

Bioresorbable stents – for all or for few?

Franz-Josef Neumann



Conflict of Interest

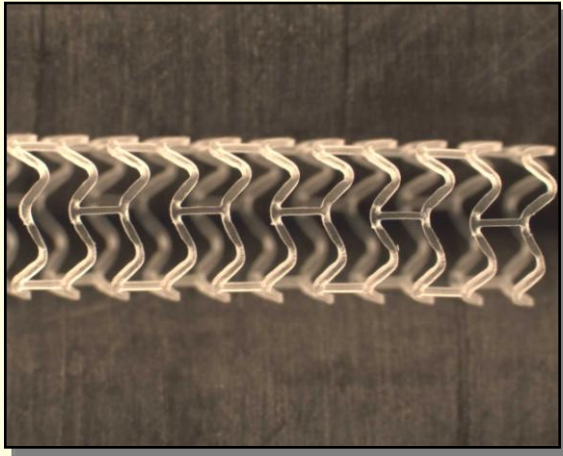
Personal: None

Institutional:

Speaker honoraria, consultancy fees and research grants from

Lilly, Daiichi Sankyo, Sanofi-Aventis, Bayer, Boehringer, The Medicines Company, Bristol, Novartis, Roche, Boston Scientific, Cordis, Biotronik, Medtronic, Edwards

Bioresorbable poly-L-lactide (PLLA) stent

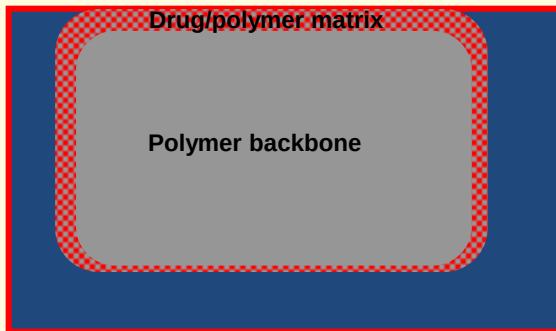


Everolimus/poly-D,L-lactide matrix coating

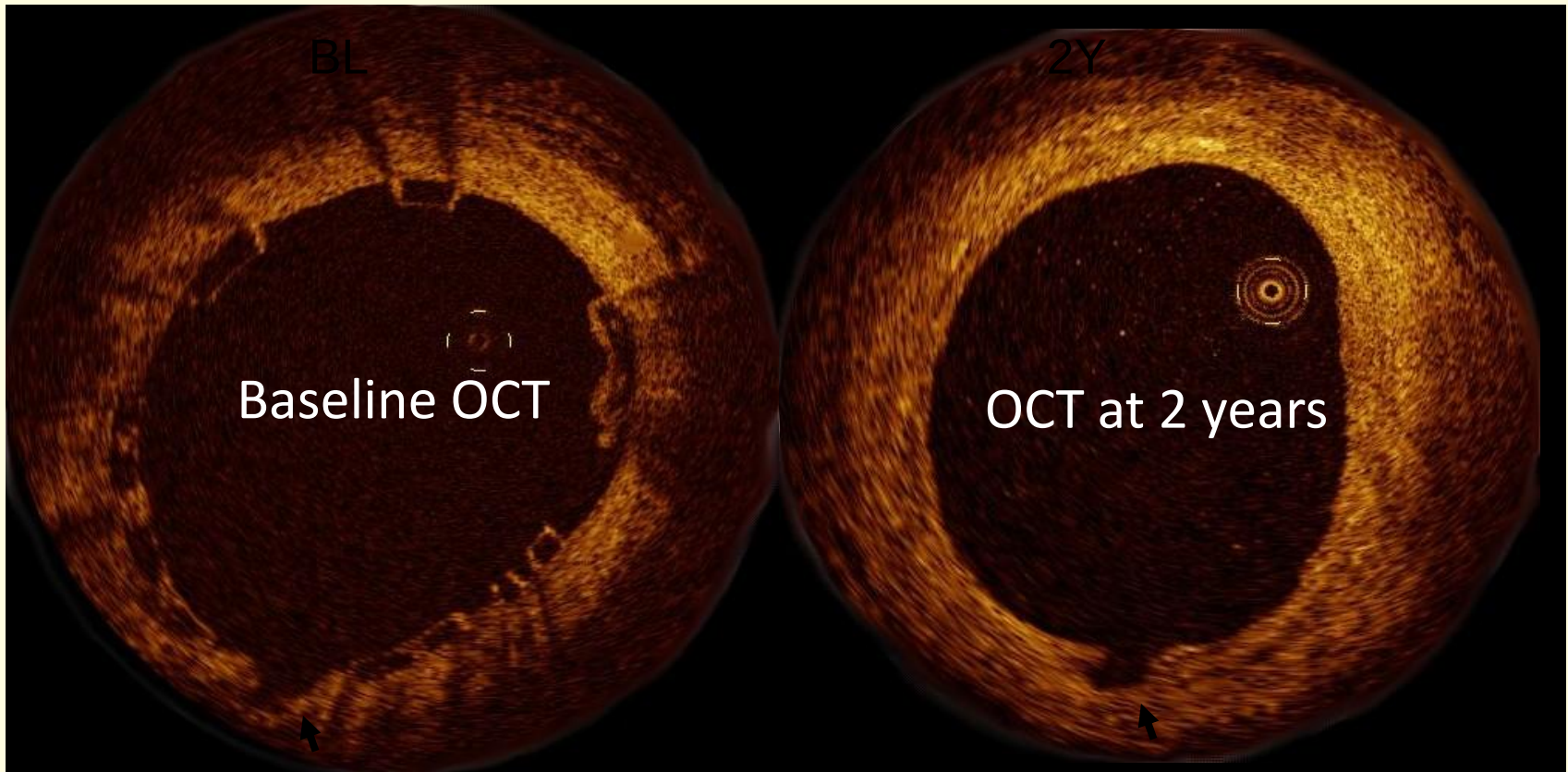
- Thin coating layer
- Amorphous (non-crystalline)
- 1:1 ratio of Everolimus/PDLLA matrix
- Conformal Coating, 2-4 μm thick
- Controlled drug release

PLLA backbone

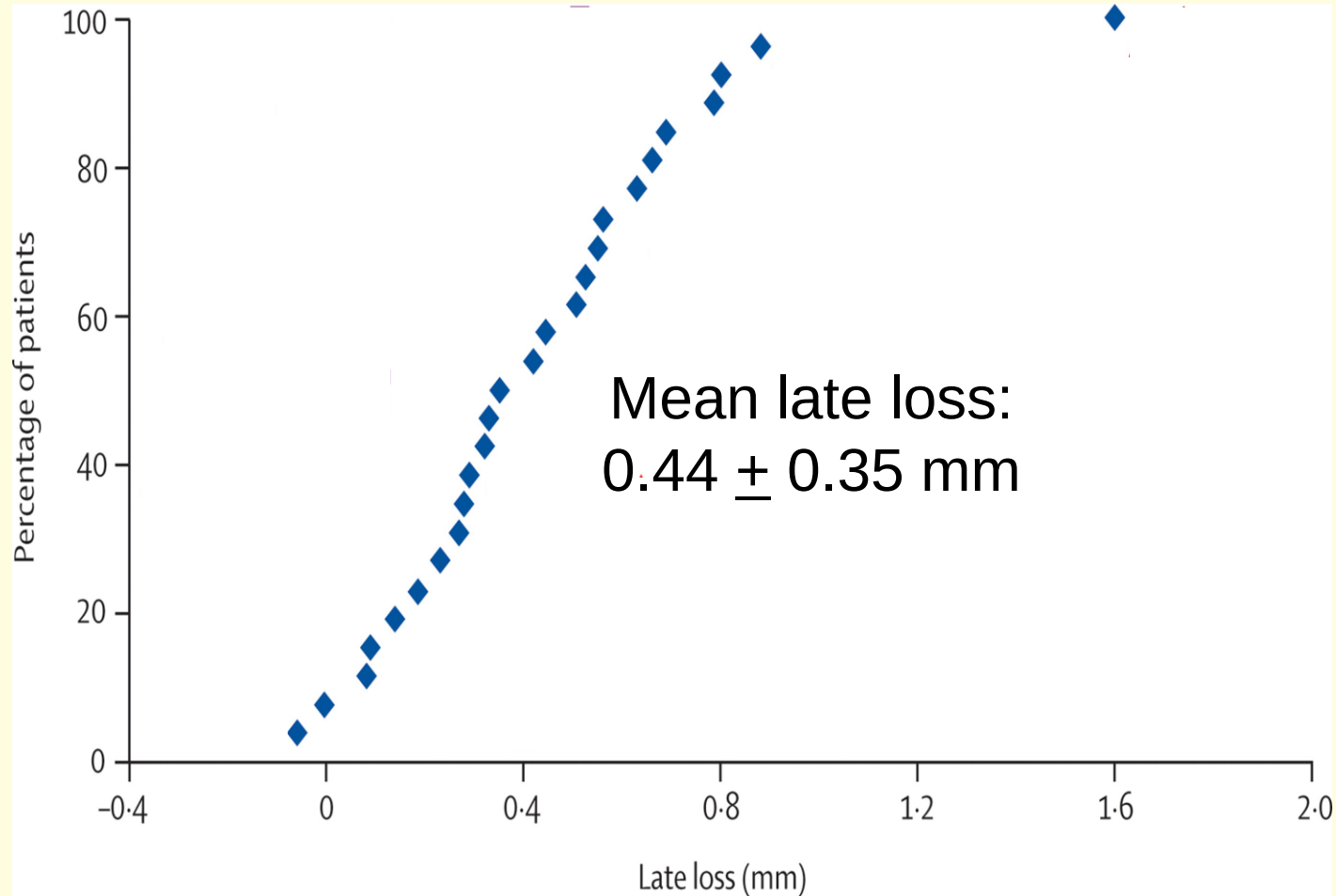
- Highly crystalline
- Provides device integrity
- Processed for increased radial strength



