Two-Year Outcomes After Everolimus- or Sirolimus-Eluting Stents in Patients With Coronary Artery Disease in the ISAR-TEST 4 Trial

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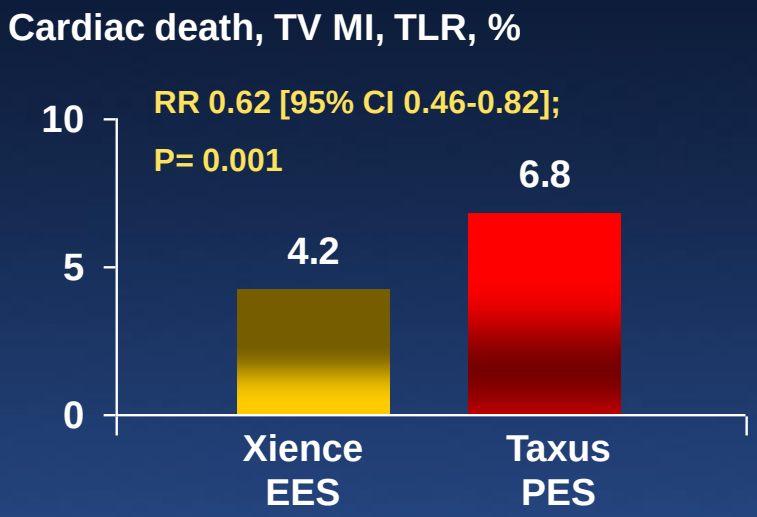
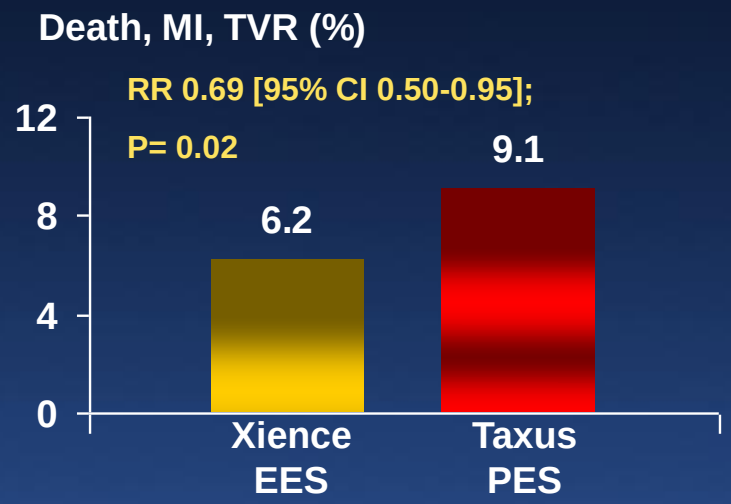
Background

- In head-to-head randomized trials, **everolimus-eluting stent (EES; Xience)** has proven superior to the pacliaxel-eluting stent (PES; Taxus)



SPIRIT IV

Stone et al. NEJM 2010



COMPARE

Kedhi et al. Lancet 2010

Background

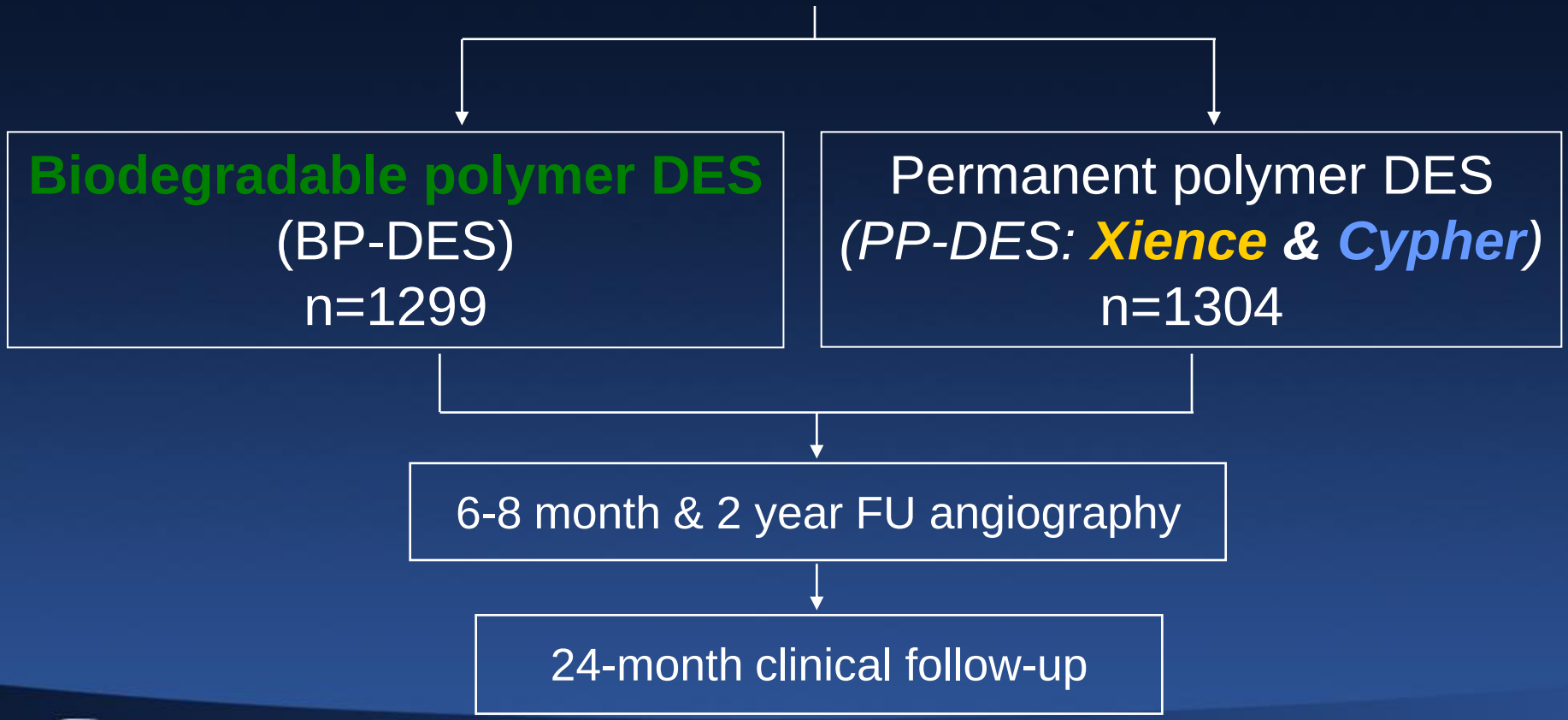
- **Significant differences exist between first-generation DES**

