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Paclitaxel-coated balloons versus percutaneous transluminal angioplasty for infrapopliteal chronic total occlusions: the IN.PACT BTK randomised trial

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KEYWORDS

- below the knee disease
- chronic limb-threatening ischaemia
- drug-coated balloon
- total occlusion

Abstract

Background: Data are mixed concerning the safety and effectiveness of drug-coated balloons (DCBs) for treating below-the-knee (BTK) lesions.

Aims: The aim of this study was to assess the safety and effectiveness of the IN.PACT 014 paclitaxel-coated balloon catheter versus conventional percutaneous transluminal angioplasty (PTA) for infrapopliteal chronic total occlusions (CTOs) in patients with chronic limb-threatening ischaemia (CLTI).

Methods: The IN.PACT BTK randomised study is a prospective, multicentre, randomised pilot study. Fifty CLTI participants (Rutherford clinical category 4-5) with BTK CTOs were randomised 1:1 to DCB (N=23) or PTA (N=27). The primary effectiveness endpoint was late lumen loss (LLL) at 9 months post procedure. Safety outcomes up to 9 months included all-cause mortality, major target limb amputation, and clinically driven target lesion revascularisation (CD-TLR).

Results: Mean lesion length was 215.41±83.81 mm in the DCB group and 218.19±80.43 mm for PTA (p=0.806). The 9-month angiographic LLL was 0.892±0.774 mm for the DCB group and 1.312±0.720 mm for the PTA group (p=0.070) in a classic analysis, and 0.592±0.944 mm for DCB and 1.260±0.810 mm for PTA (p=0.017) in a subsegmental analysis. The Kaplan-Meier estimated freedom from CD-TLR up to 9 months was 91.1% for DCB and 91.8% for PTA (log-rank p=0.942). At 9 months, 1 patient died in the DCB group and 2 in the PTA group (p=1.000); there were no major target limb amputations in either arm.

Conclusions: The 9-month subsegmental LLL was lower after treatment with the IN.PACT 014 DCB compared with PTA with no differences in safety or revascularisation events in a small complex population of patients with BTK CTOs. ClinicalTrials.gov Identifier: NCT02963649. https://clinicaltrials.gov/ct2/show/NCT02963649

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