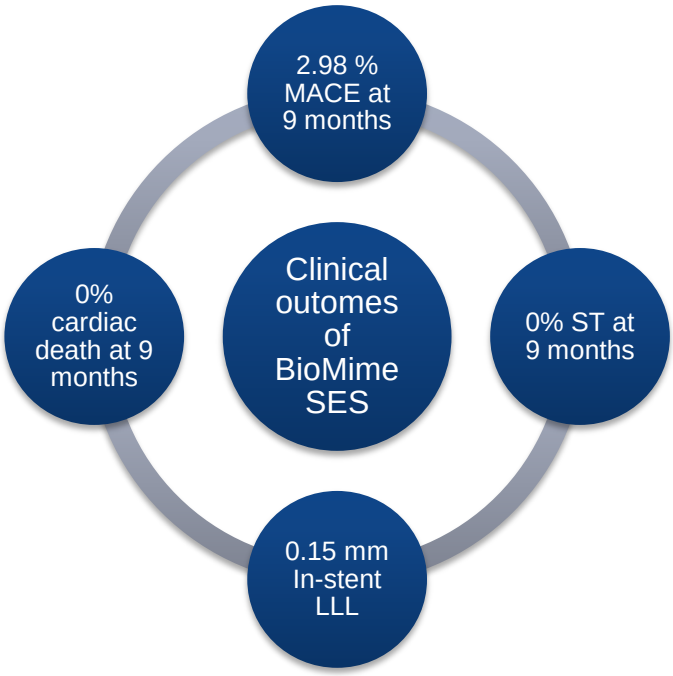
meriT-V Study

Study Highlights

- Principal Investigator: Dr. Alexandre Abizaid
- The meriT-V is a prospective, multicentre, randomized, open-label, active-controlled, non-inferiority trial of the BioMime sirolimus-eluting coronary stent system (SES) as compared to the XIENCE family of everolimus-eluting coronary stents in the treatment of patients with de novo native coronary artery lesions
- Two years clinical follow-up including angiographic analysis at 9 months.
- BioMime SES was non-inferior to XIENCE EES for the primary endpoint of in-stent late lumen loss



❖ Study Design

- **A prospective, multicentre, randomized, open-label, active-controlled, non-inferiority trial**

256 patients were enrolled and randomly assigned (2:1) to BioMime SES or XIENCE EES between November 2014 and December 2016

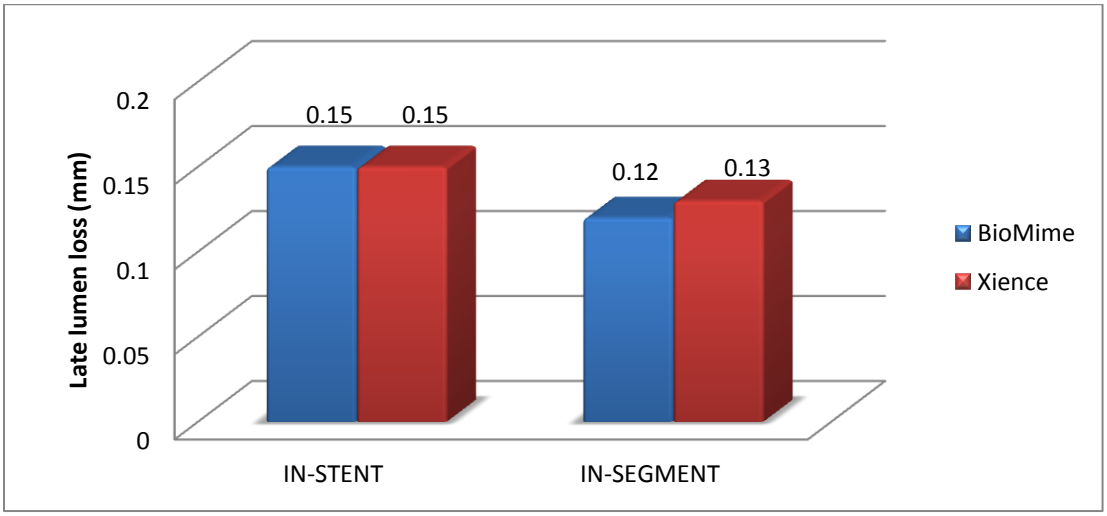
15 investigational sites in Europe (12 sites, including the Netherlands, Belgium, UK, Spain, Latvia, Macedonia, Czech Republic, and Poland) and Brazil (3 sites)

Clinical follow-up at 30 days, 5 months, 9 months, 12 months and 24 months post-procedure

