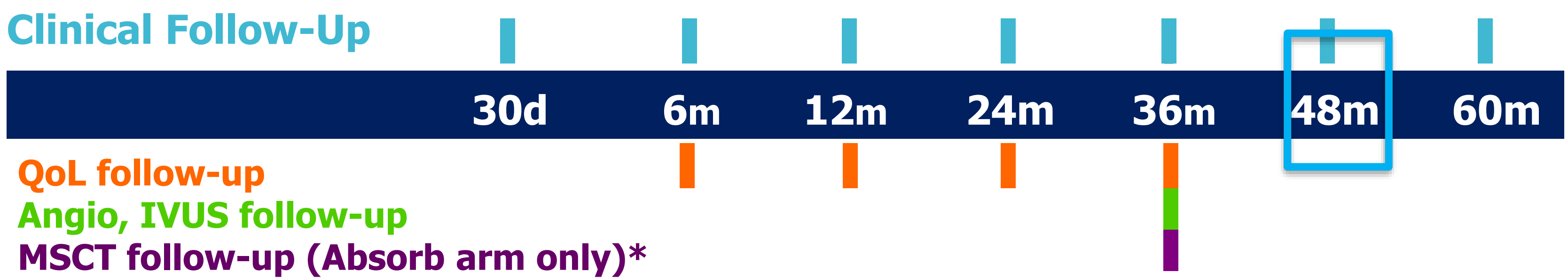
Bernard Chevalier was a Consultant for Abbott Vascular and is currently consultant for Biotronik, Colibri, Cordis, Medtronic, Terumo.

Patrick Serruys is a Member of the International Advisory Board of Abbott Vascular

ABSORB II Study Design

501 subjects

Randomized 2:1 Absorb BVS:XIENCE / 46 sites (Europe and New Zealand)



Study Objective	Randomized against XIENCE control. First Patient In: 28-Nov-2011
Co-primary Endpoints 36 months	Vasomotion assessed by change in Mean Lumen Diameter between pre- and post-nitrate at 3 years (superiority) Minimum Lumen Diameter (MLD) at 3 years post nitrate minus MLD post procedure post nitrate (non-inferiority, reflex to superiority)
Treatment	Up to 2 *de novo* lesions in different epicardial vessels Planned overlapping allowed in lesions ≤ 48 mm
Device Sizes	Device diameters: 2.5, 3.0, 3.5 mm Device lengths: 12 (3.5 mm diameter only), 18, 28 mm

The ABSORB II study is sponsored by Abbott Vascular. [NCT01425281]

4-Year Patient Flowchart

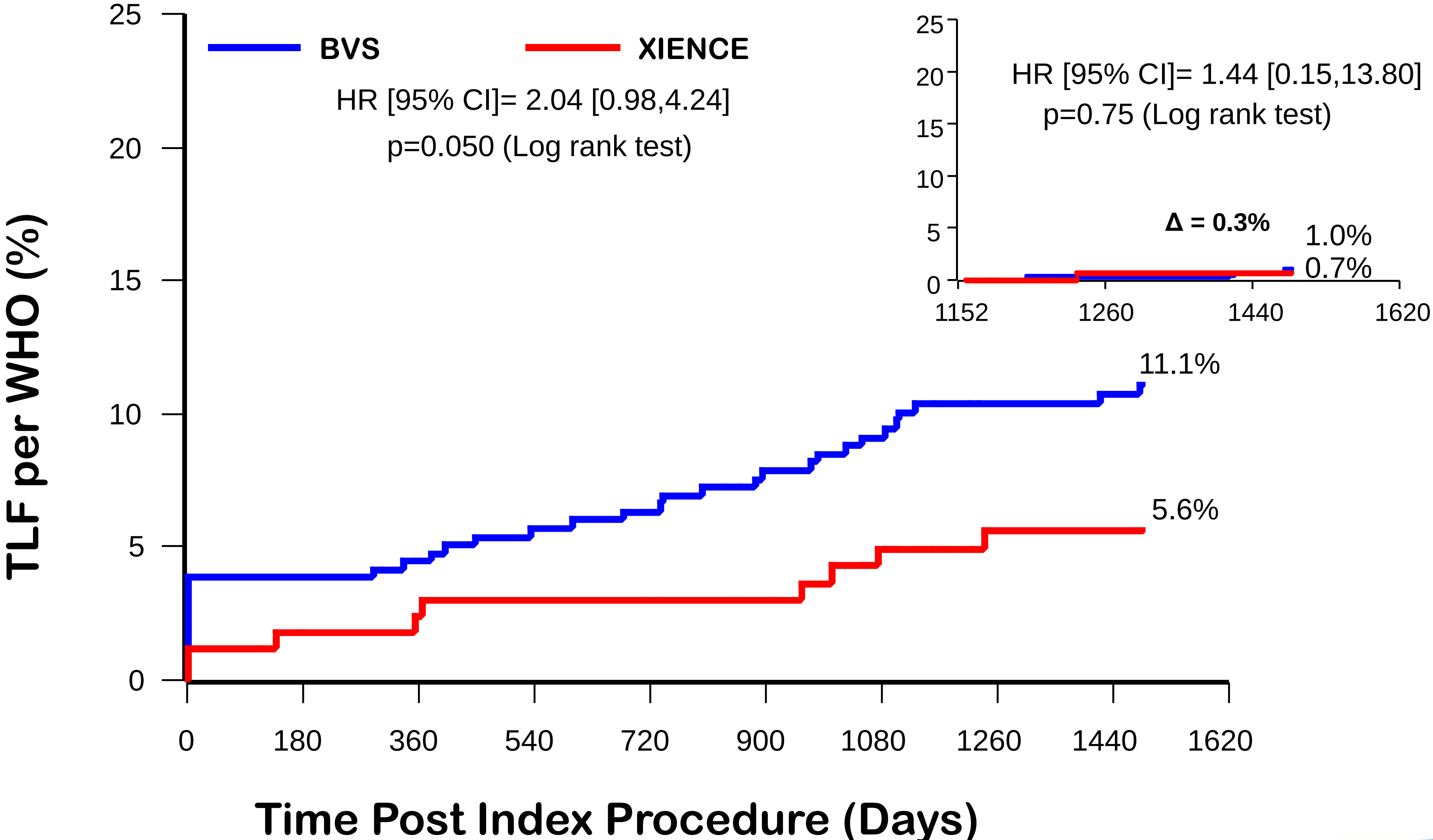
311* and 154** patients still in the study but 5 missed 3 yr FUP

