Biodegradable polymer drug-eluting stents reduce the risk of stent thrombosis at 4 years in patients undergoing percutaneous coronary intervention: a pooled analysis of individual patient data from the ISAR-TEST 3, ISAR-TEST 4, and LEADERS randomized trials.

Abstract:

The efficacy of durable polymer drug-eluting stents (DES) is delivered at the expense of delayed healing of the stented vessel. Biodegradable polymer DES aim to avoid this shortcoming and may potentially improve long-term clinical outcomes, with benefit expected to accrue over time. We sought to compare long-term outcomes in patients treated with biodegradable polymer DES vs. durable polymer sirolimus-eluting stents (SES). We pooled individual patient data from three large-scale multicentre randomized clinical trials (ISAR-TEST 3, ISAR-TEST 4, and LEADERS) comparing biodegradable polymer DES with durable polymer SES and assessed clinical outcomes during follow-up through 4 years. The efficacy endpoint of interest was target lesion revascularization and the safety endpoint of interest was definite stent thrombosis. Out of 4062 patients included in the present analysis, 2358 were randomly assigned to treatment with biodegradable polymer DES (sirolimus-eluting, n= 1501; biolimus-eluting, n= 857) and 1704 patients to durable polymer SES. No heterogeneity across the trials was observed in analyses of the primary and secondary endpoints. At 4 years, the risk of target lesion
Revascularization was significantly lower among patients treated with biodegradable polymer DES vs. durable polymer SES (hazard ratio 0.82, 95% CI 0.68-0.98, P = 0.029). In addition, the risk of stent thrombosis was significantly reduced with biodegradable polymer DES vs. durable polymer SES (hazard ratio 0.56, 95% CI 0.35-0.90, P = 0.015), driven by a lower risk of very late stent thrombosis (hazard ratio 0.22, 95% CI 0.08-0.61, P = 0.004). In keeping with this, in landmark analysis between 1 and 4 years, the incidence of myocardial infarction was lower for patients treated with biodegradable polymer DES vs. durable polymer SES (hazard ratio 0.59, 95% CI 0.73-0.95, P = 0.031). Biodegradable polymer DES improve safety and efficacy compared with durable polymer SES during long-term follow-up to 4 years.