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Potential conflicts of interest

Speaker's name: Raul Moreno

☒ **I have the following** potential conflicts of interest to report:

- ☐ Research contracts
- ☒ Consulting: Cordis, Abbott
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ **I do not have any potential conflict of interest**

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A randomised comparison between everolimus- and sirolimus-eluting stent in chronic coronary total occlusions. Final results of the CIBELES trial

Raul Moreno

on behalf of the CIBELES investigators

Clinicaltrials.gov number NCT00793221

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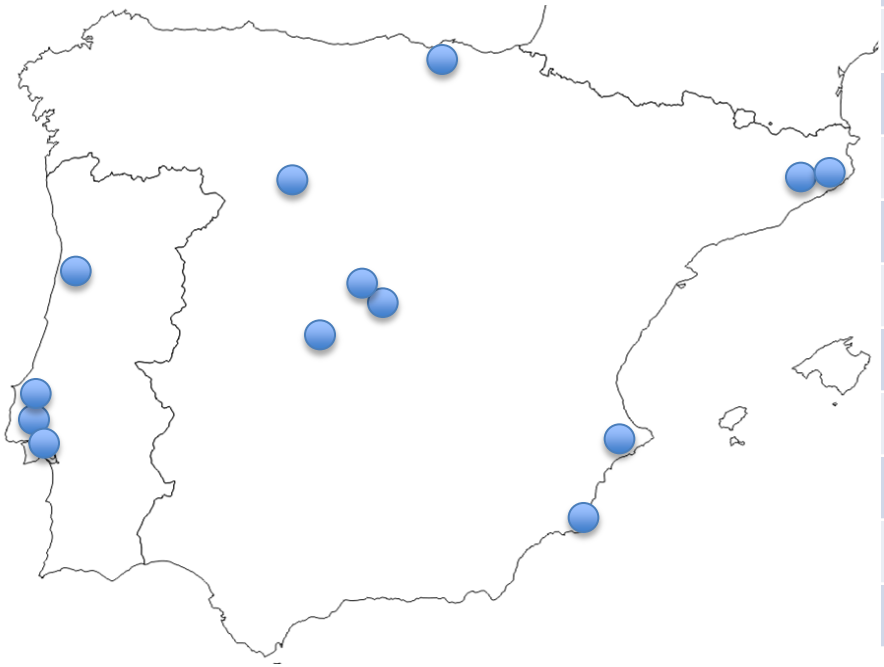

Participating center	PI	N
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Santa Cruz, Lisboa, Portugal	R.C. Teles	34
Galdakao, Bilbao, Spain	J.R. Rumoroso	28
Sto. Antonio, Porto, Portugal	H.C. Carvalho	21
Puerta de Hierro, Majadahonda, Sp	J. Goicolea	17
Virgen de la Salud, Toledo, Sp	J. Moreu	15
German Trias i Pujol, Badalona, Spain	J. Mauri	14
Sta Creu i Sant Pau, Barcelona, Spain	M. Sabate	12
Hospital General, Alicante, Spain	V. Mainar	9
Santa Marta, Lisboa, Portugal	R. Ferreira	7
Virgen de La Arrixaca, Murcia, Spain	M. Valdés	5
Complejo Hospitalario, Leon, Spain	F. Fernández	2
Garcia de Orta, Lisboa, Portugal	H. Pereira	1

- **PI:** Raul Moreno.
- **Co-PI:** Eulogio García.
- **Angiographic core-Lab:** Hospital Clinico, Madrid, Spain.
- **Clinical Events Committee:** E. Lopez de Sa, C. Macaya, J.L. Lopez-Sendon
- **Sponsor**: Sociedad Española de Cardiología
- Unrestricted grant from Abbott
- **Monitoring CRO**: Chiltern International

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BACKGROUND

- Patients with CTO are at very high risk of BAR/TVR.
- Only the sirolimus-eluting stent (SES) was randomly tested againgst BMS in this subset.

  (DES of choice in this subset).
- Everolimus-eluting stent (EES): better stent platform, low ISLL, very good safety profile (low ST rates).
- No RCT of EES in patients with CTO.

Circulation 2006;29:921–928. Eur Heart J 2010;31:2014-2020. Eurointervention 2010;6:356-60. N Engl J Med 2010;362:1663-1674.
Lancet 2010;375:201–9. JACC 2011;58:1844-1854. Eurointervention 2011;6:1003-10. Eur Heart J 2007;28:1583-91.