  Schömig JACC 2007; Stettler Lancet 2007; Gurm AHJ 2008

- **A more appropriate comparator device is sirolimus-eluting stent (SES; Cypher) due to its high antirestenotic efficacy and its similar limus-based drug-elution strategy**

ISAR-TEST 4 Study Algorithm

Intracoronary Stenting and Angiographic Results: Test Efficacy of 3 Limus-Eluting Stents - 4



Byrne et al. *Eur Heart J* 2009

Objectives of ISAR-TEST 4

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Primary:

To compare the efficacy of **biodegradable polymer DES** against **permanent polymer DES**

Secondary:

To compare the efficacy of

– **everolimus-eluting stent (Xience)** *and*

– **sirolimus-eluting stent (Cypher)**

Byrne et al. *Eur Heart J* 2009

ISAR-TEST 4 EES vs. SES

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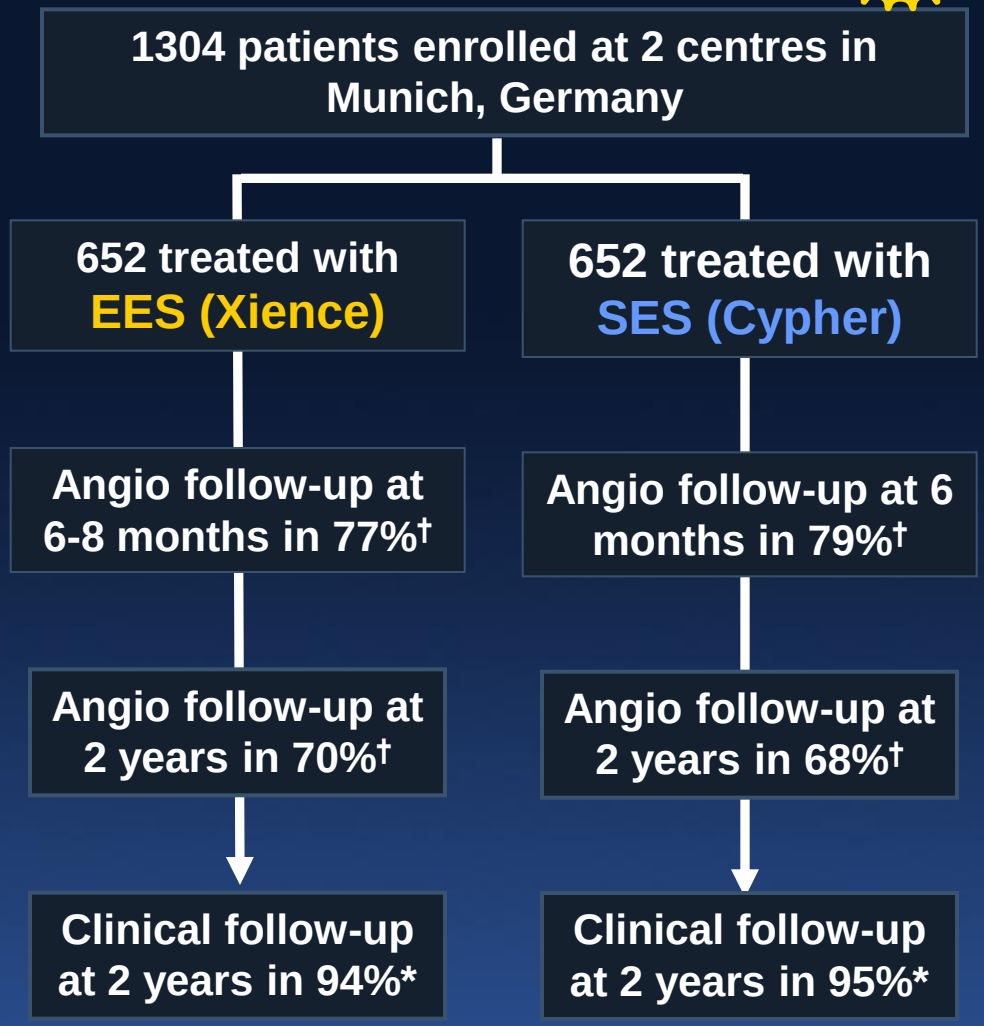
Design

- **DESIGN:** Investigator-initiated, industry-independent, randomized, two-center clinical trial
- **INCLUSION:**
  Patients with *de novo* coronary artery stenosis ≥ 50% AND symptoms or objective evidence of ischaemia
- **EXCLUSION CRITERIA:**
  Left main stem disease
  Cardiogenic shock



† of eligible

** of incomplete, median FU = 12 [3-16] mos*

ISAR-TEST 4 Endpoints

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Primary:

Composite of **cardiac death,** target vessel **MI or TLR**

Secondary:

All cause mortality

Stent thrombosis (ARC definite/probable)

Binary restenosis (in-segment)

Late luminal loss (in-stent)

Baseline clinical characteristics, I

	Xience-V n=652	Cypher n=652
Age, years	66.7±11.1	66.8±10.3
Male, %	78	76
Art. hypertension, %	68	67
Diabetes, %	28	30
Current smoker, %	16	18
Prior bypass surgery, %	11	9
Prior MI, %	29	28
Hyperlipidemia, %	65	65

Baseline clinical characteristics, I

	Xience-V n=652	Cypher n=652
Clinical presentation, %*		
acute MI	11	11
unstable angina	31	28
stable angina	59	62
Multivessel disease, %	85	87
Multilesion PCI, %	27	25
LV ejection fraction, %	53.4±12.1	53.8±11.7

