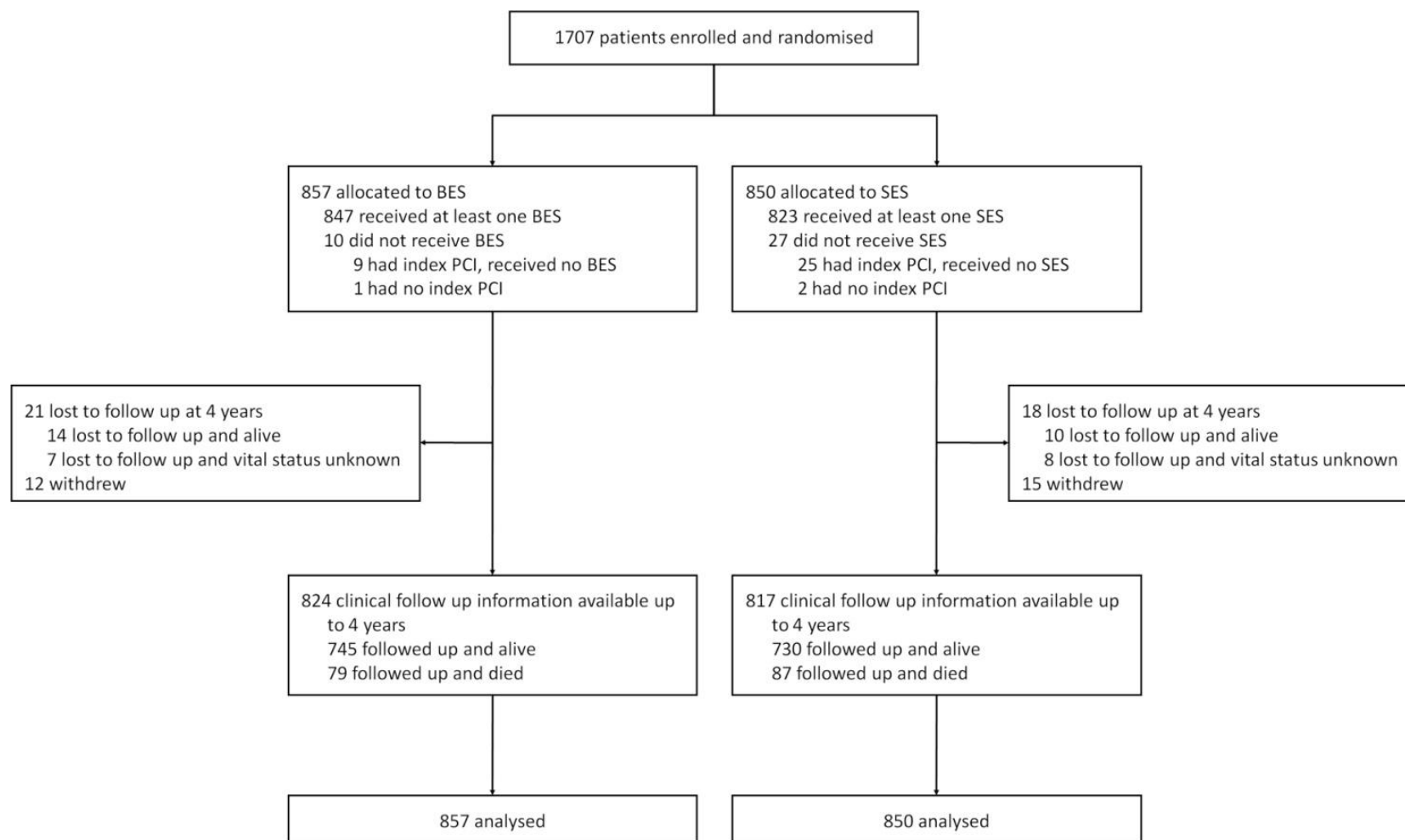


# THE LANCET

## Supplementary webappendix

This webappendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Stefanini GG, Kalesan B, Serruys PW, et al. Long-term clinical outcomes of biodegradable polymer biolimus-eluting stents versus durable polymer sirolimus-eluting stents in patients with coronary artery disease (LEADERS): 4 year follow-up of a randomised non-inferiority trial. *Lancet* 2011; published online Nov 9. DOI:10.1016/S0140-6736(11)61672-3.