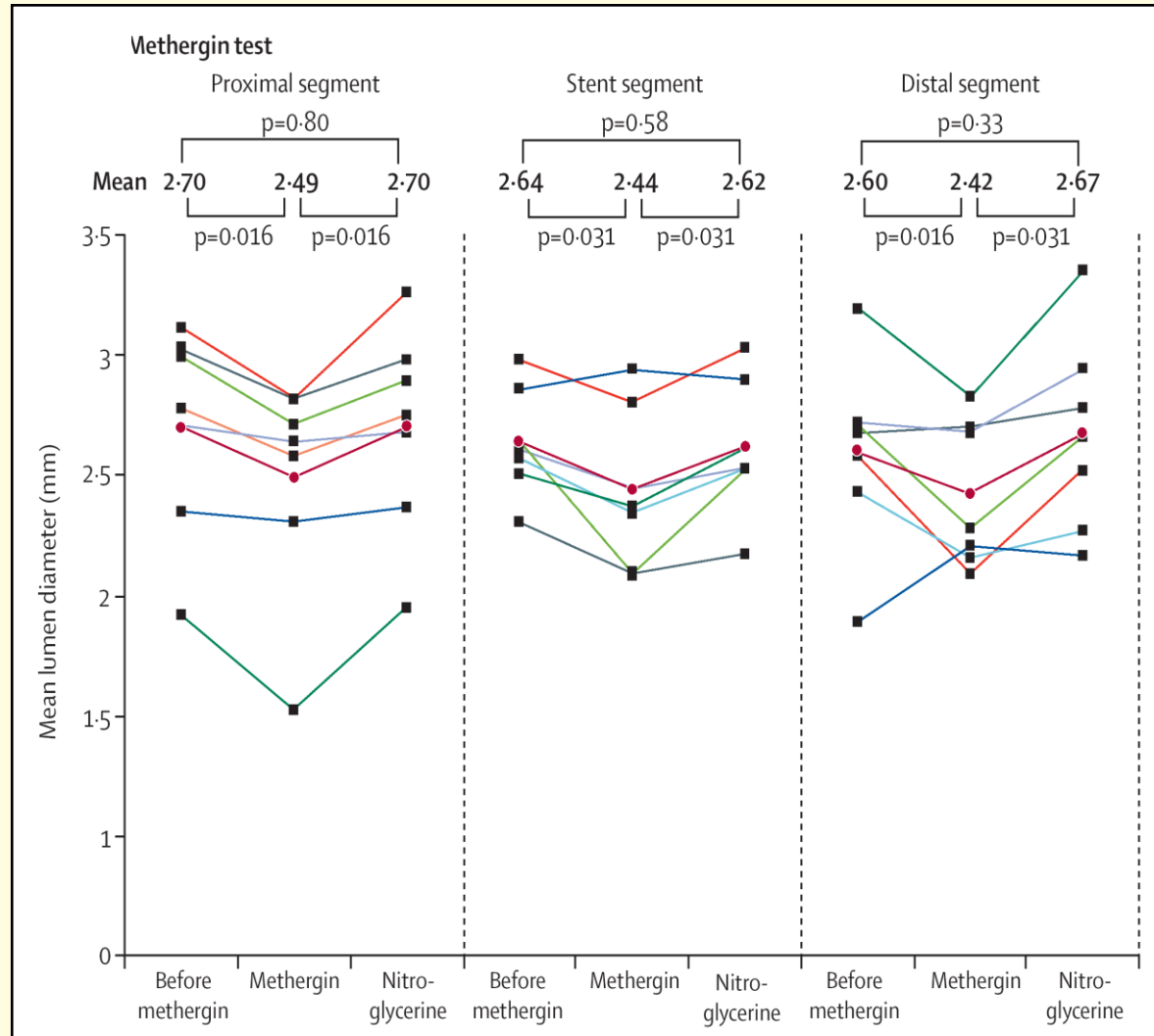
ABSORB: Complete Absorption of Stent Material



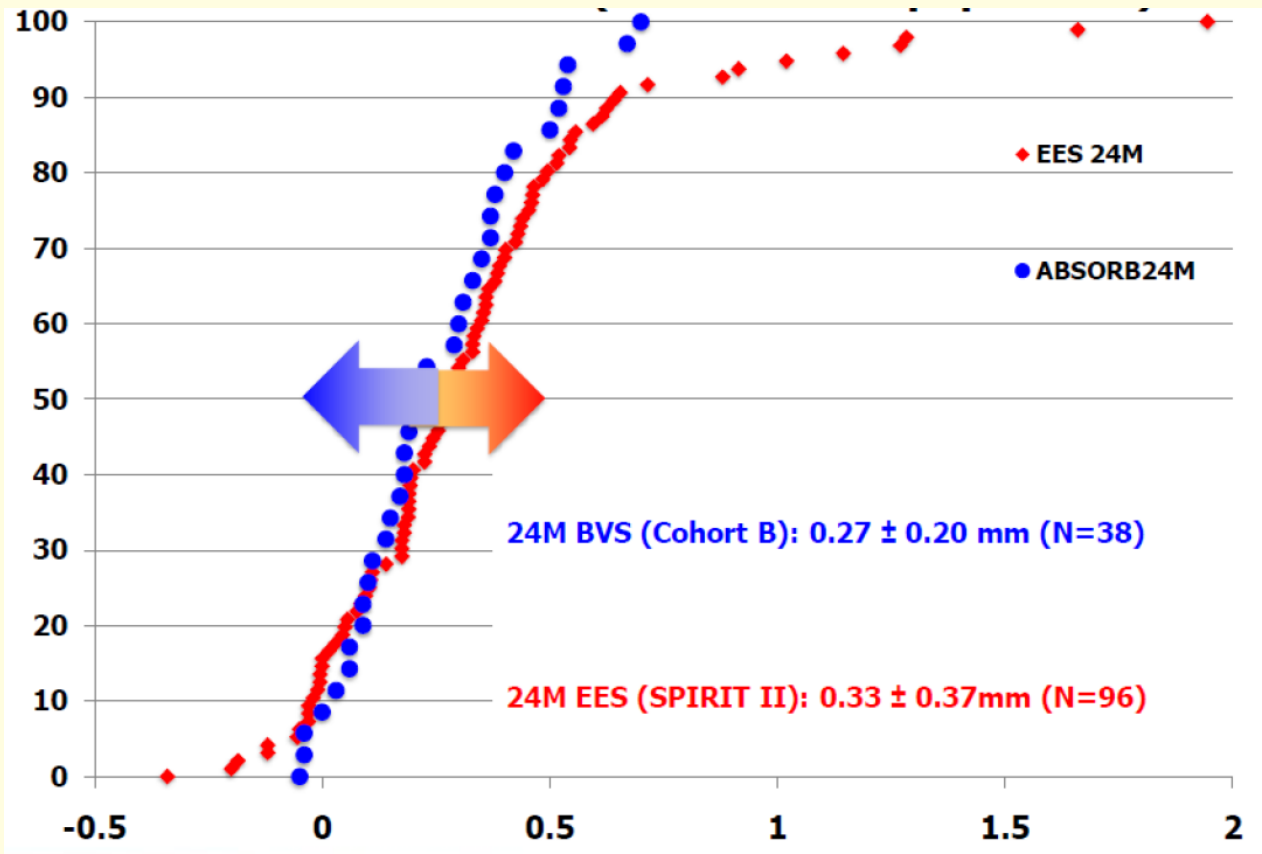
ABSORB cohort A: Late Loss



ABSORB: Restoration of vasomotor function



ABSORB Cohort B: Late lumen loss at 2 years



Target vessel failure

1 year: 6.9%

2 years: 11%

3 years: 13%

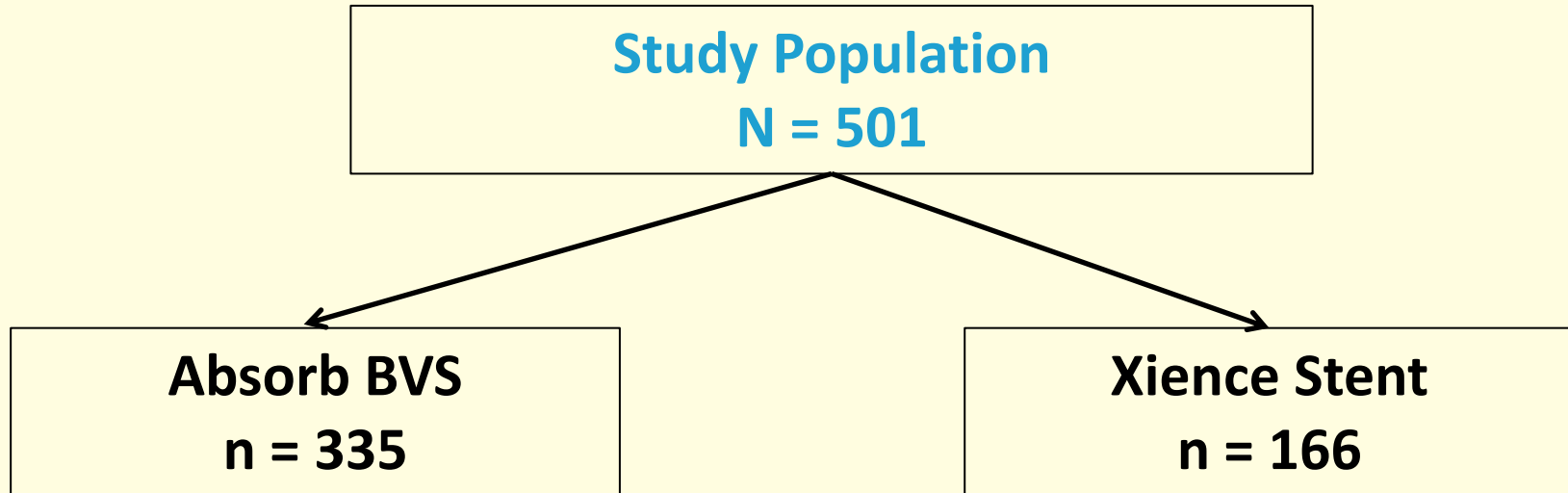
- ABSORB II -

Hypothesis:

BVS superior to XIENCE with respect to vasomotion at 3 years

BVS non-inferior to XIENCE with respect to late lumen loss at 3 years

ABSORB II: Randomisation

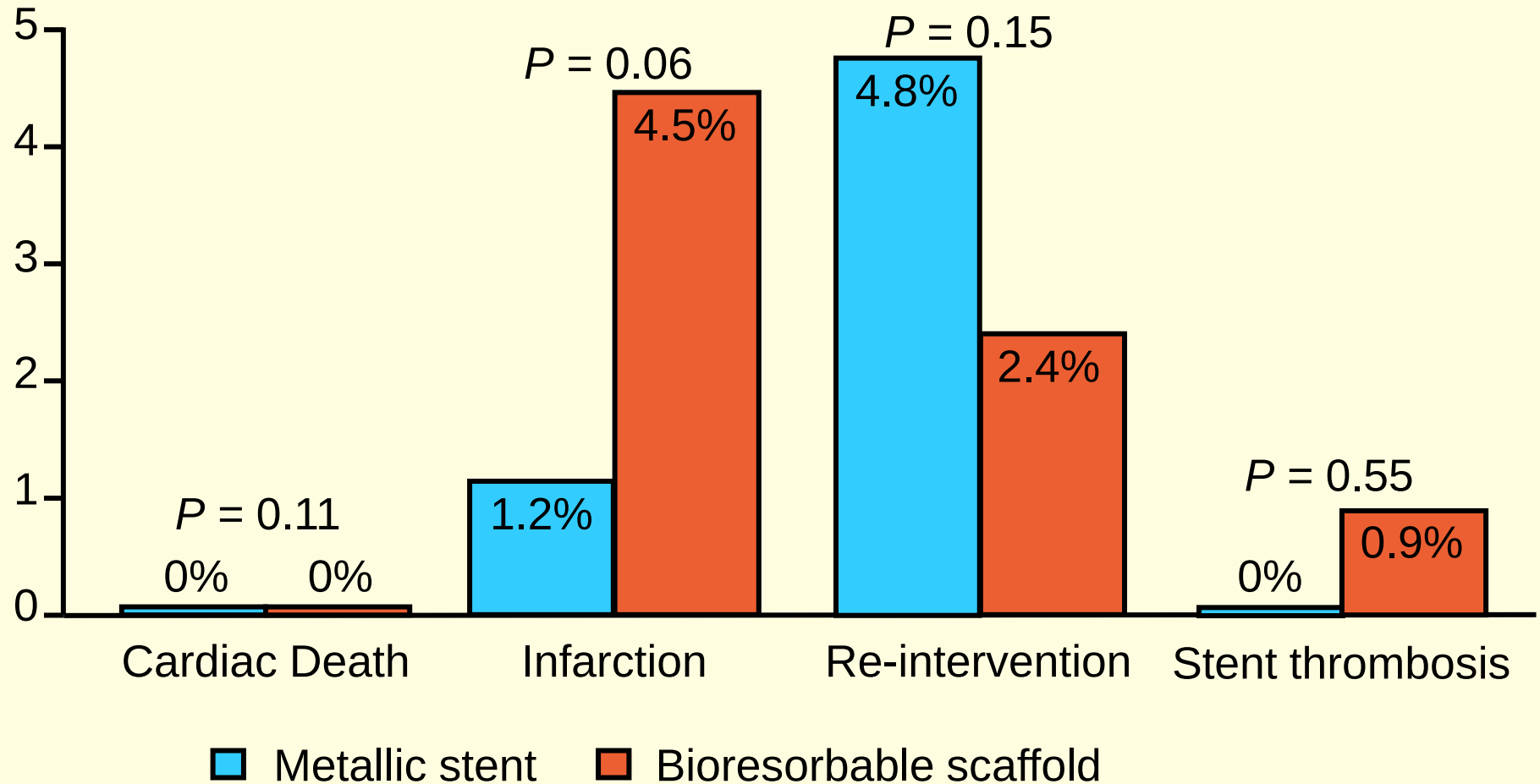


ABSORB II

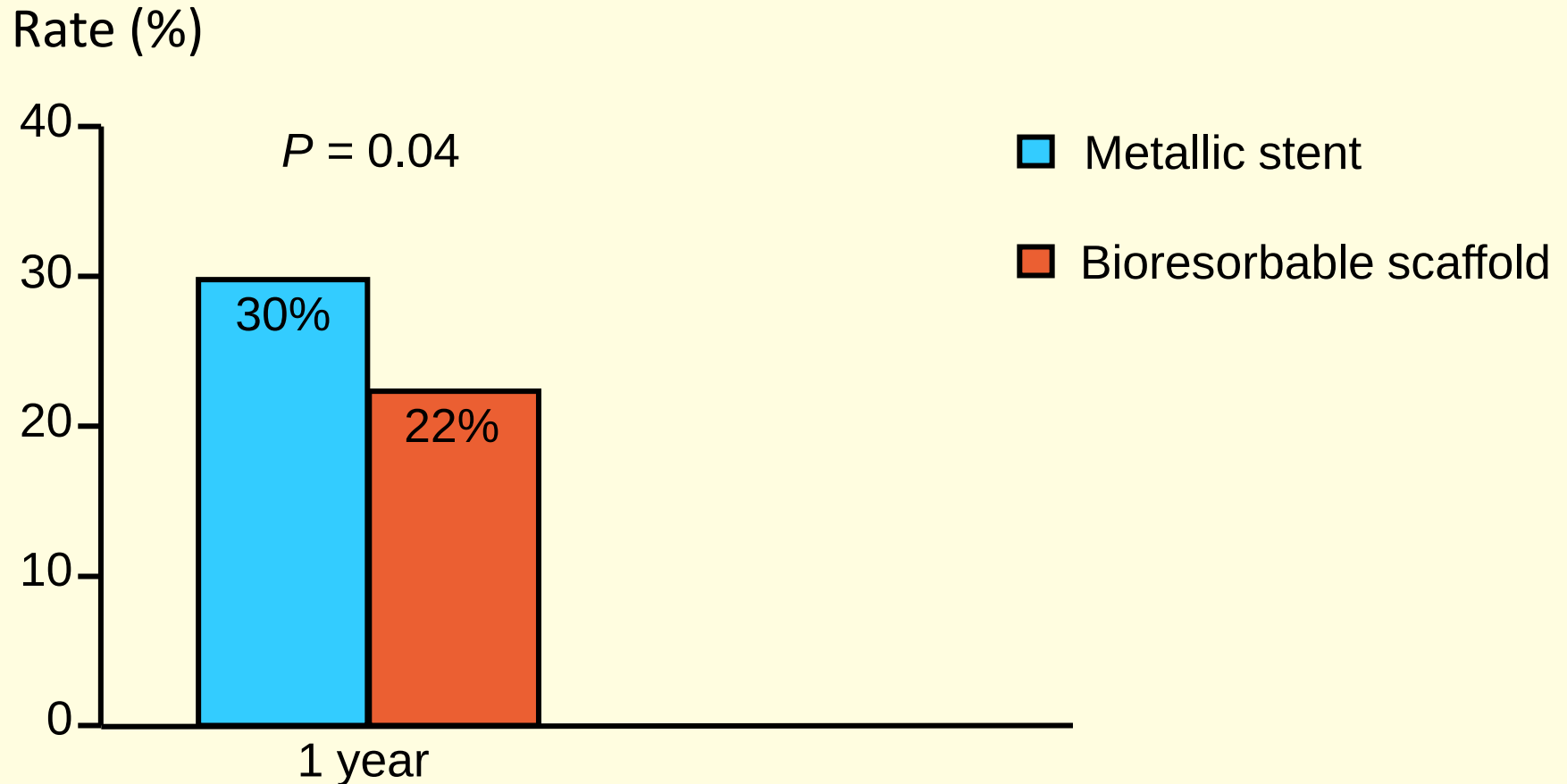
1-Year Results

No proven benefit of bioresorbable scaffolds

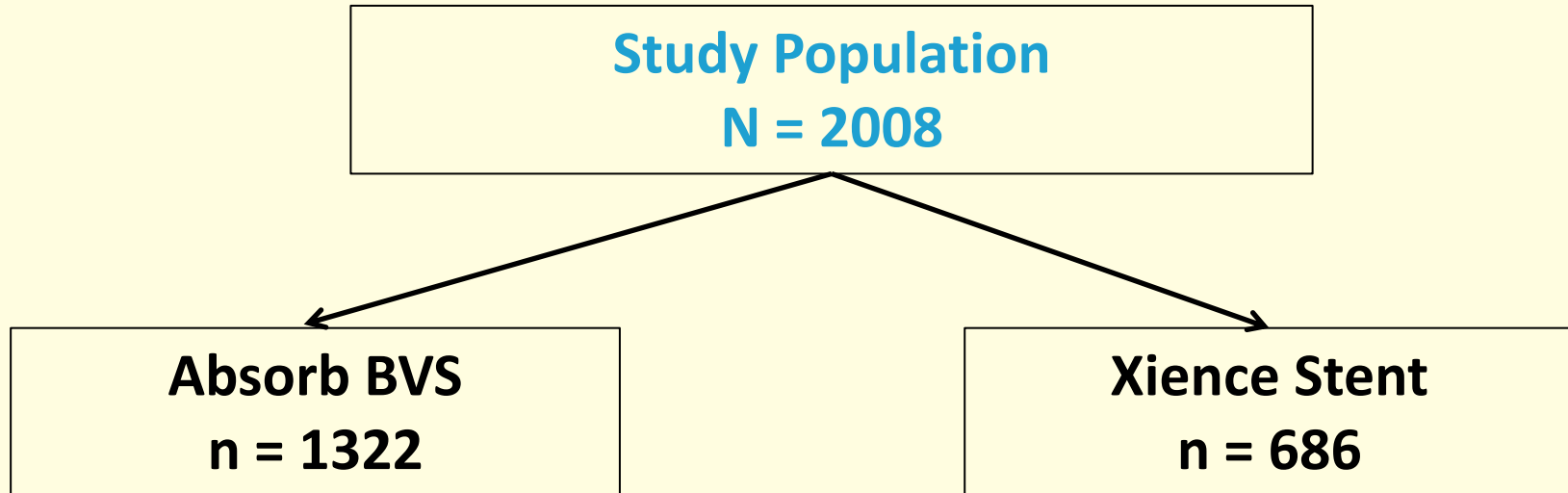
1-year incidence (%)



