EXCELLENT -REGISTRY

Efficacy of Xience/Promus versus Cypher to rEduce Late Loss in stENT

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on behalf of the investigators

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Background

Everolimus-Eluting Stent	Sirolimus-Eluting Stent
• EES has been shown to be superior to PES with regard to angiographic and clinical endpoints.	• SES has been known to be the most efficacious DES regarding inhibition of neointima and LL
Everolimus is the 40-o-(2-hydroxyethyl) derivative of sirolimus targeting mTOR	
• Thinner fluoropolymer (7.8 μm)	• EVA:BMA copolymers (13.7 μm)
• Thinner strut thickness (81 μm)	• strut thickness (140 μm)
• Cobalt–chromium alloy platform	• Stainless steel

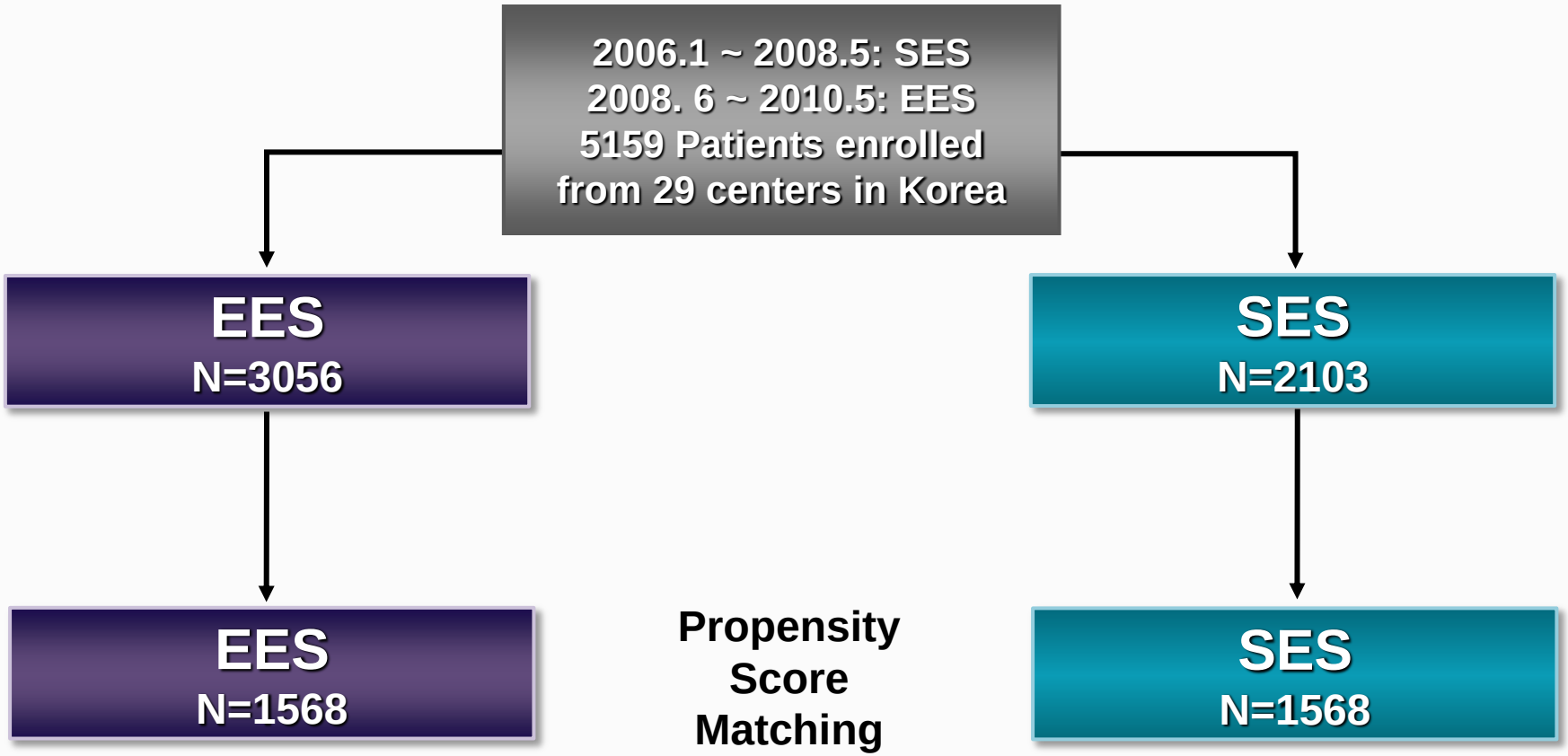
Background

- EES was non-inferior to SES in inhibition of LL after stenting, which was corroborated by similar rates of clinical outcomes in EXCELLENT RCT.

J Am Coll Cardiol 2011;58:1844-54

- This study was performed to compare efficacy and safety of EES with SES in the unselected all-comer group of patients subject to real clinical practice.

Methods


2006.1 ~ 2008.5: SES
2008. 6 ~ 2010.5: EES
5159 Patients enrolled
from 29 centers in Korea
EES
N=3056
SES
N=2103
EES
N=1568
Propensity
Score
Matching
SES
N=1568

Propensity Score Matching

- c-statistics 0.62
- Gender, Age, BMI
- Clinical diagnosis : STEMI, NSTEMI, unstable angina,
  stable angina, silent ischemia
- Disease extent : 1VD, 2VD, 3VD
- Lesion length : >28mm
- Risk factor : DM, CRF, dyslipidemia, hypertension, pph. vascular disease,
  MI, CHF, CVA, valve disease, family Hx of CAD, previous PCI,
  previous CABG
- Medication : aspirin, clopidogrel, beta blocker, statin,
  ACE inhibitor, ARB, calcium channel blocker, insulin