HYPOTHESIS AND DESIGN

- **Hypothesis**: the second generation cobalt-chromium everolimus-eluting stent (Xience V, Abbott) is as effective as the sirolimus-eluting coronary stent (Cypher ,Cordis) in the treatment of CTO.

- **Primary endpoint**: in-stent late loss at 9-mo. angiographic follow-up.

- **Design:** Multicentre, controlled, single-blinded, randomised clinical trial (1:1, phone call, Chiltern International).

- **Sample size calculation**: 208 patients with the following assumptions:
  - ISLL after SES: from 0.05-0.28 mm. SD 0.45 assumed.
  - Non-inferiority margin for ISLL: 0.20 mm.
  - 1-sided α error 0.05, β error 0.10 (90% statistical power).
  - Lost of angiographic follow-up 15%.

Eurointervention 2010;6:112-116.

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INCLUSION/EXCLUSION CRITERIA

MAIN INCLUSION CRITERIA

- Age > 18.
- Total coronary occlusion > 2 weeks.
- Symptomatic or silent ischaemia.
- Suitable for 2.25-3.5 mm stent implantation.
- Previous treatment with ASA + thyenopiridines.
- Signed informed consent.

MAIN EXCLUSION CRITERIA:

- Myocardial infarction < 2 weeks.
- Contraindications for prolonged double anti-platelet therapy.
- Treatment with chronic oral anticoagulation.
- Plasmatic creatinine > 3 g/dl.
- Previous intervention in the target vessel.
- Unsuccessful recanalization and balloon dilatation.
- Life expectancy < 1 year.

Eurointervention 2010;6:112-116.

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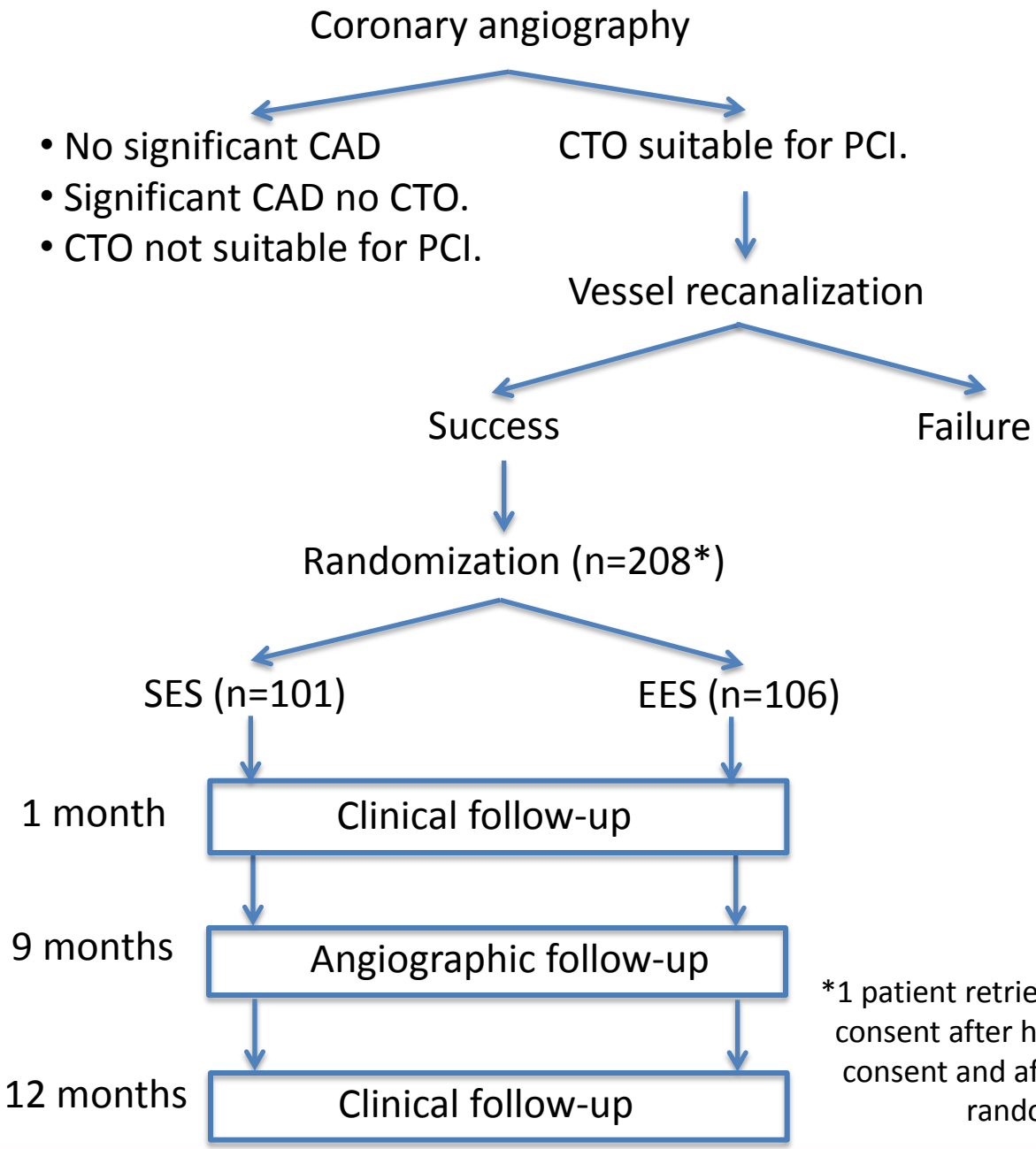