** Due to rounding totals do not equal 100*

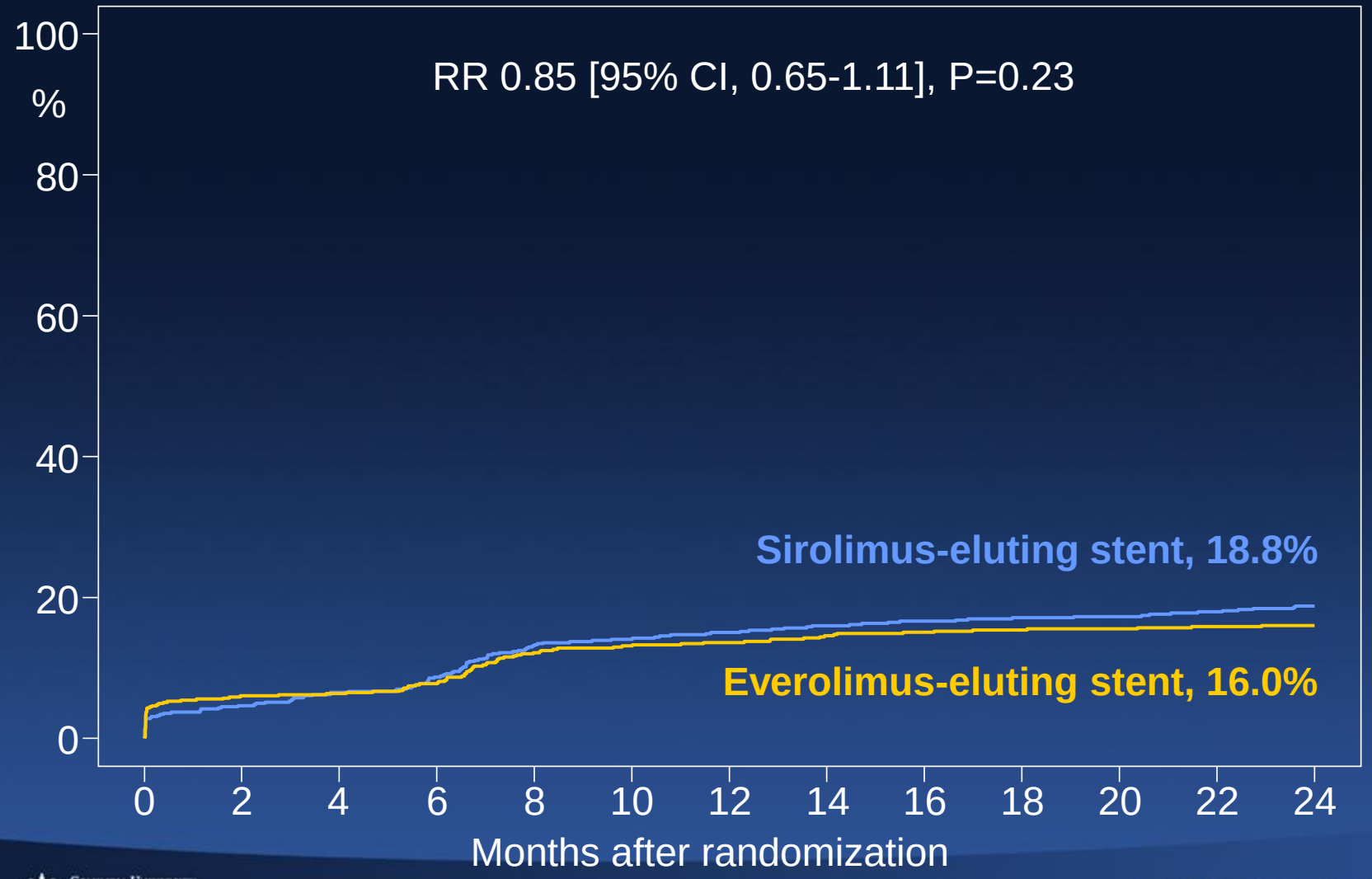
Angiographic characteristics

	Xience-V n=850	Cypher n=839
Target vessel, %		
left anterior descending	44	45
left circumflex	26	27
right coronary artery	30	28
Bifurcation, %	22	24
Complex morphology, %	71	73
Lesion length, mm	15.2±8.2	14.8±8.9
Vessel size, mm	2.80±0.48	2.80±0.45

