Paclitaxel-coated versus plain old balloon angioplasty for the treatment of infrainguinal arterial disease in diabetic patients: The Belgian diabetic IN.PACT trial

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Background: Several trials have shown that drug coated balloon (DCB) angioplasty reduce the rates of restenosis in the femoropopliteal artery. This controlled, prospective, multicenter study was designed to demonstrate the efficacy of DCB to inhibit restenosis of the infrainguinal arteries in an exclusive diabetic population.

Methods: Between 2012 and 2014, 106 diabetic patients with symptomatic peripheral arterial disease (PAD) were enrolled at 11 sites in Belgium, 54 treated with DCB angioplasty and 52 treated with plain old balloon angioplasty (POBA). The primary endpoint of the study is the primary patency, mean diameter restenosis and binary restenosis of the treated sites at 6 months without re-intervention in the interim.

Results: The 6-month mean diameter restenosis was significantly lower in the DCB arm than in the POBA group (29±36% vs. 46±35%, P=0.032) and the binary (≥50% diameter stenosis) restenosis rate was signicantly lower in DCB patients compared with the POBA's (27% vs. 49%, P=0.03). The primary patency was significantly better in the paclitaxel coated balloon group (73% vs. 51%, P=0.03). The 6-month adverse effects rates were 5.5% in the POBA and 5.7% in the DCB arm.

Conclusions: The treatment of diabetic PAD of the infra-inguinal arteries with the DCB provides a better primary patency rate compared with the plain old balloon angioplasty. The use of DCB did not increase the number of major adverse clinical events when compared with those seen with the use of the uncoated balloons.

Speaker Biography

Dr. Laura Kerselaers is a vascular and endovascular surgeon who works at the vascular department of University Hospital of Brussels (UZB), Belgium. Her clinical interest is in critical limb ischemia, aortic repair, lower extremity occlusive disease, carotid disease and varicose veins. Dr. Kerselaers obtained her medical degree at the University of Louvain (KUL) and completed training in general and vascular surgery at ZOL Genk, Imelda hospital Bonheiden and ETZ Tilburg. Later she completed fellowship training in vascular and endovascular surgery at the University Hospital of Louvain (UZL) and ZOL Genk. After completing this training, she joined the University Hospital of Brussels (UZB) as a staff vascular and endovascular surgeon in 2016.

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