10025

Mid-term Outcomes of Peripheral Drug-Coated Balloon in High-Risk Patients with Femoropopliteal Disease

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Purpose: To investigate the mid-term clinical outcomes of peripheral drug-coated balloon (DCB) in femoropopliteal (FP) segments based on FeDCLIP (female, diabetes, dialysis, critical limb ischemia, lesion length >150 mm and poor runoff) score. Method This retrospective study analyzed 95 patients (41% dialysis) and 110 affected legs undergoing DCB for symptomatic FP disease from March 2013 to December 2014. The primary outcome was 2-year primary patency (PP), whereas secondary outcomes were 2-year overall survival and freedom from clinically driven target lesion revascularization (CD-TLR) rates among different risk groupsResultsThe completion rate of 2-year follow-up was 83% with a mean follow-up time of 750±238 (152-1190) days. The mean lesion and DCB lengths was 208±107 mm and 233±119 mm, respectively. The PP and CD-TLR-free rates at 2 years was 60.4% and 67.3% for all participants. The 2-year survival rate was similar in low-, moderate- and high-risk groups (80%, 91%, and 75%, p= 0.160). The 2-year PP and CD-TLR-free rates were significantly better in low-risk groups as compared to high-risk groups (85% vs. 52%, p=0.042 and 91% vs. 56%, p=0.035, respectively). After multivariate analysis, lesion length >150 mm (Hazard ratio [HR]: 2.95, p=0.002) and Rutherford class 6 (HR: 1.95, p=0.043) remained as independent predictors of binary restenosis. Conclusions:The anti-restenotic effect of DCB in low-risk groups can be maintained up to two years, however, the efficacy of DCB in higher-risk groups was gradually lost during the follow-up. Further studies are required to confirm this observation.