AN INTERVIEW WITH...

Antonio Micari, MD, PhD

Dr. Micari discusses his protocols in Italy for treating femoropopliteal ISR, the use of bioresorbable scaffolds below the knee, and the next generation of devices in these disease settings.

In 2013, you told us that you used a drug-coated balloon (DCB) combined with prior debulking (with an excimer laser) for treating femoropopliteal in-stent restenosis (ISR) when the ISR burden was high, such as in long (> 10 cm) occlusive lesions. Is this still the case? Which data or experiences inform your decision making, and in which cases do you diverge from your normal protocol?

Absolutely, I am still committed to this type of protocol based on the data on DCBs and the good outcomes that have been achieved. Results from the ISR cohort subgroup of the IN.PACT Global study were very exciting. We will probably have a growing collection of data for combination therapy (ie, debulking plus DCB use), but even DCB use alone shows convincing results in terms of 1-year target lesion revascularization (TLR) and restenosis rates. I really do not diverge from this protocol. I would say that all the patients with ISR who are treated in my cath lab will undergo DCB treatment.

In recent years, what has affected your approach to treating patients with lower extremity peripheral artery disease (PAD)?

In PAD trials, any device should be able to demonstrate good results that are consistent over time. In a superficial femoral artery (SFA) trial that I participated in, we achieved results out to 3 years showing that a DCB worked much better than a plain balloon. As physicians, we must at least achieve these good midterm results, and therefore, it's very important for us to continue following our patients. This is especially true for patients with claudication who are in their late 60s and have a normal life expectancy, because they can live for at least another 15 years. Thus, durable results are crucial.

In general, technology has been the biggest factor to affect my PAD practice over the last few years—not only due to the advances in DCB technology, but also the new drug-eluting stents that seem to show very nice results. I am eagerly anticipating the long-term results on several of these emerging balloon and stent technologies.

I am very encouraged by the multiple ongoing PAD studies that will provide a robust amount of level 1 evidence. The fact that companies are investing money to produce well-done clinical programs is a great step forward.

The use of bioresorbable scaffolds in the setting of below-the-knee (BTK) disease has shown promise and may represent a "leave nothing behind" alternative, but they also pose unique questions in evaluating outcomes. Where do we go from here in proving this concept and further refining devices for this anatomy? Do you think that the positive results will transfer to more real-world/complex clinical situations?

Currently, we have one dedicated study on the results of bioresorbable scaffolding, and although it was a very small study, the results seem to be quite favorable.[1] I am not sure that bioresorbable stents can be expanded to complex situations, so we will continue to treat based on the results we currently have, which are based on use in very short and proximal lesions.

At the moment, we cannot generalize and say that bioresorbable scaffolds will work well in most cases of BTK disease. But even in the future, I'm not sure that they will be feasible for treating 35- or 40-cm lesions, which is usually what we treat in BTK disease.

I think there will be utility for this treatment in some specific situations (ie, short and proximal disease), but I do not expect this to change over the next few years. I doubt we will see any clinical studies that definitely prove the applicability of this technology for extensive complex critical limb ischemia or BTK disease.

Do you foresee the positive outcomes of the DEB SFA-LONG study extending out to the planned 5-year follow-up period, and what are they attributed to at this point?

This is a very difficult question to answer. I hope we will see that the 5-year results are still consistent with those from 1 and 2 years, but this is still far away. Of course, I'm a believer and so I expect that this will be the outcome, but

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I cannot definitively say that we'll see great success at 5 years. I am convinced that DCBs are a good technology. So far, we have seen very nice results in short lesions out to 3 years and in long lesions out to 2 years. I hope and expect this trend to be maintained over the 5-year follow-up period.

The early results may be attributed to drug efficacy, procedural protocols, or device attributes, but I think that it all begins with good balloon technology. The drug-delivering capability of the balloon (ie, the carrier) is very important and is different from one balloon to another.

In my opinion, balloons are very easy to use, and because this is a user-friendly technology, you should be vigilant in practicing the proper dilation technique in terms of lesion preparation with predilation, then in administering the drug during dilation, and finally in postdilation, if needed. Good technique and technology are the reasons for the good results we've seen thus far.

Do any particular next-generation methods of drug delivery in SFA disease interest you?

There is room for improved balloons and drug-eluting stents, because I don't see competition between stents and balloons, but rather that they are complementary tools. I believe that they can coexist and help us achieve the best results in different clinical and anatomic situations. I am sure that the technologic evolution will continue and the future will bring more stable drugs and delivery mechanisms. In terms of BTK disease, second-generation balloons will improve in terms of less embolization or drug loss. Of course, over time, I would expect to have a technology that combines a scoring balloon with drug delivery or some other type of combination therapy that will allow us to better elute the drug into the vessel wall.

Which outcomes do you prioritize in SFA and BTK procedures? How has your view of clinical endpoints evolved in recent years?

In the SFA, TLR, patency, and functional outcomes are the most important endpoints. Patients come to us because they cannot walk and are seeking a normal/average quality of life. The ability to be mobile, along with the factor of TLR, play into quality of life for patients with claudication.

Of course, BTK disease is a different scenario, because limb salvage is the most important goal. For example, in the IN.PACT study, we had an amputation rate of < 4% in the control arm, which is already a high standard to meet. A new device would have to show much better results than a 4% to 5% amputation rate, and that's very difficult. Even if you achieve this result, the TLR rate is > 50% at 1 year, which is a high price to pay for the initial good clinical result.

Apart from the limb salvage rate, time to wound healing is another important factor, as this can greatly vary from 1 to 6 months from patient to patient. So I think this constitutes a measure of device efficacy for any new technology. ■

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1. Varcoe RL, Schouten O, Thomas SD, Lennox AF. Experience with the Absorb everolimus-eluting bioresorbable vascular scaffold in arteries below the knee: 12-month clinical and imaging outcomes. JACC Cardiovasc Interv. 2016;9:1721-1728.