Second-versus first-generation "Limus"-eluting stents in diabetic patients with coronary artery disease: a randomized comparison in setting of ISAR-TEST-4 trial.

Patients with diabetes mellitus remain at higher risk for adverse events following percutaneous coronary intervention and the identification of the optimum drug eluting stents (DES) in these patients is of high clinical relevance. We compared effectiveness of everolimus-eluting stents (EES; Xience) versus sirolimus-eluting stents (SES; Cypher) in patients with diabetes mellitus enrolled in the Intracoronary Stenting and Angiographic Results: Test Efficacy of 3 Limus-Eluting Stents (ISAR-TEST-4) trial. In the setting of the ISAR-TEST-4 trial, 1304 patients with broad inclusion criteria were randomized to treatment with EES or SES. The focus of the present analysis is on a cohort of 377 patients with diabetes mellitus assigned to receive EES (n = 184) or SES (n = 193). The primary endpoint was the composite of cardiac death, myocardial infarction (MI) related to the target vessel, or target lesion revascularization (TLR) at 3-year follow-up. Secondary endpoints were parameters of angiographic and clinical restenosis (in-stent late lumen loss, binary restenosis, and TLR), all-cause mortality and definite/probable stent thrombosis. EES was comparable to SES concerning the incidence of the primary endpoint (21% vs. 24%,
respectively; relative risk = 0.87; 95% CI, 0.57-1.34; P = 0.53). Concerning the secondary endpoint, TLR at 3 years with EES versus SES stents was not statistically different (14.7% vs. 16.6%, respectively; relative risk = 0.85; 95% CI, 0.51-1.43; P = 0.55). In terms of angiographic outcomes patients treated with EES as compared to SES had significantly lower late lumen loss (0.22 ± 0.46 mm vs. 0.44 ± 0.66 mm, respectively; P< 0.001) and binary restenosis (8.4% vs. 17%, respectively; P = 0.02) at 6- to 8-month angiographic follow-up. EES was comparable to SES concerning the incidence of all-cause death (10% vs. 16%, respectively; relative risk = 0.66; 95% CI, 0.37-1.18; P = 0.16) and stent thrombosis (1.1% vs. 3.1%, respectively; P = 0.19). In patients with diabetes mellitus enrolled in a real-world randomized control trial, EES is comparable to SES in terms of clinical efficacy and safety out to 3 years; angiographic markers of antirestenotic efficacy favored EES.