Comparison of Zotarolimus-eluting and Everolimus-eluting Coronary Stents

2 Years Results
RESOLUTE All Comers Trial

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Articles

Unrestricted randomised use of two new generation drug-eluting coronary stents: 2-year patient-related versus stent-related outcomes from the RESOLUTE All Comers trial

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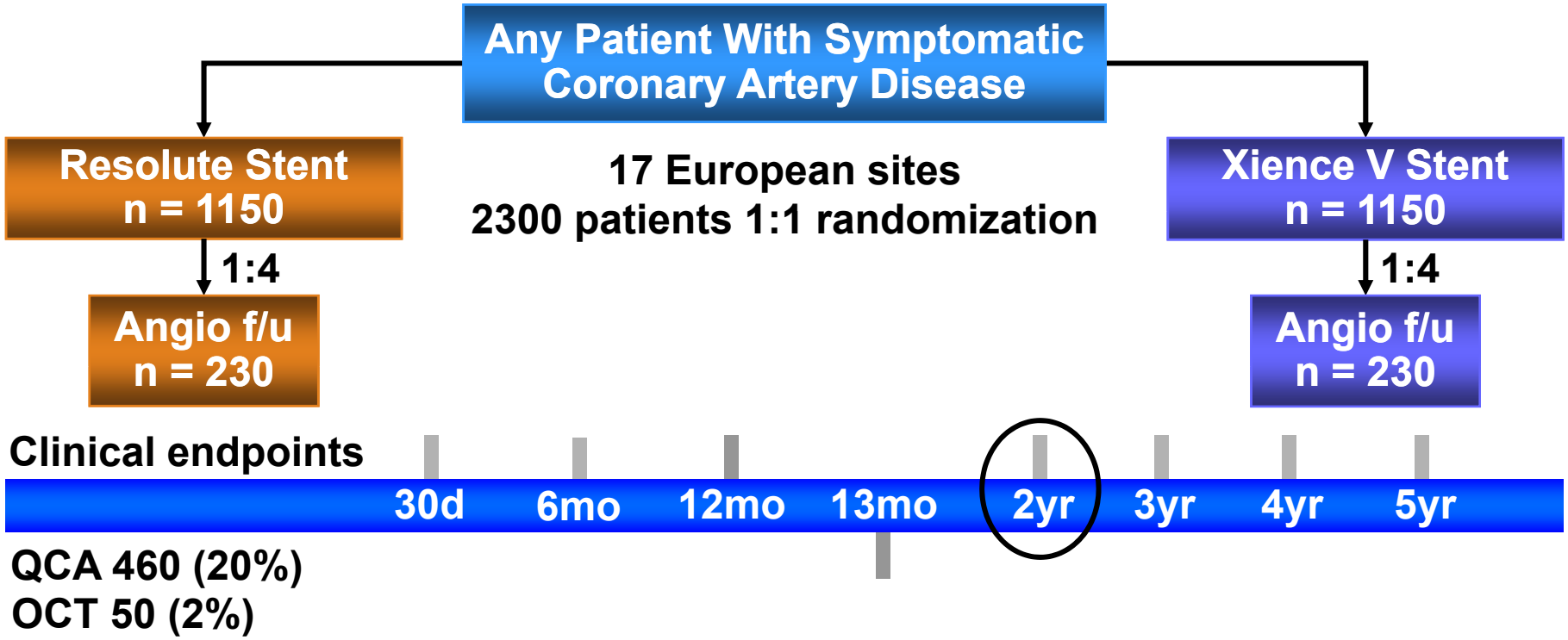
Background

- 1st generation DES reduced rates of restenosis, although long-term follow-up revealed safety concerns over *very late* stent thrombosis
- 2nd generation devices utilize new stent platforms and more biocompatible polymers
- Previous DES trials were largely performed in on-label indications, restricting wider applicability of their results to routine clinical practice
- Presently there are no randomized comparisons between 2nd generation DES followed out to 2 years

RESOLUTE All Comers Trial Design



Primary Endpoint:

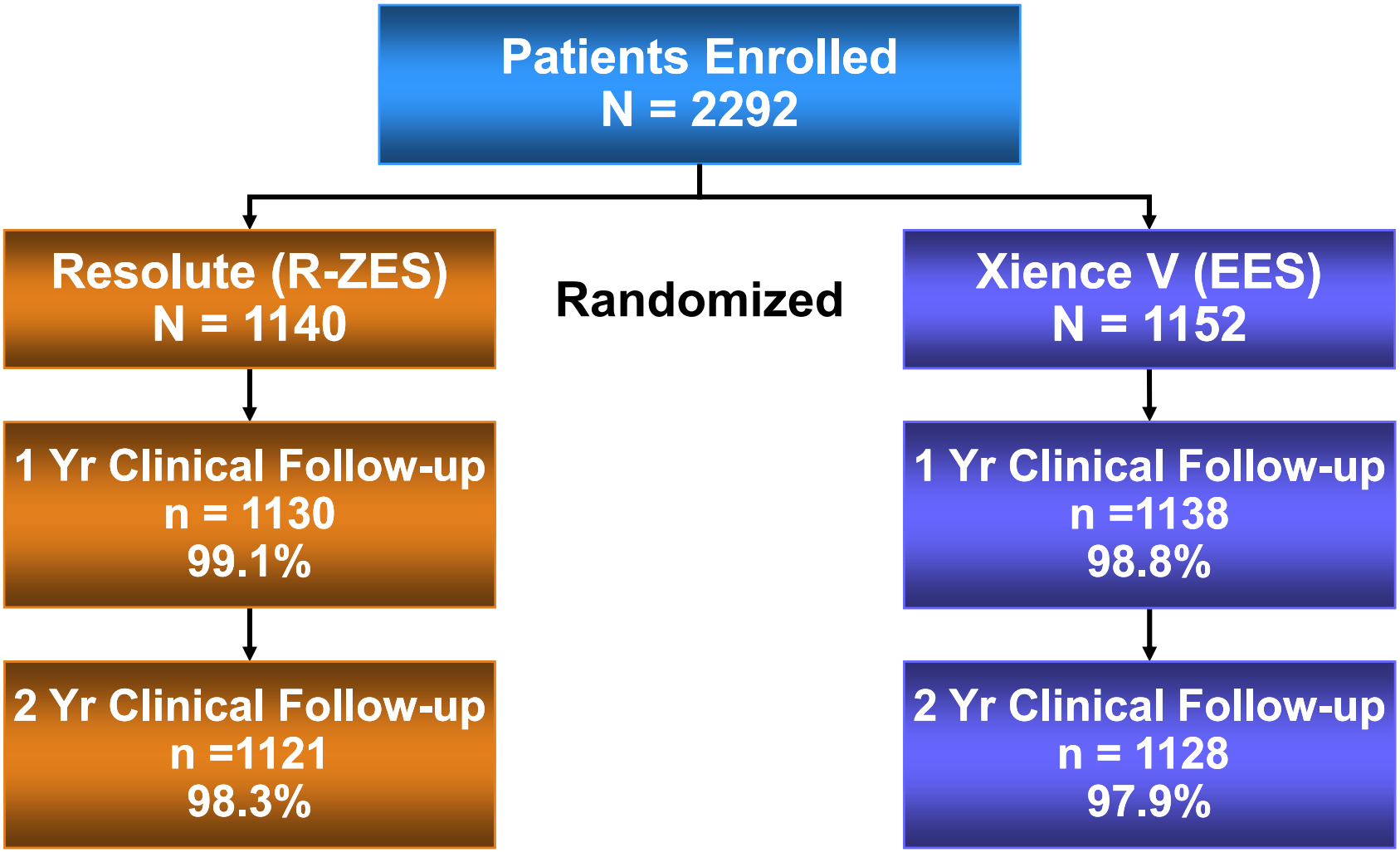
- Target Lesion Failure (composite of cardiac death, target vessel MI & clinically driven TLR) at 12mo

Secondary Endpoints:

- Clinical: Patient composite of any death, any MI, & any repeat revascularisation
- QCA (powered): 13-month in-stent % diameter stenosis
- QCA: % diameter stenosis, late loss, and binary restenosis

Drug Therapy: ASA and clopidogrel/ticlopidine ≥ 6mo (per guidelines)

