Sponsored by Boston Scientific Corporation

The State of Peripheral Drug-Eluting Technologies

BY MICHAEL R. JAFF, DO

When comparing the myriad options available for the treatment of patients with peripheral artery disease (PAD) today compared to just 1 decade ago, it is a testimony to physicians who have advocated for their patients and to innovators dedicated to advancing the field. Although these technological advances provide hope for the rapidly expanding population of patients with claudication or critical limb ischemia,[1] the selection of optimal strategies by physicians has become challenging. With the publication of important comparative trials of one technology versus another, we are finally gaining prospective, multicenter, and, in some cases, randomized data to help us make better choices.

The major classes of endovascular technologies, including percutaneous transluminal angioplasty (PTA), bare-metal balloon-expandable and self-expanding stents, fabric-covered stents, and atherectomy (directional, rotational, and laser), have all demonstrated various degrees of efficacy and acceptable safety for patients. However, it has been the advent of drug-eluting technologies, including drug-eluting stents (DESs) and drug-coated balloons (DCBs), that has rapidly influenced the decisions of endovascular specialists.

DCBs have demonstrated significant improvements in primary patency and target lesion revascularization (TLR) rates when compared to uncoated PTA catheters in high-quality, multicenter, prospective randomized controlled trials.[2,3] In addition, recently published 5-year data comparing DESs to PTA or uncoated self-expanding stents have given specialists confidence in drug-eluting technology due to durable superiority in patency and TLR.[4]

There remains confusion, however, regarding the role of DESs versus DCBs in the management of PAD. Some advocate for initial therapy with a DCB, promoting the "leave nothing behind" concept and allowing for simpler revascularization options should restenosis occur. Others believe that for longer lesions or more complex, heavily calcified atherosclerotic plaques, DESs will offer superior primary patency. Until prospective randomized trials comparing these two classes of devices are reported, we are left with best efforts at clinical decision making for individual patients.

Scientists have studied mechanisms and dosing of drug-delivery in order to determine optimal device development. It does appear that strategies to prolong exposure of therapeutic antirestenosis drug levels may offer clinical advantages, at least in animal models.[5] These data may advance the development of next generations of drug-eluting technologies.

Although we are moving closer to understanding which device strategies to use in which patients, there remains a significant knowledge gap that, until closed, will promote expert opinions, consensus, and individual patient assessments for the selection of treatment strategies. There is no doubt that in addition to patency and TLR reduction data, cost effectiveness will play an impactful role in decision making at the provider and system levels. As the cost-effectiveness data arise, TLR appears as the major driver of added costs.[6] However, the ultimate algorithm for the treatment of PAD remains elusive.[7] ■

1. Fowkes FG, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet. 2013;382:1329–1340.
2. Tepe G, Laird J, Schneider P, et al; IN.PACT SFA Trial Investigators. Drug-coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and popliteal peripheral artery disease: 12-month results from the IN.PACT SFA randomized trial. Circulation. 2015;131:495–502.
3. Rosenfield K, Jaff MR, White CJ, et al; LEVANT 2 Investigators. Trial of a paclitaxel-coated balloon for femoropopliteal artery disease. N Engl J Med. 2015;373:145–153.
4. Dake MD, Ansel GM, Jaff MR, et al; Zilver PTX Investigators. Durable clinical effectiveness with paclitaxel-eluting stents in the femoropopliteal artery: 5-year results of the Zilver PTX randomized trial. Circulation. 2016;133:1472–1483.
5. Gasior P, Cheng Y, Valencia AF, et al. Impact of fluoropolymer-based paclitaxel delivery on neointimal proliferation and vascular healing. Circ Cardiovasc Interv. 2017;10:e004450.
6. Salisbury AC, Li H, Vilain KR, et al. Cost-effectiveness of endovascular femoropopliteal intervention using drug-coated balloons versus standard percutaneous transluminal angioplasty: results from the IN.PACT SFA II trial. JACC Cardiovasc Interv. 2016;9:2343–2352.
7. Jaff MR. What's a doctor to do? Balloons, stents, drugs, drills, and treadmills. Are we closer to the optimal algorithm? JACC Cardiovasc Interv. 2015;8:1113–1114.

Michael R. Jaff, DO
Professor of Medicine
Harvard Medical School
Boston, Massachusetts
docmrjaff@aol.com
Disclosures: Noncompensated advisor for Abbott Vascular, Boston Scientific Corporation, Cordis Corporation, and Medtronic; consultant to Vactronix Scientific, Micell Technologies, Inc., Philips Volcano, American Orthotic & Prosthetic Association; equity investor in PQ Bypass, Inc. and Vascular Therapies, Inc.; board member of VIVA Physicians, a 501(c)(3) not-for-profit education and research organization.