Study Endpoints

- **Primary Endpoint :**
  : Target Lesion Failure (TLF) at 12 months
  - Cardiac death
  - Target vessel related myocardial infarction (MI)
  - Ischemic driven Target Lesion Revascularization (TLR)
- **Secondary Endpoints:**
  - In-stent & In-segment Late Loss at 9 months
  - Stent Thrombosis
  - Target Vessel Failure at 12 months (composite of cardiac death, MI, and TVR)
  - Any death, cardiac death, MI, TLR, TVR at 30 days, 9months, 1 year
  - Composite rate of cardiac death and any MI
  - Composite rate of all death and any MI
  - Composite rate of all death, any MI (Q-wave and non Q-wave) and any repeat revascularization
  - Compliance and therapy interruptions with prescribed adjunctive antiplatelet therapy
  - Clinical device and procedural success

Participating Centers

29 Hospitals in Republic of Korea

Hospital	EES	SES	SUM
Seoul National University Hospital	289	195	484
St. Carollo Hospital	195	101	296
Samsung Medical Center	182	100	282
Inje University Ilsan Paik Hospital	173	99	272
Seoul National University Bundang Hospital	154	108	262
Jeonju Presbyterian Medical Center	151	100	251
Gwangju Veterans Hospital	150	98	248
Dankook University Hospital	140	79	219
Gyeongsang National University Hospital	65	155	220
Gangnam Severance Hospital	113	101	214
Inje University Pusan Paik Hospital	103	100	203
Wonkwang University Hospital	101	101	202
Sejong General Hospital	101	100	201
Soonchunhyang University Cheonan Hospital	99	100	199

Participating Centers

29 Hospitals in Republic of Korea

Hospital	EES	SES	SUM
Chungbuk National University Hospital	99	101	200
Chonbuk National Hospital University	100	100	200
Korea University Anan Hospital	100	100	200
Kyunghee University Hospital	76	99	175
Yonsei University Severance Hospital	83	83	166
Gachon University Gil Medical Center	80	83	163
Korea University Guro Hospital	150	0	150
Daejeon St. Mary's Hospital	100	0	100
Seoul St. Mary's Hospital	70	0	70
St. Vincent Hospital	46	0	46
Boramae Medical Center	43	0	43
Soonchunhyang University Gumi Hospital	30	0	30
Gwangju Christian Hospital	32	0	32
NHIC Ilsan Hospital	19	0	19
Inha University Hospital	12	0	12

Baseline Profiles

Variables — no. (%)	EES (N=3,056)	SES (N=2103)	p-value
Age, years — mean±SD	63.9±10.8	62.3±10.8	0.966
Males	2053 (67.2)	1459 (69.4)	0.096
Body-mass index, kg/m^2	25±11.7	26±5.4	0.118
Diabetes mellitus	1149 (37.6)	718 (34.1)	0.037
Chronic renal failure	105 (3.4)	55 (2.6)	0.233
Hypertension	1980 (64.8)	1197 (56.9)	0.001
Dyslipidemia	1084 (35.5)	734 (34.9)	0.054
Current smoker	893 (29.2)	653 (31.1)	0.235
Family history of CAD	171 (5.6)	102 (4.9)	0.141
Previous myocardial infarction	212 (6.9)	216 (10.2)	0.001
Previous percutaneous coronary intervention	440 (14.4)	358 (17.0)	0.034
Previous bypass surgery	56 (1.8)	55 (2.6)	0.114
Previous congestive heart failure	62 (2.0)	32 (1.5)	0.086
Cerebrovascular disease	250 (8.2)	121 (5.8)	0.004
Peripheral vascular disease	47 (1.5)	27 (1.3)	0.172

