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COMPARATIVE ANTIRESTENOTIC EFFICACY OF BIODEGRADABLE POLYMER AND PERMANENT POLYMER DRUG-ELUTING STENTS: THE ANGIOGRAPHIC FOLLOW-UP RESULTS OF THE ISAR-TEST-4 RANDOMIZED TRIAL

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Background: We previously demonstrated that a biodegradable polymer drug-eluting stent (DES) was non-inferior to permanent polymer DES in the ISAR-TEST-4 randomized trial, a study powered for clinical endpoints. In the current analysis we compare the antirestenotic efficacy of these stents at 6-8-month angiographic follow up.

Methods: Patients with de novo coronary lesions in native vessels were randomly assigned to receive a biodegradable polymer (BP) sirolimuseluting stent or a permanent polymer (PP) sirolimus/everolimus eluting stent. In this analysis we focused on 2 major angiographic enpoints of interest: in-stent late lumen loss and in-segment binary restenosis at 6-8- month follow-up angiogram.

Results: Of a total of 2603 patients (3372 lesions): 1299 patients (1683 lesions) received BP stents, 1304 patients (1689 lesions) were treated with PP stents. Repeat angiography was available for 2637 lesions (78.2%). Mean late lumen loss was 0.24 ± 0.54 mm in the BP stent group, 0.26 ± 0.57 mm in the PP group (p=0.49). In-segment binary restenosis occurred in 153 lesions (11.6%) in the BP group and 155 lesions (11.8%) in the PP Group (p=0.85). The BP stent group showed similar rates of target vessel revascularization 170 (13.7%) in the BP and 172 (13.9%) in the PP Group, (p= 0.83).

Conclusions: This analysis showes that the antirestenotic performance of the BP stent is compareable to that of the PP stent.

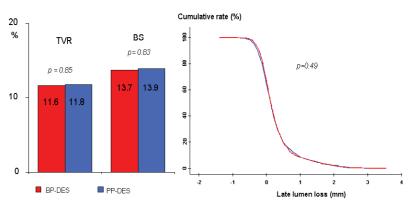


Figure 1: Target vessel revascularization (TVR) at 1 year and in segment binary restenosis (BS) at 6-8 month followup angiogram

Figure 2: Cumulative rate of late lumen loss at 6-8 month follow-up angiogram