Intent To Treat
N=501

	Absorb BVS		XIENCE	
Baseline		N=335	N=166	
	7 withdrawal			1 death 2 withdrawal
1-year		N=328	N=163	
	4 death 3 withdrawal 1 LFU			3 withdrawal
2-year		N=320	N=160	
	4 death 3 withdrawal 2 LFU, 3 MV,			5 death, 1 LFU 2 MV
3-year		N=308*	N=152**	
	2 death, 8 MV, 3 withdrawal 9 no consent, -3 still in study but missed 3yr FUP			1 death, 2 MV, 1 withdrawal 11 no consent ,-2 still in study but missed 3yr FUP
4-year		N=289 (86%)	N=139 (84%)	

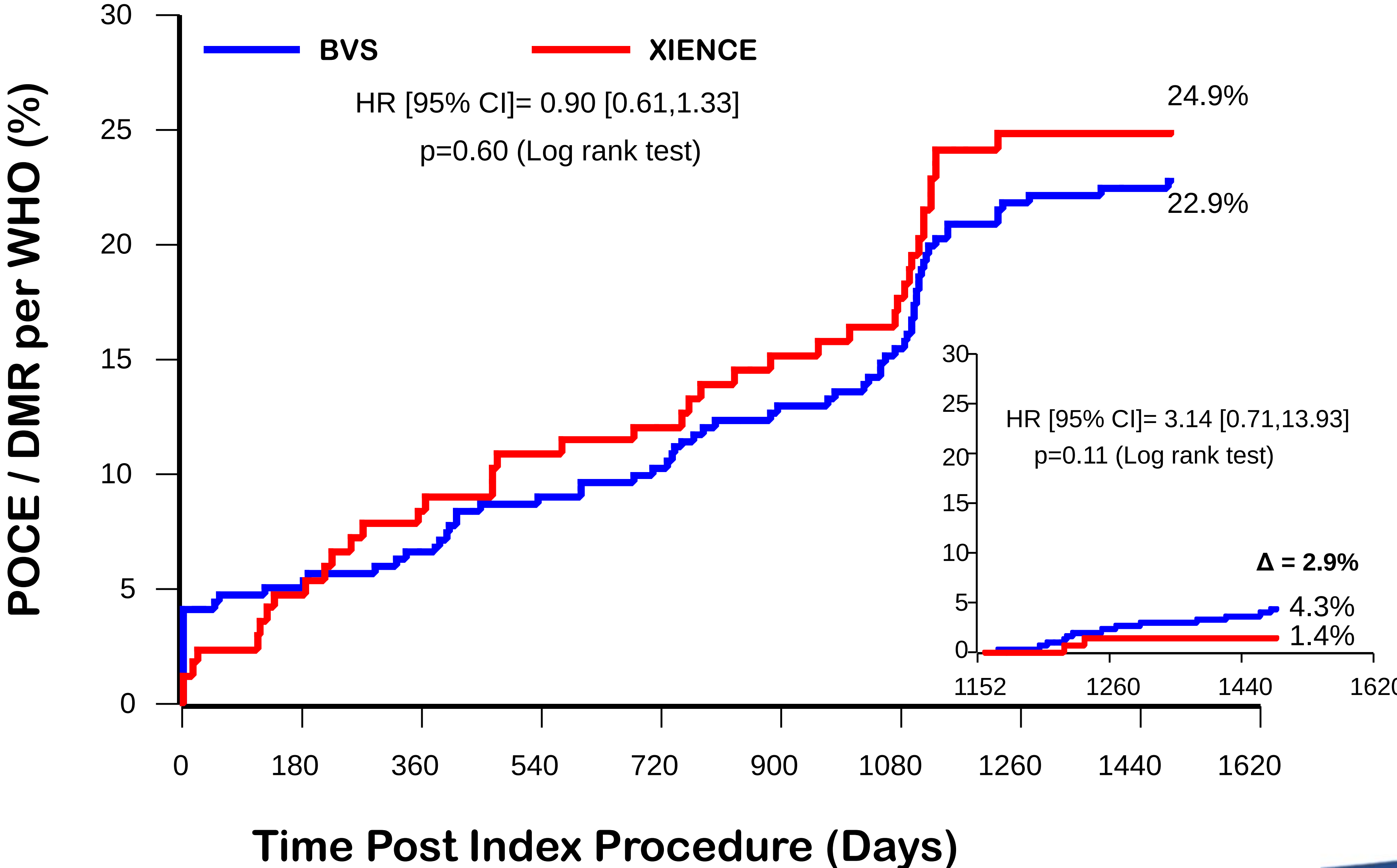