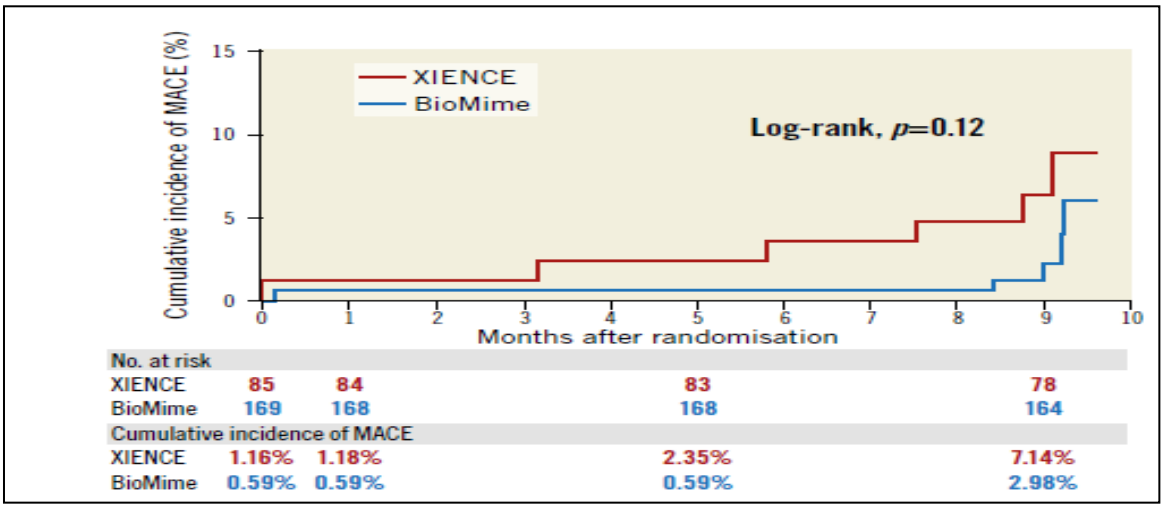
Angiographic follow-up at 9-month

Analysed by Cardiovascular Research Centre, Sao Paulo, Brazil

❖ Study Results

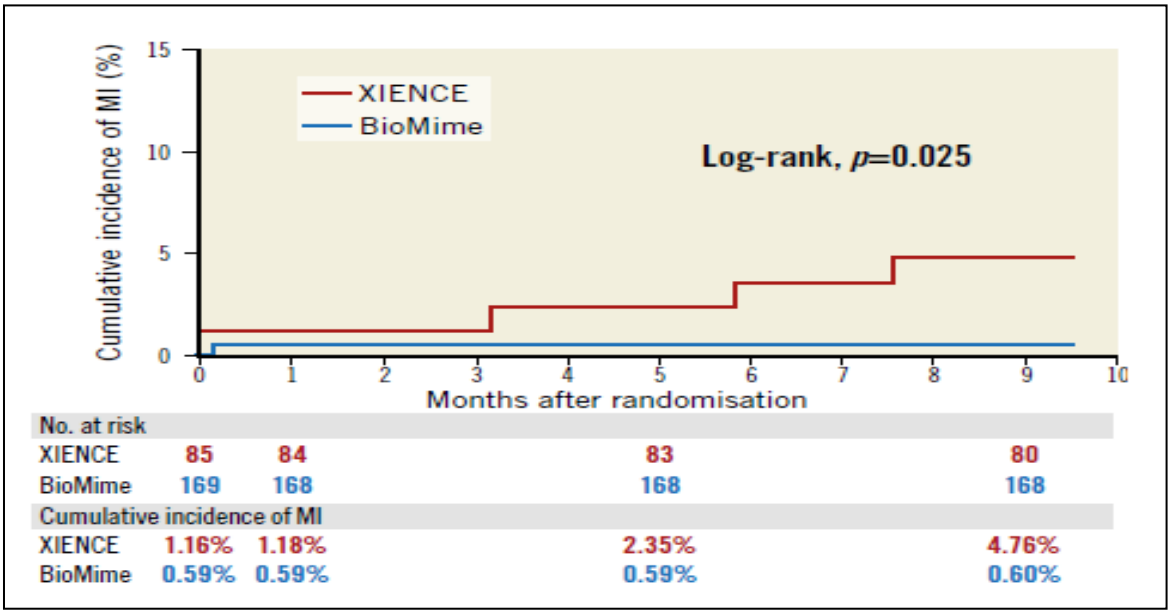


Late Lumen Loss at 9 Months Follow-up



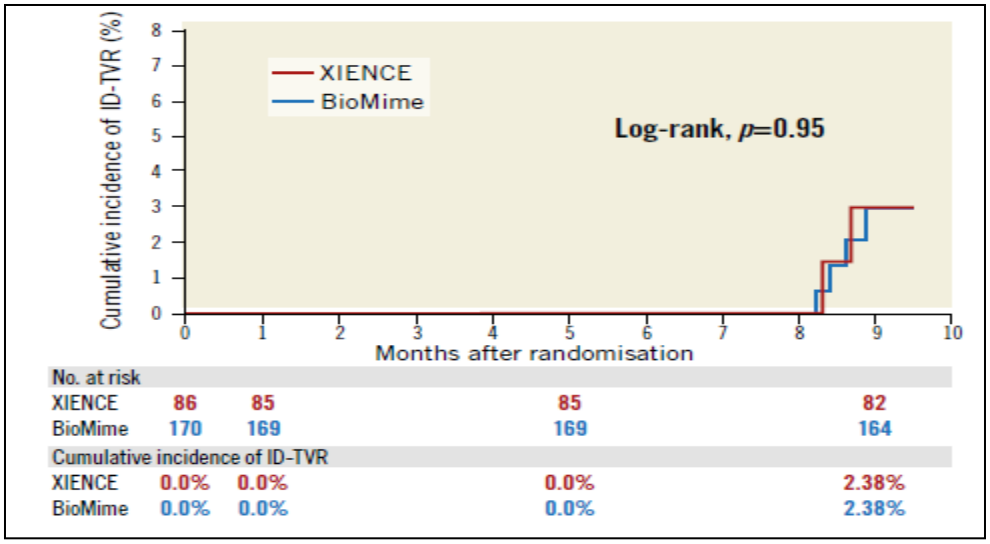
No. at risk				
XIENCE	85	84	83	78
BioMime	169	168	168	164
Cumulative incidence of MACE				
XIENCE	1.16%	1.18%	2.35%	7.14%
BioMime	0.59%	0.59%	0.59%	2.98%

Cumulative event curve of MACE



No. at risk				
XIENCE	85	84	83	80
BioMime	169	168	168	168
Cumulative incidence of MI				
XIENCE	1.16%	1.18%	2.35%	4.76%
BioMime	0.59%	0.59%	0.59%	0.60%

Cumulative event curve of MI



Cumulative event curve of ID-TVR

❖ References

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