Zilver PTX for Simple and Challenging Lesions

How I integrate this versatile tool into my lower extremity practice.

BY WILLIAM A. GRAY, MD

The host of devices available to the interventionist to address the management of their patients with superficial femoral artery disease—associated with either claudication or limb threat—are myriad and, occasionally, confusing. Relatively new to the scene, and a welcome addition, is the first drug-eluting stent with dedicated outcome data and US Food and Drug Administration approval for use in the SFA/popliteal territories, Zilver PTX (Cook Medical). It also represents the first antiproliferative device in any form and the first drug-device combination for the lower extremities. Accordingly, the application of this advancement in certain patient subsets warrants careful consideration in order to maximize both patient outcomes and cost effectiveness.

APPLICATIONS FOR ZILVER PTX

Although nonrandomized, the prospective global registry data may both inform and support the physician decision to use Zilver PTX in a variety of situations at their discretion.

Given that there is a cost differential between Zilver PTX and other commercially available devices (eg, PTA), one might consider several different strategies for its use. One approach might be to use a less-costly device as initial therapy and to use the Zilver PTX as a second-line treatment should restenosis occur. This seems reasonable in the simple, short lesion where most device choices are likely to be associated with good long-term patency. With this said, we must recognize that level-1 data collected as part of the Zilver PTX randomized study showed superiority for Zilver PTX when compared to both percutaneous transluminal angioplasty with or without provisional stenting. In complex or lengthy lesions, where a prosthesis is required to maintain acute patency and long-term patency is challenged, the choice of Zilver PTX as primary therapy may be more cost effective, especially if follow-up is extended to 2 years and repeat interventions—possibly multiple and including surgical bypass—are avoided.

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Another potential strategy for shorter, less-complex lesions with the recent introduction of drug-coated balloons in the United States is to predilate the lesion with a standard bare balloon and then assess the vessel's response and make a determination whether balloon angioplasty will be sufficient or if a scaffold will be necessary to address any apparent recoil or dissection. If angioplasty appears to be successful, one may select a drug-coated balloon. However, if a scaffold is necessary, the placement of Zilver PTX has demonstrated long-term, durable outcomes.

Beyond the complexity of the lesion being treated as a determinant of device selection, the clinical scenario may also be helpful in the choice of devices. Specifically, patients presenting with critical limb ischemia and multilevel disease involving the femoropopliteal segment may not only tend to be less tolerant of vessel failure in general but may also benefit from sustained patency in their femoropopliteal segment given the poor infrapopliteal patency rates. Thus, a multilevel patient with a wound can have direct in-line flow to their foot to the associated wound subsequent to a revascularization, heal the wound, and should their infrapopliteal vessel fail subsequently—which is a reasonable likelihood—they have nevertheless now been converted from a multilevel to a single-level patient who may be less predisposed to develop a recurrent critical limb or wound reformation.

ZILVER PTX IN OUR PRACTICE

In our lab, we use Zilver PTX in a manner similar to what has previously been described and, importantly,

have adjusted our expectations of long-term patency appropriate to the lesion and patient complexity being undertaken. This was accepted by our implanting physicians as a reasonable approach in patient selection. Although we have not yet completed formal data analysis of the 1-year outcomes in these challenging lesions and patients, we have been very impressed with the clinical effectiveness of the Zilver PTX thus far, consistent with randomized and registry data collected on Zilver PTX and noting only infrequent failures. We look forward to developing a more formal survey of Zilver PTX in our clinical environment using the aforementioned paradigm. ■

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