Baseline Profiles

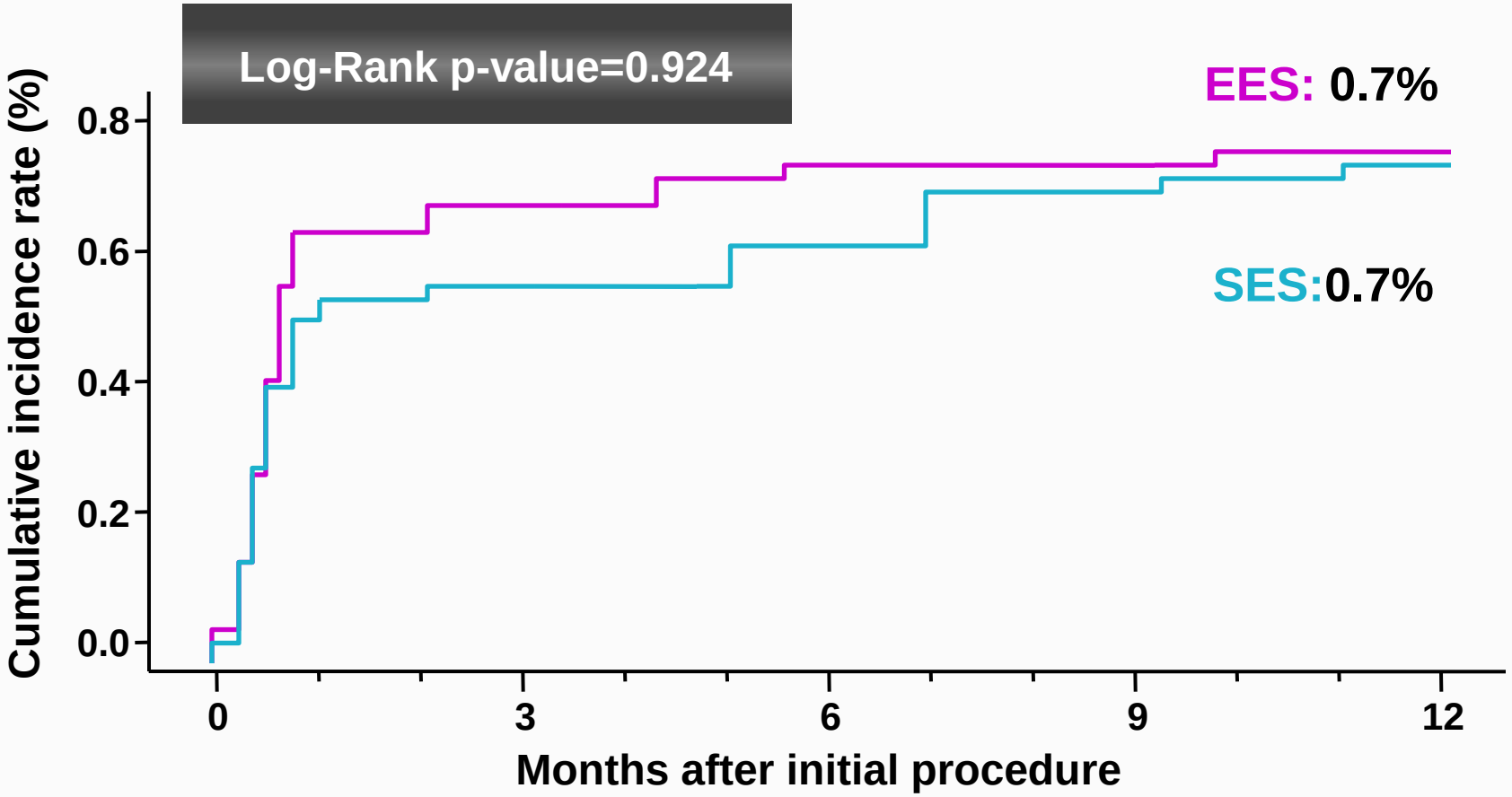
Variables — no. (%)	EES (N=3,056)	SES (N=2,103)	p-value
Multivessel disease	1622 (53.3)	1150 (54.9)	0.253
Left ventricular ejection fraction, %	59.6±16.9	59.5±17.2	0.163
Clinical indication			0.001
Silent ischemia	97 (3.2)	56 (2.7)	
Chronic stable angina	1094 (35.8)	680 (32.3)	
Unstable angina	1116 (36.5)	700 (33.3)	
NSTEMI	344 (11.3)	229 (10.9)	
STEMI	385 (12.6)	386 (18.4)	
Medications at discharge			
Aspirin	2969 (97.2)	2072 (98.5)	0.143
Clopidogrel	2974 (97.3)	2044 (97.2)	0.273
Statin	2613 (85.5)	1701 (80.9)	0.025
ACE inhibitor	1113 (36.4)	851 (40.5)	0.011
Angiotensin II-receptor antagonist	939 (30.7)	670 (31.9)	0.042
Beta-blocker	1853 (60.6)	1364 (64.9)	0.018
Calcium-channel blocker	830 (27.2)	605 (28.8)	0.061

Lesion and Procedural Profiles

Variables — no. (%)	EES (N=3,056)	SES (N=2,103)	p-value
Location			0.017
Left main	168 (5.5)	120 (5.7)	
Left anterior descending	1699 (57.0)	1313 (62.4)	
Left circumflex	844 (27.6)	450 (21.4)	
Right coronary	990 (32.4)	556 (26.4)	
Coronary graft	4(0.1)	2 (0.0)	
ACC-AHA B2/C type	1794 (58.7)	1245 (59.2)	0.721
Thrombus-containing	280 (10.3)	182 (10.2)	0.877
Bifurcation lesions	312 (10.3)	255 (12.3)	0.026
Calcification	1277 (41.8)	850 (40.4)	0.628
Lesion length > 20mm	1986 (65.0)	1542 (73.3)	0.001
No. of stents per lesion	1.21±0.49	1.20±0.49	0.480
No. of stents per patient	1.67±0.94	1.58±0.86	0.052
Total stent length per lesion — mm	27.08±14.26	29.80±14.73	0.375
Total stent length per patient	38.11±24.68	37.01±24.93	0.391
Use of GpIIb/IIIa inhibitors	61(2.0)	57 (2.7)	0.104
Use of intravascular ultrasound (IVUS)	1134 (37.5)	589 (28.3)	0.001
Device success	2996 (98.6)	2056 (98.9)	0.386
Lesion success	2994 (99.9)	2053 (98.8)	0.479
Procedure success	2994 (98.5)	2050 (98.6)	0.729