At 4 years patients with missing visits (MV) were confirmed as alive and well by site PI.
20 patients did not sign protocol amendment for 4 & 5 year follow-up

Device oriented Composite Endpoint (DOCE)/ Target Lesion Failure (TLF)



DoCE/TLF : Cardiac death, target-vessel myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)

Patient oriented Composite Endpoint (PoCE)/DMR



PoCE=DMR: All Death, all Myocardial infarction, and all Revascularisation

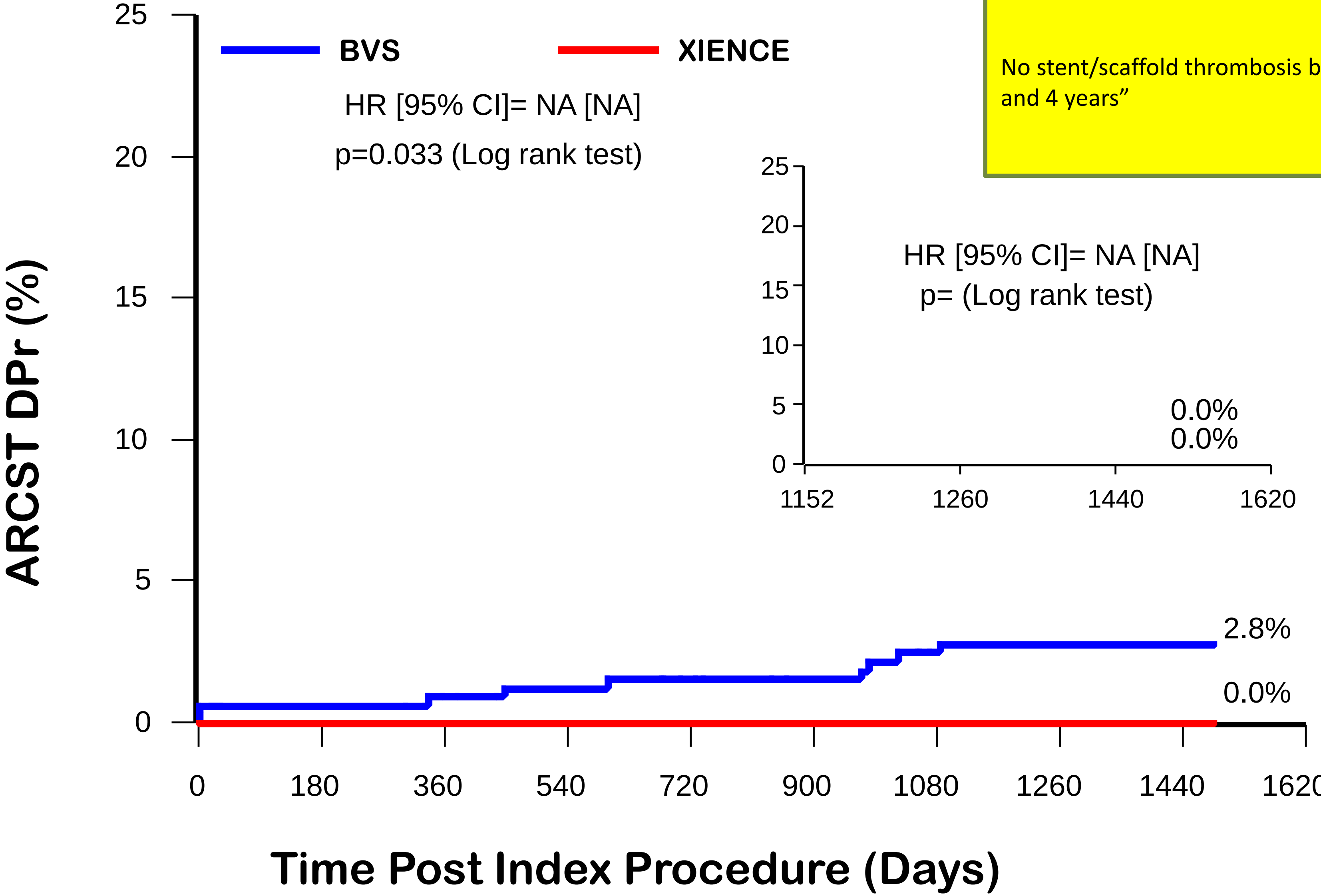
Clinical Outcomes Non Hierarchical Events

