THE FAVORABLE LONG TERM CLINICAL OUTCOMES OF A HIGH-DOSE DEXAMETHASONE-ELUTING STENT: RANDOMIZED CONTROLLED PROSPECTIVE STUDY

i2 Poster Contributions
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Background: Previous studies with dexamethasone-eluting stents showed the role of dexamethasone in the prevention of neo-intimal hyperplasia and anti-inflammatory effect. This study was designed to assess the long term clinical outcomes of dexamethasone-eluting stents, comparing them with unloaded stents of an identical design.

Methods: This was a prospective, randomized, controlled study, a total of 92 patients (98 lesions) were randomly assigned to the dexamethasone group (67 patients, 71 lesions) or control group (unloaded stents of an identical stent design, 25 patients, 27 lesions). The inclusion criteria for a stent implantation were a de novo lesion with a diameter of 2.60 to 4.0 mm. BiodivYsio Drug Delivery phosphorylcholine-coated stents (Biocompatibles Ltd, Galway, Ireland) were immersed in a 20-mg/mL dexamethasone solution, yielding a total dexamethasone dose of 0.5 ug/mm² per stent. The major adverse cardiac events were a composite of the death, nonfatal Q-wave or non-Q-wave myocardial infarction (MI), and need for target lesion revascularization (TLR).

Results: The binary restenosis rate at 6 months was 11.9% (7/59) in the dexamethasone group and 42.9% (9/21) in the control group (P = 0.002). The total major adverse cardiac events rate at 12 months was significantly lower in the dexamethasone group, as compared with the control group (10.4% [7 (1 MI, 6 TLR)/67] vs 28.0% [7 (7 TLR)/25], P = 0.037). A total of 57 (80.3%) patients in the dexamethasone group and 22 (81.5%) patients in control group could follow up at five years, and the total major adverse cardiac events rate at 5 years was also significantly lower in the dexamethasone group, as compared with the control group (15.8% [9 (1 non-cardiac death, 1 MI, 6 TLR)/57] vs 36.4% [8 (8 TLR)/22], P = 0.046).

Conclusions: This is the first prospective analysis of the long term clinical outcome of Dexamethasone-eluting stents. Our results demonstrate sustained favorable beneficial clinical effects of dexamethasone eluting stent over 5 years as compared with control group.