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Long-term safety and efficacy of drug-eluting stents: two-year results of the REAL (REgistro AngiopLastiche dell'Emilia Romagna) multicenter registry.

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BACKGROUND: The long-term safety and efficacy of drug-eluting stents (DES) have been questioned recently.
METHODS AND RESULTS: Between July 2002 and June 2005, 10,629 patients undergoing elective percutaneous coronary intervention with either DES (n=3064) or bare-metal stents (BMS, n=7565) were enrolled in a prospective registry comprising 13 hospitals. We assessed the cumulative incidence of major adverse cardiac events (death, acute myocardial infarction, and target-vessel revascularization) and angiographic stent thrombosis during 2-year follow-up. A propensity score analysis to adjust for different baseline clinical, angiographic, and procedural characteristics was performed. The 2-year unadjusted cumulative incidence of major adverse cardiac events was 17.8% in the DES group and 21.0% in the BMS group (P=0.003 by log-rank test). Angiographic stent thrombosis was 1.0% in the DES group and 0.6% in the BMS group (P=0.09). After adjustment, the 2-year cumulative incidence of death was 6.8% in the DES group and 7.4% in the BMS group (P=0.35), whereas the rates were 5.3% in DES and 5.8% in BMS for acute myocardial infarction (P=0.46), 9.1% in DES and 12.9% in BMS for target-vessel revascularization (P<0.00001), and 16.9% in DES and 21.8% in BMS for major adverse cardiac events (P<0.0001). Independent predictors of target-vessel revascularization in the DES group were diabetes mellitus (hazard ratio 1.36, 95% confidence interval 1.06 to 1.76), renal failure (hazard ratio 1.69, 95% confidence interval 1.06 to 2.69), and reference vessel diameter (hazard ratio 0.64, 95% confidence interval 0.45 to 0.93).
CONCLUSIONS: In this large real-world population, the beneficial effect of DES in reducing the need for new revascularization compared with BMS extends to 2 years without evidence of a worse safety profile.