Sebastian Sixt, MD

Dr. Sixt discusses the role of drug-coated balloons in peripheral lesions and how this technique is applied in Germany.

As drug-coated balloons (DCBs) become available for use in more markets, what advice do you have in terms of the operator learning curve? What is one major difference from PTA that every operator should be aware of?

There are some aspects of DCB use that the operator should be aware of. First, prepare the balloon before introducing it into the sheath. Handle the balloon surface with caution; the use of balloon protection for introduction into the sheath is a good option to reduce the loss of paclitaxel during this step. Furthermore, transition into the vessel, placement, and balloon inflation should be done continuously and quickly. In this context, the use of 0.018-inch DCBs might be advantageous because of the lower profile of these devices. I routinely use the combination of a guiding catheter and a DCB. Alternatively, a long sheath may also be used.

In addition, operators should be more aggressive with a prolonged balloon inflation of at least 3 minutes. Be prepared to do it repetitively (twice or even more) to improve the technical result and thus reduce the rate of bailout stenting. In challenging calcified lesions, I perform lesion preparation (eg, AngioSculpt balloon [AngioScore, Inc.] or atherectomy devices) to improve technical outcomes and, potentially, drug uptake. The difference between plain old balloon angioplasty and DCB use is that with DCBs, I can treat long lesions, as good long-term results have been shown in a clinical registry.[1]

Have DCBs lived up to expectations? What are the hurdles still to be overcome?

There is no doubt that DCBs work, although we do not yet have a class effect, and data from randomized controlled trials are still limited. Not all lesions can be treated successfully in daily practice with DCBs alone, as there remain instances of technical limitations and failure. Overall, there are still good reasons to use other available tools in settings where they have shown a proven benefit.

The uncertainty of local drug concentration delivered via the balloon in challenging lesions is still an area of concern. After DCB angioplasty, only 15% to 20% of paclitaxel transfers from the balloon surface into the vessel wall, and transmission might be even lower in calcified or thrombotic lesions at the moment of advancing the coated balloon into the lesion.[2,3]

There is a considerable number of bailout stenting procedures being performed; this high rate is related to recoil and dissection. It is clear that there are limitations of DCB use in undilatable calcified lesions.

We are also still in need of a balloon with proven safety for below-the-knee (BTK) interventions, as the results of the IN.PACT DEEP study were somewhat disappointing. The amputation rate went up, and the restenosis rate did not diminish, which was unexpected and somewhat confusing. I think that further studies are needed to solidify the proof of concept for use BTK.

In your experience treating BTK lesions using DCBs, do you think future trials will show this to be a safe and effective option? Which factors might lead to success or failure in the next trials?

I am quite positive that future trials will demonstrate the benefit of DCBs in BTK lesions. A potential future study design should focus on more focal or short lesions (not long lesions) to demonstrate the effectiveness. Furthermore, I would exclude from this trial high-risk patients who are Rutherford class 6, are on dialysis, or with heavily calcified lesions or very distally located lesions. The vessel diameter should not be too small—at least > 2 mm in diameter.

How do you weigh the economic considerations of DCB and DES use in your region?

Our economic consideration varies quite a bit from other centers, as we perform our procedures on an ambulatory platform. All of our expenses are completely covered, and the application of all devices is left to the discretion of the interventionist. The ongoing discussion in hospitals about the too-liberal use of DCBs and DES has not affected us so far. However, reimbursement in Germany is currently under discussion due to the constantly increasing use of DCBs.

In our situation, we can focus on the clinical aspects of DCB use and employing them only when we think their use is properly clinically indicated.

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What are your current research initiatives at Hamburg University Cardiovascular Center?

We are in a lucky situation to play an active part in a good number of studies. In the peripheral field, we're focusing on femoropopliteal trials investigating DCBs and DES and also standard nitinol stents or plain old balloon angioplasty and tacks (IN.PACT SFA, LEVANT trial and LEVANT Continued Access registry, REAL PTX, FAIR, ENDURE MIMICS, Peace Registry, TOBA). Furthermore, we have also been involved in investigating atherectomy (DEFINITIVE AR). We are also comparing standard nitinol stents with balloon-expandable stents in the pelvic arteries (the ICE trial).

Our cardiology team takes part in several additional studies, investigating DES and bioabsorbable stents (BioFreedom, Excella II, etc.), as well as transcatheter aortic valve repair studies such as DirectFlow Discover CE and Valtech (the CARDINAL trial and the Cardioband Adjustable Annuloplasty System for Minimally Invasive Mitral Valve Repair study), just to mention a few. ■

Sebastian Sixt, MD, is an interventional angiologist and cardiologist with the Medical Care Center, Prof. Mathey, Prof. Schofer, at Hamburg University Cardiovascular Center in Hamburg, Germany. Dr. Sixt has disclosed that he has no financial interests related to this article. Dr. Sixt may be reached at sixt@herz-hh.de.

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