AN INTERVIEW WITH...

Patrick Peeters, MD

With several drug-eluting stent trials underway, Dr. Peeters shares his involvement in two clinical studies and his opinion on the promise for future devices, from their use in various vascular beds to the potential cost benefit.

In which peripheral drug-eluting stent (DES) trials are you currently involved, and which devices are used?

At this moment, we are involved in the European part of the Cook Zilver PTX trial (Cook Medical, Bloomington, IN), looking at the results of the paclitaxel-coated Zilver PTX stent for stenotic and occlusive lesions in the superficial femoral artery (SFA) up to 28 cm. Initial results of this study look very promising, with good rates for target lesion revascularization (TLR) after 6 months. Follow-up in this trial goes up to 2 years, which is still awaited.

We are also taking part in the DESTINY study, a 1:1 randomized trial between patients treated with the bare-metal MultiLink Vision stent (Abbott Vascular, Santa Clara, CA) and the everolimus-eluting Xience V stent (Abbott Vascular). This study will compare the results at 1 year in patients with critical limb ischemia (CLI) due to short infrapopliteal stenoses or occlusions and with angiographic control after 1 year who have been treated with both stents. Inclusion is expected to be completed by the end of this year.

In what ways can compiling and comparing data be made more difficult, in relationship to differences in stent platforms and drugs, not to mention the multiple vascular beds being studied?

We all know that drug coatings have a positive effect on short- and midterm results. The long-term effect is something that is still under investigation, but common sense makes one think that these results will improve as well. However, it has been made clear in the past that this is not the only factor that plays a role in the clinical performance of a certain device. For stents placed in the SFA, for example, there is the issue of stent fractures, which may have an influence on primary patency rates, with or without clinical repercussions. In the below-the-knee (BTK) vascular beds, stent fracture might also be a contributing factor. In this respect, it is important to know the difference between balloon-expanding and self-expanding stent platforms, especially in distal areas that are undergoing constant flexion, torsion, and possible external compression.

In which vascular beds do you see the most promise and in which the most difficulty?

DES may be a promising tool for use in the renal arteries, in which we also have to deal often with in-stent restenosis. Yet, personally, I am convinced that DES will have a positive influence for BTK treatment in patients with CLI. We aim at cessation of rest pain or wound healing for limb salvage in these cases. The clinical benefit of DES up to 6 months should be long enough to alleviate symptoms. However, many CLI patients present with long diffuse BTK lesions. Covering the entire lesion length with DES is not an option because of the price tag attached, even if the results should appear to be better than with bare-metal stents (BMS). In our vascular center, our standard practice for long BTK lesions is percutaneous transluminal angioplasty with a long balloon, with bailout stenting only at the remaining focal stenotic areas.

Is it possible to estimate the cost differences between BMS and DES, first considering the costs of the devices themselves and associated medications, but also the potential for reduced reintervention rates?

Especially in times of economic crisis like today, it is also part of the responsibility of physicians to administer the government health care budget with due diligence. We may hope trials with new stent designs, such as the Zilver PTX stent, may improve the results from the SIROCCO trial. However, simple analysis teaches us that there is no cost benefit for DES in the SFA if DES cannot be provided for almost the same price as BMS. Right now, the cost of treatment with DES is more than twice the cost of BMS, doubling the treatment cost for TASC A and B lesions. Also, treatment with DES costs twice as much as surgery for TASC C and D lesions. The relative increase in primary patency for DES does not justify this high increase in costs.

In your opinion, which procedural question needs to be answered by a randomized controlled trial in the near future?

DES is just a step in the endovascular evolution. I am convinced that it is not the final solution. At this moment, I think it would be very interesting to know how drug-coated balloons would compare in the long run to DES. ■