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INSIDE THIS ISSUE

FOCUS ON DRUG DELIVERY IN PERIPHERAL AND CORONARY INTERVENTIONS

Adventitial Drug Delivery of Dexamethasone to Improve Primary Patency in the Treatment of Superficial Femoral and Popliteal Artery Disease: 12-Month Results From the DANCE Clinical Trial

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Mahmood K. Razavi, Dennis Donohoe, Ralph B. D'Agostino, Jr., Michael R. Jaff,
George Adams, on behalf of the DANCE Investigators

A complex cascade of events leads to neointimal hyperplasia and loss of patency after peripheral artery disease interventions. Although the use of drug-coated balloons (DCB) and drug-eluting stents has been associated with improved patency in femoropopliteal segments, they are limited by the type, number, and dose of therapeutic agents used. In the DANCE (Dexamethasone to the Adventitia to Enhance Clinical Efficacy After Femoropopliteal Revascularization) trial, a first-of-its-kind, prospective, multicenter trial, adventitial and perivascular delivery of dexamethasone has produced promising results suggesting upstream targeting of inflammation could reduce restenosis. Respective 12-month primary patency rates of 78.4% or 75.5% after atherectomy or percutaneous transluminal angioplasty (PTA) compare favorably to historical PTA performance and contemporary DCB performance.

■ EDITORIAL COMMENT

Needle-Delivered Drug Elution in Femoral Artery Disease

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Antonio Micari, Roberto Nerla

12-Month Results From the First-in-Human Randomized Study of the Ranger Paclitaxel-Coated Balloon for Femoropopliteal Treatment

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Sabine Steiner, Andrea Willfort-Ehringer, Horst Sievert, Volker Geist, Michael Lichtenberg,
Costantino Del Giudice, Antoine Sauguet, Juan Diaz-Cartelle, Claudia Marx, Armin Ströbel,
Ingolf Schult, Dierk Scheinert, on behalf of the RANGER SFA Investigators

The prospective, randomized RANGER SFA (Comparison of the Ranger™ Paclitaxel-Coated PTA Balloon Catheter and Uncoated PTA Balloons in Femoropopliteal Arteries) study enrolled 105 patients with symptomatic lower limb ischemia and stenotic lesions in the femoropopliteal segment at 10 European centers. The drug-coated balloon group ($n = 71$) had a greater primary patency rate at 12 months (Kaplan-Meier estimate 86.4% vs. 56.5%), with a significantly longer time to patency failure (log-rank $p < 0.001$). The estimated freedom from target lesion revascularization rate was 91.2% in the drug-coated balloon group and 69.9% in the control group at 12 months, with a significantly longer time to reintervention ($p = 0.010$). No target limb amputations or device-related deaths occurred in either group.



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■ EDITORIAL COMMENT

More Evidence and More Questions About Paclitaxel-Coated Balloons in the Femoropopliteal Segment

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Konstantinos Katsanos



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accompanied by videos. Please go to
www.jacc-interventions.org to view.



Drug-Coated Balloon Treatment of Femoropopliteal Lesions for Patients With Intermittent Claudication and Ischemic Rest Pain: 2-Year Results From the IN.PACT Global Study

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Antonio Micari, Marianne Brodmann, Koen Keirse, Patrick Peeters, Gunnar Tepe, Martin Frost, Hong Wang, Thomas Zeller, for the IN.PACT Global Study Investigators

The IN.PACT Global Study is the largest prospective, multicenter, independently adjudicated trial of a paclitaxel drug-coated balloon for atherosclerotic femoropopliteal lesions. A total of 1,406 subjects (1,773 lesions) were included in the pre-defined clinical cohort analysis. Mean lesion length was 12.1 cm, 35.5% were total occlusions, and 18.0% had in-stent restenosis. Two-year freedom from clinically driven target lesion revascularization was 83.3%, the composite safety endpoint was met in 81.7%, the 2-year all-cause mortality rate was 7.0%, and the major target limb amputation rate was 0.7%. Increased lesion length and the presence of de novo in-stent restenosis or coronary artery disease were associated with increased risk for clinically driven target lesion revascularization by 24 months.



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■ **EDITORIAL COMMENT**

2-Year Outcomes From the Largest Real-Life Global Registry Investigating Drug-Coated Balloon Angioplasty for Femoropopliteal Artery Disease: Time for a Treatment Shift Toward Drug Elution and Minimal Stenting?

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Stavros Spiliopoulos, Elias Brountzos

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

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Theodosios Bisdas, Efthymios Beropoulos, Angeliki Argyriou, Giovanni Torsello, Konstantinos Stavrulakis

The safety and effectiveness of a new-generation fluoropolymer-based paclitaxel-eluting stent, which enables controlled and sustained paclitaxel delivery, were assessed in patients with long (20 ± 12 cm) and complex (79% chronic total occlusions) femoropopliteal lesions. Primary patency and freedom from target lesion revascularization were 87% at 1 year. Amputation-free survival was 100% for patients with claudication and 87% in patients with critical limb ischemia ($p = 0.052$). Five patients (8%) developed local aneurysmal degenerations along the implanted stents. In conclusion, the second-generation fluoropolymer-based paclitaxel-eluting stent showed encouraging results in a real-world cohort, while the long-term impact of aneurysm formation remains to be further assessed.

■ **EDITORIAL COMMENT**

Paclitaxel-Eluting Stents and Aneurysm Formation, A Worrisome Association

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Bernardo Cortese

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