All-comer

All Death

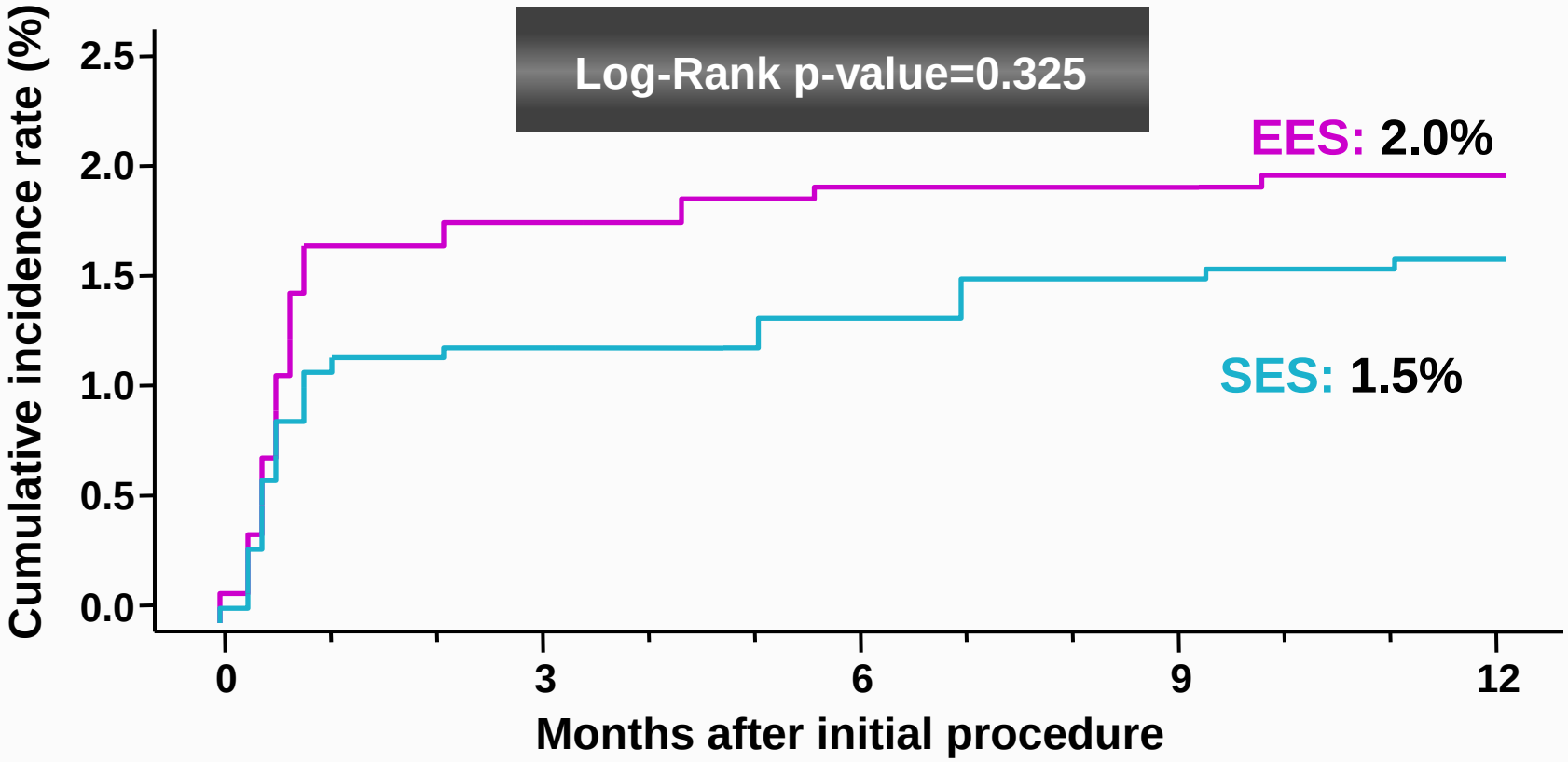


Patient Number at Risks

EES	3056	3010	3003	2987	2923
SES	2103	2082	2075	2059	2014

Matching

All Death



