Abstract:

OBJECTIVES: The aim of this trial was to compare the safety and efficacy of paclitaxel-eluting stents (PES) and sirolimus-eluting stents (SES) for treatment of unprotected left main coronary artery (uLMCA) disease. BACKGROUND: Both PES and SES have reduced the risk of restenosis, particularly in high-risk patient and lesion subsets. However, their comparative performance in uLMCA lesions is not known.

METHODS: In this randomized study, 607 patients with symptomatic coronary artery disease undergoing percutaneous coronary intervention for uLMCA were enrolled: 302 were assigned to receive a PES (Taxus, Boston Scientific, Natick, Massachusetts) and 305 assigned to receive a SES (Cypher, Cordis, Johnson& Johnson, New Brunswick, New Jersey). The primary end point was the combined incidence of death, myocardial infarction, and target lesion revascularization (TLR) at 1 year. The secondary end point was angiographic restenosis on the basis of the LMCA area analysis at follow-up angiography. RESULTS: At 1 year the cumulative incidence of death, myocardial infarction, or TLR was 13.6% in the PES and 15.8% in the SES group (relative risk [RR]: 0.85,
95% confidence interval [CI]: 0.56 to 1.29, p = 0.44). One patient in the PES group (0.3%) and 2 patients in the SES group (0.7%) experienced definite stent thrombosis (p = 0.57). Mortality at 2 years was 10.7% in the PES and 8.7% in the SES group (RR: 1.14, 95% CI: 0.66 to 1.95, p = 0.64). Angiographic restenosis was 16.0% with PES and 19.4% with SES (RR: 0.82, 95% CI: 0.57 to 1.19, p = 0.30). CONCLUSIONS: Implantation of either PES or SES in uLMCA lesions is safe and effective; both of these drug-eluting stents provide comparable clinical and angiographic outcomes.

(Drug-Eluting-Stents for Unprotected Left Main Stem Disease [ISAR-LEFT-MAIN]; NCT00133237).