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One Year Follow-Up of TAXUS-I: A Randomized Study with the Paclitaxel-Eluting NIR Conformer Stent

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The TAXUS-Stent carries 85 micro g paclitaxel on the 16 mm NIR-Conformer stent with a dose density of 1 micro g/mm² in slow release form. Approx. 80% of the drug is released within the first 1-3 days. The purpose of the TAXUS I study was to evaluate the safety and performance of the NIRx, a NIR-Conformer coronary stent coated with paclitaxel incorporated in a polymer carrier matrix. Sixty-one patients with de-novo coronary lesion (=12 mm length, 3.0 mm and = 3.5mm reference diameter, 50 and = 99% diameter stenosis) were randomized. MACE was determined at 30 days, 6 month and at one year. Angiographic and IVUS evaluations were pre, post and 6 month after PCI. Both groups were comparable regarding baseline demographics. Reference vessel diameter in the groups was 2.99 +/- 0.46 vs. 2.94 +/- 0.52, lesion length 10.7 +/- 3.3 vs. 11.89 +/- 4.9 and minimum lumen diameter (MLD) 1.3 +/- 0.43 vs. 1.23 +/- 0.43. Results: At 30 days, MACE was 0 in either group. At 6 month, cumulative MACE was 0% in the drug-eluting group and 7% in the control group. These 7% were all TVR with 0% death, MI or thrombosis. Binary restenosis was 0% in the drug-eluting group and 10% in the control group. The paclitaxel-eluting stent significantly increased MLD by 19% with a 51% reduction in diameter stenosis and late lumen loss was significantly reduced by 49% with a late loss index reduction of 51%. No significant differences in proximal or distal edges between the NIR and NIRx was detectable. IVUS revealed a significant reduction of neointimal volume index of 32%. At 1 year, cumulative MACE was 3.3% in the drug-eluting group and 10.3% in the control group. Whereas all MACE in the control group was TLR, the TLR in the drug-eluting group was 0. The only TVR in the paclitaxel group was a new lesion far distal from the stent in the RCA. There was no death, MI or stent thrombosis in either group after 12 month. Conclusion: The paclitaxel-eluting NIR stent is safe with no stents thrombosis even after 12 month. Like in RAVEL, in TAXUS-I the angiographic in-stent restenosis rate after 6 month is 0 and there is no evidence of an edge effect. Also like in RAVEL, the clinical in-stent restenosis rate after one year is 0.