	3-4 years		
	Absorb BVS N=335	**XIENCE** N=166	*p* value
Death* n(%)	**2(0.7)**	**1(0.7)**	**1.0000**
Cardiac	**1(0.3)**	**1(0.7)**	**0.5408**
Vascular	**0(0.0)**	**0(0.0)**	**1.0000**
Non-cardiovascular	**1(0.3)**	**0(0.0)**	**1.0000**
Myocardial Infarction n(%)	**1(0.3)**	**0(0.0)**	**1.0000**
Q-wave	**0(0.0)**	**0(0.0)**	**1.0000**
Non Q-wave	**1(0.3)**	**0(0.0)**	**1.0000**
All Revascularization* n(%)	**10(3.3)**	**1(0.7)**	**0.1142**
All TLR	**2(0.7)**	**0(0.0)**	**1.0000**
All NTL-TVR	**4(1.3)**	**0(0.0)**	**0.3102**
All NTVR	**6(2.0)**	**1(0.7)**	**0.4373**

*Per ARC. Cutlip *et al.*, *Circulation*. 2007;115:2344-2351

Definite/Probable Scaffold/Stent Thrombosis*

No stent/scaffold thrombosis between 3 and 4 years"



*Per ARC. Cutlip *et al.*, *Circulation*. 2007;115:2344-2351

Post-Procedure Usage of Antiplatelet Medication through 4 years

	Absorb BVS N=335	**XIENCE** N=166	*p* value
On Aspirin (%)			
at 1 year	**95.8**	**95.2**	**0.7473**
at 4 years	**84.4**	**81.3**	**0.3794**
On DAPT (%)			
at 1 year	**81.0**	**80.7**	**0.9357**
at 2 years	**28.6**	**28.9**	**0.9442**
at 3 years	**29.8**	**27.7**	**0.6254**
at 4 years	**25.9**	**21.1**	**0.2372**

Limitations

- The ABSORB II study was not powered for clinical endpoints
- Patients in the ABSORB II Study were enrolled before the current recommendations for scaffold implantation

Conclusions

- The Absorb scaffold polymer has been reported to be completely bio-resorbed by 3 years. Between 3 and 4 years follow up
  - there were no ST events in the Absorb arm
  - DOCE/TLF events were similar between Absorb and Xience
- In a trial which was not powered for clinical events, at 4 years there were no statistically significant differences in the clinical outcomes between the two arms:
  - PoCE (all death, all MI and all revascularization)
    Absorb BVS: 23.6% vs XIENCE: 26.7%, p=0.47
  - DoCE/TLF (cardiac death, TV-MI and TLR)
    Absorb BVS: 11.5% vs XIENCE: 6.0%, p=0.06
- The exploratory observations presented in this report are hypothesis generating and need to be confirmed in larger randomized trials such as ABSORB III and ABSORB IV

jaa
Just accepted article

EuroIntervention

Title: **Four-year follow-up of the randomised comparison between an everolimus-eluting bioresorbable scaffold and an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II trial).**

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