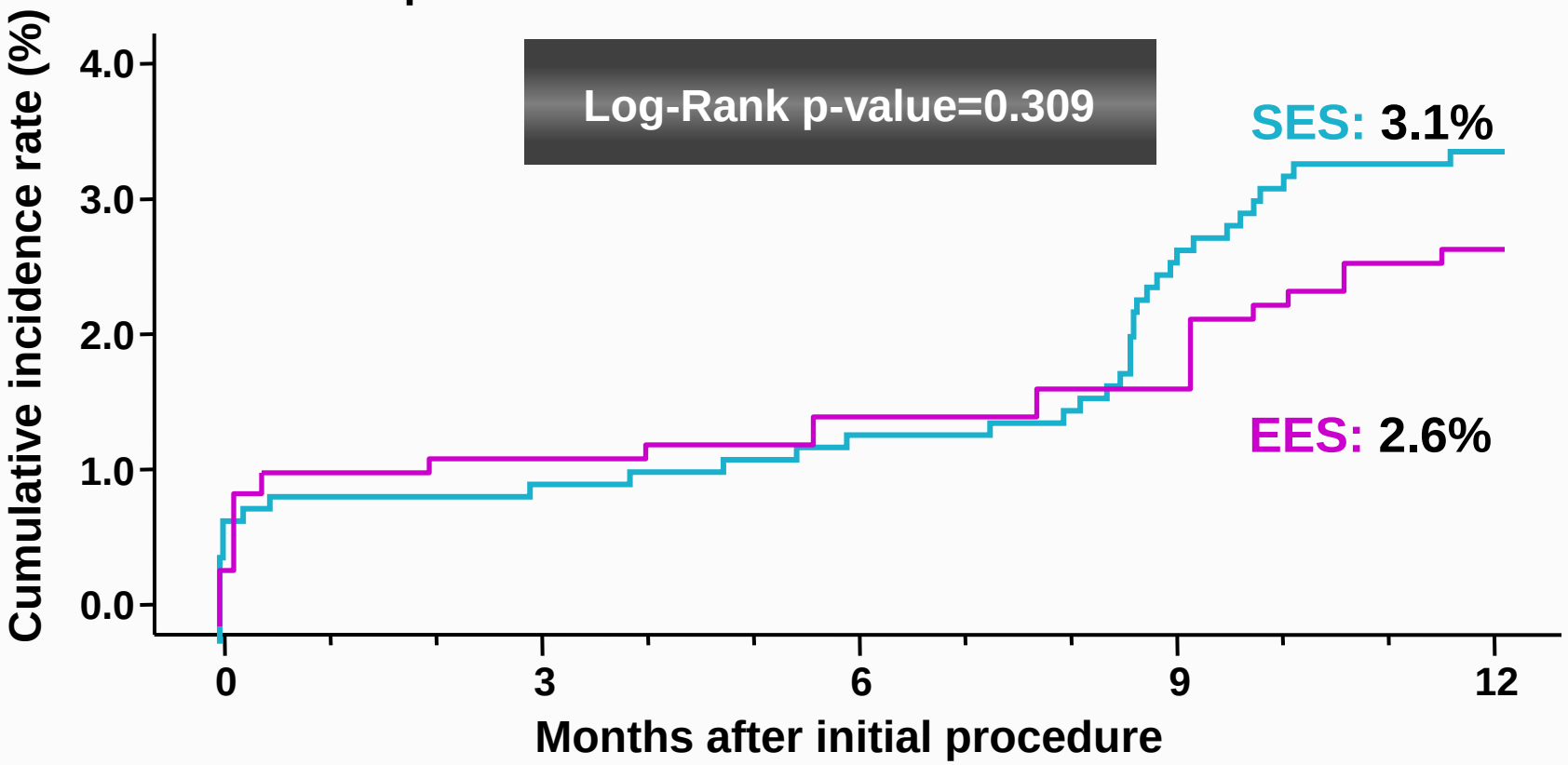
Patient Number at Risks

EES	1568	1547	1545	1535	1503
SES	1568	1555	1550	1537	1505

All-comer

Target Lesion Failure

