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cal irritation causing intimal hyperplasia, no problems with the treatment of delayed in-stent restenosis, no stent breaks, no limitations for noninvasive imaging (MRA), and no problems if vascular surgery is later required. The hurdles are in developing the technology, including a bio-absorbable scaffold that has sufficient expansible force to compress even calcified plaques and withstand external compression, that can achieve the optimal speed of bio-absorption, reduce the strut thickness and device profile, and find a material with good biocompatibility.

When presented with a new device option that has limited data, how do you decide whether to give it a chance?

Of course, there has to be a lot of discussion in the Ethics Committee. However, it is also the duty of the academic institutions to test new technology, but under the highest ethical standards. The informed consent discussions with the patients are very important in such trials. Personally, I believe that patients with borderline TASC A and B lesions may be good candidates for the ESPRIT trial.

Regarding other devices with early but limited data (ie, drug-eluting balloons), I use these devices only for indications when we know that conventional therapy has poor outcomes, such as in-stent restenosis.

Are there any technologies (imaging, devices, medications, etc.) that you are using in Europe that you think would provide significant benefit to patients in the United States?

In terms of imaging, MRA and CTA are an important step forward in noninvasive vascular imaging. However, this is already used in the United States. Contrast-enhanced ultrasound for follow-up after EVAR is a very useful technology that is underused even in Europe. Drug-eluting balloons and stents are currently available in Europe and will certainly have an important impact on the treatment of PAD. However, it will still need more evidence for which indications it should be used and when it is cost effective. ■

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Johannes Lammer, MD

Prof. Lammer provides an update on peripheral interventions in Europe, as well as efforts to bring diabetic vascular disease to the forefront of the medical community.



What are the goals of the International Working Group on the Diabetic Foot?

Our goal is to define the current evidence of diagnosis and treatment and to standardize and set minimal requirements for diagnosis and treatment. This

is especially important for countries where diabetes is an increasing health care problem but medical care is not at the appropriate level for various reasons (economy, lack of physician training, and shortage of physicians, podiatrists, nurses, etc.).

In the 2011 guidelines for the diagnosis and treatment of peripheral arterial disease in patients with diabetes and foot ulcers, which specific areas have been updated from the previous version, and why?

More evidence in noninvasive imaging and endovascular therapy were the main topics for updates. For instance, if peripheral artery disease (PAD) is diagnosed in a diabetic foot, imaging of the entire lower extremity arterial circulation with detailed visualization of below-the-knee arteries is required. In terms of imaging modalities, magnetic resonance angiography (MRA) and computed tomographic angiography (CTA) are now accepted.

Regarding revascularization therapy, the guidelines now advise, "There are no RCTs comparing open with endovascular revascularization techniques in patients with diabetes, a foot ulcer, and PAD. Broadly speaking, major outcomes of both techniques appear similar." My practice, like any other practice, will be affected by this update because endovascular treatment is accepted as equivalent to bypass surgery for this specific group of patients who have diabetes and multilevel PAD mainly involving tibial arteries.

Do you believe that sufficient progress is being made in PAD awareness among both patients and physicians in Austria?

No, the main focus remains on coronary artery disease. Patients with PAD are still primarily referred to orthopedic surgeons. However, the campaigns for smoking cessation and treatment of hypertension and hyperlipidemia seem to have an increasingly positive influence.

With United States and global markets seeing more approvals for superficial femoral artery/femoropopliteal artery stenting, are there any concerns regarding efficacy that you would like to see addressed by current and future platforms?

At the moment, we have good evidence that TASC B lesions in claudicants should be treated by primary stenting. However, claudicants with TASC C and D lesions have a high recurrence rate of symptoms after percutaneous transluminal angioplasty and stenting due to intimal hyperplasia. Drug-eluting and/or covered stents may be the solution for this problem, but we have to wait for the results of ongoing studies. Unfortunately, there is a lack of evidence on whether or not primary stenting (drug-eluting or covered stent) is beneficial in patients with critical limb ischemia. A problem with all device studies is that they include a mixed population of patients with intermittent claudication and critical limb ischemia that is heavily dominated by claudicants.

What can you tell us about the design of the ESPRIT I trial, which is studying bioresorbable stents in the treatment of peripheral artery disease?

The bioresorbable vascular scaffold by Abbott (Santa Clara, CA) has been tested successfully in the coronary arteries (ABSORB trial). In the ESPRIT I trial, a bioresorbable/everolimus eluting stent/scaffold for the external iliac and superficial femoral artery will be tested. This scaffold is initially placed by balloon expansion; however, it also has self-expandable properties in case of external compression. Bioresorption is expected within approximately 2 years.

The ESPRIT I trial is a first-in-man trial; it includes many additional tests, such as intravascular ultrasound or optical coherence tomographic imaging, MRA or CTA imaging, a pharmacokinetic evaluation, and angiographic follow-up with intravascular ultrasound or optical coherence tomographic imaging. The inclusion and exclusion criteria are very strict—as usual in a first-in-man trial—and the follow-ups are many. The informed consent process is also very strict, which may slow the recruitment process. However, if the concept proves to be successful, this may be a complete game changer in endovascular therapy.

What do you believe are the potential benefits and hurdles for this technology?

The benefits are many, such as no prolonged mechani-

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