Clinical Outcomes of Drug-Eluting Balloon in Real-world Practice of Femoropopliteal Intervention

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Purpose: The aim of this study is to evaluate the efficacy of peripheral drug eluting balloon (DEB) in real-world femoropopliteal (FP) intervention

Methods: From March 2013 to April 2014, a total of 48 patients, 55 limbs with 104 symptomatic FP lesions underwent peripheral DEB. The efficacy and clinical outcomes were analyzed.

Results: The mean age of study population was 72±10 years. Of 55 treated limbs, 74% critical limb ischemia and 50% restenotic lesions were noted. The procedure success rate was 100% and adjuvant atherectomy (3 Turbohawk, 2 Lasers and 1 Rotablator) were used. The mean lesion length and the length treated by DEB were 18.2±11.4 and 21.0±11.9 cm, respectively. The numbers of DEB per leg was 1.9 and the stent crossover rate was 31% (25/80, mean length 10.5±5.7 cm). The rate of major adverse event at 30 day was 2.1%. During the mean follow-up 267±117 days (45-542), 3 patients died and 1 required major amputation. The rates of binary restenosis and target lesion revascularization (TLR) at 12 months was 11.8% and 5.9%. In addition, there is no statistical difference regarding the rates of binary restenosis and TLR for Denovo, restenotic or in-stent lesion at 12 months (p=0.78)

Conclusion: DEB is feasible and effective in the real-world FP intervention. It reduce the need of long stent implantation and improve the vessel patency in this short-term observation.