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Interim Results of the Basket of Real-World Randomised Clinical PRISM Trials for M'Sure-S, a Next-Generation Sirolimus-Eluting Stent, Versus Eliminator, an Everolimus-Eluting Stent

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Abstract

Objective: This study compared sirolimus-eluting stents (SES) with everolimus-eluting stents (EES) in coronary artery disease patients.

Methods: A total of 1,174 patients were enrolled in the study; 290 patients (25.28%) were treated with EES and 884 patients (74.72%) were treated with SES. The trial (PRISM) was a randomised (in a 3:1 ratio), multicentre, single-blind, all-comers, single-arm, non-inferiority trial comparing SES and EES-implanted patients with coronary artery disease. The primary endpoint was a composite of safety parameters (including major adverse cardiac events [MACE], cardiac death, and myocardial infarction) and efficacy (parameters concerned to quantitative coronary angiogram). An intention-to-treat analysis was performed at 9 and 18-month follow-ups.

Results: The baseline characteristics were similar for both EES and SES groups. At the 9-month follow-up, MACE occurred in 5.86% and 2.43% of patients in the EES and SES groups, respectively. At the 18-month follow-up, this differential remained almost the same (i.e., 5.17 % of patients treated with the EES versus 2.14% treated with the SES). The rate of definite stent thrombosis at 9-month follow-up was lower in the SES group (11 patients [1.24%]) compared to the EES group (9 patients [3.10%]). At 18-month follow-up, the rate was 2.14% (19 patients) in the SES group and 4.13% (12 patients) in the EES group. When censoring the patients at the time of stent thrombosis, no significant differences between the two stent groups were found.

Conclusion: In this real-world trial, at 9 and 18-month follow-ups, SES (M'Sure-S) exhibited a better safety and efficacy profile when compared to EES in terms of MACE rates and definite stent