*1 patient retrieved the informed consent after having signed the consent and after having been randomized

Eurointervention 2010;6:112-116.

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BASELINE CHARACTERISTICS

	SES	EES	P
Age	63±11	65±10	0.094
Female gender (%)	13.9	19.8	0.254
Diabetes mellitus (%)	31.7	40.6	0.184
Insulin dependent diabetes (%)	5.9	9.4	0.347
Hypertension (%)	67.3	68.9	0.812
Hypercholesterolemia (%)	77.2	66.0	0.075
Smoking (%)	61.4	50.0	0.099
Previous PCI (%)	42.6	25.5	0.012
Previous CABG (%)	4.0	4.7	1.000
Previous infarction	42.6	33.0	0.202
Time of occlusion > 3 mo.	83.2	76.4	0.227
Clinical indication (%)			0.324
Angina	66.3	72.6	
Silent ischaemia	33.7	27.4	
Left ventricular ejection fraction	54±14	52±13	0.305

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PROCEDURAL CHARACTERISTICS

	SES	EES	P
No. vessels diseased	1.8±0.8	1.8±0.8	0.873
Treated vessel (%)			0.420
Left main	1.0	0.0	
Anterior descending	41.6	40.6	
Left circumflex	20.8	17.0	
Right coronary artery	35.6	42.5	
2 vessels (RCA & LCX)	1.0	0.0	
Radial approach (%)	25.7	20.8	0.395
Retrograde approach (%)	5.0	4.7	1.000
No. stents	1.9±0.9	2.1±1.0	0.767
Total stent length (mm)	47.2±24.4	49.8±23.2	0.375
Maximum stent diameter (mm)	2.9±0.4	2.9±0.4	0.675
Minimum stent diameter (mm)	2.6±0.4	2.6±0.4	0.767
Angiographic success	98%	98%	0.930

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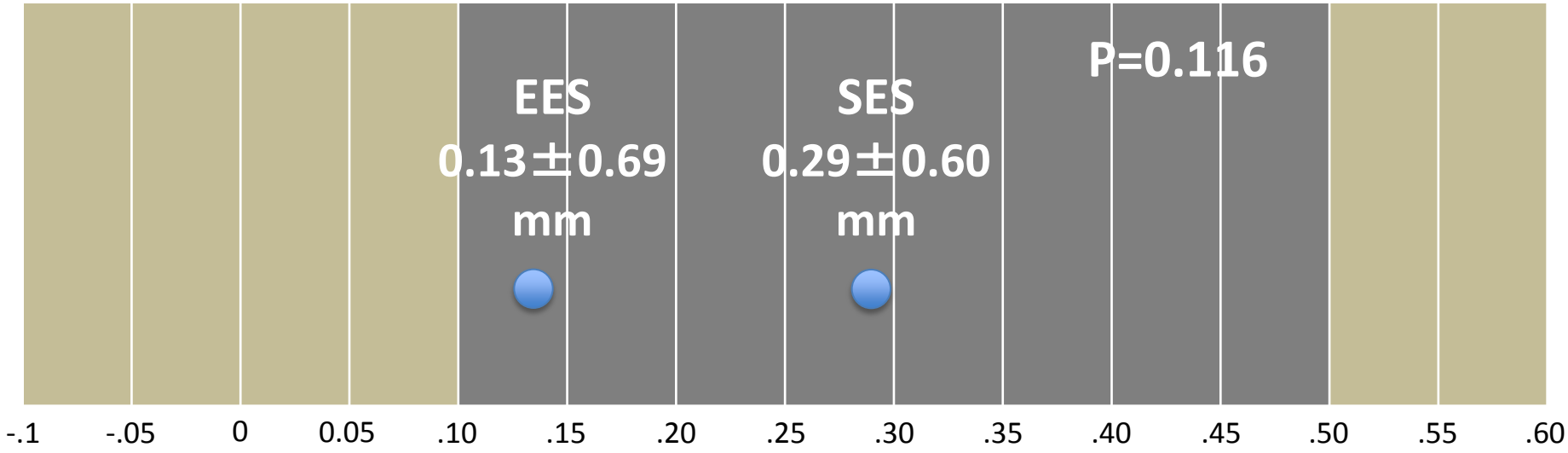
ANGIOGRAPHIC FOLLOW-UP