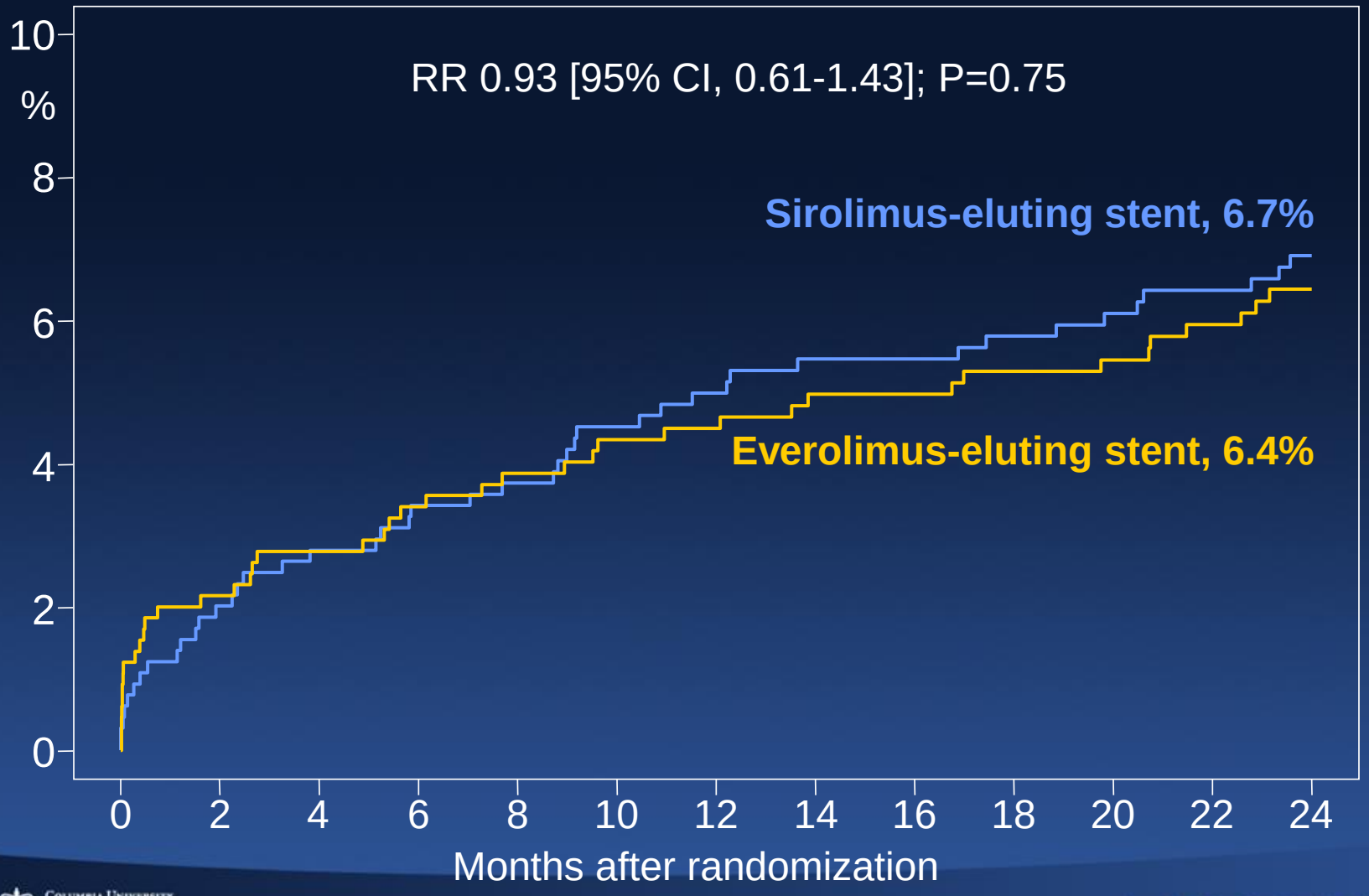
Procedural characteristics

	Xience-V n=850	Cypher n=839
Stenosis pre-procedure, %	64.9±16.0	65.4±16.1
Max ballon pressure, atm	15.7±3.1	15.2±3.2
Balloon vessel ratio	1.1±.1	1.1±.1
Stenosis post-procedure, in-stent, %	11.8±6.3	10.8±6.2
Stenosis post-procedure, in-seg, %	23.6±11.4	23.3±11.4