### Study Flow

BES=biodegradable polymer biolimus-eluting stent, SES=durable polymer sirolimus-eluting stent, PCI=percutaneous coronary intervention. Note that we have no reliable data on the number of patients assessed for eligibility

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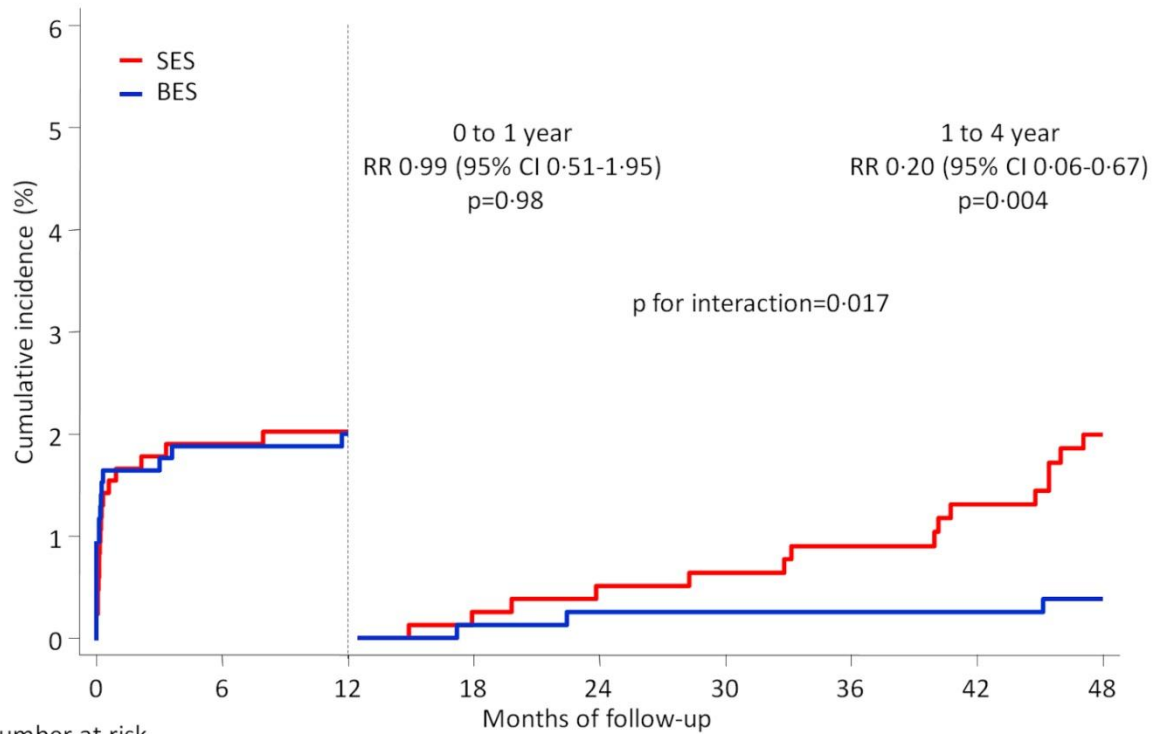
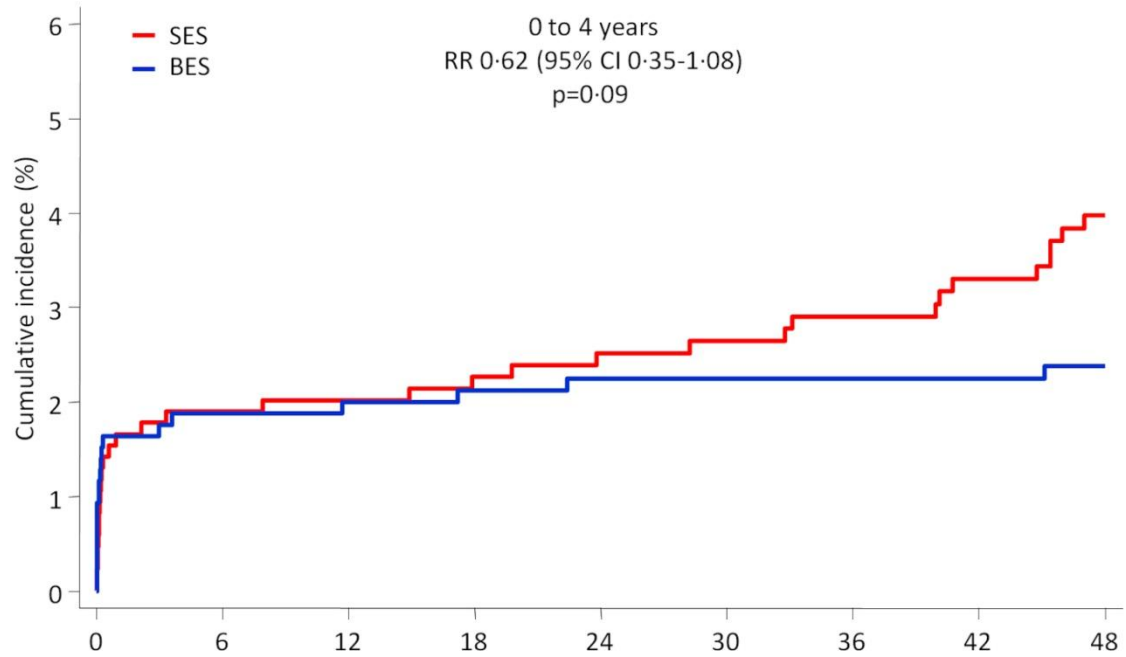
**Baseline characteristics**