Patient Flow Chart



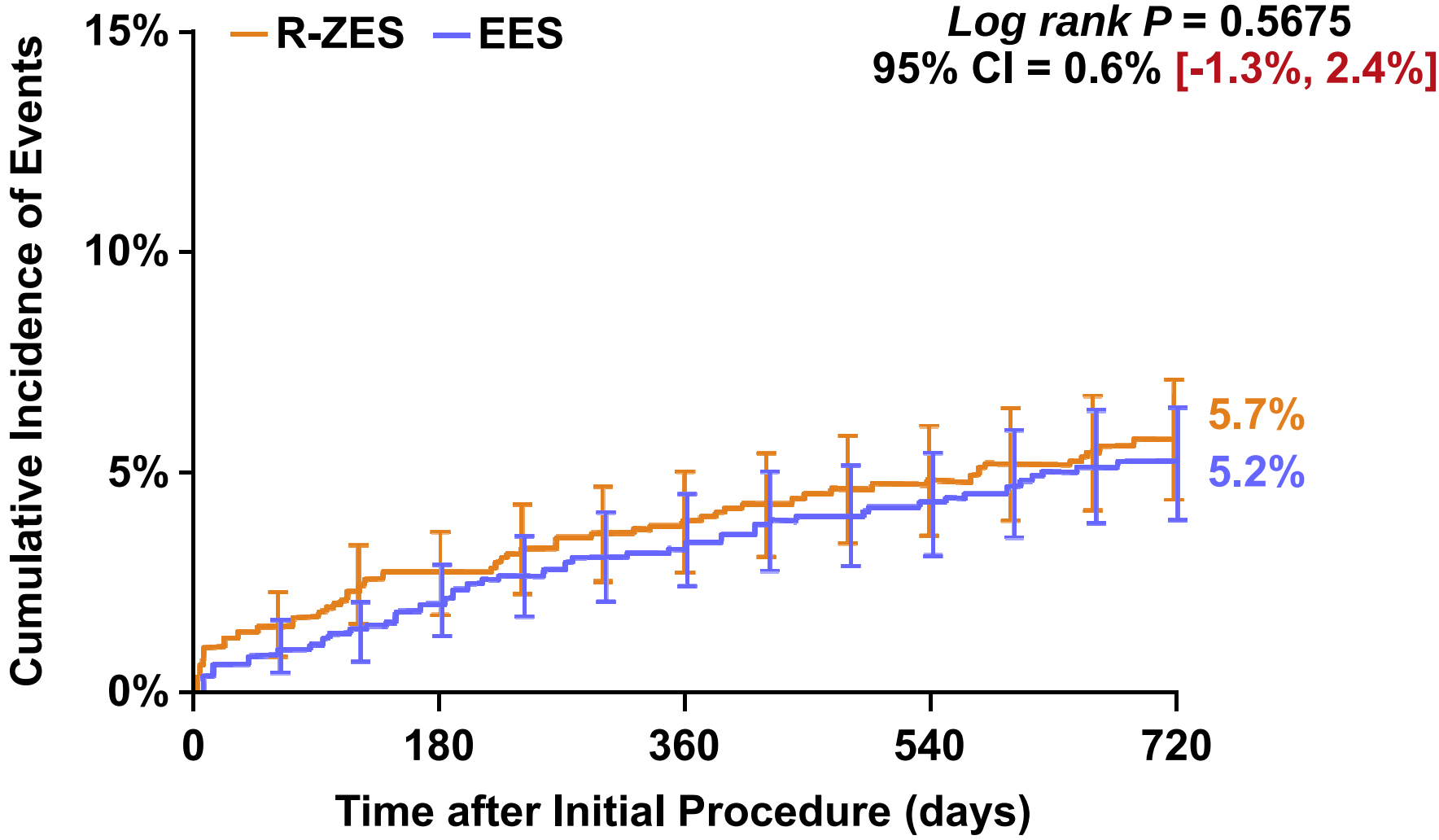
Baseline Patient Characteristics

Variable, %	*R-ZES (N = 1140 pts)*	*EES (N = 1152 pts)*
Age, years (Mean±SD)	64.4±10.9	64.2±10.8
Men	76.7	77.2
Diabetes mellitus	23.5	23.4
Insulin treated	8.4	7.1
Arterial hypertension	71.1	71.3
Hyperlipidemia	64.0	67.7
Current smoker	26.5	26.5
Premature CAD in first degree relative	34.1	36.7
Prior myocardial infarction	28.9	30.4
Prior percutaneous coronary intervention	31.8	32.1
Prior coronary artery bypass grafting	10.0	9.5
Stable angina	33.5	36.1
Unstable angina	19.4	18.9
Acute myocardial infarction ≤72 hours	28.9	28.8