: Composite of cardiac death, MI or ID-TLR



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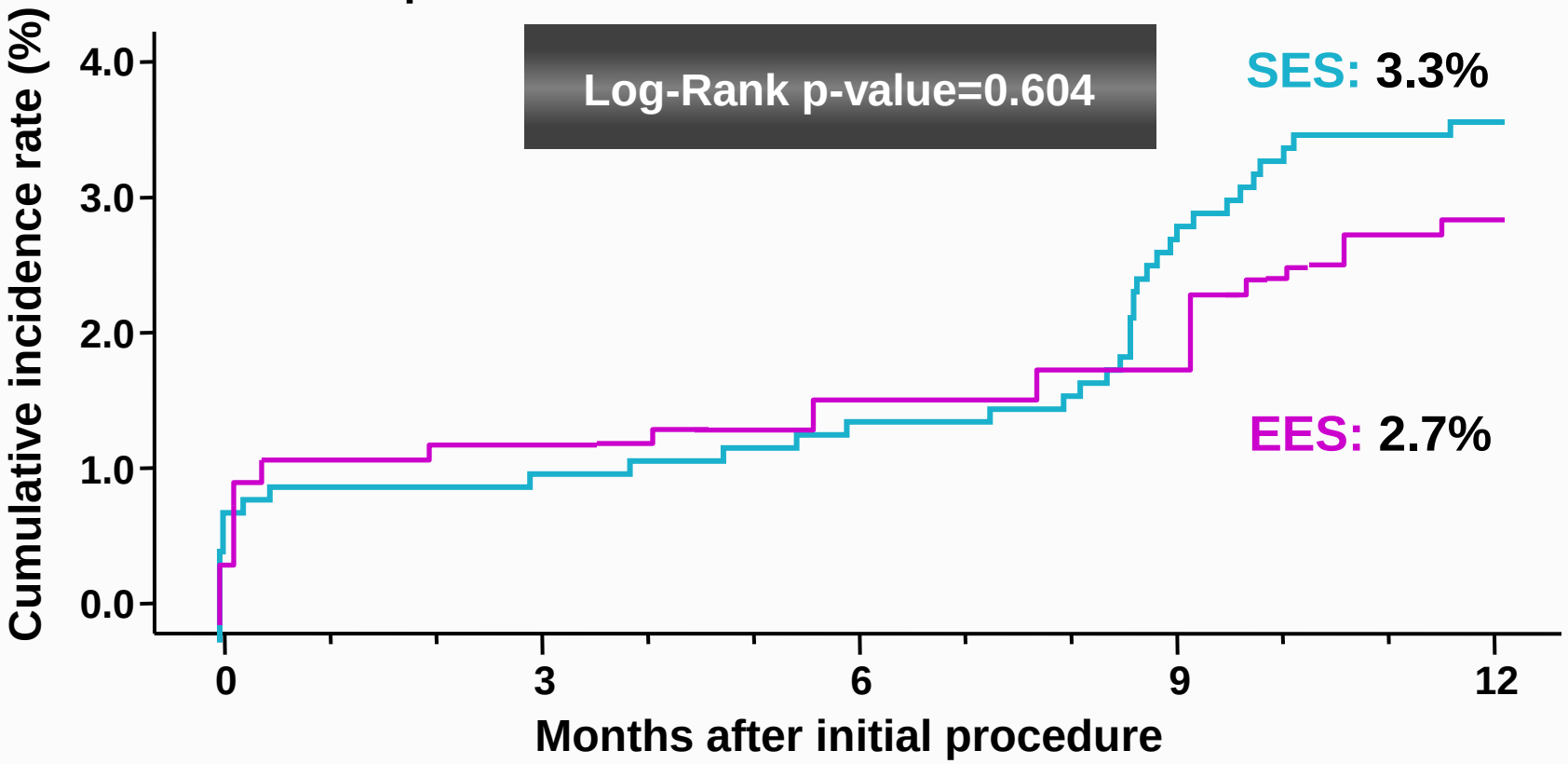
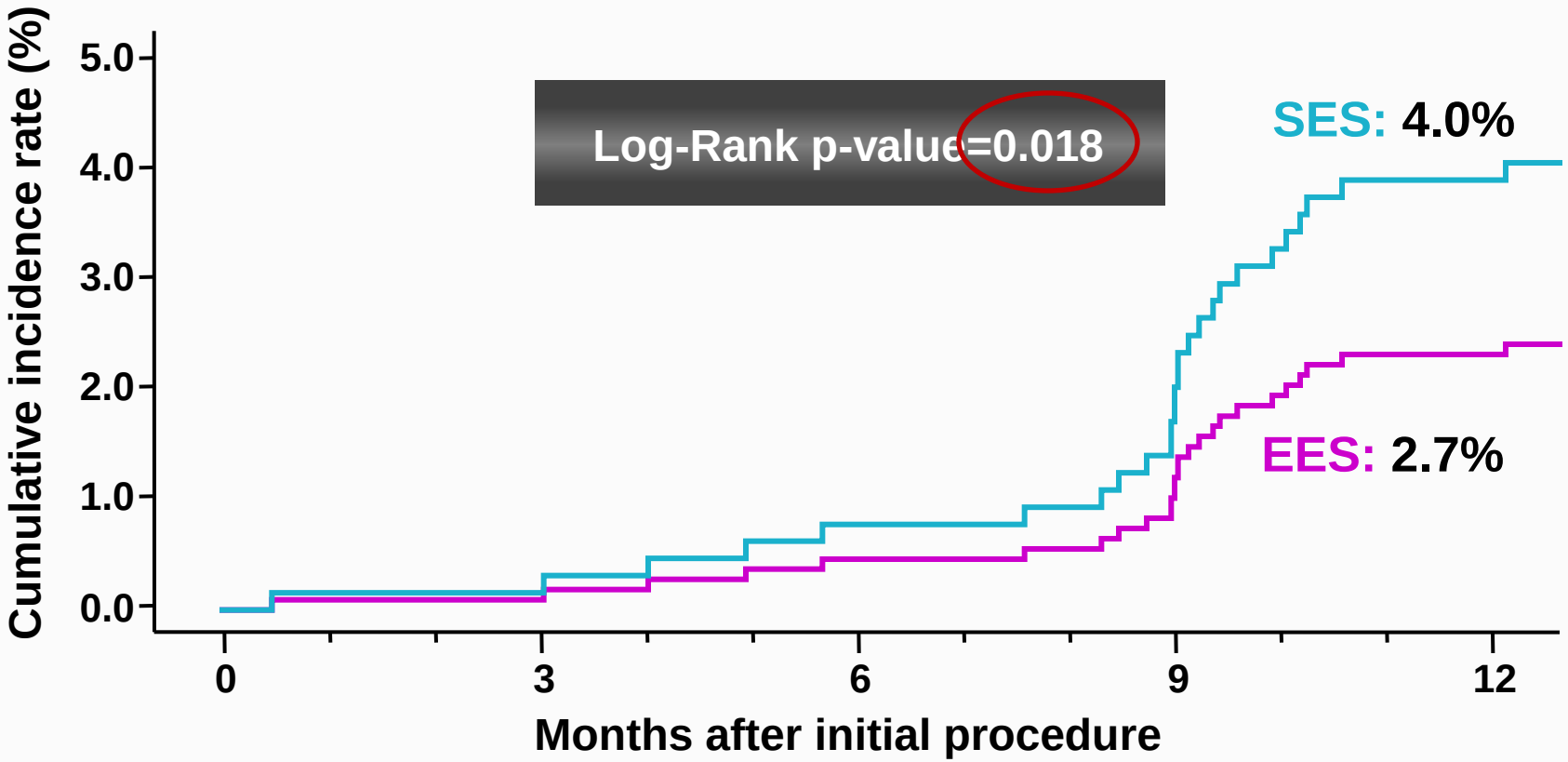


