ISAR-PEBIS (Paclitaxel-Eluting Balloon Versus Conventional Balloon Angioplasty for In-Stent Restenosis of Superficial Femoral Artery): A Randomized Trial.

Abstract:
Paclitaxel-eluting balloon (PEB) angioplasty has superior efficacy compared with conventional balloon angioplasty (BA) for de novo lesions of superficial femoral artery (SFA). Studies investigating the angiographic and clinical performance of PEB angioplasty versus BA for in-stent restenosis of SFA are limited. We performed a randomized trial to investigate angiographic and clinical performance of PEB versus BA for in-stent restenosis of SFA. Patients with symptomatic in-stent restenosis of SFA were randomly assigned to either PEB or BA at 2 centers in Munich, Germany. The primary end point was the percentage diameter stenosis at 6- to 8-month follow-up angiography. Secondary end points were the rate of binary restenosis at follow-up angiography and target lesion revascularization, target vessel thrombosis, ipsilateral amputation, bypass surgery of the affected limb, and all-cause mortality at 24-month follow-up. Seventy patients were assigned to PEB (n=36) or BA (n=34). Mean lesion length was 139±67 mm, and roughly one third of lesions were completely occluded at the time of the index procedure. At control angiography, the percentage diameter...
stenosis (44±33% versus 65±33%, =0.01) and binary restenosis were significantly reduced with PEB versus BA (30% versus 59%, =0.03). At 24-month follow-up, PEB was associated with a significant reduction of target lesion revascularization in comparison to BA (19% versus 50%, =0.007). There was no difference with respect to other outcomes of interest. In patients with in-stent restenosis of SFA, a percutaneous therapy with PEB compared with BA has superior angiographic performance at 6 to 8 months and improved clinical efficacy up to 24-month follow-up. URL: http://www.clinicaltrials.gov. Unique identifier: NCT01083394.