- Patients non-elegible for angio FU: n=7 (3 deaths, 4 unsuccessful result).
- Patients elegible for angio FU: n=200.
- Patients undergoing angio FU: n=181 (90.5%).
- Primary end-point: in-stent late loss at 9 months
- Margin for non-inferiority: 0.20 mm



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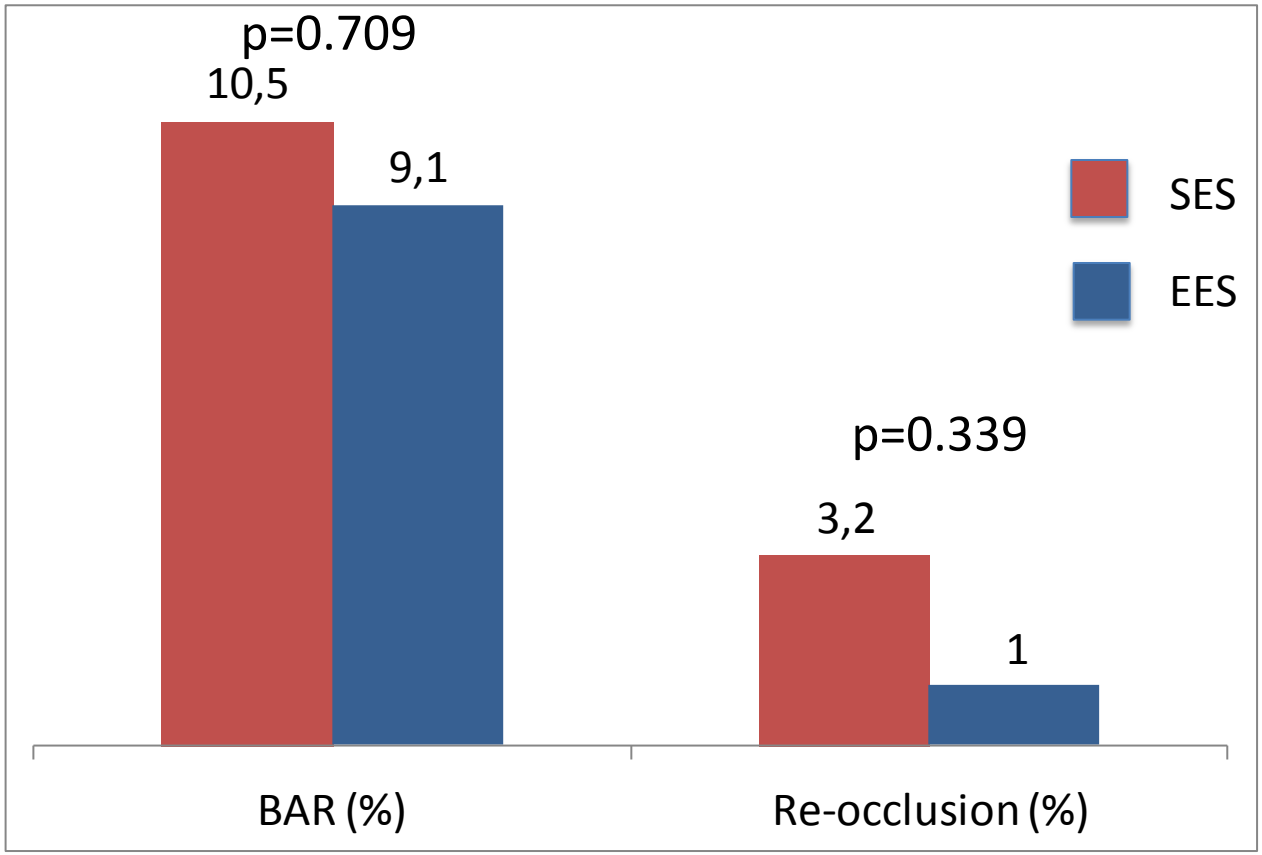
ANGIO FOLLOW-UP: BINARY EVENTS



