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Comparative Analysis of Drug-Coated Balloons

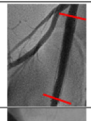
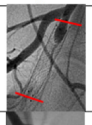
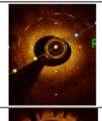
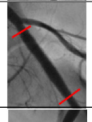
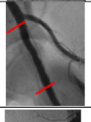
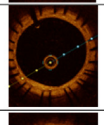
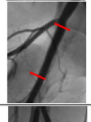
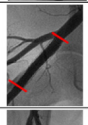
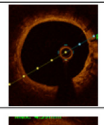
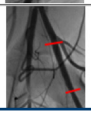
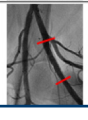
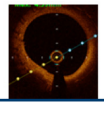
BY JUAN F. GRANADA, MD, FACC

Drug-coated balloons (DCBs) are rapidly becoming the leading strategy for the treatment of peripheral artery disease. Despite the fact that all clinically available DCB concepts are based on paclitaxel, important technological differences influence biological efficacy and clinical outcomes. Experimental validation of DCBs has been key to unveil the mechanism of action and efficacy and safety profiles of these technologies. Specifically, the impact of reduced-dose DCBs on biological efficacy and restenosis prevention is not fully understood. A comparative study of three clinically available DCBs (In.Pact Admiral [Medtronic], 3.5 µg/mm^2; Lutonix [Bard Peripheral Vascular, Inc.], 2 µg/mm^2; and Stellarex™ [Spectranetics Corporation], 2 µg/mm^2) versus percutaneous transluminal angioplasty (PTA) with the Armada PTA balloon (Abbott Vascular) was performed by the CRF Skirball Center for Innovation in a validated familial hypercholesterolemic swine model of in-stent stenosis to assess treatment efficacy at 28 days.[1] Two weeks after stent implantation, each in-stent stenotic lesion was randomly treated with a DCB or PTA. Quantitative vascular analysis (QVA) was performed on both the treatment day and at day 28 after treatment by blinded evaluators to the assigned treatment; optical coherence tomography (OCT) was performed on day 28 after treatment. The vessels treated with DCBs maintained a larger luminal diameter than the vessels treated with PTA (Table 1).

Comparing the percent stenosis on day 28 after treatment, all DCBs showed improvement over PTA; however, Stellarex had negligible luminal loss, similar to higher-dose DCB competitors, despite having a 43% lower drug dose. Variation in percent diameter stenosis was also lowest for the Stellarex DCB, as confirmed by the low standard deviation of ± 4% for Stellarex compared to a standard deviation of ± 17% for Lutonix.

This predictability in results may be due to the consistent integrity and durability of the Stellarex coating. This head-to-head comparison study, performed in a porcine lesion model, shows for the first time that the reduced-dose Stellarex balloon achieved a comparable biological efficacy to higher-dose DCB and has the potential to improve the safety profile of DCB technologies. ■

TABLE 1. VESSELS TREATED WITH DCBs VERSUS PTA AS ASSESSED BY QVA AND OCT

	Treatment	Termination	
		QVA	OCT
PTA n = 7			
Stellarex n = 8			
In.Pact Admiral n = 6			
Lutonix n = 7			

1. Granada JF, Milewski K, Zhao H, et al. Vascular response to zotarolimus-coated balloons in injured superficial femoral arteries of the familial hypercholesterolemic swine. Circ Cardiovasc Interv. 2011;4:447-455.

Juan F. Granada, MD, FACC
Executive Director and Chief Innovation Officer
Cardiovascular Research Foundation
Skirball Center for Innovation
Orangeburg, New York
jgranada@crf.org
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