How will you apply drug-eluting stents in your SFA practice?

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First, let me say that I cannot wait for this approval. Having Japan approve this device before the United States based on the same data is an embarrassment, as we are really becoming a "third world country" in medical therapy. Lagging behind the EU often by 5 to 6 years, and now even Japan—historically one of the slowest countries regarding device approval—leaves one asking, "What is going on with our own approval process here in the US?" As a practicing physician, frustration certainly is growing every year.

Once approved, I am hopeful that it will be economically reasonable to allow for immediate "on-label use." This device has significantly improved restenosis rates, and this is now coupled with an impressive 3-year freedom from target lesion revascularization rate, as recently presented in Japan. With a very low fracture rate of < 2%, I believe that Zilver PTX (Cook Medical, Bloomington, IN) will become the gold standard for femoral and proximal popliteal endovascular treatment. The pattern of restenosis also appears to be more focal in nature, so that when infrequent restenosis does occur, it may be simpler and thus more economical to treat. A postmarket study is planned to help further evaluate this device, but the large registry from the EU appears to show that this approach also works well in the more commonly encountered lesions. Certainly, diabetic patients have experienced the benefit as well, which is encouraging with the epidemic of diabetes that is occurring worldwide.

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Drug-eluting stent (DES) technology has been the mainstay of percutaneous coronary interventional procedures for well over a decade. This revolution was driven by substantially lowering the risk for poststent restenosis. This has had a diverse and significant impact on patient care, catheterization laboratory volume, coronary bypass graft surgery, and posttreatment pharmaceutical therapy. The medical community has eagerly awaited the adaptation of this same technology for high-risk patients with peripheral arterial disease. This early enthusiasm for using DES in superficial femoral artery (SFA) disease was tempered by the results of several small negative studies (SIROCCO and STRIDES trials), which failed to prove the concept that DES work well in this anatomy/disease.

The medical community was left feeling skeptical about the role of DES in the SFA. Now, Zilver PTX trial results have shown not only a strong signal that drug-elution does affect restenosis for SFA disease, but also that this effect can be demonstrated at long-term follow-up (3-year follow-up data). Not everyone has become a believer, however, perhaps because the mean lesion length in the trial was relatively short (< 7 cm). Many questions regarding peripheral DES remain to be answered, but in the meantime, Zilver PTX represents another step forward, improving the lives of our peripheral artery disease patients.

This technology has costs, yet demonstrates value beyond a bare nitinol stent. The relative cost of the Zilver PTX (compared to bare nitinol) will dictate its

role as a workhorse stent or the default stent for complex disease. Regardless of the price, when the DES enters the market, I believe bare-nitinol stent cost will spiral downward in response to maintain some market share. The more "cost effective" DES are when they enter the market, the more widespread their adoption, and the more likely it is that they will replace existing stents on our shelves. Therefore, this still undefined variable will definitely have an impact on my usage.

With that said, my personal intention is to use Zilver PTX for short-to-medium–length SFA disease that requires stenting. I do not intend to use it for long-segment disease, extensive popliteal disease, or iliac stenoses. I do not think it will greatly escalate the number of SFA interventions, nor will it offset the number of bypasses currently being performed. It will affect postintervention pharmaceutical care because I intend to use dual-antiplatelet therapy indefinitely (or as long as the patient can afford it). Importantly, DES will be further studied, have its role defined, and any ancillary issues refined by its postapproval use. My patients may not demand it by name, but I will use it.

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First off, we already utilize DES for select tibial cases, as well as small renal arteries, with great success. Often on follow-up, these stented segments have much better preserved patency than adjacent arterial segments that are treated with percutaneous transluminal angioplasty alone. We are excited about the impending availability of femoropopliteal DES with the Zilver PTX platform. Early data have been very promising across a wide subset of patients, including de novo and recurrent lesions, long-segment disease, and in patients who have diabetes. These data appear to improve upon currently available treatment options in many cases.

The main limitations of the Zilver PTX are that it will only be available in lengths of up to 8 cm, and the cost is expected to be high. Cost is a big deal given the current reimbursement climate, and it will have a significant impact on our utilization. However, given the available facts regarding the strengths and weaknesses of the Zilver PTX, our anticipated practice approach is that we will primarily use this device for patients with de novo femoropopliteal stenosis that can be treated with one or two stents and secondarily for patients with amenable patterns of restenosis following prior (stent-based or nonstent) therapy. Our goal is to track our outcomes during our early-to-midterm "real-world" experience to determine the efficiency of this strategy and guide subsequent patterns of usage in our practice.

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The approval of DES will represent an important advancement and addition to the armamentarium of devices available for the treatment of patients with peripheral vascular disease. At least initially, we will likely incorporate DES in a selective manner, utilizing these stents in patients with anticipated high rates of restenosis/thrombosis. The intermediate results of the Zilver PTX study are very encouraging, with reduced restenosis and stent fracture rates. There was an even greater advantage in certain subgroups, such as patients with diabetes. As "real-world" experience with a larger number of patients across a larger number of centers accumulates, the role for these devices should become better defined.

Another factor that will have an impact on the eventual breadth of use for these devices is cost. Whether the overall reduction in restenosis/occlusion seen in clinical trials persists when they are used in the general population remains to be seen. If improved outcomes that also translate to cost savings are demonstrated, these devices will be widely applied.

Finally, the concurrent development of other technologies, such as drug-eluting balloons and biodegradable stents, and their efficacy, may have an impact on the overall use of DES. In addition to these technologies, there may be other novel, as yet unexplored modalities, that when used in combination with DES, further improve results and increase the value of DES. ■

WEIGH IN ...

How do you anticipate drug-eluting stents will be incorporated into your SFA practice once approved?

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