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ANGIO FOLLOW-UP: QCA DATA

	SES	EES	P
Post-procedure			
In-stent RVD (mm)	2.8±0.5	2.7±0.5	NS
In-stent MLD (mm)	2.2±0.5	2.1±0.5	NS
In-stent % stenosis	20.1±10.7	21.4±9.6	NS
In-segment RVD (mm)	2.6±0.6	2.5±0.6	NS
In-segment MLD (mm)	1.8±0.5	1.7±0.6	NS
In-segment % stenosis	31.0±12.7	32.2±14.0	NS
Follow-up			
In-stent RVD (mm)	2.8±0.6	2.7±0.6	NS
In-stent MLD (mm)	2.0±0.6	2.0±0.7	NS
In-stent % stenosis	30.0±18.1	28.9±18.7	NS
In-stent late loss (mm)	0.29±0.60	0.13±0.69	NS
In-segment RVD (mm)	2.8±0.5	2.6±0.6	NS
In-segment MLD (mm)	1.8±0.5	1.6±0.7	NS
In-segment % stenosis	33.1±16.1	37.9±22.9	NS
In-segment late loss (mm)	0.0±0.6	0.1±0.7	NS

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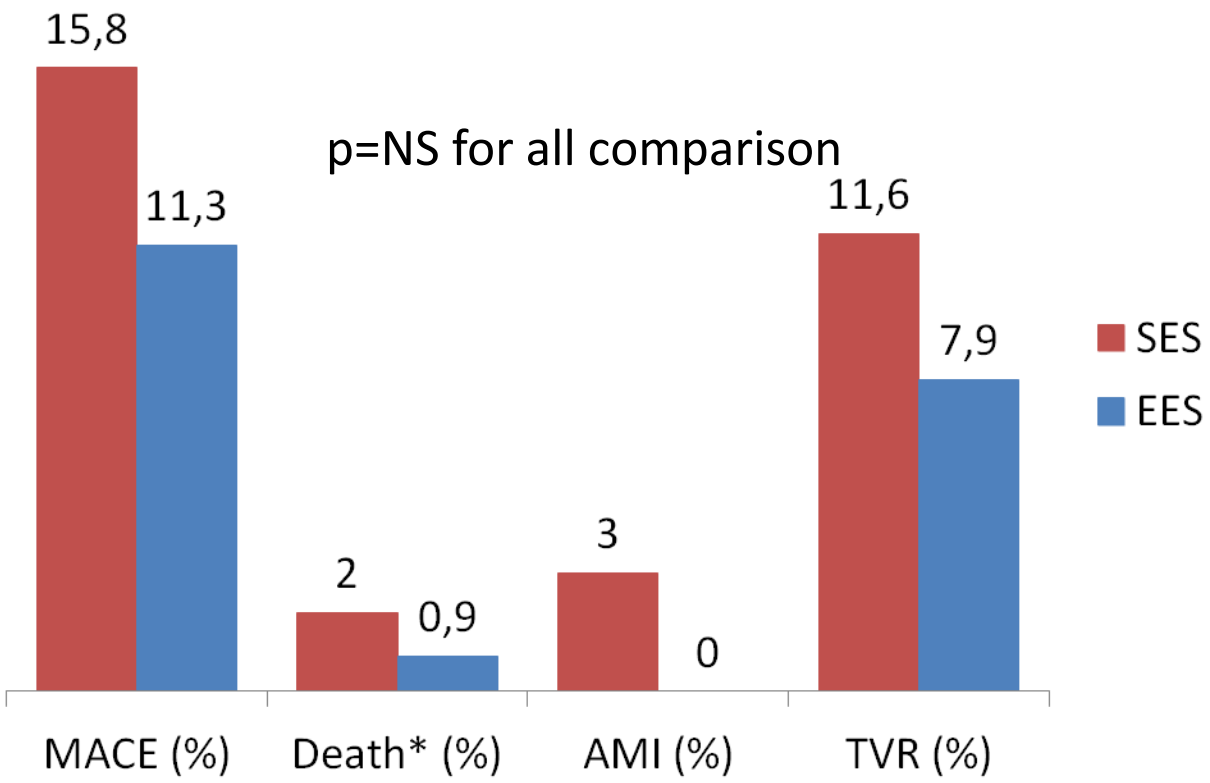
% OF PATIENTS WITH EVENTS AT 365 DAYS