Lower cumulative angina rates with bioresorbable scaffolds

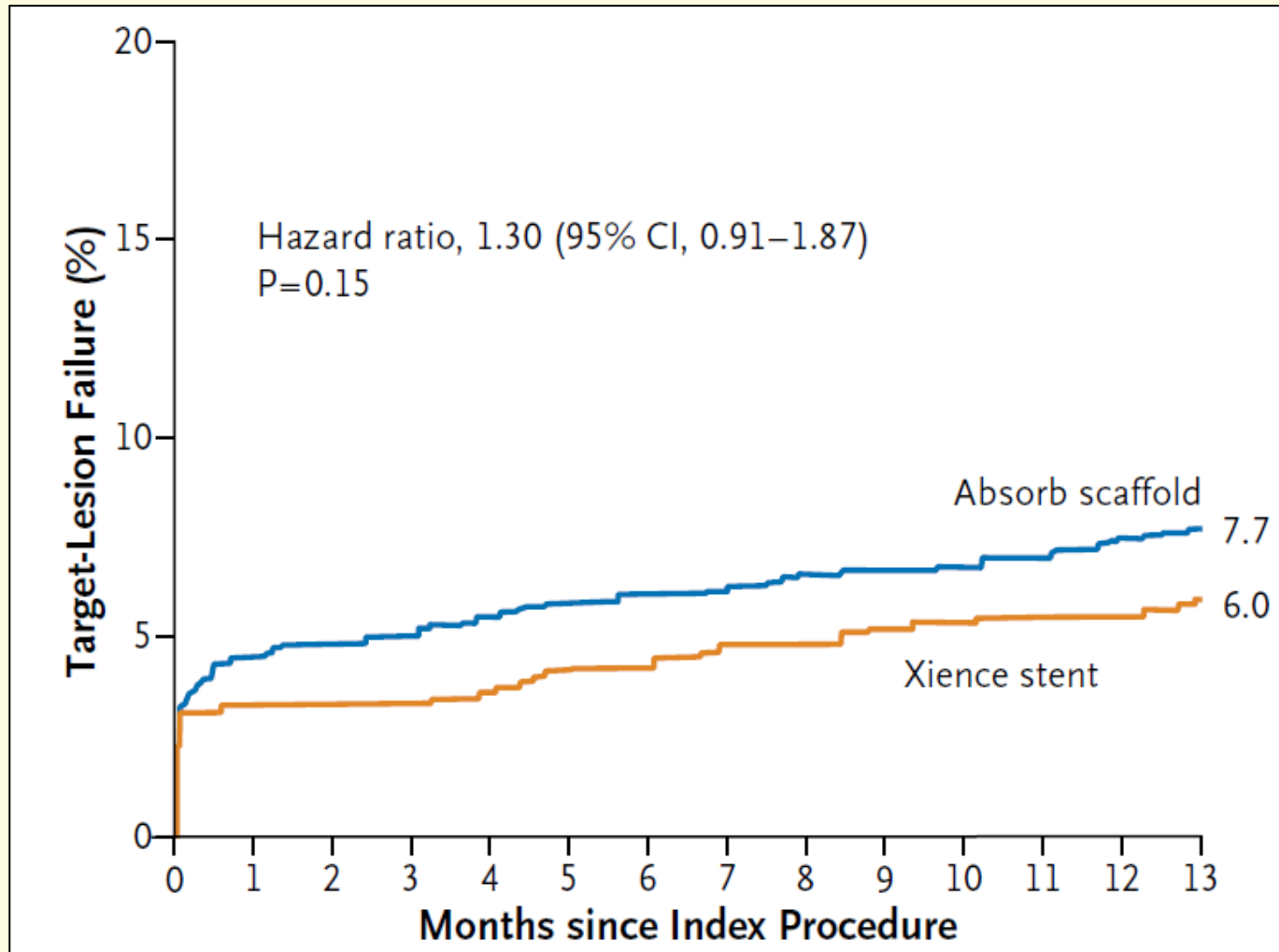


ABSORB III: Randomisation



ABSORB III:

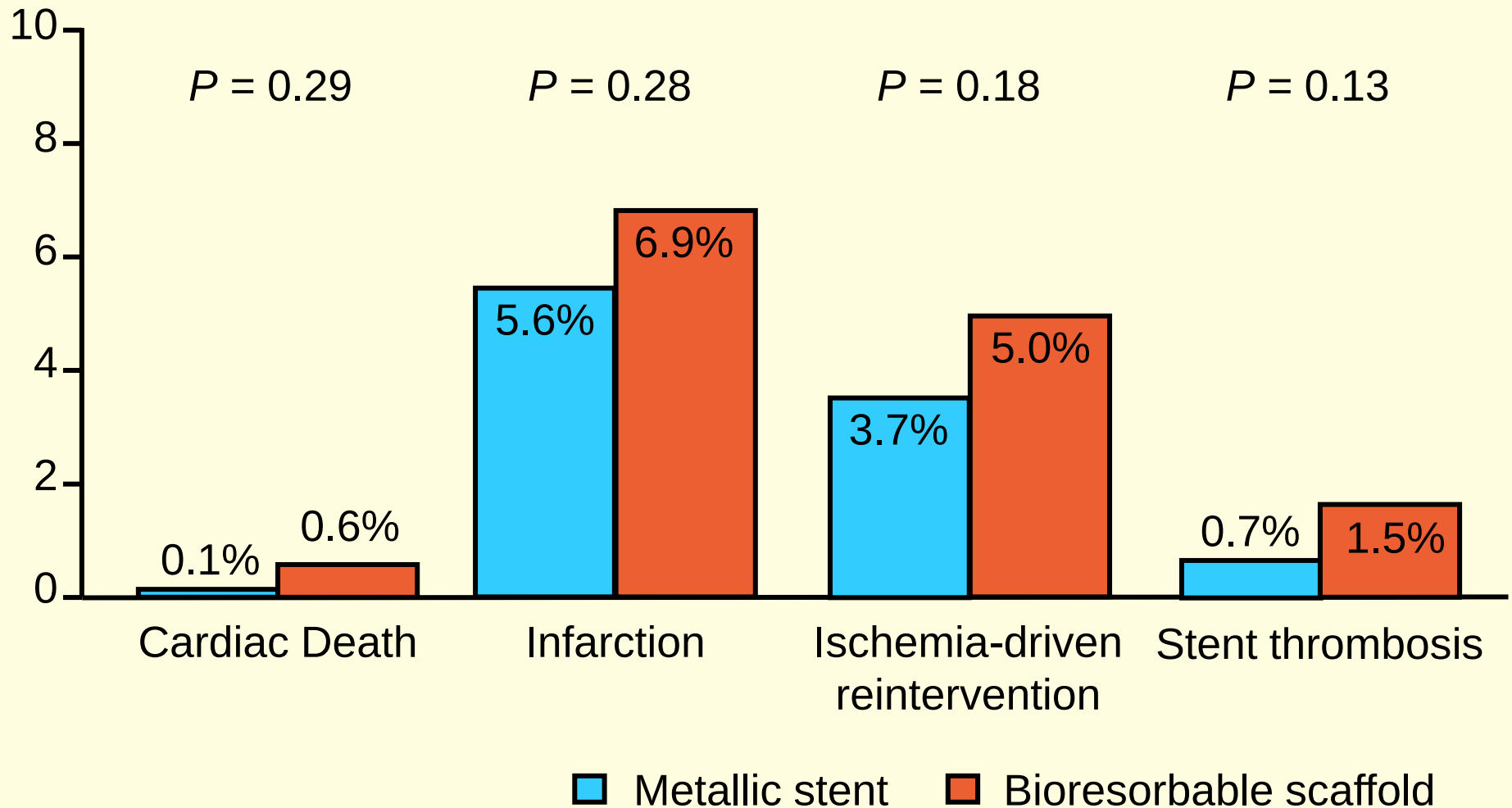
Numerical increase in target lesion failure with scaffold



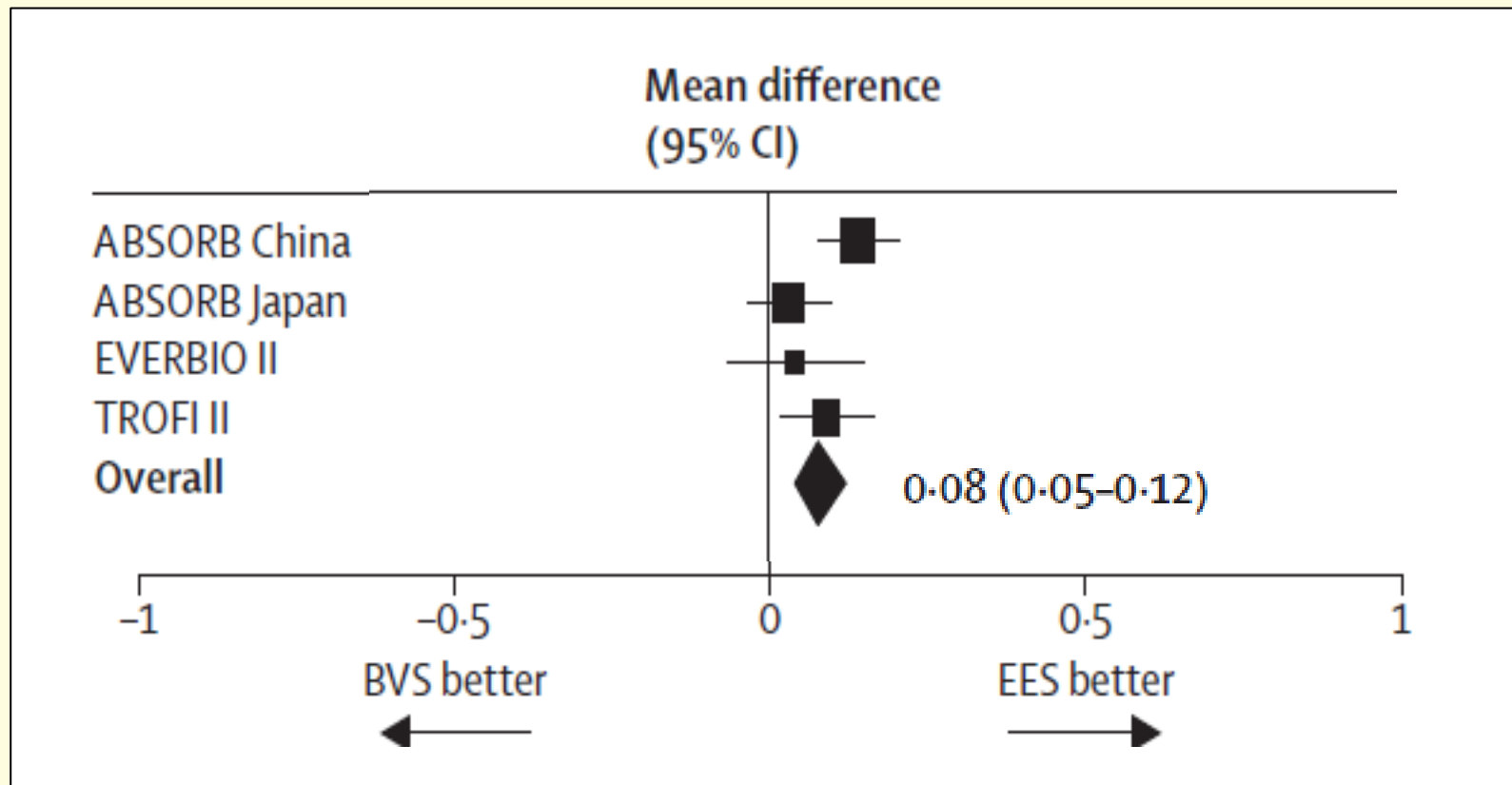
ABSORB III:

Numerically higher risk with bioresorbable scaffolds

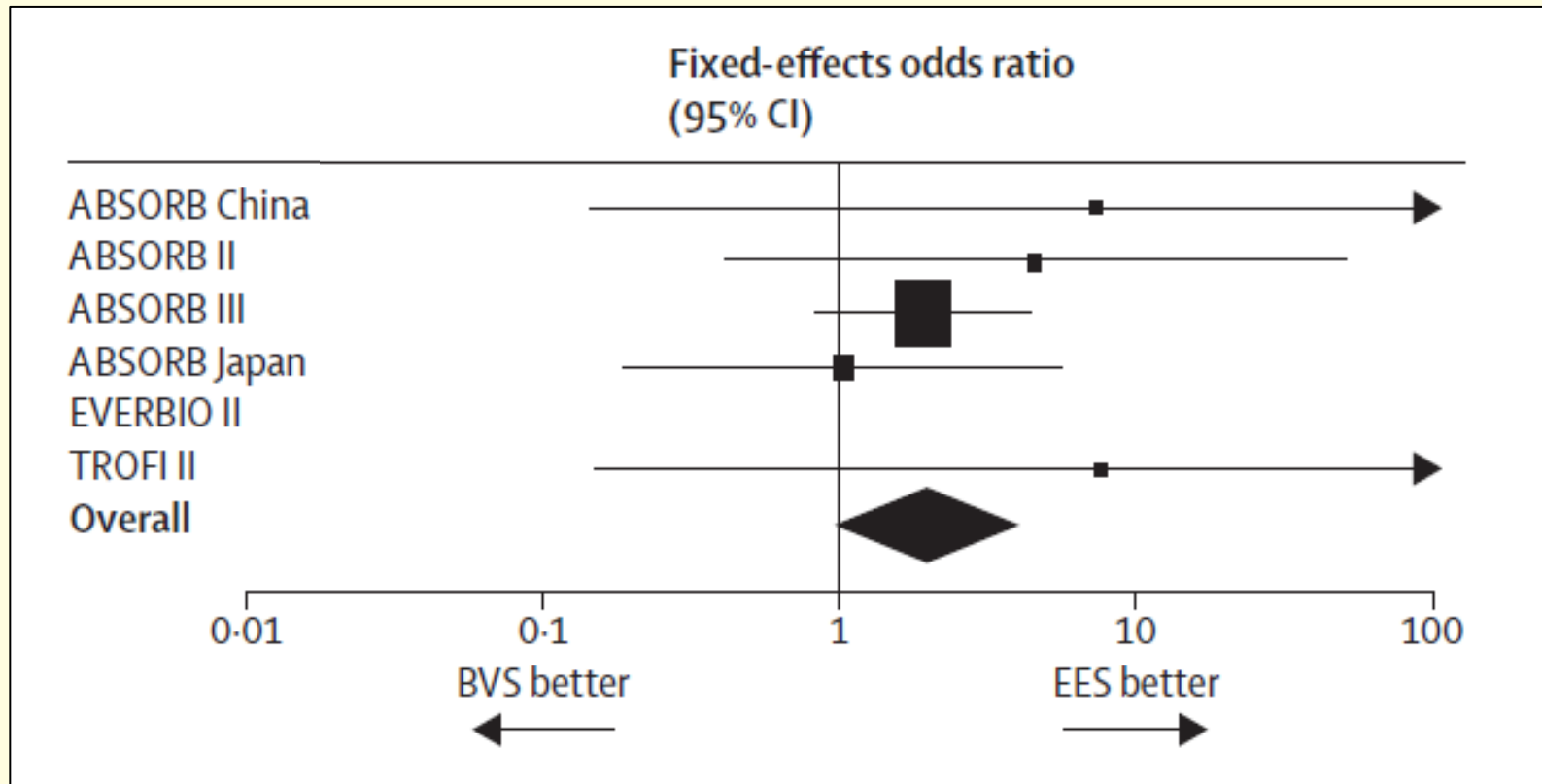
1-year incidence (%)



Meta-analysis: Higher in-device late lumen loss with scaffold



Meta-analysis: Higher risk of stent thrombosis with scaffold



ABSORB II

3-Year Results: Primary endpoints

ABSORB II: Primary endpoint

Co-primary endpoint:

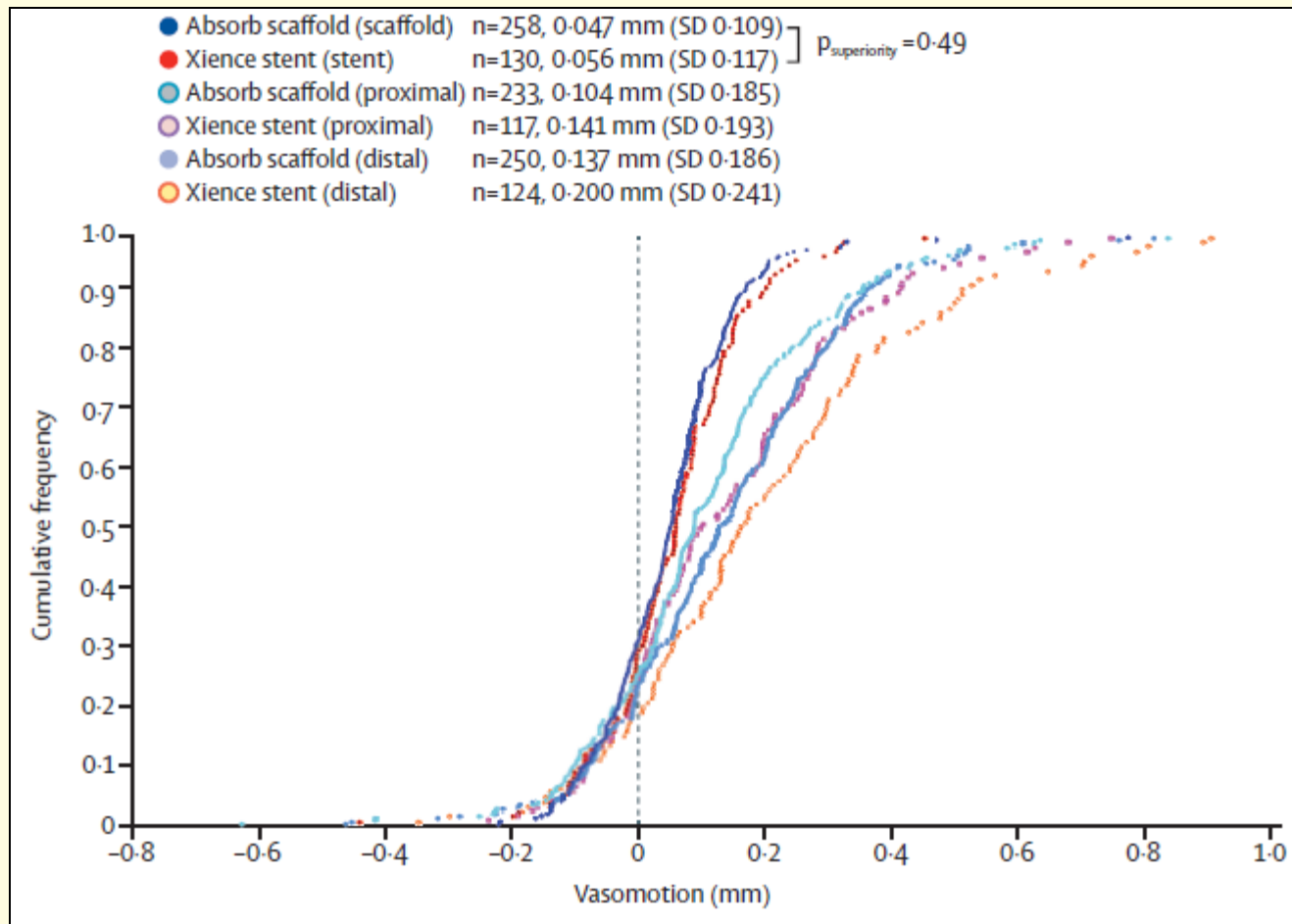
Vasomotion in response to nitrate at 3 years - **Superiority**

