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Five-year outcomes in patients with diabetes mellitus treated with biodegradable polymer sirolimus-eluting stents versus durable polymer everolimus-eluting stents

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Background: Patients with diabetes mellitus (DM) remain at higher risk for adverse events after percutaneous coronary intervention (PCI) compared with non-diabetic individuals. Among available drug-eluting stents (DES), thin-strut durable polymer everolimus-eluting stents (DP-EES) were shown to provide the best safety and efficacy profile in diabetics. Whether biodegradable polymer DES provide additional long-term clinical benefit compared with DP-EES among diabetic patients remains uncertain.

Purpose: To compare the long-term performance of ultrathin-strut biodegradable polymer sirolimus-eluting stents (BP-SES) versus DP-EES for PCI in patients with insulin-requiring and non-insulin-requiring DM.

Methods: We performed a prespecified subgroup analysis of the randomized, multicenter, non-inferiority BIOSCIENCE trial (NCT01443104). Patients with stable coronary artery disease or acute coronary syndrome were randomly assigned to treatment with ultrathin-strut BP-SES or thin-strut DP-EES. Patients were further divided according to diabetic status. The primary endpoint was target lesion failure (TLF), a composite of cardiac death, target-vessel myocardial infarction (MI) and clinically-indicated target lesion revascularization (TLR), within 12 months.

Results: Among 2'119 patients enrolled between March 2012 and May 2013, 486 (22.9%) presented with DM (insulin-requiring, 33.1%). Compared with non-diabetics, patients with DM were older and had a greater baseline cardiac risk profile, including higher prevalence of hypertension, hypercholesterolaemia, peripheral artery disease, chronic renal failure and prior PCI, coronary artery bypass graft surgery, or stroke. At 5 years, TLF occurred similarly in 74 patients (cumulative incidence, 31.0%) treated with BP-SES and 57 patients (25.8%) treated with DP-EES (RR 1.23; 95% CI 0.87–1.73; p=0.24) in diabetics, and in 124 patients (16.8%) treated with BP-SES and 132 patients (16.8%) treated with DP-EES (RR 0.98; 95% CI 0.77–1.26; p=0.90) in non-diabetics (p for interaction=0.31). Cumulative incidences of cardiac death (14.9% vs. 9.5%; p=0.10), target-vessel MI (11.4% vs. 11.0%; p=0.81), clinically-indicated TLR (16.9% vs. 15.8%; p=0.68), and definite thrombosis (3.0% vs. 2.5%; p=0.63) at 5 years were similar among diabetic patients treated with ultrathin-strut BP-SES or thin-strut DP-EES. Overall, there was no interaction between diabetic status and treatment effect of BP-SES versus DP-EES.

Conclusion: In a prespecified subgroup analysis of the BIOSCIENCE trial, we found no difference in clinical outcomes throughout five years between diabetic patients treated with ultrathin-strut BP-SES or thin-strut DP-EES.