

WORLD HEART CONGRESS

May 22- 24, 2017 Osaka, Japan

36 months outcome of drug-eluting balloon angioplasty in the femoropopliteal and infrapopliteal arteries

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Drug-eluting balloons (DEBs), which allow the homogeneous delivery of an anti-proliferative drug (e.g., paclitaxel) to the arterial vessel wall without leaving residual prosthetic material, have become an effective strategy for treating lesions of the femoropopliteal arteries. In contrast, the outcomes of medical therapy in below-the-knee (BTK) region are often unsatisfactory, and early, aggressive percutaneous revascularization with the aim of ensuring direct flow to the foot is increasingly considered a first-line strategy. On the basis of this background, we designed a prospective study to evaluate the performance and outcomes of DEB therapy for infrapopliteal atherosclerotic disease, using the primary patency rate at 12, 24 and 36 months. Patients with infrapopliteal PAD were enrolled in this independent, non-industry-supported, prospective study. From August 2010 to December 2013, 307 arteries of 123 patients were revascularized. The patients' demographic characteristics (e.g., age, sex, ankle-brachial index [ABI], Rutherford class, hyperlipidemia, hypertension, coronary artery disease, smoking, diabetes, and calcification) were documented. The ABI after 36 months was significantly higher than the baseline ABI ($p < 0.001$), and the Rutherford classification after 36 months was significantly lower than the baseline Rutherford classification ($p < 0.001$; Table). The median baseline Rutherford classification was 4 (3.0-4.0). Both Rutherford reduction and ABI improvement were statistically significant ($p < 0.001$). ABI improvement was 59.3% (38 of 64) at 36 months ($p = 0.032$). Limb salvage was achieved in 73.6% (28 of 38) of the critical limb ischemia (CLI) patients and complete wound healing occurred in 67.8% (19 of 28) of patients with Rutherford category 5. Given the unavoidable disease progression within and outside the treated arterial lesion, DEBs represent an attractive alternative without limiting future treatment options, in comparison to first-line revascularization strategies.

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