Late lumen loss at 3 years – **Non inferiority**

Non-inferiority margin for late loss: 0.14 mm

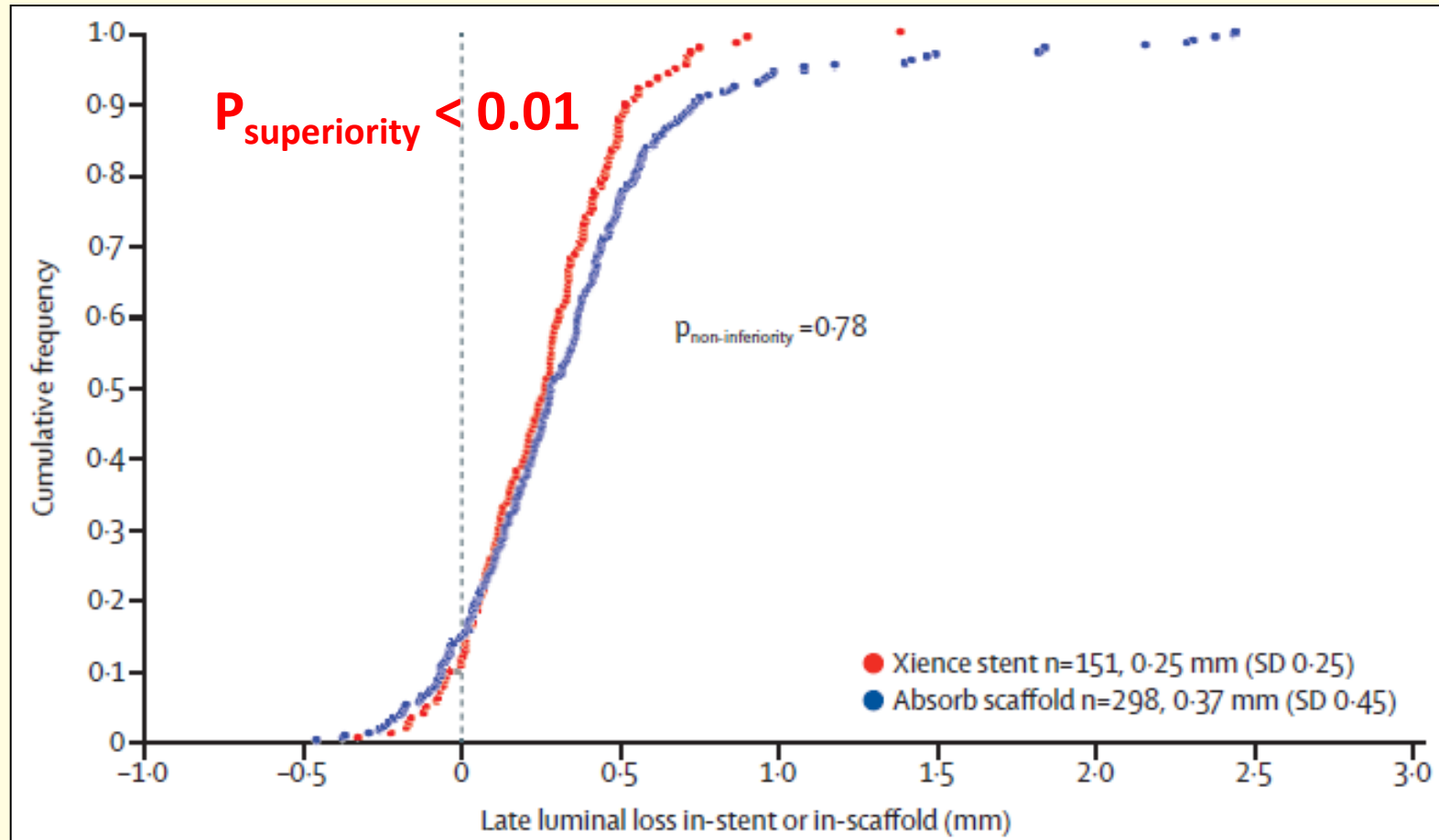
- ABSORB II -

Vasomotion: Scaffold non-superior to stent

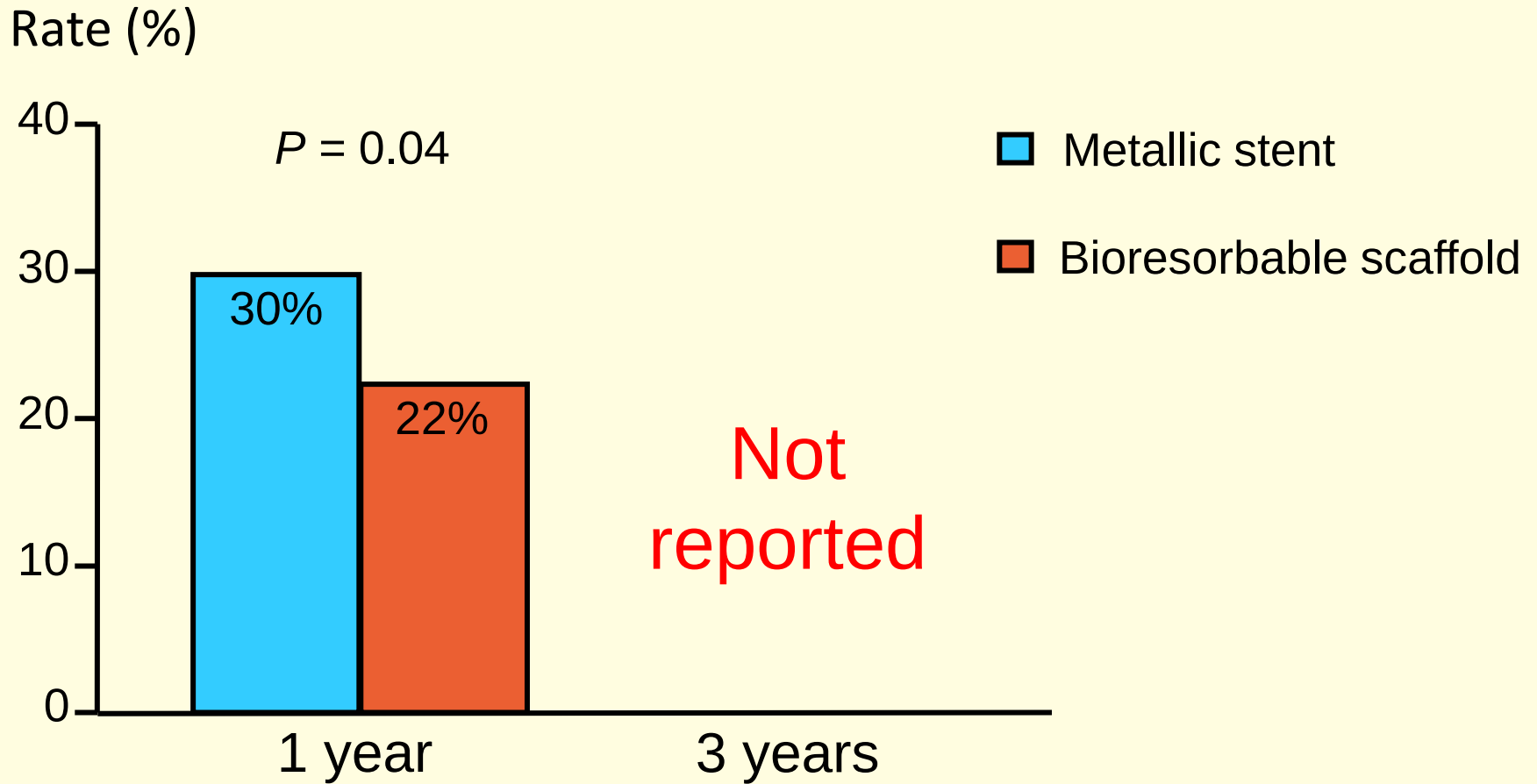


- ABSORB II -

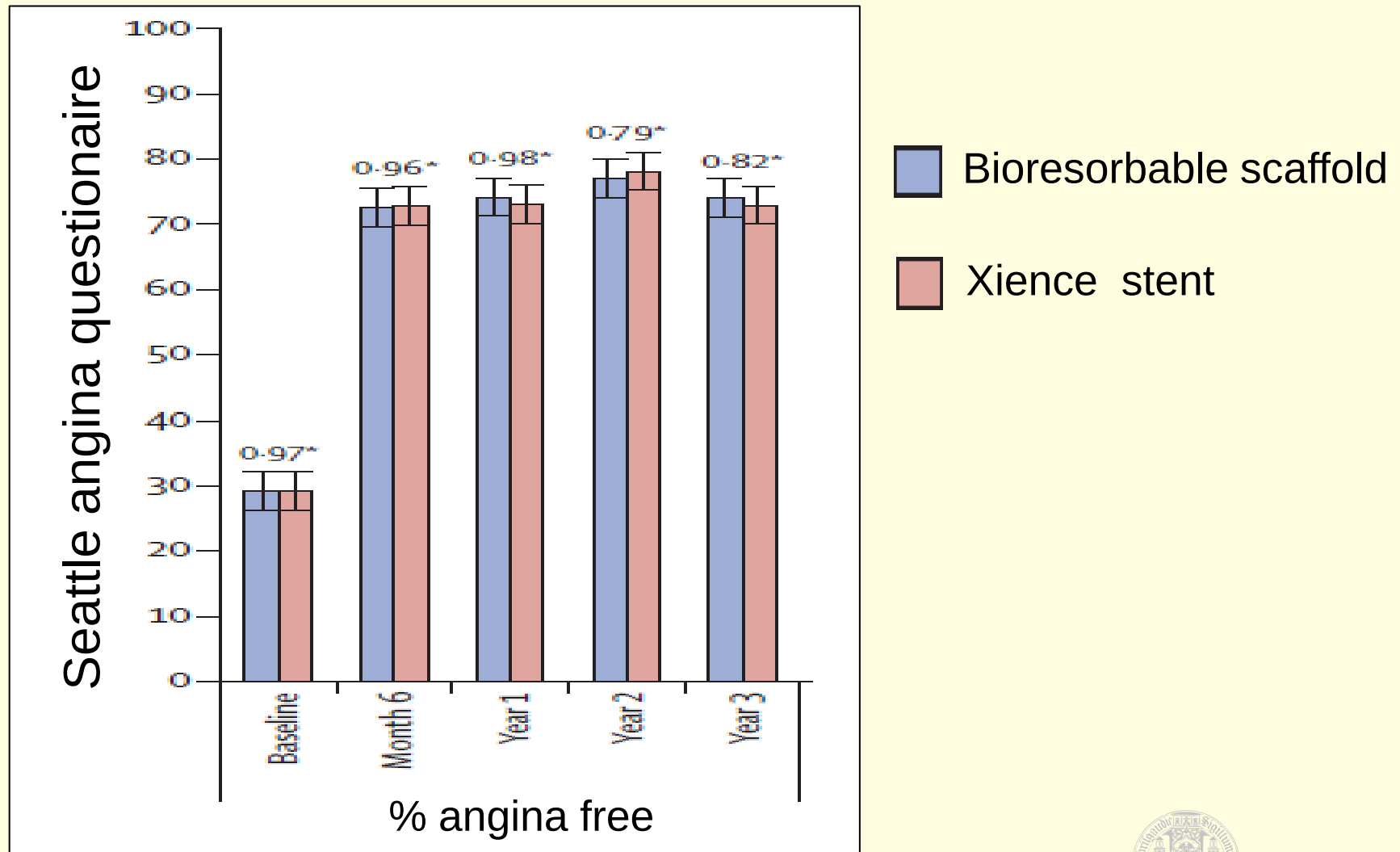
Late lumen loss: Scaffold inferior to stent



Lower cumulative angina rates with bioresorbable scaffolds?

