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CLINICAL AND ANGIOGRAPHIC OUTCOMES OF BIODEGRADABLE POLYMER BIOLIMUS-ELUTING STENTS VERSUS DURABLE POLYMER ZOTALOLIMUS-ELUTING STENTS WITH 6 MONTHS DUAL ANTIPLATELET THERAPY; ASSOCIATED WITH OPTICAL COHERENCE TOMOGRAPHY SUBSTUDY

Oral Contributions
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Background: While second generation drug-eluting stents promote more favorable vascular healing, biodegradable polymer containing stents might have a yield in terms of duration of dual antiplatelet therapy (DAPT) than durable polymer stents. We aimed to test whether biolimus-eluting stent (BES) with 6-month DAPT would be non-inferior 12-month clinical and angiographic outcome to Zotarolimus-eluting stent (ZES) with 6-month DAPT.

Methods: This is a prospective, randomized, open-label, multicenter trial to compare clinical events and angiographic data between BES and ZES stents. Currently, 621 patients were randomly assigned. The primary end point was a major adverse cardiac events (MACE) at 12 months. Optical coherence tomography (OCT) at 6 month was performed in 30 patients of each group. The primary endpoint was MACE, secondary end points are target lesion failure, in-segment late loss (LL) at 12 months, and neointimal hyperplasia (NIH) and uncovered stent strut (USS) by OCT at 6month.

Results: Currently, clinical follow-up was available in 325 patients and angiographic follow-up in 311 patients. The primary endpoints were not statistically different between the BES and ZES, including MACE (5.5 vs. 6.4%; p =0.76) and stent thrombosis (0.3 vs. 0.3%; p = 0.99). The secondary endpoints also were not significantly different between BES and ZES, including target lesion failure (2.0 vs. 1.6%; p = 0.53), in-segment LL (mm) at 12 months (0.09±0.37 vs. 0.05±0.39, p =0.61). OCT at 6 month revealed that mean NIH thickness (μm) of BES and ZES were 59.1±30.3, 54.0±25.6, respectively (p=0.49), and USS percentage (%) of BES and ZES were 20.5±21.8, 17.7±22.4, respectively (p=0.63).

Conclusions: BES with biodegradable polymer with 6 month DAPT did not increase the risk of MACE, stent thrombosis, target lesion failure, and LL at 12 months comparing with ZES with durable polymer. The 2nd generation DES including BES and ZES are comparably efficacious. Our results need to be confirmed in larger trials, and further follow up data.