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i2 SUMMIT

LONG-TERM CLINICAL OUTCOME AFTER IMPLANTATION OF SIROLIMUS-ELUTING AND PACLITAXEL-ELUTING STENTS IN PATIENTS WITH AND WITHOUT DIABETES MELLITUS - A PREDEFINED SORT OUT II SUBSTUDY

i2 Oral Contributions
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Background: Diabetes is associated with an increased risk of major adverse cardiac events (MACE) following percutaneous coronary intervention (PCI). It is controversial whether the first two commercially available drug-eluting stents, the sirolimus-eluting Cypher™ stent and the paclitaxel-eluting Taxus™ stent have similar long-term clinical outcomes, especially in the diabetic subpopulation.

Methods: We randomized 2126 patients to treatment with SES (n=1,074, diabetes: n=184) or PES (n=1045, diabetes: n=186). Median follow-up was 3.4-year. Primary endpoint was MACE defined as a composite of cardiac death, myocardial infarction, target lesion revascularization, or target vessel revascularization. Secondary endpoints were each of these individual endpoints.

Results: Patients with diabetes, as compared to patients without diabetes, had an increased risk of MACE (22.9% versus 17.1%; hazard ratio 1.38, 95% confidence interval 1.08 to 1.89; p=0.012) and target vessel revascularization (12.6% versus 9.1%; hazard ratio 1.40, 95% confidence interval 1.02 to 2.06; p=0.038), whereas cardiac death (4.4% versus 3.7%), myocardial infarction (8.4% versus 9.3%), and target lesion revascularization (9.9% versus 8.8%) did not differ significantly. Stent type (sirolimus-eluting versus paclitaxel-eluting) did not influence any of the clinical outcome parameters in patients with or without diabetes.

Conclusions: Diabetes is associated with increased risks of MACE and target vessel revascularization in patients treated with the first two commercially available drug-eluting stents. In patients with and without diabetes, we found no significant differences between sirolimus-eluting and paclitaxel-eluting stents over a median follow-up of 3.4-year.