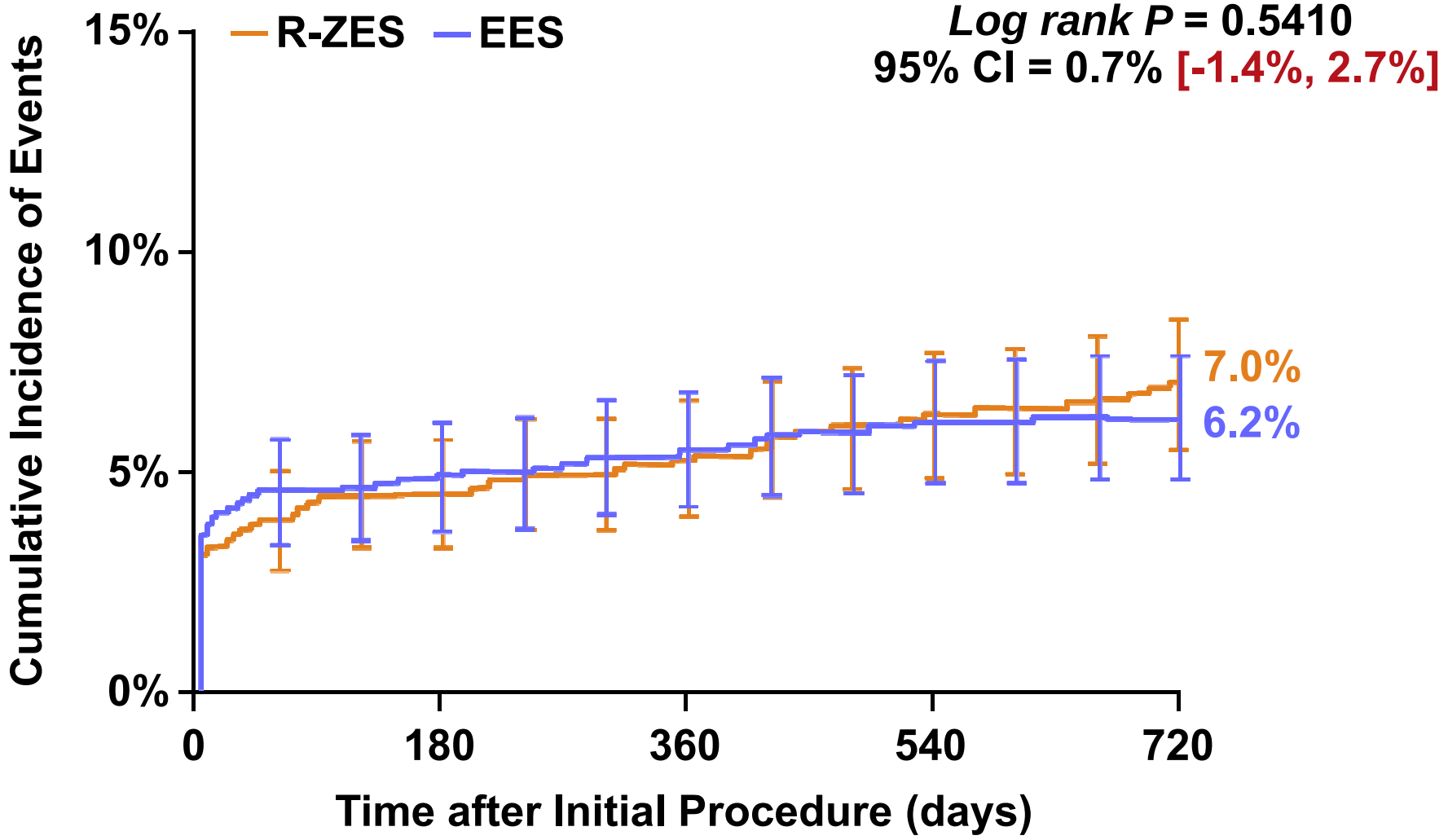
Baseline Patient Characteristics

Variable, %	*R-ZES (N = 1140 pts)*	*EES (N = 1152 pts)*
Left ventricular ejection fraction <30%	2.8	2.1
Multi-vessel disease	58.4	59.2
Target vessel location (per patient)		
Left main	2.2	2.5
Left anterior descending	52.6	48.6
Left circumflex	33.0	32.9
Right coronary	37.3	41.3
Bypass graft	2.5	2.4
