Gunnar Tepe, MD

The Head of Diagnostic and Interventional Radiology at the Academic Hospital RoMed Clinic of Rosenheim in Germany discusses the recent CIRSE meeting, as well as the current study of drug-coated balloons for treating lower extremity disease.

What were some of the highlights of the CIRSE meeting this year?

CIRSE exceeded expectations, even from previous years. It was a great meeting with a lot of physicians coming from the United States, Europe, and Asia. It is getting to be one of the most important conferences in Europe on interventions in general and, more specifically, vascular interventions. The highlights included talks on vascular interventions and new endovascular approaches to treating tumors. The scientific content and the educational aspect of training physicians in interventional procedures were exceptional.

We know that favorable outcomes with drug-coated balloons (DCBs) depend on the total amount of drug that is delivered to the arterial wall, but what specific mechanisms of drug loading onto the balloon produce superior outcomes?

I think this is an important question, but no one really knows yet which coating is the best. I have seen different coating technologies, and I have seen different effects in the vessel. Some DCBs will be more effective than others. This will be most likely seen in long-term patency. The effect of DCBs might even be equal after 6 months, and differences might be seen in long-term outcomes, especially out to 2 years or even longer.

What are the latest developments in the IN.PACT SFA I and DEFINITIVE AR studies in which you are involved?

IN.PACT SFA I has concluded, with 150 total patients enrolled. We are currently conducting the 1-year follow-up, with outcomes that may be available as soon as spring of next year. Also, the second phase, IN.PACT SFA II, is set to begin soon. For DEFINITIVE AR, we have enrolled approximately five patients so far, and enrollment will continue at three or four different clinical sites.

In which cases do you use DCBs as a primary option, and in which settings do you opt for combination procedures?

At this time, I frequently use DCBs in very difficult cases, such as restenosis or for below-the-knee lesions when there is a proximal lesion with only one-vessel runoff that I do not want to lose. Additionally, I use DCBs in very long SFA lesions that are subintimal and in which I am concerned that if it does reocclude, I might not be able to cross the lesion again. Most data are in reference to moderate or short lesions, and in those lesions, I usually utilize regular angioplasty balloons first and then use DCBs only if the regular balloon does not produce a satisfactory result. Thus, the primary use of DCBs in my daily practice is for challenging cases.

As far as DCBs as an adjunct tool, I have used them in combination with atherectomy in the DEFINITIVE AR study. I use atherectomy to remove calcium and then attempt to prevent restenosis with the DCB. I have also used DCBs as an adjunct to scoring balloons in arteriovenous fistulas.

When using DCBs in calcified long lesions, is there any reasonable risk of harm associated with increasing the loaded drug dose? Have any potential benefits been shown?

As of now, I have not seen one case of overdose with DCBs or any adverse side effects of using a high dosage. What I do see are the side effects of underdosing in some patients. This may occur if some of the drug is lost while going through the sheaths. Underdosing may also occur in calcified lesions, as calcification reduces drug uptake. So, in patients who do not receive an adequate amount of drug, the likelihood of restenosis is greater, and the patients often do not receive the full potential benefit that would be expected. I have also performed some cases in which a single DCB was not

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effective, so I use two DCBs, which then provides better results. In the future, we need to talk more about increasing the dose for certain cases versus the concerns regarding side effects from high doses.

Why do you think that Germany has become such a hot spot for many of the recent/ongoing DCB trials?

First, the DCB was invented in Germany by Professor Ulrich Speck, and therefore, the first studies have been performed here. Also, those who most believe in the technology seem to be in Germany. There are also several sites in Germany that are very well organized in performing clinical studies, which is very important.

What do you see for the future of DCB use in the United States?

So far, I think DCBs are only being used in studies. I know that LEVANT II has begun and is enrolling quite a lot of patients. Additionally, there are two other manufacturers that are trying to enter this market and begin studies.

DCBs will play an important role in the future because they provide better patency rates without leaving any foreign material behind. ■

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