Patient Number at Risks

EES	1568	1547	1545	1535	1503
SES	1568	1555	1550	1537	1505

All-comer

Target Vessel Revascularization

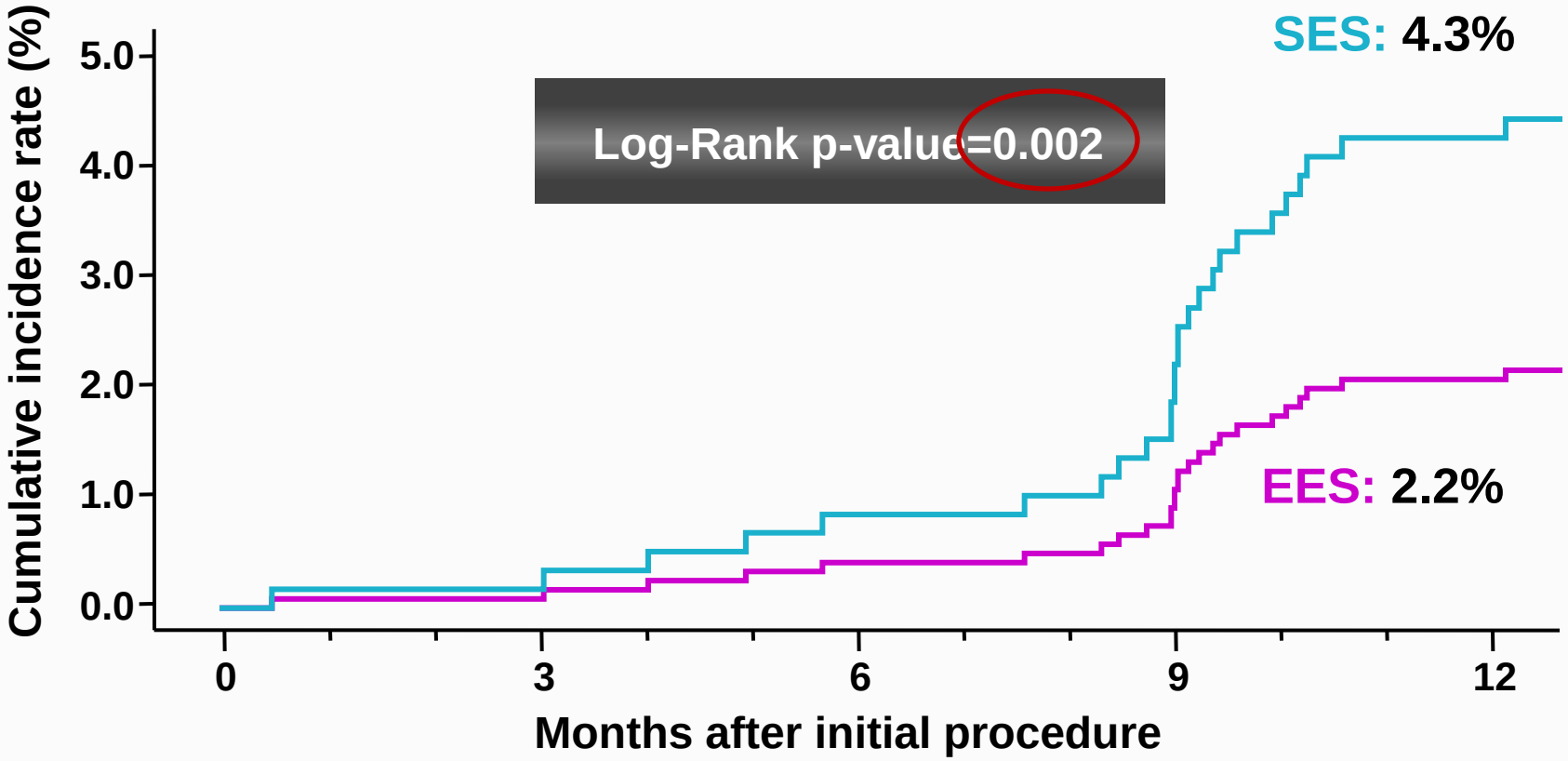


Patient Number at Risks

EES	3056	3025	3016	2986	2922
SES	2103	2051	2029	2003	1925

Matching

Target Vessel Revascularization



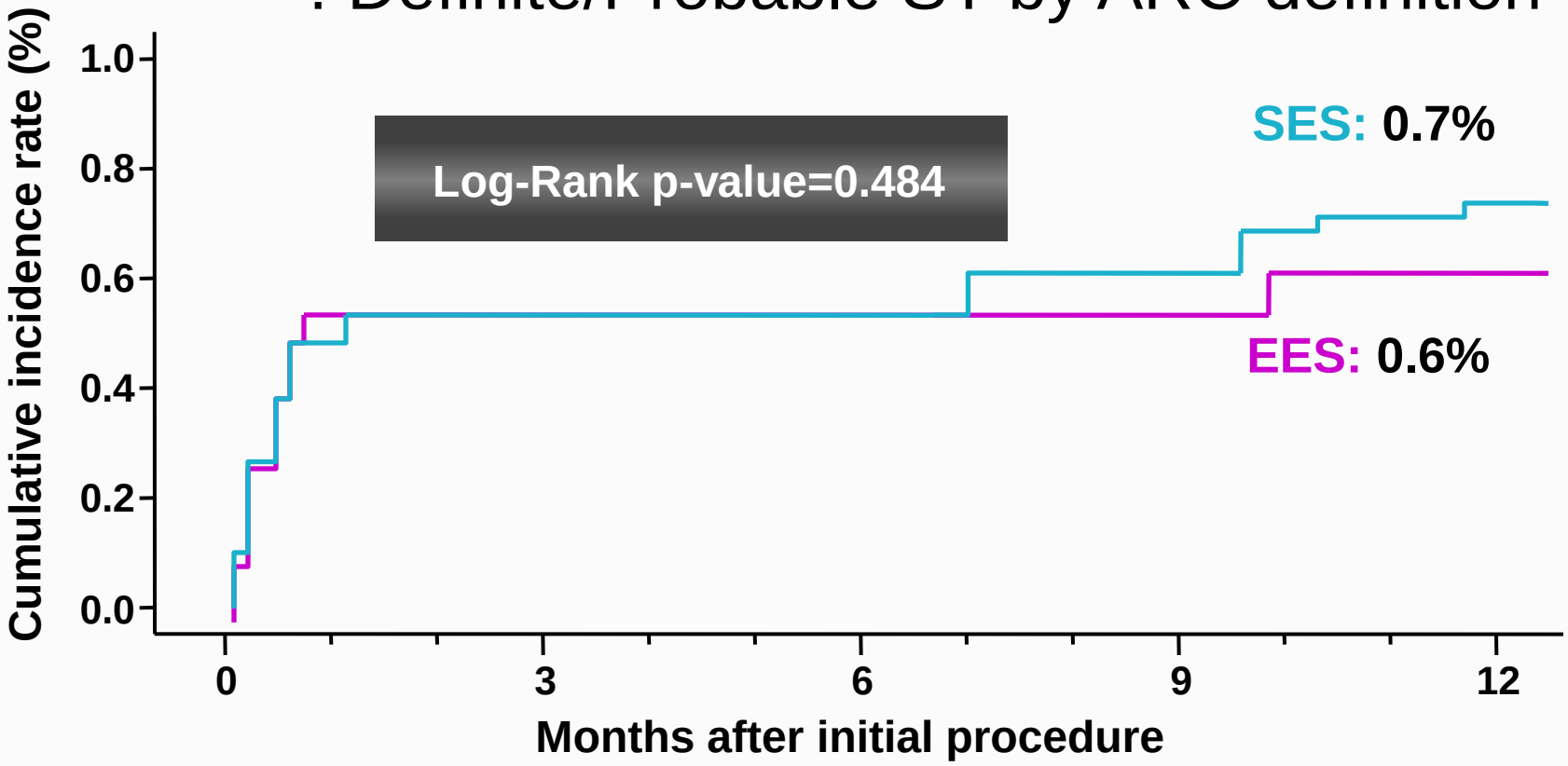
Patient Number at Risks

EES	1568	1547	1545	1535	1503
SES	1568	1555	1550	1537	1505

All-comer

Stent Thrombosis

: Definite/Probable ST by ARC definition



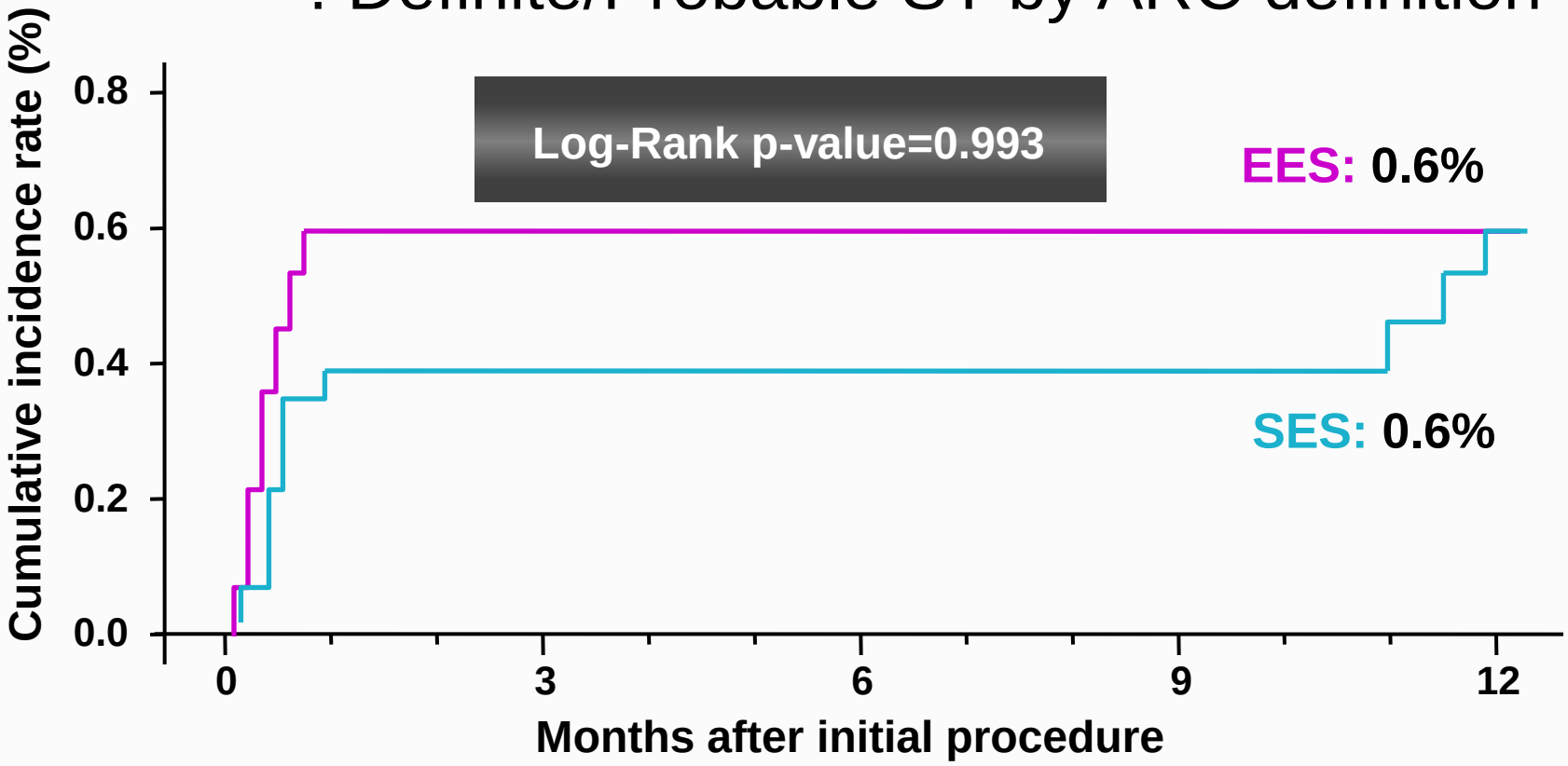
Patient Number at Risks

EES	3056	3010	3003	2987	2922
SES	2103	2082	2075	2058	2014

Matching

Stent Thrombosis

: Definite/Probable ST by ARC definition



Patient Number at Risks

EES	1568	1547	1545	1535	1502
SES	1568	1554	1550	1537	1504

Cases of Stent Thrombosis in whole patients N=5159

- Acute (<1 day) : 7 patients
- Subacute (1~30days) : 19 patients
- Late (>1month) : 6 patients
  - 5 patients : dual-antiplatelet
  - 1 patient : only clopidogrel after 1 month d/t aspirin intolerance
- Clopidogrel stop patient → no ST
  - 1~3months : 43 patient
  - 3~6months : 38 patients
  - 6~9months : 99 patients
  - 9~12months : 76 patients

Summary : EXCELLENT-REGISTRY

- Up to one year post-PCI in an **all-comer** population, the efficacy and safety of EES was not significantly different with SES.
- **Propensity score-matched pairs** showed same results as whole patients.
- The incidence of **ST** was not different between EES and SES although numerically lower in EES.
- **TVR** were significantly more frequent in SES than EES.
- Long term follow up will tell us whether Xience/Promus will offer **similar efficacy along with better long term safety** compared with the best 1st generation DES, Cypher.

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Efficacy of Xience/Promus versus Cypher to rEduce Late Loss in stENT

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on behalf of the investigators

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Background

- IRIS-DES Registry
  - EES : SES = 3084 : 3085
  - Primary end point

    MACE 1Y f/u HR 0.81, CI 0.59-1.13, P=0.22
  - Death : significant lower in EES

    HR 0.54, CI 0.31-0.92, P=0.03
  - Stent thrombosis : HR 0.72, CI 0.25-2.12, P=0.55