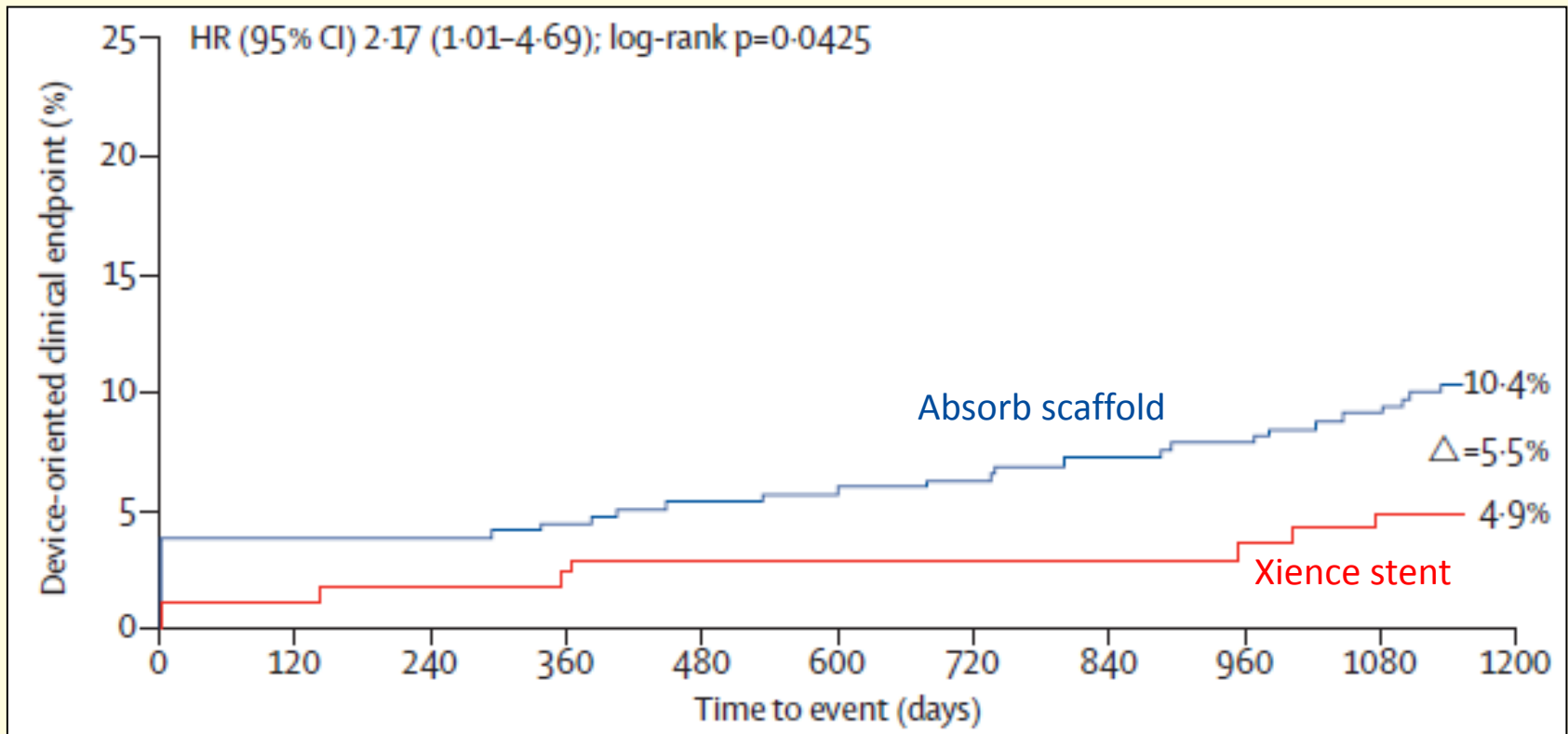


No benefit of scaffold with respect to angina relief



- ABSORB II -

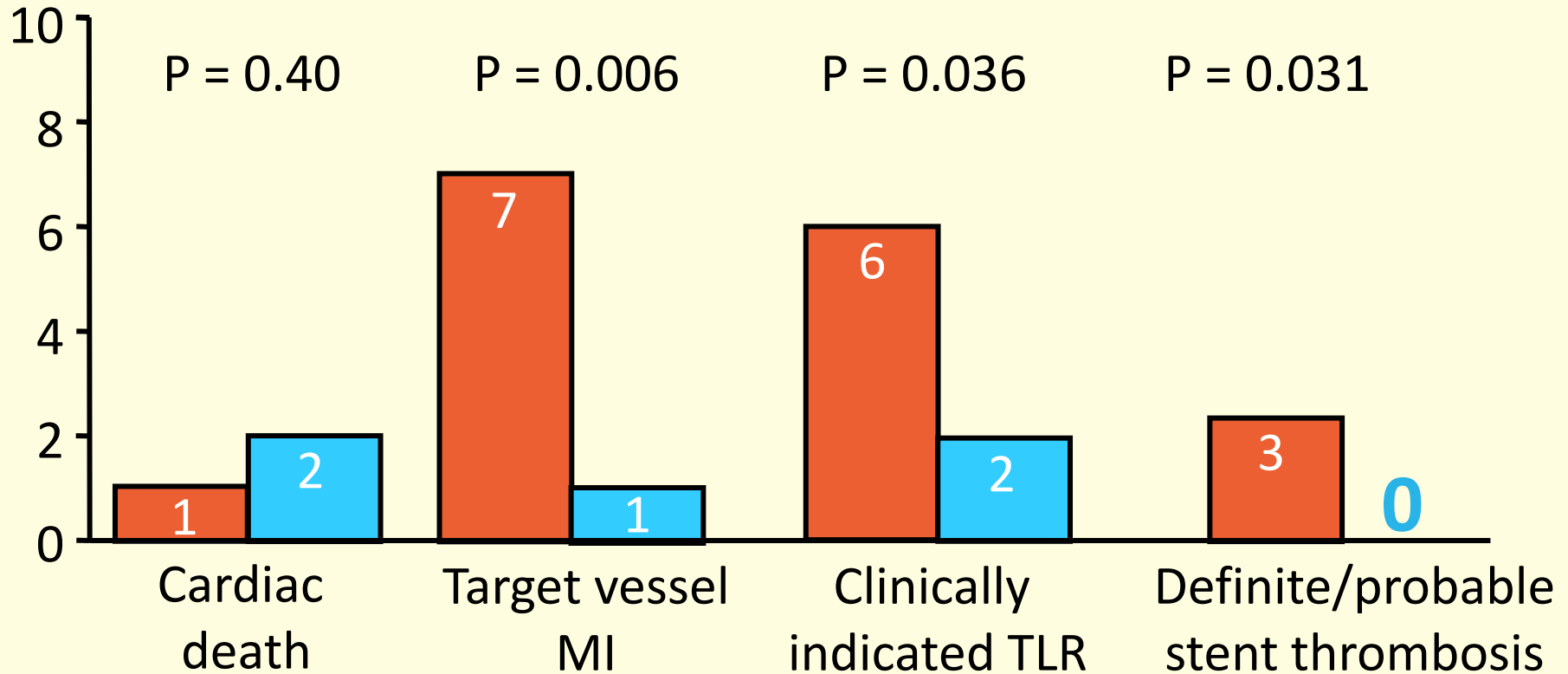
Device-oriented outcome: Scaffold inferior to stent



- ABSORB II -

Device-oriented outcome: Scaffold inferior to stent

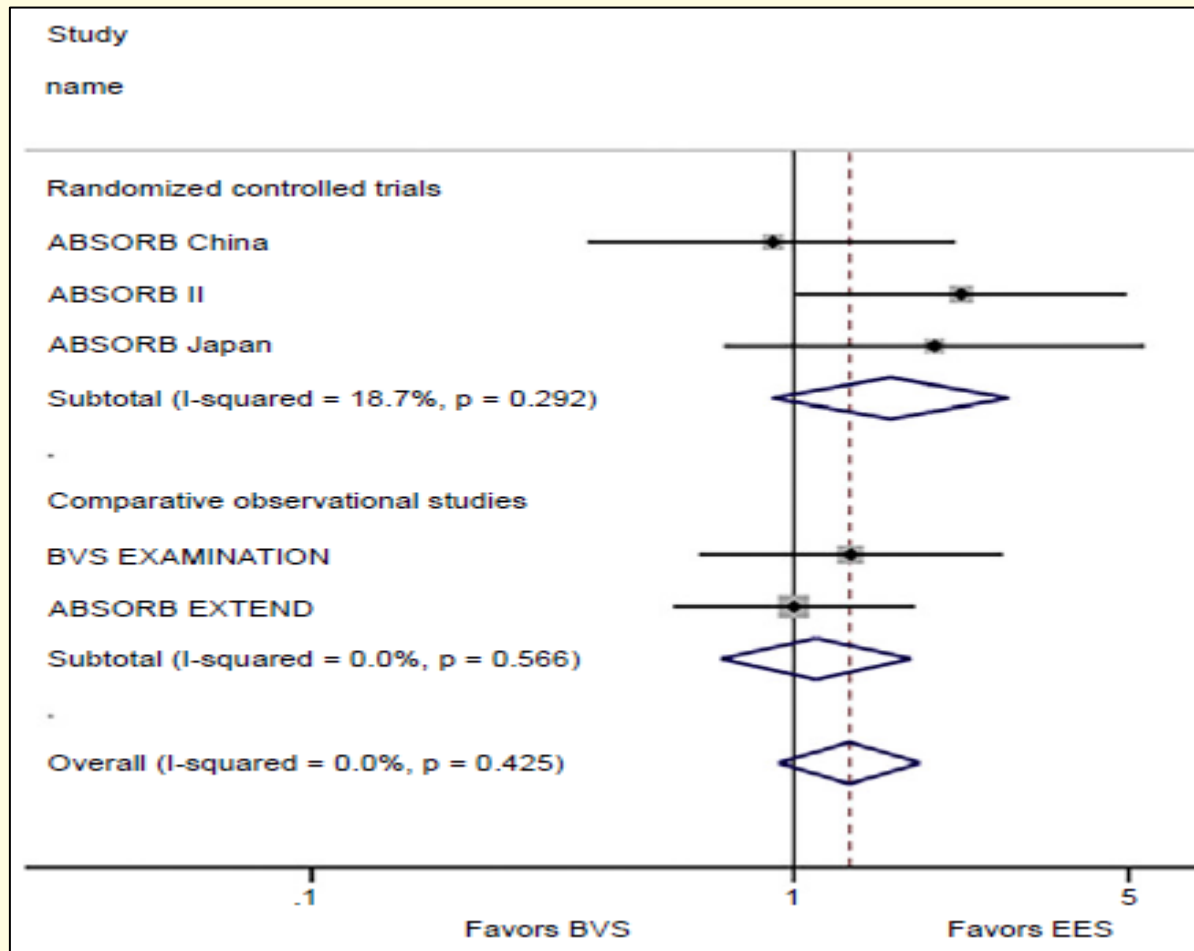
Proportion with event at 3 years (%)



