The DCB Technology Evolution

Future perspectives on DCB

BY JUAN F. GRANADA, MD, FACC

More than 10 years of progress in drug-coated balloon (DCB) research, development, and manufacturing have passed since the first paclitaxel-based DCB prototype was developed and tested.[1,2] During this decade, DCB design goals have been refined to match four clear targets: (1) limit drug dose, (2) minimize drug loss during balloon transit, (3) maximize drug transfer efficiency during inflation, and (4) maintain clinical efficacy over time.

Improving drug transfer efficiency so that more is delivered and less is lost builds upon the desire to have a reliably stable coating during all stages, from balloon preparation and handling to its final delivery to the target lesion. Ultimately, this improved efficiency is meant to secure sufficient and predictable drug levels to be transferred to the tissue wall and, just as important, to limit potential side effects related to drug distal embolization.

While the clinical relevance of distal embolization is still unclear, some concern exists about the potential for downstream effect of paclitaxel within specific clinical and anatomical situations. DCB use for the treatment of infrapopliteal arterial disease in the presence of foot ulcers due to critical limb ischemia has raised some questions in relation to possible reaction from paclitaxel embolization on wound healing and ultimately on limb loss. Moreover, besides the pharmacological side effect of paclitaxel, the risk of jeopardizing distal perfusion by drug mass embolization has been anecdotally raised in the treatment of very distal targets characterized by single-vessel run off and preexisting poor microcirculation, which is typical in patients with diabetes and end-stage renal disease. Although the particle burden of paclitaxel is normally negligible compared to the plaque debris dislodged by standard angioplasty of atherosclerotic lesions,[3] such a small amount of paclitaxel mass may turn out to be relevant in specific and challenging settings like those described previously. Therefore, more sophisticated and drug-efficient delivery technologies are needed to continue improving clinical outcomes as well as the safety profile of first-generation DCB technologies. ■

1. Scheller B, Speck U, Abramjuk C, et al. Paclitaxel balloon coating, a novel method for prevention and therapy of restenosis. Circulation. 2004;110:810-814.
2. Tepe G, Zeller T, Albrecht T, et al. Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. N Engl J Med. 2008;358:689-699.
3. Rogers C, Huynh R, Seifert PA, et al. Embolic protection with filtering or occlusion balloons during saphenous vein graft stenting retrieves identical volumes and sizes of particulate debris. Circulation. 2004;109:1735–1740.

Juan F. Granada, MD, FACC
Executive Director and Chief Innovation Officer
Cardiovascular Research Foundation
Skirball Center for Innovation
Orangeburg, New York
(845) 580-3084
Disclosures: The Skirball Center for Innovation has received research grants from Spectranetics Corporation.