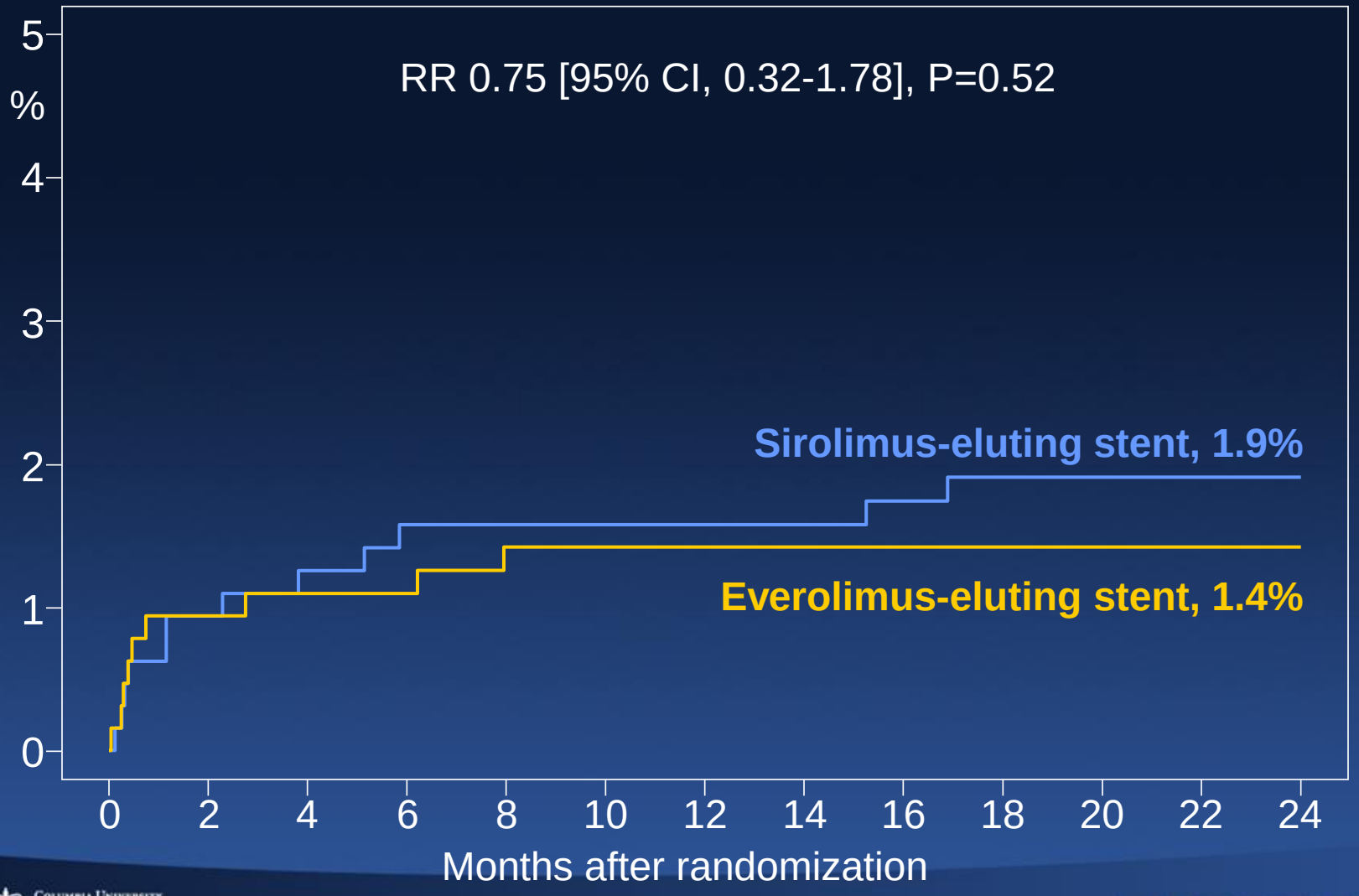
Cardiac Death, Target Vessel MI, TLR



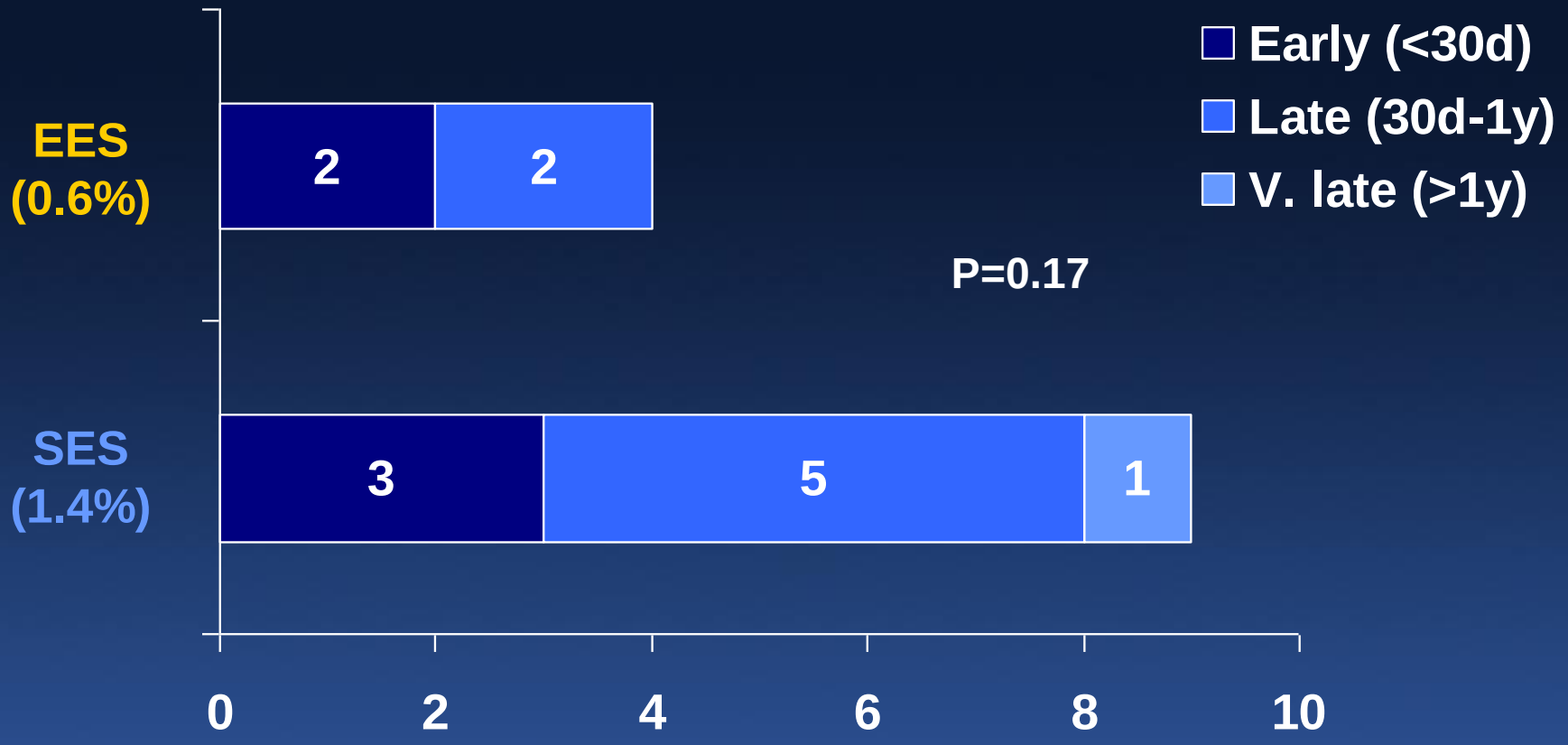
All Cause Death



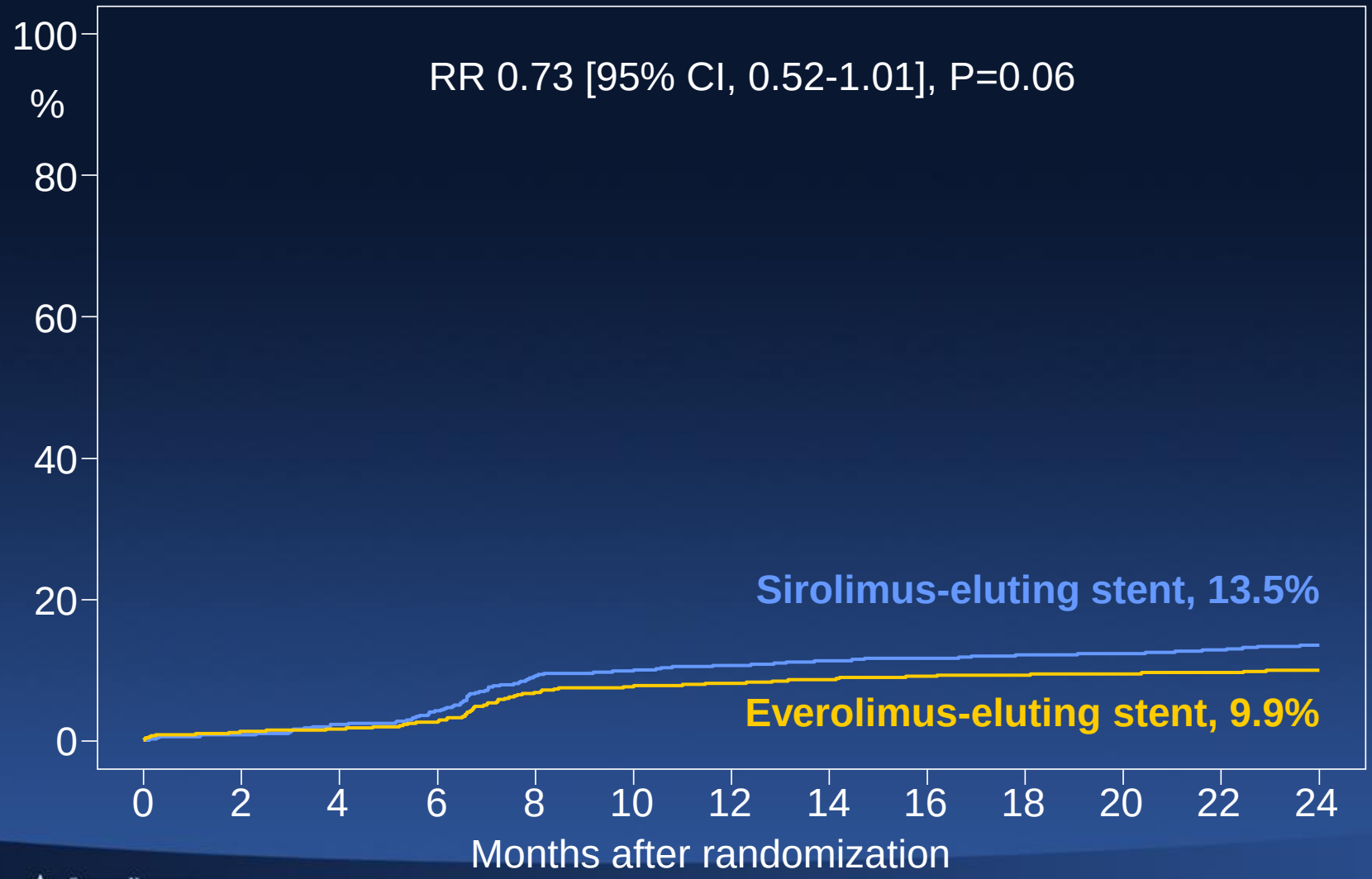
Definite or Probable Stent Thrombosis



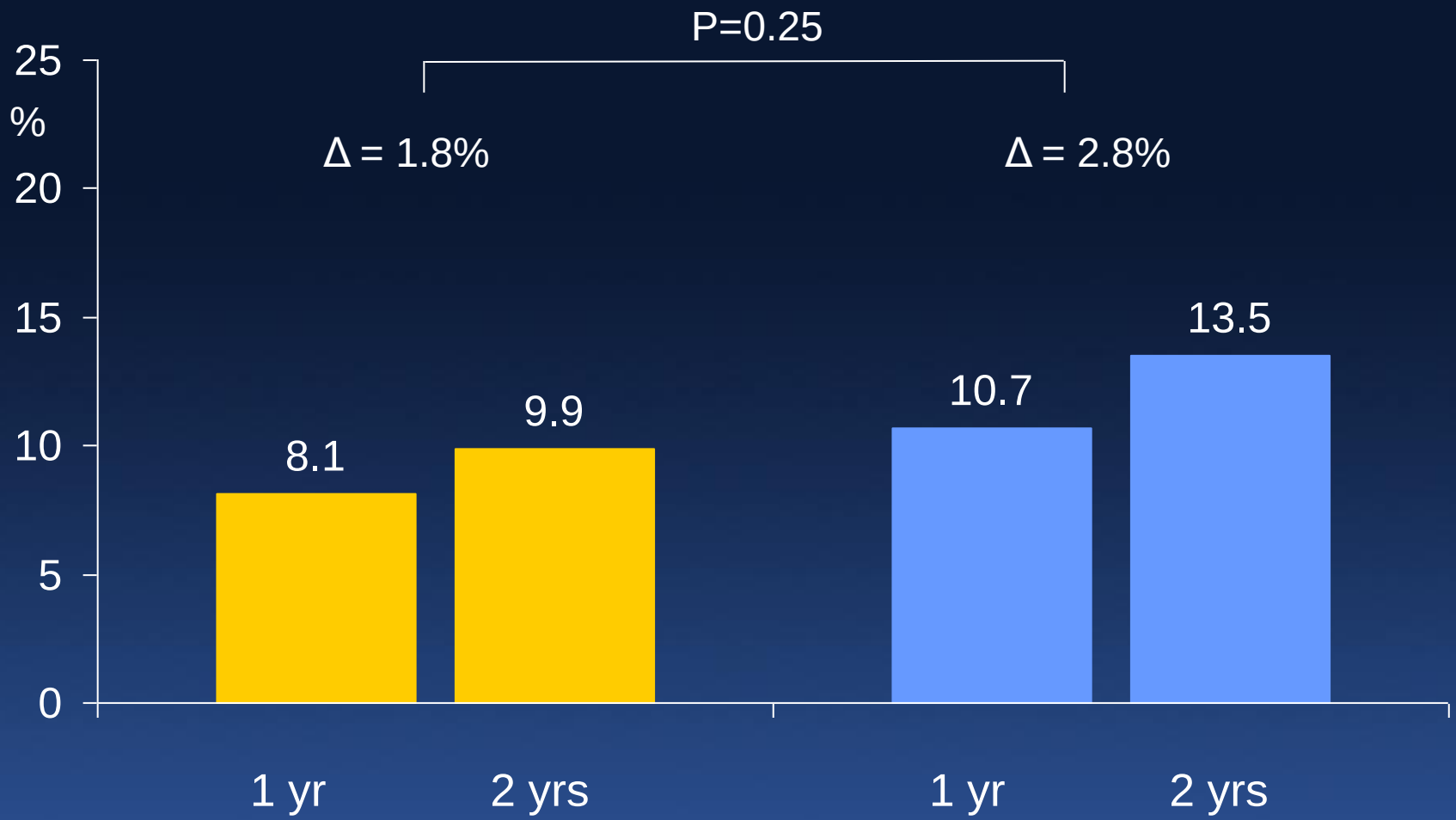