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	Biodegradable polymer BES (N=857)	Durable polymer SES (N=850)
Age (years)	64.6 (10.8)	64.5 (10.7)
Male	643 (75.0%)	634 (74.6%)
Diabetes mellitus	223 (26.0%)	191 (22.5%)
Insulin requiring	81 (9.5%)	77 (9.1%)
Hypertension	630 (73.5%)	618 (72.7%)
Hypercholesterolemia	560 (65.3%)	580 (68.2%)
Current smoker	206 (24.0%)	214 (25.2%)
Family history of coronary artery disease	339 (39.6%)	374 (44.0%)
History of MI	276 (32.2%)	277 (32.6%)
History of PCI	312 (36.4%)	312 (36.7%)
Previous CABG	90 (10.5%)	107 (12.6%)
Peripheral vascular disease	70 (8.2%)	63 (7.4%)
Multi-vessel disease	209 (24.4%)	176 (20.7%)
Left ventricular ejection fraction* (%)	55.9% (11.3)	55.4% (12.4)
SYNTAX score†	13.2 (8.7)	13.3 (8.7)
Acute coronary syndrome	470 (54.8%)	473 (55.7%)
ST-elevation MI	135 (15.8%)	140 (16.5%)
Non ST-elevation MI	145 (16.9%)	153 (18.0%)
Unstable angina	190 (22.2%)	180 (21.2%)
Stable angina	387 (45.2%)	377 (44.4%)
De-novo lesions only	788 (91.9%)	774 (91.1%)
Off-label use	696 (81.2%)	665 (78.2%)
Multivessel disease	209 (24.4%)	176 (20.7%)
Small-vessel disease (RVD <2.75 mm)	585 (68.3%)	568 (66.8%)
Long lesions (>20 mm)	262 (30.6%)	225 (26.5%)
Number of lesions per patient	1.5 (0.7)	1.4 (0.7)
Reference vessel diameter (mm) ‡	2.60 (0.61)	2.60 (0.57)
Minimum lumen diameter (mm) §	0.91 (0.50)	0.95 (0.52)
Diameter stenosis (%) §	64.6% (17.9)	63.3% (18.2)

