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The IN.PACT Global Study is the largest prospective, multicenter, independently adjudicated trial of a paclitaxel drug-coated balloon for atherosclerotic femoropopliteal lesions. A total of 1,406 subjects (1,773 lesions) were included in the pre-defined clinical cohort analysis. Mean lesion length was 12.1 cm, 35.5% were total occlusions, and 18.0% had in-stent restenosis. Two-year freedom from clinically driven target lesion revascularization was 83.3%, the composite safety endpoint was met in 81.7%, the 2-year all-cause mortality rate was 7.0%, and the major target limb amputation rate was 0.7%. Increased lesion length and the presence of de novo in-stent restenosis or coronary artery disease were associated with increased risk for clinically driven target lesion revascularization by 24 months.

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The safety and effectiveness of a new-generation fluoropolymer-based paclitaxel-eluting stent, which enables controlled and sustained paclitaxel delivery, were assessed in patients with long (20 ± 12 cm) and complex (79% chronic total occlusions) femoropopliteal lesions. Primary patency and freedom from target lesion revascularization were 87% at 1 year. Amputation-free survival was 100% for patients with claudication and 87% in patients with critical limb ischemia (p = 0.052). Five patients (8%) developed local aneurysmal degenerations along the implanted stents. In conclusion, the second-generation fluoropolymer-based paclitaxel-eluting stent showed encouraging results in a real-world cohort, while the long-term impact of aneurysm formation remains to be further assessed.