*All cardiac

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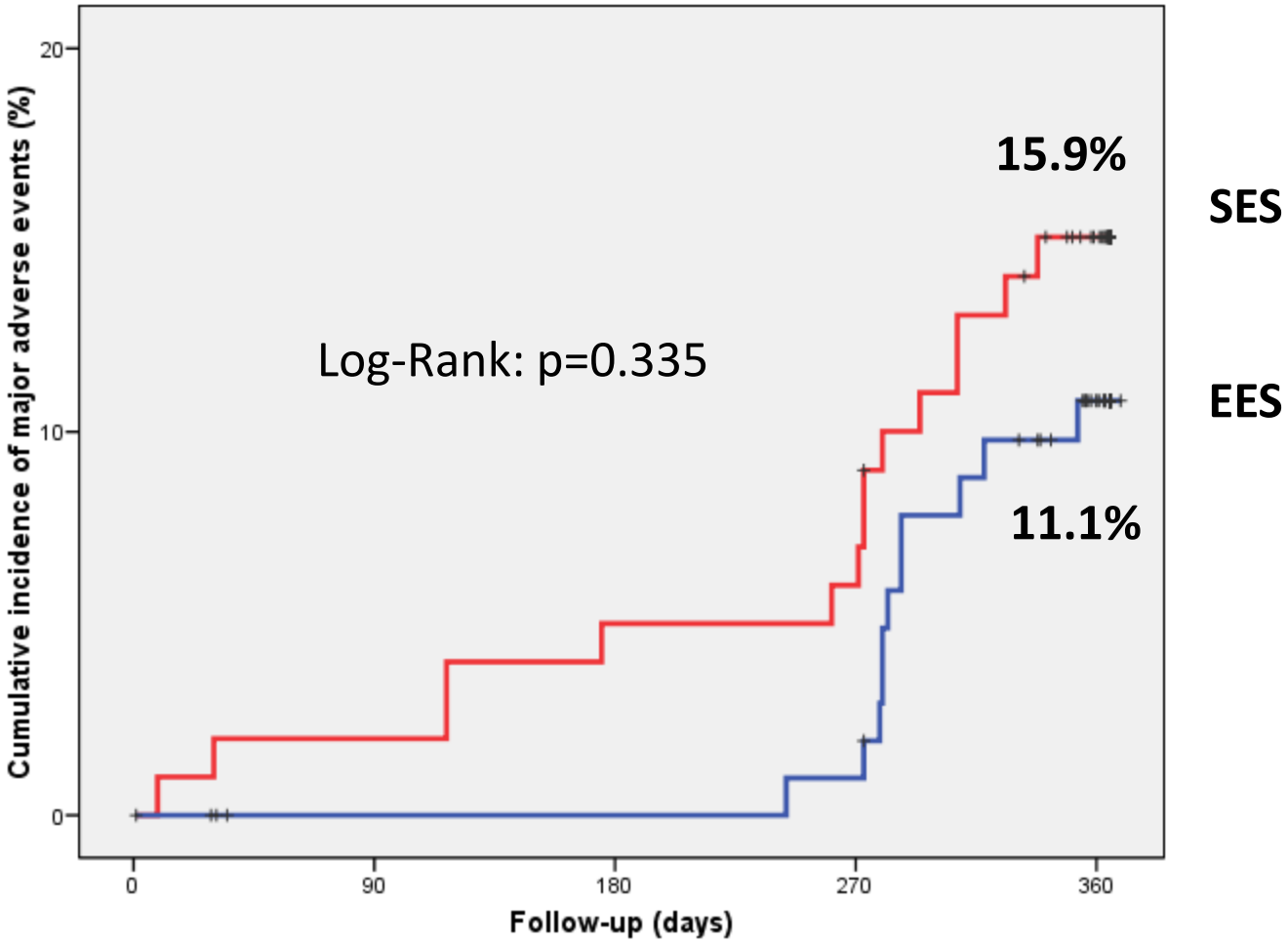
INCIDENCE OF CARDIAC EVENTS



