The European Experience With Drug-Coated Balloons and Vessel Prep

With a 5-year head start using DCBs before US physicians, Prof. Jos van den Berg shares his take on best practices with this tool, as well as the available data.



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EVT: As someone who has had the opportunity to use drug-coated balloons (DCBs) for a number of years, what would you say to the US physicians who are looking to understand how well DCBs work?

Prof. van den Berg: When we started using DCBs 5 years ago, we actually didn't know anything about how they worked or whether they worked. So in that respect, being a little bit late may be an advantage, because we know now how they work. When we started, not having any data, we were just using those balloons in difficult lesions. We now have, more or less, the picture that it also works in primary lesions—at least TASC A and B.

EVT: Is that knowledge you've gleaned from the randomized studies or from your own practice?

Prof. van den Berg: It's mainly from the randomized studies. Seeing that it worked in my own practice also helps, but I think when you have the confirmation from larger randomized trials, then you can really be confident that the new technique is working.

EVT: From a clinical standpoint, what are some of the salient points about vessel prep that you have learned over the past several years?

Prof. van den Berg: Vessel preparation can be very

helpful. In patients who don't have [a lot of] calcification in the vessel wall, you can do it with just optimal balloon angioplasty. In cases where patients have highly calcified SFAs, then you probably need to do something additional [such as atherectomy].

Regarding optimal balloon angioplasty, I think it's important to be very meticulous with your technique. A lot of people just inflate a balloon rapidly and deflate very rapidly, and that's one of the things that probably enhances the incidence of restenosis by creating this trauma to the vessel wall. By gently inflating the balloon, you really give the vessel some time to adapt to the balloon, not creating much vessel wall injury. By leaving the balloon inflated for a long time, recoil will probably be much less. We know this from studies in the past, in the 1980s and 1990s, when stents were not available, and people had balloon angioplasty as the only tool. Even in the long lesions with long dissections, you can actually get rid of the complication of dissection with a long balloon inflation. That is something we had forgotten about when long stents became available for the SFA.

EVT: In heavily calcified lesions, what are some of the additional steps that you try to take?

Prof. van den Berg: One of the problems with the heavily calcified lesions, as we know from the Fanelli study, is that the calcium is really interfering with the good results of DCBs.¹ You probably need to get rid of (or crack) the calcium in order to enhance the results in those specific patients. Fanelli et al made a classification from grade 1 to 4, and they really saw a drop off in primary patency in the grade 4 lesions that had calcium all around the vessel wall, almost at 360°. So, the idea is to get that out in order to get better results with the DCBs.

There are some data from a small study from Cioppa et al² in Italy that indicate that by using atherectomy to take out the calcium and then following up with a DCB

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in very heavily calcified occlusions and long lesions, you can get good results with patency rates of 90% at 1 year.

EVT: In your experience, what is the best way to remove calcium from these particular lesions?

Prof. van den Berg: I think you need some kind of mechanical atherectomy. I'm using laser atherectomy a lot, but in these cases merely as a tool to modify the calcium because we know that laser is not really good at completely removing calcium.

EVT: Are there particular characteristics of the balloons that you use for percutaneous transluminal angioplasty that you find to be advantageous?

Prof. van den Berg: I typically use semicompliant balloons that give me a little bit of space to play around with the diameter. By using the compliance chart, the diameter of the balloon can be adapted to the diameter of the vessel wall. It's very important to be aware of the fact that when you use compliant or semicompliant balloons when there is a tight stenosis, in the areas where the balloon opens up more than in the area of the tight stenosis, the vessel wall might get injured much more at the proximal and distal end of the balloon (ie, the dogbone effect). That might, again, be a factor that is influencing restenosis in the long term.

^{1.} Fanelli F, Cannavale A, Gazzetti M, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. Cardiovasc Intervent Radiol. 2014;37:898-907.

^{2.} Cioppa A, Stabile E, Popusoi G, et al. Combined treatment of heavy calcified femoro-popliteal lesions using directional atherectomy and a paclitaxel coated balloon: one-year single centre clinical results. Cardiovasc Revasc Med. 2012;13:219-273