Number of treated lesions per patient	1.5±0.7	1.5±0.8
SYNTAX score	15±9	15±9
≥1 small vessel (RVD ≤2.75 mm)	67.8	67.4
≥1 lesion length >18 mm	18.2	21.2
≥1 bifurcation/trifurcation	16.9	17.7
≥1 total occlusion	16.3	17.2
≥1 In-stent restenosis	8.1	8.0
Off-label use	67.0	65.6

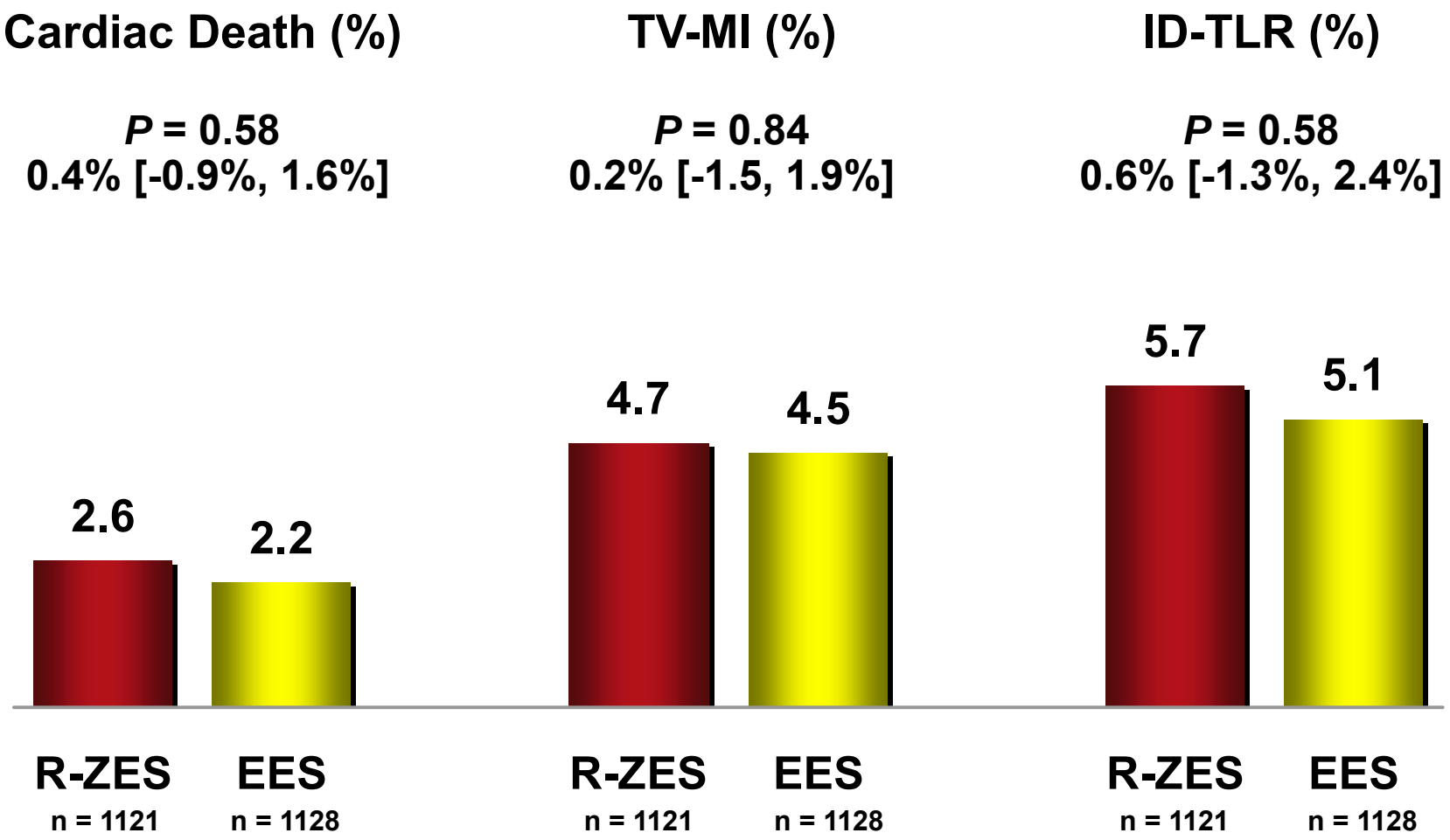
Clinically Driven Target Lesion Revascularization Through 2 Years



