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Two-year clinical outcomes with drug-eluting stents for diabetic patients with de novo coronary lesions: results from a real-world multicenter registry.

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BACKGROUND: The long-term effectiveness of drug-eluting stents (DES) in unselected diabetics in routine practice is currently unclear.

METHODS AND RESULTS: To evaluate the long-term effectiveness of bare metal stents and DES in a real-world setting of diabetic patients, we analyzed 2-year follow-up data from all diabetic patients with de novo lesions enrolled in a prospective Web-based multicenter registry (Registro Regionale Angioplastiche dell'Emilia-Romagna; study period, 2002 to 2004) comprising all 13 hospitals performing percutaneous coronary interventions in the Emilia-Romagna region of Italy. Among the 1648 eligible patients treated with either bare metal stents alone (n=1089) or DES alone (n=559), 27% were insulin dependent and 83% had multivessel coronary disease. At 2 years, use of DES was associated with lower crude incidence of major adverse cardiac events (all-cause mortality, nonfatal myocardial infarction, and target vessel revascularization) compared with bare metal stents (22.5% versus 28.1%; P=0.01). After propensity score adjustment, only target vessel revascularization appeared significantly lower in the DES group (11.6% versus 15.0%; hazard ratio, 0.66; 95% confidence interval, 0.46 to 0.96; P=0.041). Two-year angiographic stent thrombosis occurred in 1.5% DES patients and 0.7% of the bare-metal-stents patients (P=0.18). At Cox regression analysis, predictors of 2-year major adverse cardiac events were left ventricular ejection fraction <35%, Charlson comorbidity index, insulin-dependent diabetes, and total lesion length.

CONCLUSIONS: In this large, real-world, diabetic population, the use of DES was associated with a moderate reduction in the 2-year risk of target vessel revascularization, a benefit that was limited to non-insulin-dependent diabetic patients. Larger long-term studies are needed to clarify the long-term effectiveness and safety of such devices in diabetic patients.