# 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.

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**Source**

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## Abstract

**BACKGROUND:**

The effectiveness of durable polymer drug-eluting stents comes at the expense of delayed arterial healing and subsequent late adverse events such as stent thrombosis (ST). We report the 4 year follow-up of an assessment of biodegradable polymer-based drug-eluting stents, which aim to improve safety by avoiding the persistent inflammatory stimulus of durable polymers.

**METHODS:**

We did a multicentre, assessor-masked, non-inferiority trial. Between Nov 27, 2006, and May 18, 2007, patients aged 18 years or older with coronary artery disease were randomly allocated with a computer-generated sequence to receive either biodegradable polymer biolimus-eluting stents (BES) or durable polymer sirolimus-eluting stents (SES; 1:1 ratio). The primary endpoint was a composite of cardiac death, myocardial infarction, or clinically-indicated target vessel revascularisation (TVR); patients were followed-up for 4 years. Analysis was by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT00389220.

**FINDINGS:**

1707 patients with 2472 lesions were randomly allocated to receive either biodegradable polymer BES (857 patients, 1257 lesions) or durable polymer SES (850 patients, 1215 lesions). At 4 years, biodegradable polymer BES were non-inferior to durable polymer SES for the primary endpoint: 160 (18·7%) patients versus 192 (22·6%) patients (rate ratios [RR] 0·81, 95% CI 0·66-1·00, p for non-inferiority <0·0001, p for superiority=0·050). The RR of definite ST was 0·62 (0·35-1·08, p=0·09), which was largely attributable to a lower risk of very late definite ST

between years 1 and 4 in the BES group than in the SES group (RR 0·20, 95% CI 0·06-0·67, p=0·004). Conversely, the RR of definite ST during the first year was 0·99 (0·51-1·95; p=0·98) and the test for interaction between RR of definite ST and time was positive (p(interaction)=0·017). We recorded an interaction with time for events associated with ST but not for other events. For primary endpoint events associated with ST, the RR was 0·86 (0·41-1·80) during the first year and 0·17 (0·04-0·78) during subsequent years (p(interaction)=0·049).

**INTERPRETATION:**
Biodegradable polymer BES are non-inferior to durable polymer SES and, by reducing the risk of cardiac events associated with very late ST, might improve long-term clinical outcomes for up to 4 years compared with durable polymer SES.

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