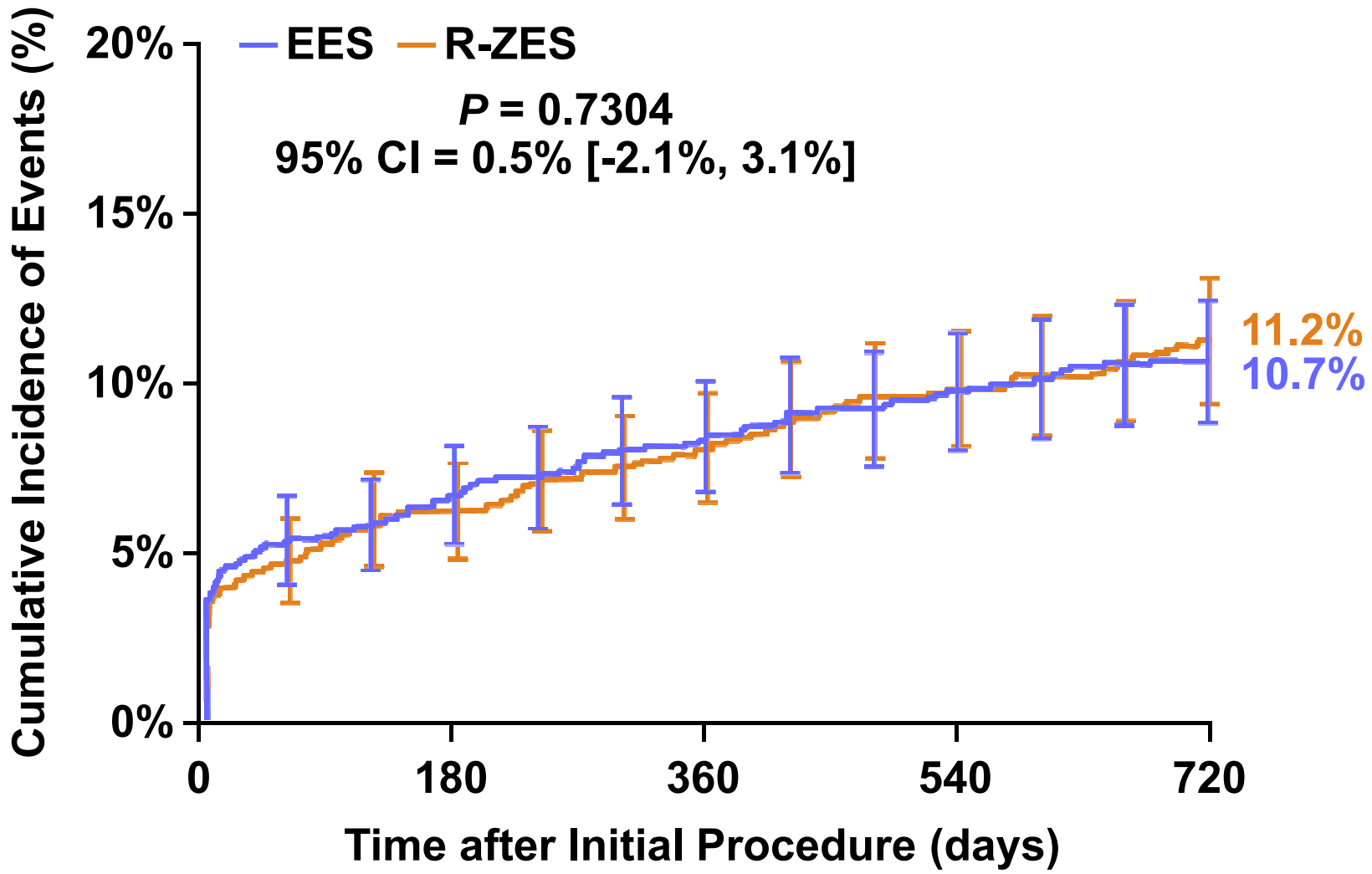
Cardiac Death and Target Vessel MI Through 2 Years