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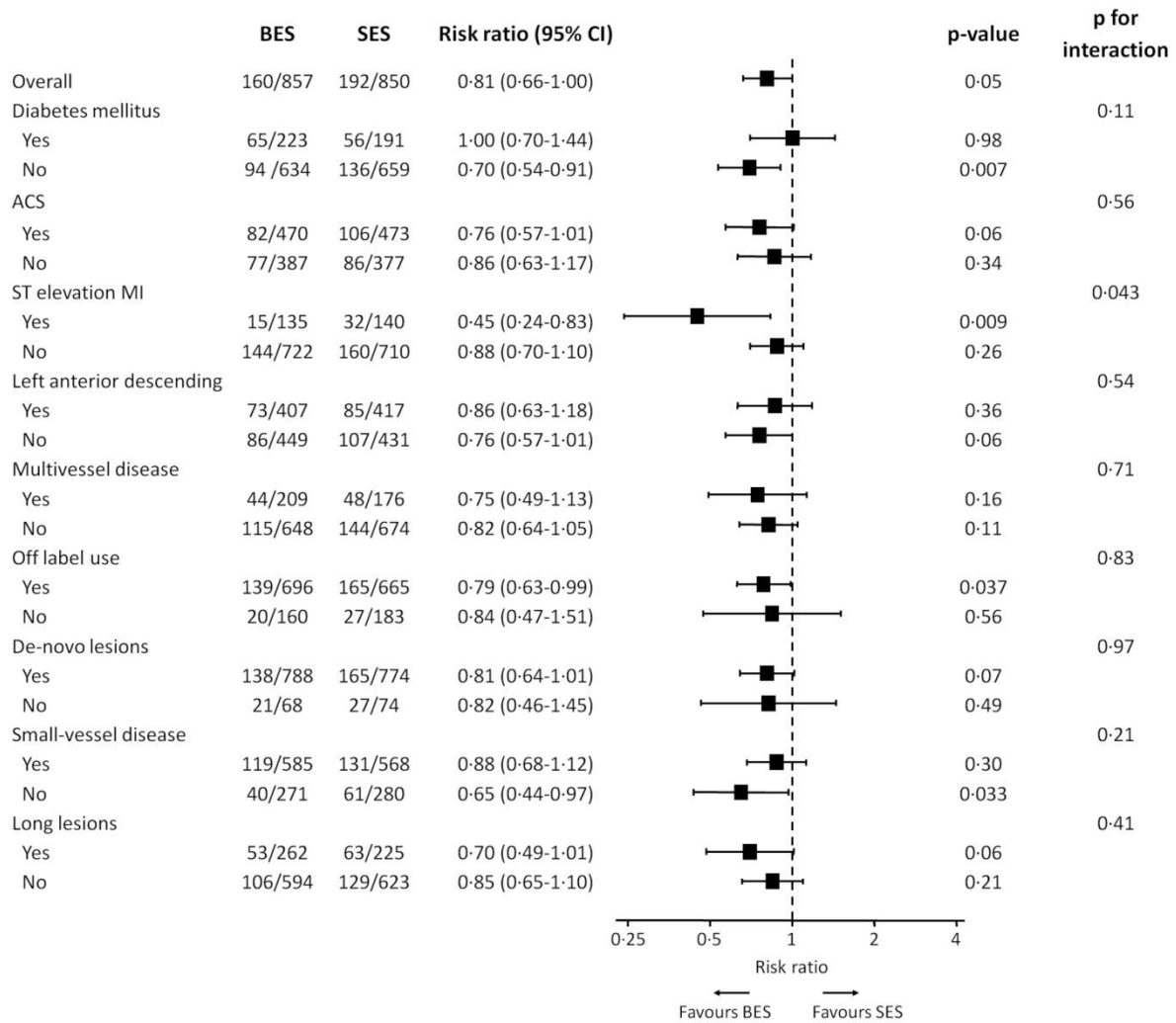
Data are mean (SD) or number (%). MI=myocardial infarction, PCI=percutaneous coronary intervention, CABG=coronary artery bypass grafting, RVD=reference vessel disease. \*Left ventricular ejection fraction is available in 601 allocated to biolimus-eluting stent and 607 allocated to sirolimus-eluting stent. †678 patients in the biolimus-eluting stent group, and 673 in the sirolimus-eluting stent group. ‡1246 assessed in the biolimus-eluting stent group, and 1199 in the sirolimus-eluting stent group. §1209 assessed in the biolimus-eluting stent group, and 1186 in the SES group.



Number at risk		0	6	12	18	24	30	36	42	48
SES	850	817	801	787	776	759	750	730	714	
BES	857	821	804	792	787	780	774	757	746	

### Definite stent thrombosis

Kaplan-Meier curves for definite stent thrombosis through 4 years, overall and according to a landmark analysis at 1 year. BES=biodegradable polymer biolimus-eluting stent, SES=durable polymer sirolimus-eluting stent.



### Stratified analysis of the primary endpoint at 4 years.

One patient allocated to biolimus-eluting stent (one lesion) and two patients allocated to sirolimus eluting stent (two lesions) did not undergo any diagnostic or angiographic procedure after randomisation; lesion characteristics are unavailable and these patients could not be included in stratified analyses for left anterior descending artery, off -label use, de-novo lesions, small-vessel disease, and long lesions. MI=myocardial infarction.