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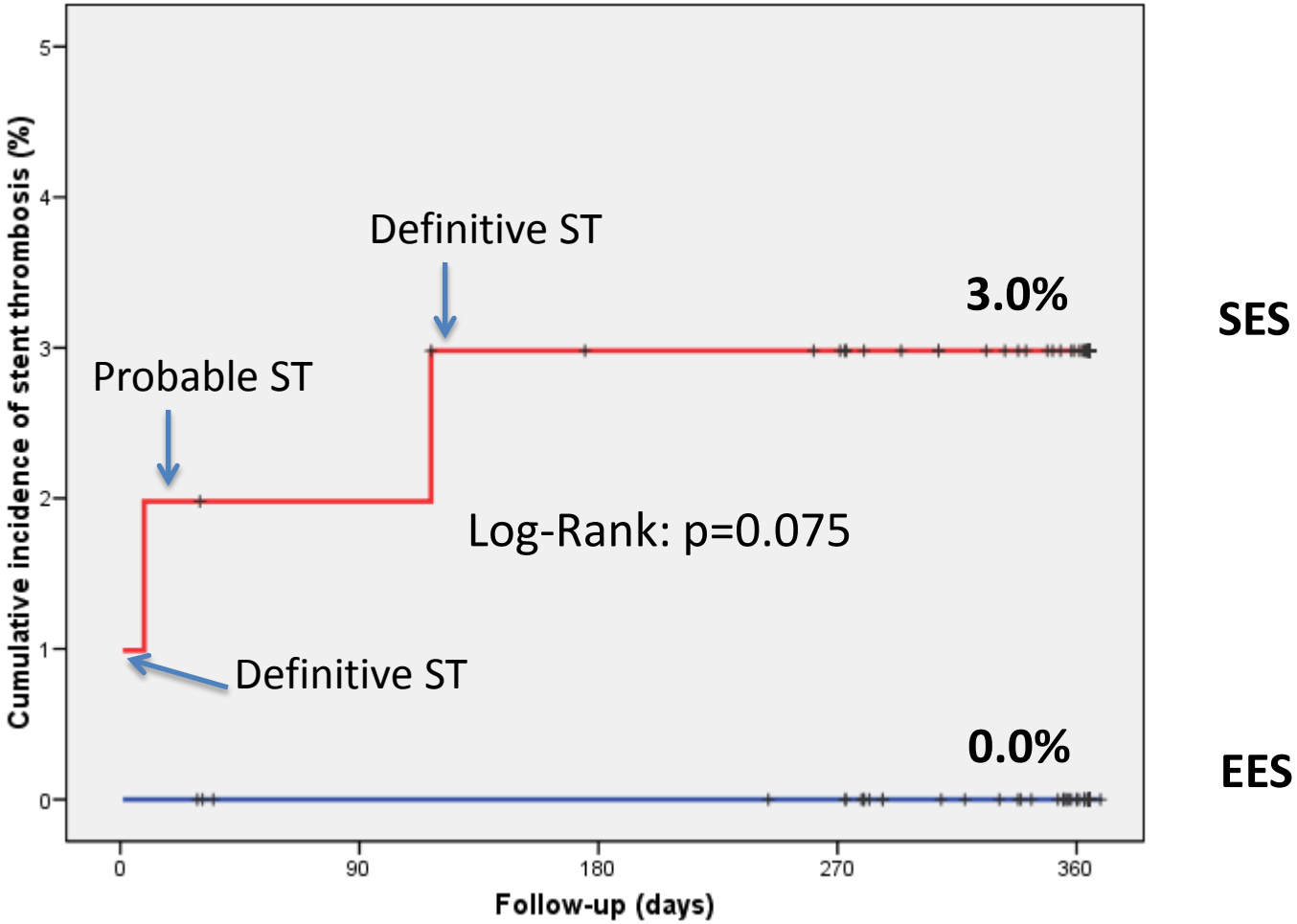
DEFINITIVE / PROBABLE STENT THROMBOSIS



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CONCLUSIONS

- In the CIBELES trial, the primary end-point was reached (non-inferior ISLL between EES and SES).
- Clinical events were similar between SES and EES.
- There was a trend to lower rates of definitive or probable stent thrombosis in patients allocated to EES.

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