Definite Stent Thrombosis



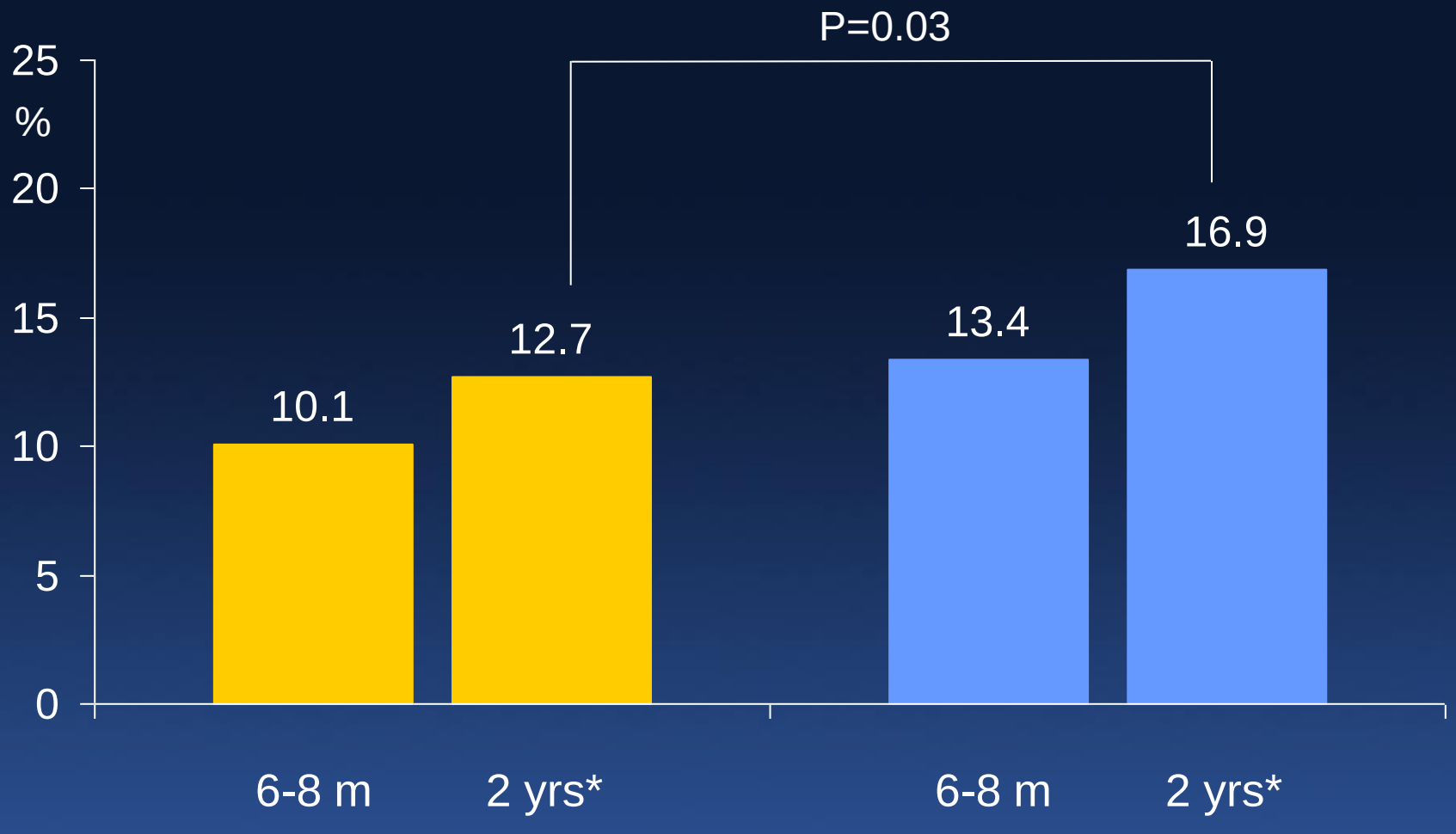
Target Lesion Revascularization



Target Lesion Revascularization



Binary Angiographic Restenosis

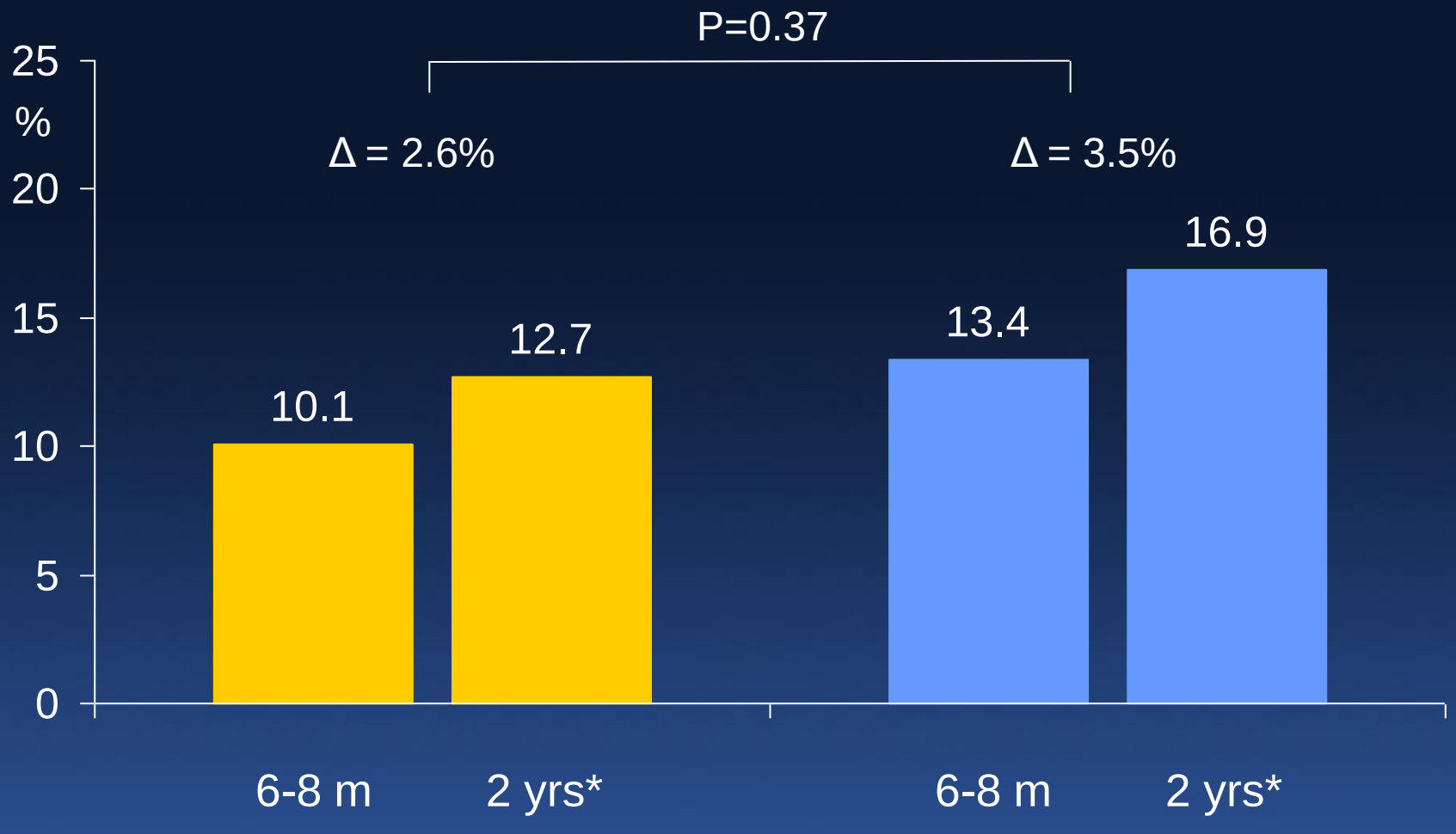


EES

