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1-Year All-Comers Analysis of the Eluvia Drug-Eluting Stent for Long Femoropopliteal Lesions After Suboptimal Angioplasty

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ABSTRACT

OBJECTIVES The aim of this study was to assess the performance of the fluoropolymer-based paclitaxel-eluting stent (PES) in long femoropopliteal lesions.

BACKGROUND The new-generation fluoropolymer-based PES showed promising outcomes in short femoropopliteal lesions. The main feature of the stent is its controlled and sustained paclitaxel release over 12 months. However, the safety and efficacy of this technology in longer femoropopliteal lesions remain unclear.

METHODS Between March 2016 and March 2017, 62 patients were included in this analysis. Indications for fluoropolymer-based PES deployment were insufficient luminal gain or flow-limiting dissection after plain old balloon angioplasty in a femoropopliteal lesion. Primary patency, freedom from target lesion revascularization, amputation-free survival, and paclitaxel-related adverse events were retrospectively analyzed for up to 1 year of follow-up.

RESULTS Lesions were de novo in 84% of patients. Mean lesion length was 20 ± 12 cm, and 79% of the lesions (n = 49) were chronic total occlusions. Moderate or severe calcification was present in 42% of the lesions (n = 26). Stent implantation involved the distal superficial femoral artery and the proximal popliteal artery in 76% (n = 47) and 44% (n = 27) of patients, respectively. The Kaplan-Meier estimate of primary patency and freedom from target lesion revascularization was 87%. Amputation-free survival was 100% for patients with claudication (n = 32 [52%]) and 87% in patients with critical limb ischemia (n = 30 [48%]) (hazard ratio: 6.3; 95% confidence interval: 1.25 to 31.54; p = 0.052). Five aneurysm formations of the treated segments (8%) were thought to be attributable to paclitaxel.

CONCLUSIONS The fluoropolymer-based PES showed promising 1-year clinical and angiographic outcomes in real-world long femoropopliteal lesions. The long-term impact of aneurysm formation remains to be further investigated. (J Am Coll Cardiol Intv 2018;11:957–66) © 2018 by the American College of Cardiology Foundation.

The technical success and durability of the endovascular therapy in patients with atherosclerotic arterial disease are dependent on acute luminal gain and freedom from restenosis in the long run, respectively. The use of bare-metal stents as permanent scaffolds leads to excellent acute luminal gain, but it is associated with a high rate of restenosis (1,2). Although the use of drug-coated balloons (DCBs) has been suggested as an attractive alternative for short lesions (3), the high bailout stenting rate observed in the all-comers DCB registries and the inferior results of DCBs in long and calcified lesions limit the performance of "leave nothing behind" strategies (4–6). Vessel preparation prior to paclitaxel delivery in the vessel wall might improve the outcomes of paclitaxel-based angioplasty, but the lack of reimbursement, the increased need for repeated angiography and

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ABBREVIATIONS AND ACRONYMS

CLTI = critical limb-threatening ischemia

DCB = drug-coated balloon

PES = paclitaxel-eluting stent(s)

POBA = plain old balloon angioplasty

SFA = superficial femoral artery

TLR = target lesion revascularization

consequently contrast medium, the higher radiation exposure, and the lack of randomized controlled trials proving a clear benefit still limit its applicability (7–9).

In contrast, paclitaxel-eluting stents (PES) combine the acute luminal gain of the permanent scaffolding and the antirestenotic effect of the antiproliferative agent. The first generation of polymer-free PES showed excellent and durable (up to 5 years) efficacy in short superficial femoral artery (SFA) lesions compared with plain old balloon angioplasty (POBA) and bare-metal stents (10). However, the outcomes of polymer-free PES in longer femoropopliteal lesions did not always confirm the initial enthusiasm (11–13). Toward the concept of a polymer-free stent coating, a new generation of fluoropolymer-based PES (Eluvia, Boston Scientific, Marlborough, Massachusetts) was developed to preclude the biology of in-stent restenosis in the SFA by allowing the sustained and controlled release of paclitaxel over the first 12 months after stent implantation (14).

SEE PAGE 967

At present, the performance of the Eluvia drug-eluting stent is not well investigated. Only 1 prospective, core laboratory–adjudicated single-arm study including 57 patients assessed the safety and efficacy of the new stent platform in short lesions (71 ± 28 mm) (15). Although freedom from target lesion revascularization (TLR) was high, the patency rate in this small study cohort amounted to 91% and 82% at 1 and 2 years, respectively (15). Several prospective ongoing randomized controlled trials are now assessing the effectiveness of the device in different scenarios but still in short lesions. The REGAL (Real World Evaluation of the Eluvia Stent in Subjects With Lesions Located in the Femoropopliteal Arteries) registry will assess the performance of the device in all comers and more complex femoropopliteal lesions, but the results will not be available until 2020. Therefore, the aim of our study was to assess for the first time the safety and efficacy of fluoropolymer-based PES in a real-world study cohort of patients with long and complex femoropopliteal lesions after suboptimal POBA.

METHODS

This was a single-center, retrospective analysis of prospectively collected data, performed in line with the requirements of the local ethics committee and adhering to the Declaration of Helsinki. All patients provided informed consent prior to the intervention. The study was performed without financial support from industry.

Between March 2016 (when the stent became commercially available) and March 2017, the clinical records of all patients who underwent endovascular treatment of a femoropopliteal lesion with the Eluvia drug-eluting stent were included in this study. The main criterion for stent implantation was any recoil or flow-limiting dissection after POBA. Patients with in-stent restenosis, concomitant common femoral artery stenosis, or stenosis of a bypass anastomosis were not treated with PES. Patients with additional interventions due to iliac or infrapopliteal occlusive disease were not excluded from our analysis. In case of recoil after DCB angioplasty, PES deployment was principally not performed.

All patients underwent a thorough clinical examination at baseline. Patient demographics and comorbidities as well as imaging and clinical data were prospectively collected and retrospectively analyzed. Follow-up examinations were scheduled at 6 and 12 months after the initial procedure. The patency of the treated vessels was assessed using duplex ultrasound at each follow-up visit. In cases of clinical worsening, angiography was performed. At 6 months, radiographic control of stent integrity was performed.

Dual-antiplatelet therapy with aspirin (100 mg/day) and clopidogrel (75 mg/day) was routinely prescribed for 3 months, followed by lifelong aspirin or clopidogrel monotherapy. Patients previously taking warfarin or oral anticoagulant agents were maintained on the anticoagulant agents with additional clopidogrel therapy for 3 months after the procedure. Patient with aspirin allergy received lifelong clopidogrel.

INSTITUTIONAL PROTOCOL. Vessel preparation was performed using a standard uncoated balloon catheter inflated to a diameter of 1 mm less than the reference vessel diameter. The inflation time is standardized at our institution (60 s). In cases of a flow-limiting dissection or residual stenosis >50%, repeated prolonged (>2 min) balloon inflation with an uncoated balloon was applied. In case of persistent suboptimal angiographic outcomes, adjunctive implantation of the Eluvia stent was performed from healthy to healthy vessel. The maximum overlap between 2 stents was 1 cm. The stent was dilated after deployment using a standard uncoated balloon catheter to achieve its reference diameter. In case further interventions for other lesions were necessary, these were treated upon the discretion of the treating physician.