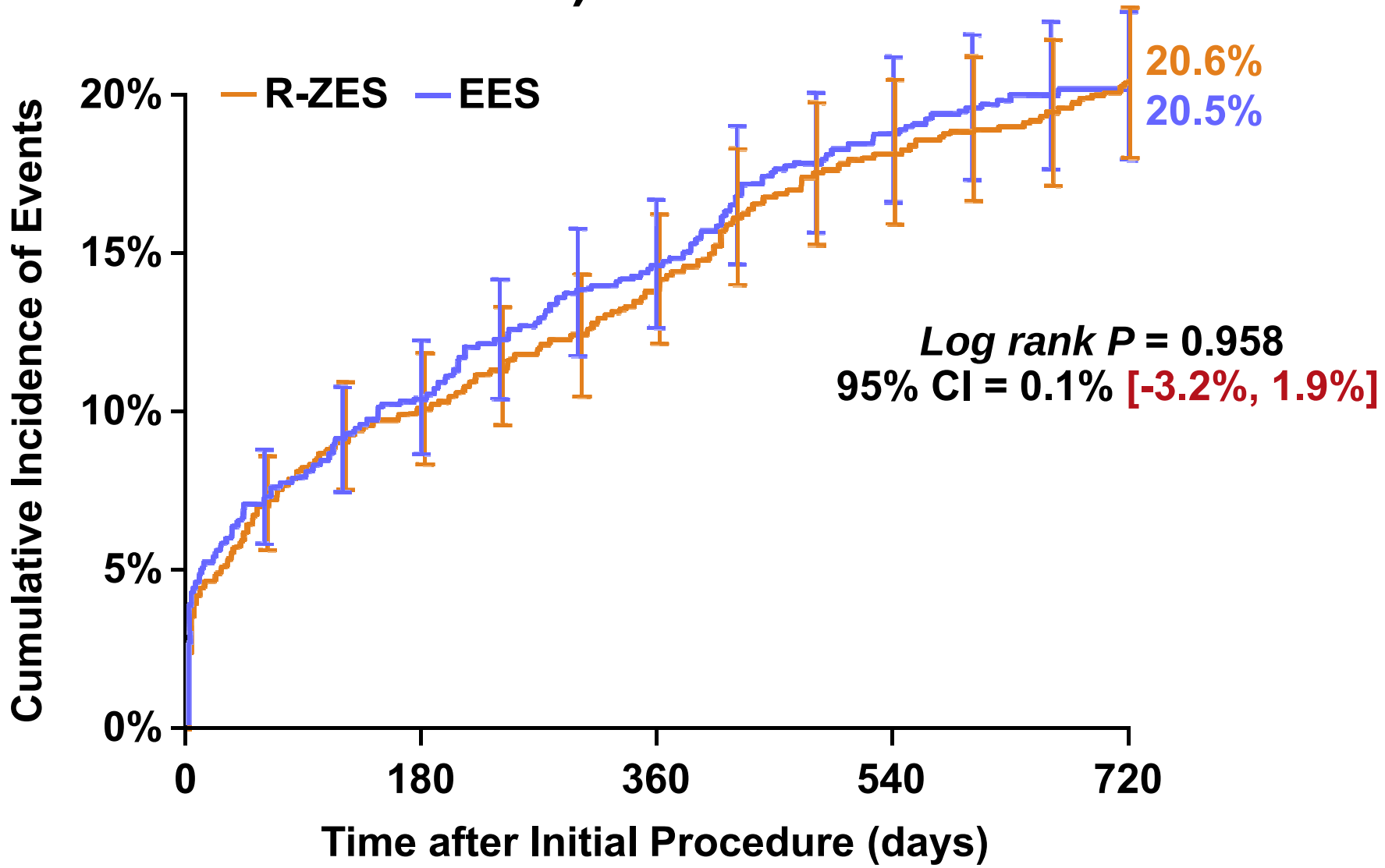
Components of Target Lesion Failure



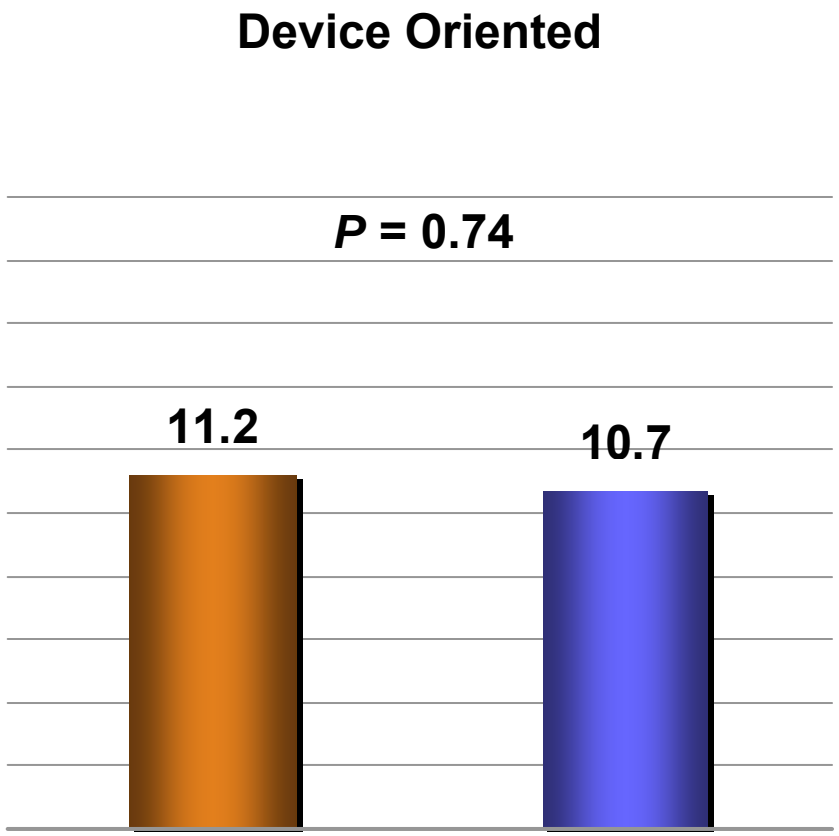
Cumulative Incidence for Cardiac Death/TVMI and Clinically Driven TLR (TLF)



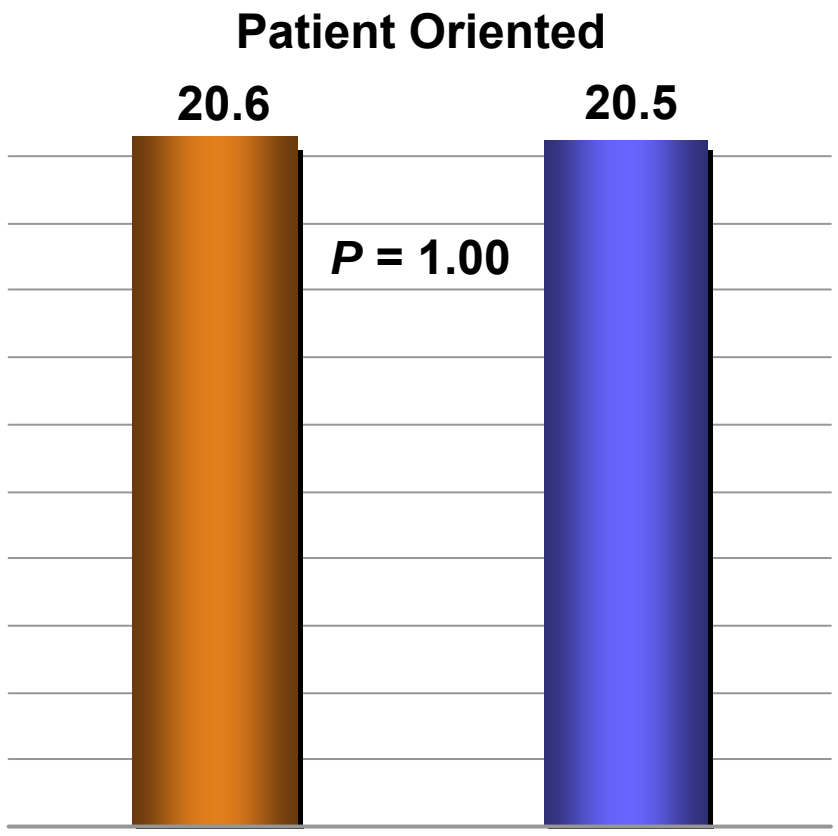
Patient Composite Endpoint Through 2 Years (All Death, All MI, Any Revascularizations)



Composite Clinical Endpoint Results at 2 Years



TLF (%)
(Cardiac Death, Target Vessel MI, TLR)

