Comparison of 1-year clinical outcomes of treatment of instent restenosis with Cypher or Taxus stents or Dior paclitaxel-eluting balloon

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Objectives. Implantation of drug-eluting stents (DES) for in-stent restenosis (ISR) is a promising treatment option, even if it may amplify the restenosis rate of the overlaying stents and the occurrence of late stent thrombosis. Drug-eluting balloon (DEB) can be attractive treatment mode for coronary ISR avoiding the limitations of the stent-in stent. The aim of this 3-center prospective Registry of Treatment of Instent Restenosis with DES or DEB was to compare the 1-year clinical outcomes of Cypher or Taxus stent implantation or balloon dilatation with Dior paclitaxel-eluting balloon in "real-world" practice.

Methods. Consecutive patients with significant ISR were treated by implantation of either Cypher (group ISR-Cypher, n=80, 73% male, mean age 64±12 years) or Taxus stent (group ISR-Taxus, n=80, 79% male, 63±11 y) or dilatation with Dior balloon (group ISR-Dior, n=60, 78% male, 60±13 y). All patients were clinically controlled 240±81 days after stent implantation. Non-fatal myocardial infarction, cerebral insult, cardiac death and target vessel revascularization (TVR) were considered as major adverse cardiac and cerebral events (MACCE).

Results. No significant differences were found between the groups as regards the baseline clinical (including age, gender, coronary risk factors) and qualitative angiographic parameters. The implanted stent or Dior balloon size and the applied balloon pressure were similar in the groups. The balloon inflation time was significantly longer after Dior balloon use. Significantly more bare metal stents (BMS) were treated with DES, while DES-in-stent restenosis was treated rather with Dior balloon (p<0.05). ISR of the left anterior descending coronary artery (LAD) was treated with Cypher stent in 44% of cases (p<0.05). No intervention complication or short-term (within 30 days after stenting) MACCE occurred. During the 1-year FUP, 2 patients died in the ISR-Taxus group, while late thrombosis occurred in 1 patient in both DES groups. TVR was performed in 15.6% in Dior group vs 16.3 % of patients

in ISR-Taxus and 8.8% in the Cypher groups. Stroke occurred in 1 patient in Taxus group (1.3%). The composite 1-year MACCE was 15.6%, 10% and 20% in groups Dior, ISR-Cypher and ISR-Taxus (p=0.202). Multivariate Cox regression revealed treatment of bypass vessel in-stent restenosis with either DES or DEB as a significant predictor for restenosis (p<0.05).

Conclusions. This study highlights the successful treatment of ISR with DES and DEB. Use of Dior balloon for ISR might be as effective as DES in prevention of clinical events in patients with recurrent in-stent restenosis.

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