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Introduction: The optimal treatment strategy for coronary in-stent restenosis (ISR) is unclear. Drug-eluting balloons (DEB) offer an alternative to drug-eluting stents (DES) by avoiding risks of stent thrombosis, and by lowering the risks of restenosis associated with standard balloon angioplasty and bare-metal stents. The objectives were to compare clinical outcomes of DEB versus second-generation DES for the treatment of ISR. The hypothesis was that DEB and DES would provide similar outcomes.

Methods: From December 2009 to November 2012, 102 coronary ISR were treated with a paclitaxel-eluting balloon in all-comer patients in a Canadian tertiary center. The comparator group consisted of a random sample of 100 patients with ISR treated with a second-generation DES during the same time period. Data was collected from medical files and telephone interviews. Median follow-up was 15 months (interquartile range: 4 to 21 months) (229 patient-years). Baseline characteristics were similar between both groups (mean age: 65±11 [p=0.91]; 28% women [p=0.69]). Diabetes was present in 45% of patients (p=0.79). Indication for revascularization was non-ST-elevation acute coronary syndrome in 72% of cases (p=0.37).

Results: At follow-up, the composite outcome of MACE (death from any cause, non-fatal myocardial infarction [MI], or target-lesion revascularisation [TLR]) occurred in 26% of patients in the DEB group, compared to 24% in the DES group (p=0.80). Freedom from MACE was similar between both groups after adjustment for confounding factors. Two in-hospital deaths occurred in each group. One-year actuarial survival was 89±4% in the DEB group, and 96±2% in the DES group (p logrank=0.07). Non-fatal MI occurred in 8 cases (9%) in the DEB group and in 10 cases (13%) in the DES group (p=0.43). TLR occurred in 7 cases (8%) in the DEB group, and in 10 cases (13%) in the DES group (p=0.26). Lesion restenosis ≥50% occurred in 10 (12%) patients in each group. One lesion thrombosis occurred in each group. Compared to diffuse, proliferative or occlusive lesions, a focal ISR was a protective factor against death (OR=0.2 [95%CI: 0.1-0.7]; p=0.01), and TLR (OR=0.3 [95%CI: 0.1-0.9] p=0.04), but not against MACE (p=0.29), MI (p=0.95), or ≥50% restenosis (p=0.19). DEB/DES length was associated with MACE (OR=1.0 [95%CI: 0.9-1.0]; p=0.03), and death (OR=0.9 [95%CI: 0.8-1.0]; p=0.001), but not with TLR (p=0.86), MI (p=0.85), and ≥50% restenosis (p=0.36). DEB/DES diameter was not associated with MACE, death, MI, TLR, and ≥50% restenosis (p>0.05 each). Chronic kidney disease was the only independent clinical or angiographic risk factor identified upon multivariate logistic regression for MACE (OR=2.4 [95%CI: 1.0-5.3]; p=0.04), and death (OR=6.8 [95%CI: 2.1-21.3]; p=0.001).

Discussion: DEB appears as a safe and effective treatment for ISR as compared to second-generation DES. Our data suggest that clinical outcomes following revascularization with both devices are similar. Long-term clinical outcomes following ISR treatment with a DEB compared to second-generation DES remain to be prospectively studied.

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No conflict of interest