* = composite

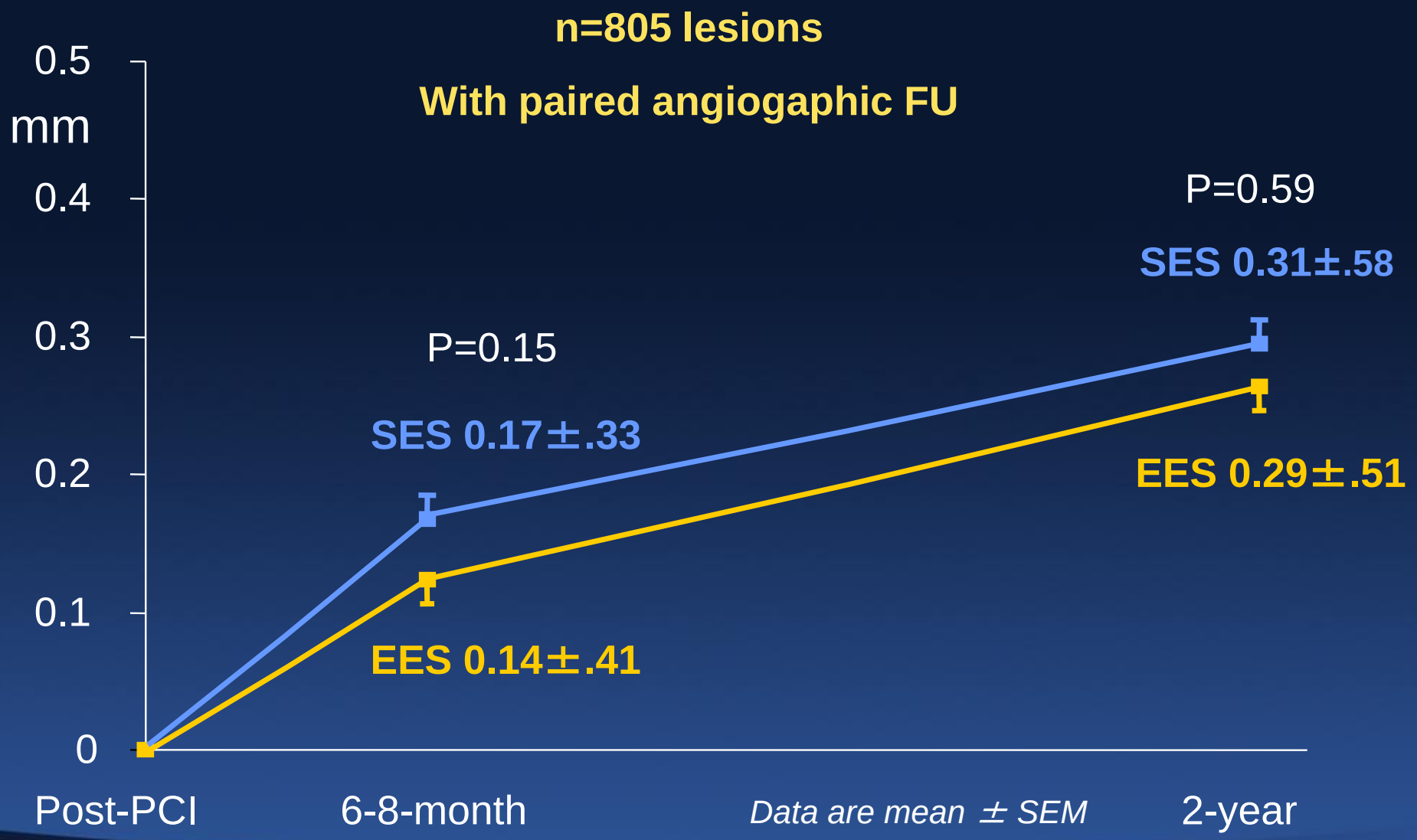
SES

Binary Angiographic Restenosis



EES * = composite SES

Late Lumen Loss to 2 Years



Conclusions

- In a randomized clinical trial with broad inclusion criteria, **EES (Xience)** and **SES (Cypher)** provide comparable clinical outcomes out to 2 years

- While there was a trend towards superior antirestenotic efficacy with **EES (Xience)**, specifically-powered studies are needed to evaluate the clinical significance of this finding