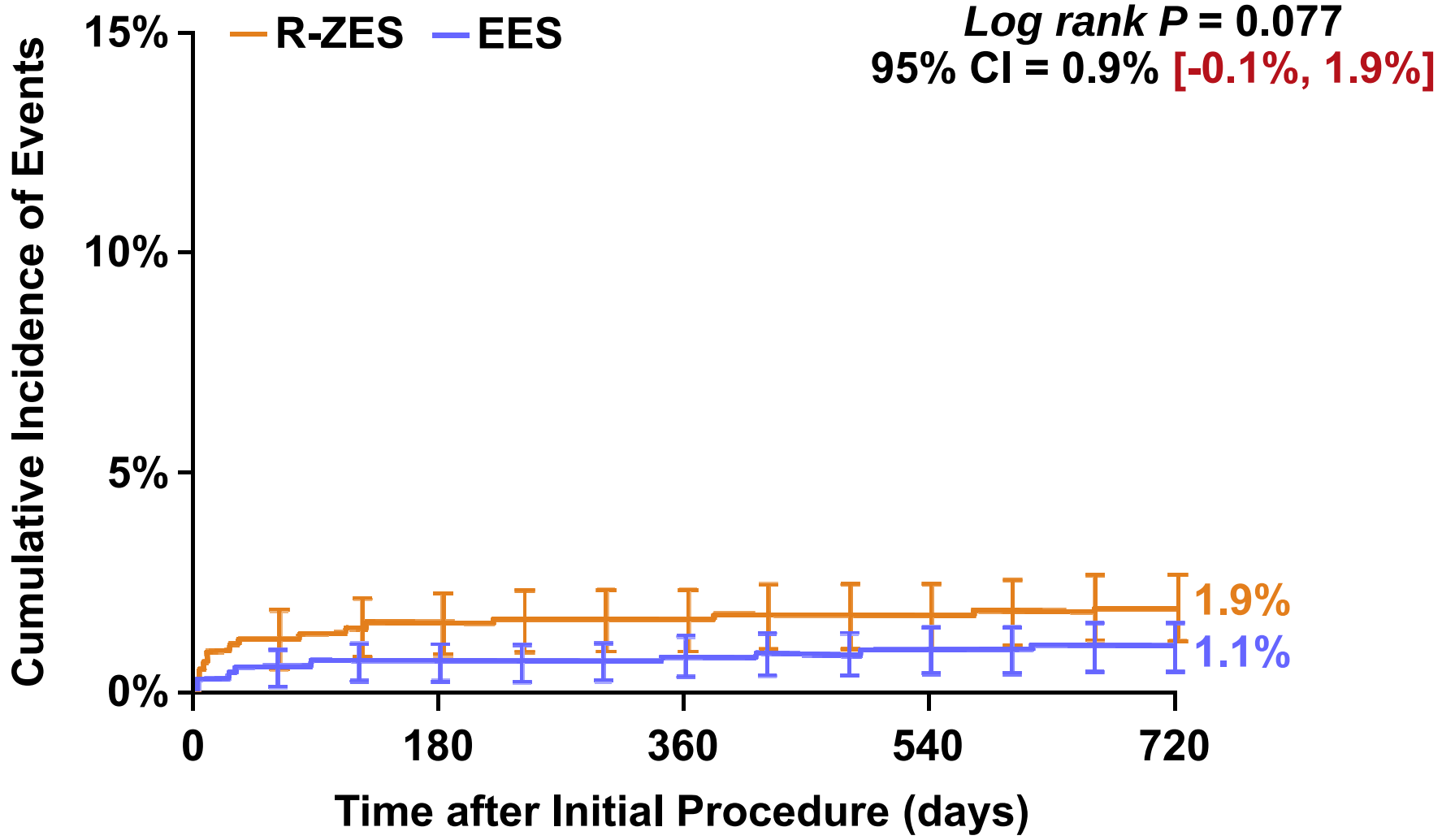


All Event Composite (%)
(All Death, All MI, Any Revasc)

Definite or Probable Stent Thrombosis at 2 Years

% (n)	*R-ZES N = 1140*	*EES N = 1152*	*95% CI*	*P value*
Early (≤30 days)	1.1% (12)	0.5% (6)	0.5% [-0.2%, 1.3%]	0.16
Late (31-360 days)	0.6% (7)	0.2% (2)	0.4% [-0.1%, 1.0%]	0.11
Def/prob ST at 1 year	1.6% (18)	0.7% (8)	0.9% [0.0%, 1.8%]	0.05
Very Late (>360 days)	0.3% (3)	0.3% (3)	0.0% [-0.4%, 0.4%]	1.00
Def/prob ST at 2 years	1.9% (21)	1.0% (11)	0.9% [-0.1%, 1.9%]	0.08

Stent Thrombosis (ARC Definite /Probable) Through 2 Years



DAPT* Compliance to 2 Years

% patients on DAPT at	*R-ZES*	*EES*	*P value*
30 days	93.8	94.6	0.43
180 days	93.1	93.3	0.93
360 days	84.1	83.8	0.91
720 days	18.6†	18.1†	0.78

* Aspirin and (Clopidogrel or Ticlopidine)
† Majority on DAPT considered complex or ACS at time of procedure

Conclusion

- **Both the Resolute ZES and the Xience V EES were associated with a relatively low frequency of adverse events even in this complex, all-comers patient population through 2 years**
- **The new generation Resolute ZES remained clinically equivalent to the Xience V EES in this predominantly complex patient population through 2 years**