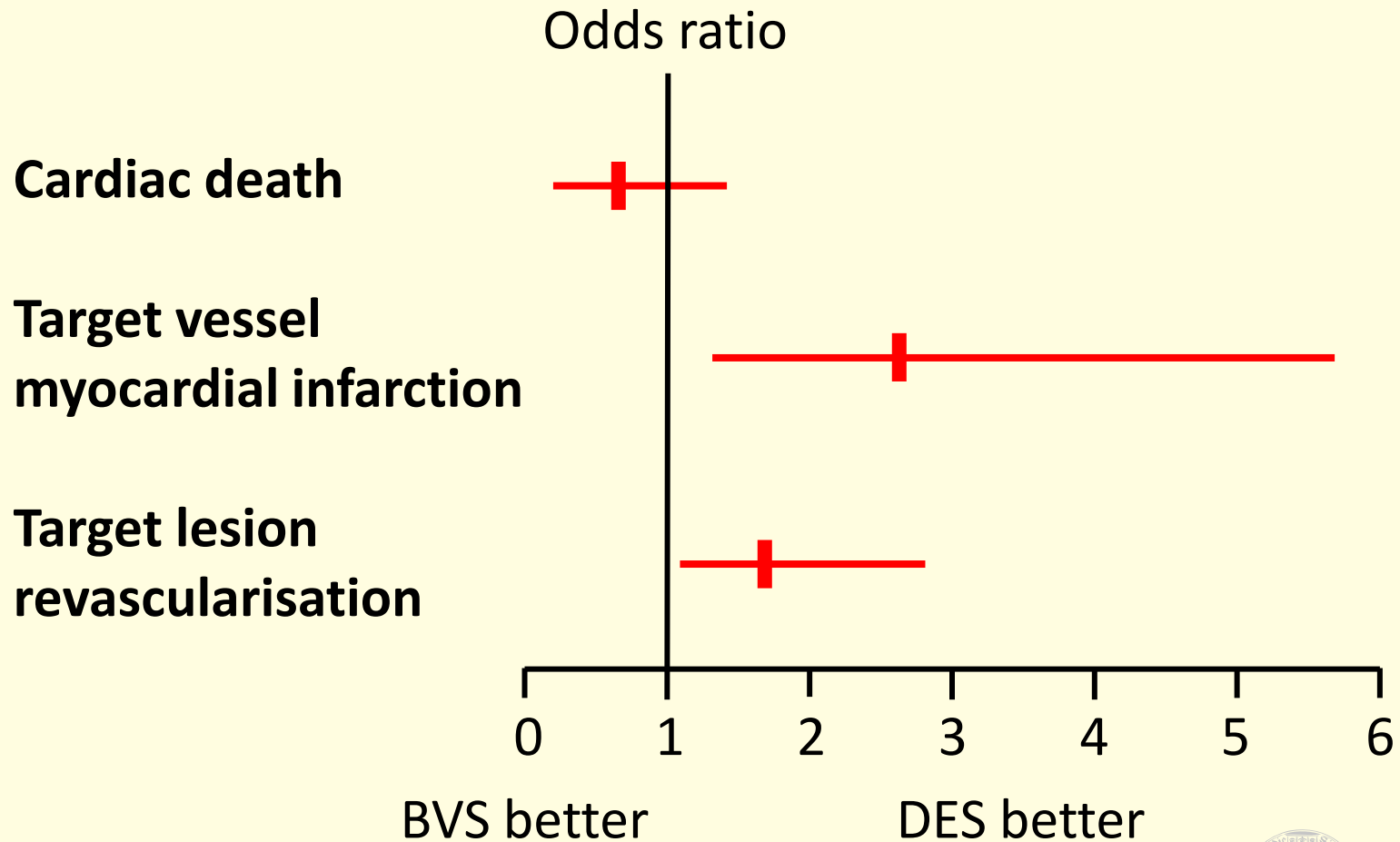
- Device-oriented clinical outcome -

■ Absorb scaffold ■ Xience stent

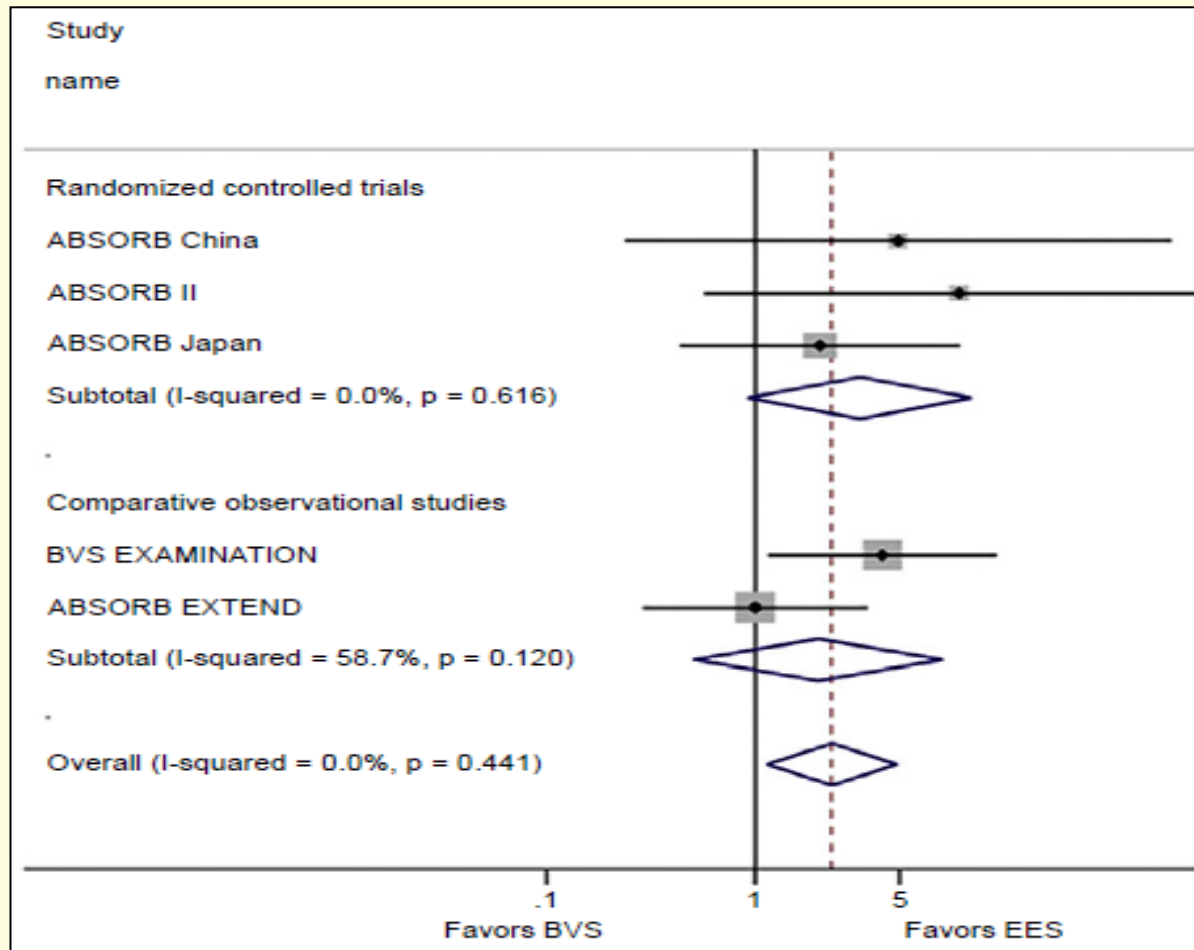
Updated meta-analysis: More target lesion failures with scaffold



Updated meta-analysis: More target lesion problems with scaffold



Updated meta-analysis: Higher risk of stent thrombosis with scaffold



Bioresorbable Mg - Stent

2nd Generation Drug Eluting Mg Scaffold - MAGMARIS -



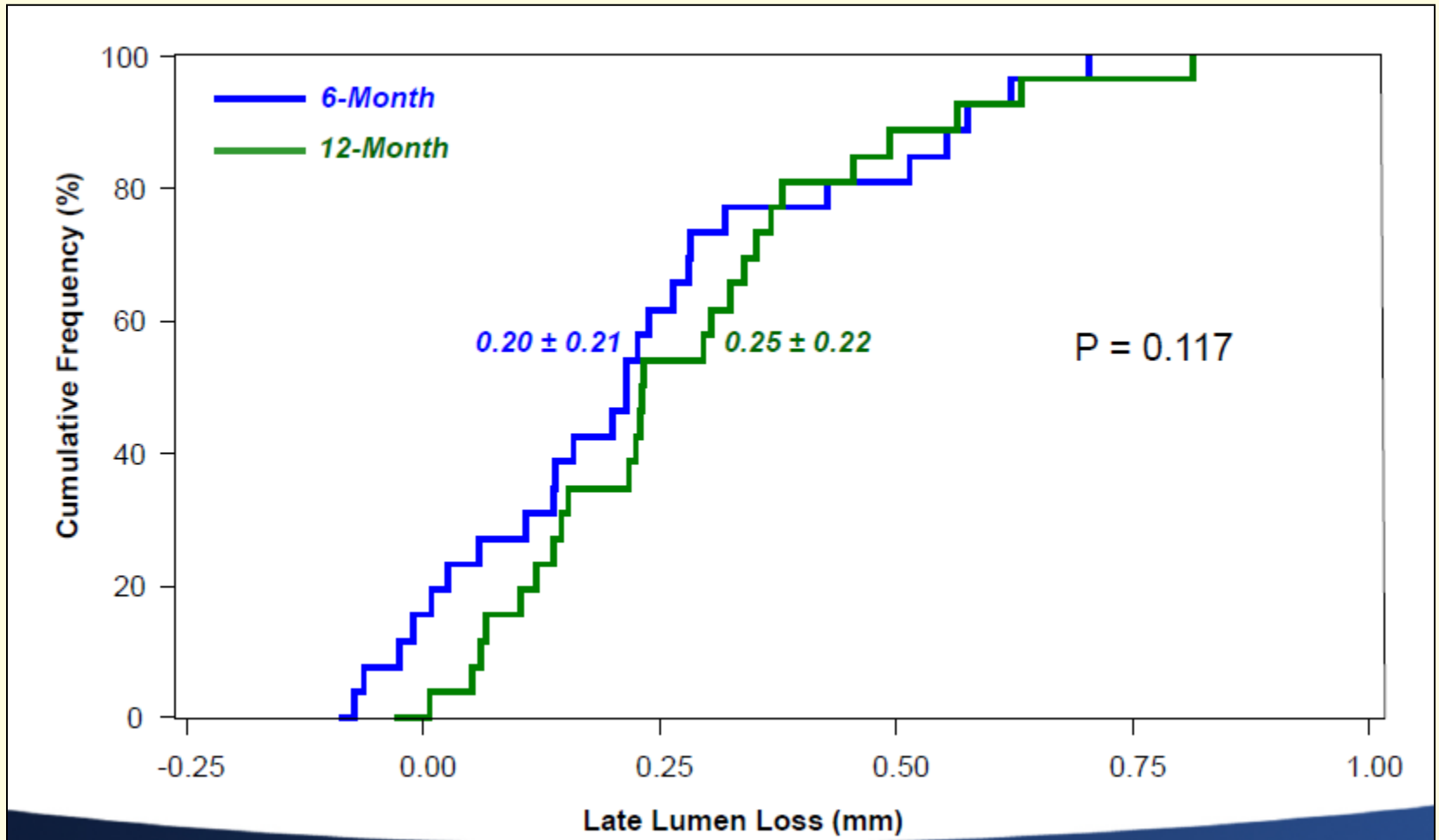
Sirolimus + PLLA (BIOlute)

BIOSOLVE II

	6-Month		12-Month	
	N=120	%	N=118	%
TLF¹	4	3.3	4	3.4
Cardiac death	1 ²	0.8	1 ²	0.8
Target vessel MI	1	0.8	1	0.8
Clinically driven TLR	2	1.7	2	1.7
CABG	0	0.0	0	0
Definite-or-probable scaffold thrombosis	0	0.0	0	0.0



BIOSOLVE II



Bioresorbable Scaffolds

- Summary -

- The development of bioresorbable scaffolds continues.
- Further clinical studies are needed.
- Bioresorbable scaffolds are not ready for clinical use outside studies.

Bioresorbable stents – for all or for few?

For none

(except clinical studies)

